NATIONAL QUALITY FORUM

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Measure Applications Partnership (MAP) Clinician Workgroup: 2021-2022 Cycle Preliminary Analyses

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Merit-based Incentive Payment System–Quality

MUC2021-127 Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Merit-based Incentive Payment System–Quality

Workgroup
Clinician

Measure Description
Percentage of patients aged 18 years and older with a diagnosis of CKD (Stages 1-5, not receiving Renal Replacement Therapy (RRT) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.

Numerator
Patients who were prescribed ACE inhibitor or ARB therapy within a 12-month period

Definitions:

Prescribed – May include prescription given to the patient for ACE Inhibitor or ARB therapy OR patient already taking ACE Inhibitor or ARB therapy as documented in the current medication list

Numerator Exclusions
N/A

Denominator
All patients aged 18 years and older with the diagnosis of CKD (Stages 1-5, not receiving RRT) and proteinuria.

Definitions:

Proteinuria:

1. >300mg of albumin in the urine per 24 hours OR

2. ACR >300 mcg/mg creatinine OR

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3. Protein to creatinine ratio > 0.3 mg/mg creatinine

RRT (Renal Replacement Therapy): For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney transplantation

Denominator Exclusions
ACE inhibitor (ACE-I) or ARB therapy not prescribed during the measurement period, medical reason(s) documented (e.g., pregnancy, history of angioedema to ACE-I, other allergy to ACE-I and ARB, hyperkalemia or history of hyperkalemia while on ACE-I or ARB therapy, acute kidney injury due to ACE-I or ARB therapy, other medical reasons.

ACE inhibitor or ARB therapy not prescribed during the measurement period, patient reason(s) documented (e.g., patient declined, other patient reasons).

Denominator Exceptions
N/A

State of development
Fully Developed

State of Development Details
The measure has been fully tested for validity and reliability.

Data abstracted from patient records were used to calculate inter-rater reliability for the measure.

Patients were randomly selected from visits for ESRD.

Data analysis included:

- Percent agreement
- Can1Kappa statistic with 95% confidence interval to adjust for chance agreement

Cohen's kappa coefficient is a statistical measure of inter-rater agreement or inter-annotator agreement for qualitative (categorical) items. It is generally thought to be a more robust measure than simple percent agreement calculation since ? takes into account the agreement occurring by chance.

The statistical results from reliability testing was:

Measure (N, % Agreement, Kappa (95% Confidence Interval))

ACE Inhibitor or ARB Therapy Measure (73, 93.15%, 0.8047 (0.6395- 0.9699)

An expert panel was used to assess face validity of the measure. This panel consisted of 21 members, with representation from the following specialties: nephrology, pediatric nephrology, endocrinology, nursing, methodology, internal medicine, preventive medicine and family medicine.

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What is the target population of the measure?
Medicare fee for service, patients over 18 years old with CKD

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Nephrology ;Primary care

Measure Type
Process

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Claims Data;Electronic Health Record;Paper Medical Records;Registries

If applicable, specify the data source
N/A

If EHR or Chart-Abstracted data, description of parts related to these sources
N/A

At what level of analysis was the measure tested?
Clinician; Group

In which setting was this measure tested?
Ambulatory/office-based care

What one healthcare domain applies to this measure?
Chronic Conditions

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
ASN has been in contact with the CMS MIPS Value Pathway (MVP) Development Team. There is strong interest from CMS in incorporating this measure into a Nephrology MVP. This measure is a central component of high-quality nephrology care, as it decreases the rate of kidney failure, cardiovascular outcomes, and mortality in patients with CKD. ;ASN has been in contact with the CMS MIPS Value Pathway (MVP) Development Team. There is strong interest from CMS in incorporating this measure into a Nephrology MVP. This measure is a central component of high-quality nephrology care, as it decreases the rate of kidney failure, cardiovascular outcomes, and mortality in patients with CKD. ;ASN has been in contact with the CMS MIPS Value Pathway (MVP) Development Team. There is strong interest from CMS in incorporating this measure into a Nephrology MVP. This measure is a central component of high-quality nephrology care, as it decreases the rate of kidney failure, cardiovascular outcomes, and mortality in patients with CKD.

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CMIT ID
N/A

Alternate Measure ID
AKID2 and NQF #1662

What is the endorsement status of the measure?
Endorsed

NQF ID Number
NQF #1662

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
Yes

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
2015

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
2021

Submitter Comments
This measure was used in PQRS in 2008 and in the RPA Kidney Quality Improvement Registry from 2014-2020.

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?
No

If eCQM, enter Measure Authoring Tool (MAT) number
N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

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If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
Measure currently used in a CMS program being submitted as-is for a new or different program

Range of years this measure has been used by CMS Programs
Used by RPA as a QCDR measure from 2015-2020; not available for reporting outside of QCDR until now. Formerly used in PQRS in 2008

What other federal programs are currently using this measure?
Merit-based Incentive Payment System–Quality

Is this measure similar to and/or competing with a measure(s) already in a program?
No

Which measure(s) already in a program is your measure similar to and/or competing with?
N/A

How will this measure be distinguished from other similar and/or competing measures?
N/A

How will this measure add value to the CMS program?
N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure
Clinical practice guidelines support the use of ACE and ARB in CKD patients not on RRT.

Kidney Disease Improving Global Outcomes (KDIGO) 2012

Chapter 3: Blood pressure management in CKD Non-Dialysis (ND) patients without diabetes mellitus

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3.4: We suggest that an ARB or ACE-I be used in non-diabetic adults with CKD ND and urine albumin excretion of 30 to 300 mg per 24 hours (or equivalent*) in whom treatment with BP-lowering drugs is indicated. (2D)

3.5: We recommend that an ARB or ACE-I be used in non-diabetic adults with CKD ND and urine albumin excretion 4300 mg per 24 hours (or equivalent*) in whom treatment with BP-lowering drugs is indicated. (1B)

Chapter 4: Blood pressure management in CKD ND patients with diabetes mellitus

4.3: We suggest that an ARB or ACE-I be used in adults with diabetes and CKD ND with urine albumin excretion of 30 to 300 mg per 24 hours (or equivalent*). (2D)

4.4: We recommend that an ARB or ACE-I be used in adults with diabetes and CKD ND with urine albumin excretion 4300 mg per 24 hours (or equivalent*). (1B). Guideline available at https://kdigo.org/wp-content/uploads/2016/10/KDIGO-2012-Blood-Pressure-Guideline-English.pdf

This measure was rated as HIGH for Overall Measure Validity in Mendu ML, Tummalapalli SL, Lentine KL, Erickson KF, Lew SQ, Liu F, Gould E, Somers M, Garimella PS, O'Neil T, White DL, Meyer R, Bieber SD, Weiner DE. Measuring Quality in Kidney Care: An Evaluation of Existing Quality Metrics and Approach to Facilitating Improvements in Care Delivery. J Am Soc Nephrol. 2020 Mar;31(3):602-614. doi: 10.1681/ASN.2019090869. Epub 2020 Feb 13. PMID: 32054692; PMCID: PMC7062216.

Evidence that the measure can be operationalized

This measure was included in the RPA Kidney Quality Improvement Registry, a CMS-approved QCDR. This measure has also been NQF endorsed.

How is the measure expected to be reported to the program?

Clinical Quality Measure (CQM) Registry;Claims

Feasibility of Data Elements

ALL data elements are in defined fields in electronic health records (EHRs)

Evidence of Performance Gap

Among patients with any CKD, use of ACEIs/ARBs is 40% according to data from the National Health and Nutrition Examination Survey (1). Among those with severely increased albuminuria (urine albumin-to-creatinine ratio of >300 mg/g) and hypertension without diabetes, ACEi/ARB use was only 33% (2). According to 2020 USRDS data, only 56% of Medicare beneficiaries are receiving ACEi/ARBs (3).

Unfortunately, concerns about lower eGFRs and hyperkalemia have potentially led physicians to reduce the use of these medications. More research is needed into the causes of lowered utilization of ACEIs/ARBs to determine the risks and benefits with advancing CKD.

1. Murphy DP, Drawz PE, Foley RN. Trends in angiotensin-converting enzyme inhibitor and angiotensin II receptor blocker use among those with impaired kidney function in the United States. Journal of the American Society of Nephrology. 2019 Jul 1;30(7):1314-21.
2. Chu CD, Powe NR, McCulloch CE, Banerjee T, Crews DC, Saran R, Bragg-Gresham J,

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Morgenstern H, Pavkov ME, Saydah SH, Tuot DS. Angiotensin-Converting Enzyme Inhibitor or Angiotensin Receptor Blocker Use Among Hypertensive US Adults With Albuminuria. Hypertension. 2021 Jan;77(1):94-102.

3. United States Renal Data System. 2020 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020.

Unintended Consequences

We are not aware of any unintended consequences related to this measurement.

Outline the clinical guidelines supporting this measure

The Kidney Disease: Improving Global Outcomes (KDIGO) 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease (CKD) states

- We recommend that an ARB or ACE-I be used in both diabetic and non-diabetic adults with CKD and urine albumin excretion > 300 mg/24 hours (or equivalent) (1B)

These guidelines are evidence-based.

The guideline recommendations supporting this measure are focused on the use of ACE inhibitors and ARBs in patients with CKD, with or without hypertension. The guideline focuses on the adult CKD population but also includes special considerations for the pediatric CKD population. This measure specifically focuses on patients with CKD stages 1-5 that are not receiving renal replacement therapy. The measure also includes patients that have proteinuria, and is therefore, more specific, with regards to the patient population. Proteinuria, which includes the measurement of all proteins in the urine, is discussed in the guideline with regards to therapy and improved outcomes for CKD patients. The requirement for proteinuria in the denominator for these measures is based on growing controversy regarding the appropriateness of prior recommendations for a BP <130/80 and for the use of ACE inhibition/angiotensin receptor blockade in non-proteinuric kidney disease (Chang TI, Cheung AK, Chertow GM. Blood pressure control in type 2 diabetes mellitus. Am J Kidney Dis 2010; 56: 1029-1031 & Agarwal R. Blood pressure goal in chronic kidney disease: what is the evidence? Current Opinion in Nephrology & Hypertension 2011; 20:229–232).

The evidence cited in support of the measure, demonstrates the association between patients with chronic kidney disease and hypertension. The guideline states that patients with CKD should be considered in the "highest risk" group for cardiovascular disease, that the target blood pressure for CVD risk reduction in CKD should be <130/80 mmHg, that patients with diabetic kidney disease (with or without hypertension) should be treated with an ACE inhibitor or an ARB, that ACE inhibitors and ARBs are effective in slowing the progression of kidney disease with microalbuminuria due to type 1 and type 2 diabetes, that patients with nondiabetic kidney disease and spot urine total protein to creatinine ratio >= 200 mg/g (with or without hypertension) should be treated with an ACE inhibitor or ARB, that ACE inhibitors are more effective than other antihypertensive agents in slowing the progression of most nondiabetic kidney diseases, and that the beneficial effect is greater in patients with higher levels of proteinuria. The measure numerator captures patients with CKD and albuminuria who were prescribed

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ACE inhibitor or ARB therapy within a 12-month period.

The recommendation statements from the guideline need to be qualified based upon the available data. First, no claims of superiority between ACE inhibitors and ARBs can be made since no randomized trials have compared these agents "head-to-head" in slowing the progression of kidney disease. Second, efficacy of therapy in many studies of diabetic kidney disease with microalbuminuria, efficacy of antihypertensive agents was based on reduced risk of kidney disease progression, as assessed by development of macroalbuminuria, rather than decline in GFR or onset of kidney failure. It is not practical, however, to conduct studies for the duration of follow-up required to observe a reduction in GFR decline or onset of kidney failure in patients with microalbuminuria; this would take more than 20 years of follow-up. Consequently, evidence from such studies was graded "strong." Moreover, since the level of albumin excretion in normotensive patients with diabetic kidney disease generally does not exceed "microalbuminuria," the recommendation for treating patients without hypertension is graded as "A." A limitation in approaching nondiabetic kidney disease is that there are few large studies of a single type of nondiabetic kidney disease. Further modifications of these recommendations will require the development of more discriminating diagnostic techniques and large studies focusing on single types of nondiabetic CKD.

KDOQI 2012 Update: The Work Group suggests that an angiotensin receptor blocker (ARB) or angiotensin converting enzyme inhibitor (ACE-I) be used in non-diabetic adults with CKD ND and urine albumin excretion of 30 to 300 mg per 24 hours (or equivalent*) in whom treatment with BP-lowering drugs is indicated. (2D)

The Work Group recommends that an ARB or ACE-I be used in non-diabetic adults with CKD ND and urine albumin excretion >300 mg per 24 hours (or equivalent*) in whom treatment with BP-lowering drugs is indicated. (1B)

Were the guidelines graded?
Yes

If yes, who graded the guidelines?
Kidney Disease Improving Global Outcomes

If yes, what was the grade?
1B

Estimated Impact of the Measure: Estimate of Annual Denominator Size
According to the National Health and Nutrition Examination Survey data from 2017-2018, 3,923,000 US adults have CKD with a UACR>300 mg/g.

Estimate of Annual Improvement in Measure Score
This measure was used in the CMS Physician Quality Reporting Initiative, in the claims option (2008)

44.9 % of patients reported on did not receive the optimal care. There is significant variation in performance on this measure in the

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PQRI program as shown by the 2008 data, the most recent available (1).

10th percentile: 11.4 %

25th percentile: 33.3 %

50th percentile: 62.5 %

75th percentile: 100.0 %

90th percentile: 100.0 %

Type of Evidence to Support the Measure
Clinical Guidelines;Systematic Review

Is the measure risk adjusted, stratified, or both?
None

Are social determinants of health built into the risk adjustment model?
No

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
unable to determine

Cost Avoided Annually by Medicare/Provider
unable to determine

Source of Estimate
N/A

Year of Cost Literature Cited
N/A

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
No

If yes, choose all methods of obtaining patient/caregiver information
N/A

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
N/A

Total Number of Patients and/or Caregivers Consulted
N/A

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Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
N/A

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
N/A

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Working groups;Standard TEP

Total Number of Clinicians/Providers Consulted
21

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
19

Burden for Provider: Was a provider workflow analysis conducted?
Yes

If yes, how many sites were evaluated in the provider workflow analysis?
4

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

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How many data elements will be collected for the measure?
26

Measure Testing Details

Reliability Testing Interpretation of Results

This measure is highly reliable, as shown in results from the inter-abstrator analysis (above).

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
IRR (Inter-rater reliability)

Reliability Testing Sample Size
73

Reliability Testing Statistical Result
Measure (N, % Agreement, Kappa (95% Confidence Interval))

ACE Inhibitor or ARB Therapy Measure (73, 93.15%, 0.8047 (0.6395- 0.9699))

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
Yes

If yes, specify the number of cases and the percentage of providers
Minimum denominator cases is 30, given that 30 records for CKD and 30 records for ESRD were sampled at each of the 4 practice sites. Samples of 112 CKD patients and 169 ESRD patients (62 with PD and 107 with HD), provides ample power with 5% statistical significance, power of 0.80 to 0.90, substantial agreement (kappa = 0.8) versus moderate agreement (kappa = 0.4), and trait prevalence of 0.5 to 0.75. (See Donner and Eliasziw,1992; and Sims and Wright, 2005.) 100% of the providers in the test sample met minimum denominator requirements.

Type of Validity Testing
Measure Score Validity

Validity Testing: Type of Validity Testing Analysis
Face Validity

Validity Testing Sample Size
An expert panel was used to assess face validity of the measure. This panel consisted of 21 members,

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with representation from the following specialties: nephrology, pediatric nephrology, endocrinology, nursing, methodology, internal medicine, preventive medicine and family medicine.

Validity Testing Statistical Result

An expert panel was used to assess face validity of the measure. This panel consisted of 21 members, with representation from the following specialties: nephrology, pediatric nephrology, endocrinology, nursing, methodology, internal medicine, preventive medicine and family medicine.

The results of the expert panel rating of the validity statement were as follows:

N = 19; Mean rating = 4.47

Frequency Distribution of Ratings

1 - 0 (Strongly Disagree)

2 - 0

3 - 0 (Neither Disagree nor Agree)

4 - 10

5 - 9 (Strongly Agree)

Validity Testing Interpretation of Results

Face validity of the measure score as an indicator of quality was consistent.

Measure performance – Type of Score

Proportion

Measure Performance Score Interpretation

Higher score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have

Testing Project Results - Conducted by AMA PCPI on behalf of RPA.

Scores on this measure: N = 58 Mean = 86.0 %, Range (79.0% - 92.0%)

CMS Physician Quality Reporting Initiative:

This measure was used in the CMS Physician Quality Reporting Initiative, in the claims option (2008)

44.9 % of patients reported on did not receive the optimal care. There is significant variation in performance on this measure in the

PQRI program as shown by the 2008 data, the most recent available (1).

10th percentile: 11.4 %

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25th percentile: 33.3 %

50th percentile: 62.5 %

75th percentile: 100.0 %

90th percentile: 100.0 %

The inter-quartile range (IQR) provides a measure of the dispersion of performance. The IQR is 66.8, and indicates that 50% of

physicians have performance on this measure ranging from 33.3% and 100.00%. A quarter of reporting physicians have

performance of 100%, while a quarter have performance on this measure less than 33.3%.

Benchmark, if applicable
N/A

Measure Contact Information

Measure Steward
Renal Physicians Association

Measure Steward Contact Information
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301-468-3515

Long-Term Measure Steward
N/A

Long-Term Measure Steward Contact Information
N/A

Primary Submitter Contact Information
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Section 2: Preliminary Analysis – MUC2021-127 Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

Justification and Notes: This measure focuses on nephrology, a gap within the Merit-Based Incentive Payment System (MIPS) program and considered a priority area for future measurement. This measure was initially endorsed in 2015 and is currently seeking continued endorsement in the Fall 2021 cycle. Measure addresses the treatment of diabetic and nondiabetic kidney diseases with Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes

Justification and Notes: This is a process measure focused on increasing the number of patients with chronic kidney disease (CDK) who receive ACE inhibitors or ARB therapy within 12 months. Clinical guidelines recommend ACE inhibitors and ARBs as preferred agents for diabetic kidney disease and nondiabetic kidney diseases with proteinuria. These treatments lower blood pressure, reduce proteinuria, slow the progression of kidney disease, and reduce the risk of cardiovascular disease. In controlled trials of CKD, ACE inhibitors and ARBs reduce protein excretion by approximately 35% to 40%, which is greater than other antihypertensive agents (*NKF KDOQI guidelines* 2015).

Does the measure address a quality challenge?
Yes/No: Yes

Justification and Notes: An estimated 37 million Americans have chronic kidney disease. CKD is associated with a higher risk of cardiovascular disease, end-stage kidney disease (ESKD), infection, malignancy, and mortality. In the 2015-2016 National Health and Nutrition Examination Survey, prevalence of CKD stages G1-4 was 14.2% among participants while 1 in 3 adults is at risk for diabetes and/or high blood pressure (Alfego et al., 2021). Several trials and meta-analyses have demonstrated that combination ACE inhibitor/ARB therapy has a greater antiproteinuric effect than either agent alone (Mann et al., 2021).

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Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?
Yes/No: Yes

Justification and Notes: This measure is currently in use in the MIPS program. There are several related measures, however, the measure developers did not note any as competing measures.

Can the measure be feasibly reported?
Yes/No: Yes

Justification and Notes: The measure has been included in the Renal Physicians Association (RPA) Kidney Quality Improvement Registry, a CMS-approved Qualified Clinical Data Registry (QCDR). This measure uses claims data, electronic health records (EHRs), paper medical records, and registry data for reporting.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?
Yes/No: Yes

Justification and Notes: The measure is specified and tested at the ambulatory/office-based care setting, clinician/group level of analysis. The measure was initially endorsed by the National Quality Forum (NQF) in October 2015 by the Renal Standing Committee. The measure will next be reviewed in the Renal Fall Cycle of 2021.

If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure been identified?
Yes/No: Yes

Justification and Notes: The measure developer did not report any unexpected findings. Patients not prescribed ACE inhibitors or ARB therapy during the measurement period or have a medical reason documented (e.g., pregnancy, history of angioedema to ACE-I, other allergy to ACE-I and ARB, hyperkalemia, or history of hyperkalemia while on ACE-I or ARB therapy, acute kidney injury due to ACE-I or ARB therapy) have been excluded by the measure developers to avoid any unintended issues.

PAC/LTC Core Concept?
N/A

Impact Act Domain
N/A

Hospice High Priority Areas
N/A

MAP Rural Health Advisory Group Input:
Relative priority/utility:

- The measure was suggested to be important for the rural communities, and opportunities for improvement exist.

Data collection issues:

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- None identified.

Calculation issues:

- Concerns were raised that low patient volume in rural settings may impact the reliability/validity of the measure.

Unintended consequences:

- None identified.

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 4.1
1 – 0 votes
2 – 0 votes
3 – 3 votes
4 – 7 votes
5 – 5 votes

MAP Health Equity Advisory Group Input:

Relative priority/utility:

- The Advisory Group noted the Importance of this clinical area and relative low performance among disadvantaged populations.
- There is a gap in care, and this is an important intervention that is evidence based.

Data collection issues:

- There were concerns expressed related to collection burden. It is more burdensome, since it requires some chart detail to understand exclusions, and providers with fewer resources may struggle. The developer further clarified during the MAP Clinician workgroup meeting that the measure should be captured electronically and there should be limited burden to providers.

Calculation issues:

- None identified.

Unintended consequences:

- Concern expressed over access to care.
- Concern expressed regarding the exacerbation of disparities.

Votes: Range is 1 – 5, where higher number has greater potential for positive impact on health equity.
Average: 3.1
1 – 0 votes
2 – 5 votes
3 – 10 votes
4 – 7 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:

Support for Rulemaking

Summary: What is the potential value to the program measure set?

The measure concentrates on nephrology and the critical condition of diabetes, both identified as gaps

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within the MIPS program and considered priority areas for future measurement. This NQF endorsed measure focuses on using clinically recommended CKD therapeutic interventions to treat diabetic kidney disease and nondiabetic kidney diseases with proteinuria (albuminuria).

Summary: What is the potential impact of this measure on quality of care for patients?
This measure is aimed at increasing the number of patients receiving high-quality nephrology care (prescribed ACE inhibitors or ARB therapy), as it decreases the rate of kidney failure, cardiovascular outcomes, and mortality in patients with chronic kidney disease.

Section 3: Public Comments

National Kidney Foundation
The National Kidney Foundation (NKF) wishes to express our support for the measure, Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy. We believe this measure is highly relevant to patient care and its benefits dramatically outweigh any data collection burden.

An estimated 37 million people in the United States are living with chronic kidney (CKD) disease (1). In 2017, more than 500,000 individuals received life-saving dialysis treatment and 220,000 were living with kidney transplants (2). In that same year, 124,500 individuals developed end-stage renal disease (ESRD) (3). Medicare spending for patients with CKD not yet on dialysis in 2017 exceeded $84 billion, while progression of CKD leads to end-stage renal disease (ESRD) requiring dialysis which costs $49 billion annually (4). Despite the impact of CKD and ESRD on the healthcare system, there is a paucity of clinician-level measures related to kidney disease.

ACEi/ARB medications are first-line treatments for CKD and reduce progression to ESRD. They are recommended by clinical practice guidelines (Kidney Disease: Improving Global Outcomes [KDIGO] Class 1A recommendation), yet there is a clear performance gap in ACEi/ARB usage among patients with CKD - only 40% of patients with CKD are on ACEi/ARB in NHANES data (Murphy et al., JASN, 2019). We believe that including this NQF-endorsed measure (NQF #1662) in the MIPS program would increase focus on this important step in reducing or delaying progression to ESRD.

We would welcome the opportunity to discuss our support for this measure further. Please contact Miriam Godwin (miriam.godwin@kidney.org).

References:

1. Centers for Disease Control and Prevention. Chronic Kidney Disease Surveillance System website. https://nccd.cdc.gov/CKD. Accessed March 5, 2019

2. US Renal Data System 2019 Annual Data Report: epidemiology of kidney disease in the United States, p 32, 2019

3. US Renal Data System 2019 Annual Data Report: epidemiology of kidney disease in the United States, p 23-24, 2019

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4. US Renal Data System 2019 Annual Data Report: epidemiology of kidney disease in the United States, p 11, 2019

American Society of Nephrology

A total of 37 million Americans have chronic kidney disease (CKD), which causes an enormous burden to our healthcare system. ACEi/ARBs are first-line medications for CKD to prevent its progression to end-stage renal disease (ESRD). ACEi/ARBs are recommended for patients with CKD by Kidney Disease: Improving Global Outcomes [KDIGO] international guidelines. There is a clear performance gap in ACEi/ARB usage among patients with CKD – only 40% of patients with CKD are on ACEi/ARB in NHANES data (Murphy et al., JASN, 2019). We support the approval of MUC2021-127 which is endorsed by the National Quality Forum (NQF 1662) and has been used in MIPS since 2014 within the RPA Kidney Quality Improvement Registry, a Qualified Clinical Data Registry. This measure is a central component of the MIPS Value Pathway for Nephrology, which is currently in development with the QPP Education & Outreach Team.

Association of American Medical Colleges (AAMC)

The Clinician MAP Workgroup supported the Adult Kidney Disease measure (MUC2021-127) for MIPS. The measure assesses the percentage of adult patients with a diagnosis of chronic kidney disease (CKD), not receiving Renal Replacement Therapy, and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period. The AAMC supports the recommendation. We agree that the measure addresses a priority area for measurement and appreciate that the measure is currently endorsed by NQF. Furthermore, we believe the measure as specified appropriately balances clinical guidelines for high-quality nephrology care with medically necessary exclusions, such as pregnancy or history of allergy to ACE inhibitor or ARB therapy.

OCHIN, Inc.

Support recommendation of Committee.

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MUC2021-058 Appropriate intervention of immune-related diarrhea and/or colitis in patients treated with immune checkpoint inhibitors

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Merit-based Incentive Payment System–Quality

Workgroup
Clinician

Measure Description
Percentage of patients, aged 18 years and older, with a diagnosis of cancer, on immune checkpoint inhibitor therapy, and grade 2 or above diarrhea and/or grade 2 or above colitis, who have immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered.

Numerator
Patients with immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered.

Numerator Guidance:

· Immune checkpoint inhibitors should be held for patients who have grade 2 or above diarrhea and/or grade 2 or above colitis.

· Corticosteroids examples include but are not limited to methylprednisolone, prednisone, or dexamethasone. Route of administration may be oral or intravenous dependent on agent.

· Immunosuppressants include but are not limited to vedolizumab or anti-TNF agent such as infliximab. Route of administration may vary dependent on agent.

Numerator Exclusions
None

Denominator
Patients, 18 years and older, with a diagnosis of cancer and on immune checkpoint inhibitors and who have grade 2 or above diarrhea and/or grade 2 or above colitis.

Denominator Guidance:

· Immune checkpoint inhibitors-class of medications that prevent tumors from “hiding” or “evading” the

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body's natural immune system. This is a form of cancer immunotherapy. Immune checkpoint inhibitor medications include PD-1 inhibitor drugs, PD-L1 inhibitor drugs, and CTLA-4 inhibitor drug.

- PD-1 inhibitors drugs include: Pembrolizumab, Nivolumab, Cemiplimab
- PD-L1 inhibitors drugs include: Atezolizumab, Avelumab, Durvalumab
- CTLA-4 inhibitor drug includes: Ipilimumab

· Grade 2 Diarrhea - 4-6 bowel movements above baseline per day. Moderate increase in ostomy output compared to baseline; limiting instrumental ADL

· Grade 3 Diarrhea - increase of >=7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self care ADL

· Grade 4 Diarrhea - Life-threatening consequences; urgent intervention indicated

· Grade 2 Colitis - Abdominal pain, mucus or blood in stool

· Grade 3 Colitis – Severe abdominal pain; peritoneal signs · Grade 4 Colitis – Life-threatening consequences; urgent intervention indicated

*Grading for GI toxicity by Common Terminology Criteria for Adverse Events (CTCAE) v5.0

Denominator Exclusions
Patients with pre-existing inflammatory bowel disease (IBD) (e.g., ulcerative colitis, Crohn's disease).

Denominator Exceptions
Documentation of medical reason(s) for not prescribing or administering corticosteroid or immunosuppressant treatment (e.g., allergy, intolerance, infectious etiology, pancreatic insufficiency, hyperthyroidism, prior bowel surgical interventions, celiac disease, receiving other medication, awaiting diagnostic workup results, other medical reasons/contraindication).

Denominator Exceptions Guidance:

Diarrhea is not attributed to immune checkpoint inhibitor mucosal inflammation. Examples include but are not limited to infection, pancreatic insufficiency, hyperthyroidism, prior bowel surgical interventions, and celiac disease.

Clinician did not yet prescribe or administer corticosteroid or immunosuppressant due to awaiting diagnostic workup or results for alternative etiologies.

State of development
Fully Developed

State of Development Details
Face validity testing was performed as part of alpha testing between February 25, 2021 and March 19, 2021 through a public comment survey. Feasibility testing was completed as part of alpha testing between March 29, 2021 and April 23, 2021. Finally, measure score reliability testing was carried out between April 26, 2021 and May 7, 2021 as part of beta testing.

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Data collected showed that the measure was feasible (with some data elements in defined fields in electronic sources), and that the measure presented an average burden to the providers.

Additionally, measure demonstrated high face validity with 92% of subject matter experts agreeing on the denominator, 73% of subject matter experts agreeing on denominator exclusions, 88% of subject matter experts agreeing on denominator exceptions, and 83% of subject matter experts agreeing on the numerator. An average of 92% of subject matter experts agreed that the measure is meaningful, addresses a gap in care, will improve care, and addresses a serious ailment with dangerous consequences.

Lastly, measure scores showed high reliability as indicated by an adjusted split-sample correlation coefficient of 0.8952. For more details, please refer to the testing fields in this form.

What is the target population of the measure?
Medicare Fee for Service

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Gastroenterology ;Gynecological oncology ;Hematology/oncology;Medical oncology

Measure Type
Process

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Registries

If applicable, specify the data source
N/A

If EHR or Chart-Abstracted data, description of parts related to these sources
N/A

At what level of analysis was the measure tested?
Clinician; Group

In which setting was this measure tested?
Ambulatory/office-based care;Hospital outpatient department (HOD);PPS-exempt cancer hospital

What one healthcare domain applies to this measure?
Safety

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MIPS Quality: Identify any links with related Cost measures and Improvement Activities
This measure could be linked to the below MIPS Cost measures, as the timely and appropriate interventions of this measure can impact the overall cost attributed to clinicians and also avoid hospitalization and the costs associated with hospitalization.

MIPS Cost Measures:

1. Total Per Capita Cost

2. Medicare Spending Per Beneficiary

This measure could be linked to the below listed MIPS Improvement Activities, as the measure can be performed by eligible providers via a telehealth encounter; the measure addresses routine and timeliness in disease management (i.e., cancer diagnosis on immunotherapy); and the measure addresses a medication related adverse event (i.e., immune-related diarrhea or colitis).

MIPS Improvement Activities:

1. Use of telehealth services that expand practice access

2. Implementation of episodic care management practice improvements

3. Communication of Unscheduled Visit for Adverse Drug Event and Nature of Event

CMIT ID
N/A

Alternate Measure ID
Not Applicable

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

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Submitter Comments
N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?
No

If eCQM, enter Measure Authoring Tool (MAT) number
N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs
N/A

What other federal programs are currently using this measure?
N/A

Is this measure similar to and/or competing with a measure(s) already in a program?
Yes

Which measure(s) already in a program is your measure similar to and/or competing with?
Similar measures include:

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1) NQF 3490 (CMS steward)

Measure Title: Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy

Program: Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting Program

Data Source: claims; enrollment data

2) ONSQIR23 (Premier Clinician Performance Registry) (QCDR)

Measure Title: Assessment for and management of immune-related adverse events during cancer treatment with checkpoint inhibitors (ICPi)

Program: MIPS QCDR

How will this measure be distinguished from other similar and/or competing measures?
Same answer as above: The proposed measure is significantly different from NQF 3490 and ONSQIR23. The proposed measure is a registry measure for the MIPS program (not QCDR). NQF 3490 is a claim based measure and ONSQIR23 is a QCDR measure. In addition, the target population of the proposed measure is cancer patients on immunotherapy whereas NQF 3490 targets patients only on chemotherapy. Additionally, NQF 3490 is an outcome measure looking at ED and hospital admissions due to side effects from chemotherapy. The proposed measure is an intermediate outcome measure trying to prevent ED and hospital admissions by appropriate interventions of immune-related diarrhea or colitis in the outpatient setting.

Finally, the proposed measure targets diarrhea and/or colitis starting at a grade 2 and above, whereas ONSQIR23 does not target immune-related adverse events until grade 3 and grade 4. If clinicians address interventions for immune-related colitis earlier at grade 2 as noted in the clinical guidelines, there is potential for reducing ED and hospital admissions.

How will this measure add value to the CMS program?
The proposed measure is significantly different from NQF 3490 and ONSQIR23. The proposed measure is a registry measure for the MIPS program (not QCDR). NQF 3490 is a claim based measure and ONSQIR23 is a QCDR measure. In addition, the target population of the proposed measure is cancer patients on immunotherapy whereas NQF 3490 targets patients only on chemotherapy. Additionally, NQF 3490 is an outcome measure looking at ED and hospital admissions due to side effects from chemotherapy. The proposed measure is an intermediate outcome measure trying to prevent ED and hospital admissions by appropriate interventions of immune-related diarrhea or colitis in the outpatient setting.

Finally, the proposed measure targets diarrhea and/or colitis starting at a grade 2 and above, whereas ONSQIR23 does not target immune-related adverse events until grade 3 and grade 4. If clinicians address interventions for immune-related colitis earlier at grade 2 as recommended in the clinical guidelines, there is potential for reducing ED and hospital admissions.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

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Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure

All the 5 clinical guidelines below address the measure's quality actions of holding immunotherapy and administering corticosteroids or immunosuppressant for grade 2 or above diarrhea and/or grade 2 or above colitis. The measure will enhance compliance with the clinical guidelines by ensuring the eligible provider is addressing the adverse event of diarrhea or colitis by immediately providing an intervention to prevent the adverse event from worsening.

NCCN Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities.2020.- (Evidence Based)

AGA Clinical Practice Update on Diagnosis and Management of Immune Checkpoint Inhibitor (ICI) Colitis and Hepatitis: Expert Review. 2020.- (Evidence-based and Consensus-based)

Chemotherapy and Immunotherapy Guidelines and Recommendations for Practice. ONS. 2019.

American Society of Clinical Oncology Clinical Practice Guideline. Management of immune-related adverse events in patients treated with immune checkpoint inhibitor therapy. Journal of Clinical Oncology. 2018-(Consensus-based)

Management of toxicities from immunotherapy: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. 2017 -(Evidence-based)

Evidence that the measure can be operationalized

This measure is not an eCQM. The measure has not currently been collected by a registry, but the data elements necessary for registry submission methods are present in the way the measure is written. HCPCS codes will need to be generated by CMS for reporting some of the required elements in this registry measure. Please see attached registry specification, flow diagram, and flow narrative. Please also refer to the burden results (Rows #10-20).

How is the measure expected to be reported to the program?

Clinical Quality Measure (CQM) Registry

Feasibility of Data Elements

Some data elements are in defined fields in electronic sources

Evidence of Performance Gap

One study found that only 49% of health care professionals are comfortable with recognizing and managing immune related adverse events. (Schwartzberg et al. 2018).

In 2017, a survey conducted by the Association of Community Cancer Centers (ACCC) reported that only 24% of respondents reported that they had a deep familiarity with checkpoint inhibitors, 32% with monoclonal antibody therapy, and only 17% with combination treatment regiments (ACCC 2018).

Association of Community Cancer Centers (ACCC)(2017-2018). Immuno-Oncology: Transforming the Delivery of Cancer Care in the Community [White paper]. http://www.informz.net/ACCC/data/images/Attachments/2017%20IO%20White%20Paper.pdf

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Schwartzberg, L.S., & Perloff, T. (2018). Identifying Gaps in Immunotherapy Education: Beyond the Oncology Team. Abstract #PS26. https://www.mascc.org/assets/2018_Meeting_Files/Sat30/Strauss_3/1324_Perloff_Strauss%203_Sat.pdf

Unintended Consequences

The TEP for this measure did not identify any unintended consequence with the measure if appropriately implemented and followed by eligible providers.

Outline the clinical guidelines supporting this measure

All the 5 guidelines below address the measure's quality actions of holding immunotherapy and administering corticosteroids or immunosuppressant for grade 2 or above diarrhea and/or grade 2 or above colitis. The measure will enhance compliance with the clinical guidelines by ensuring the eligible provider is addressing the adverse event of diarrhea or colitis by immediately providing an intervention to prevent the adverse event from worsening.

1. NCCN Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities. 2020.- (Evidence Based):

Recommendation: For moderate diarrhea/colitis (G2), hold immunotherapy and administer prednisone/methylprednisolone (1mg/kg/day). If no improvement is noted within 2 to 3 days, increase corticosteroid dose to 2mg/kg/day and consider adding infliximab.

2. AGA Clinical Practice Update on Diagnosis and Management of Immune Checkpoint Inhibitor (ICI) Colitis and Hepatitis: Expert Review. 2020.- (Evidence-based and Consensus-based): Recommendation for >= Grade 2 Colitis or Diarrhea (suspected immune-mediated): Withhold ICI therapy.

Best Practice Advice (BPA) 6-ICI colitis typically responds to high dose systemic glucocorticoids, given in doses of 0.5-2 mg/kg prednisone equivalent daily with a taper of 4-6 weeks, although these doses and schedules have not been rigorously examined. Infliximab and vedolizumab are reasonable options for treatment of glucocorticoid refractory colitis.

3. Chemotherapy and Immunotherapy Guidelines and Recommendations for Practice. ONS. 2019.:

Recommendation for Grade 2 Diarrhea: Hold immunotherapy. Administer IV methylprednisolone (1 mg/kg/day). If no response in 2-3 days:

-increase dose to 2mg/kg/day

-consider infliximab

-if refractory to infliximab, consider vedolizumab

Recommendation for Grade 2 Colitis: Hold checkpoint inhibitor therapy, and continue treatment with antidiarrheal. If symptoms persist up to one week, it is recommended to initiate corticosteroids.

4. American Society of Clinical Oncology Clinical Practice Guideline. Management of immune-related adverse events in patients treated with immune checkpoint inhibitor therapy. Journal of Clinical

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Oncology. 2018.-(Consensus-based):

Recommendation: ICPi therapy may be suspended for most grade 2 toxicities, with consideration of resuming when symptoms revert to grade 1 or less. Corticosteroids may be administered.

5. Management of toxicities from immunotherapy: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. 2017.-(Evidence-based):

Recommendation: In grade 2 diarrhea, ICPi should be interrupted and the patient should start with corticosteroids depending on the severity and other symptoms (either budesonide or oral corticosteroids 1 mg/kg). In the case of no improvement within 3–5 days, colonoscopy should be carried out and, in the case of colitis, infliximab 5 mg/kg should be administered.

Were the guidelines graded?

Yes

If yes, who graded the guidelines?

1. NCCN Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities. 2020.- (Evidence Based) · NCCN Categories of Evidence and Consensus 2. AGA Clinical Practice Update on Diagnosis and Management of Immune Checkpoint Inhibitor (ICI) Colitis and Hepatitis: Expert Review. 2020.- (Evidence-based and Consensus-based) · No evidence strength grading provided. 3. Chemotherapy and Immunotherapy Guidelines and Recommendations for Practice. ONS. 2019. · No evidence strength grading provided. 4. American Society of Clinical Oncology Clinical Practice Guideline. Management of immune-related adverse events in patients treated with immune checkpoint inhibitor therapy. Journal of Clinical Oncology. 2018.-(Consensus-based) · All recommendations are expert consensus based, with benefits outweighing harms, and strength of recommendations is moderate. 5. Management of toxicities from immunotherapy: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. 2017.-(Evidence-based) · Levels of evidence and grades of recommendation (adapted from the Infectious Diseases Society of America-United States Public Health Service Grading Systema)

If yes, what was the grade?

1. NCCN Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities. 2020.- (Evidence Based) • Category 2A-Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Estimated Impact of the Measure: Estimate of Annual Denominator Size

Unable to determine at this time. An estimate of the annual denominator size will be established once more data is collected.

Estimate of Annual Improvement in Measure Score

Not applicable at this time. An estimate of the annual improvement in measure score will be established once more data is collected.

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Type of Evidence to Support the Measure
Clinical Guidelines

Is the measure risk adjusted, stratified, or both?
None

Are social determinants of health built into the risk adjustment model?
Not Applicable

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
Cost avoided per patient for a gastrointestinal adverse event for a patient undergoing either targeted therapy or immunotherapy is about $13,699. The 95% confidence interval for this figure is estimated to be $10,138 – $17,261. Mean 30-day costs in patients with gastrointestinal adverse events who are receiving immunotherapy are about $21,887.

Cost Avoided Annually by Medicare/Provider
Unable to determine at this time. An estimate of cost avoided annually by Medicare/provider will be established once more data is collected.

Source of Estimate
The cost estimates are based on research by Ghate et al., where researchers conducted a retrospective cohort study on a sample of 844 melanoma patients who had Medicare claims data from 2011 to 2014. Of 844 patients, 65% were male, 95% were white, and the average age was approximately 75 years.

Patients in the study received either targeted therapy or immunotherapy and were sorted into two cohorts, those who had adverse events and those who did not. The predicted costs were estimated by using the generalized linear model coefficients for the adverse events and control cohorts, and recycled predictions were adopted. This allowed the regression model to calculate a predicted 30-day cost for every patient that was predicated on the covariate values that assumed that the patient had an adverse event, and that the patient did not. All costs were inflation-adjusted to 2017 US dollars.

Citation: Ghate, S. R., Li, Z., Tang, J., & Nakasato, A. R. (2018). Economic Burden of Adverse Events Associated with Immunotherapy and Targeted Therapy for Metastatic Melanoma in the Elderly. American health & drug benefits, 11(7), 334–343.

Year of Cost Literature Cited
2017 dollars adjusted for inflation

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

If yes, choose all methods of obtaining patient/caregiver information
Standard Technical Expert Panel (TEP) inclusive of patient/caregiver representatives;Surveys

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How many times and at what phase(s) of measure development was the patient/caregiver engaged?
A patient advocate was engaged on the TEP throughout the measure development of the measure. In addition, we had patients submit a survey on the face validity of this measure during public comment.

Total Number of Patients and/or Caregivers Consulted
3

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
1:8

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
2

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Surveys;Standard TEP;Other: Public Comment

Total Number of Clinicians/Providers Consulted
43

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
43

Burden for Provider: Was a provider workflow analysis conducted?
Yes

If yes, how many sites were evaluated in the provider workflow analysis?
6

Did the provider workflow have to be modified to accommodate the new measure?
Yes

If yes, how would you describe the degree of effort?
3

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Does the measure require manual abstraction?
Yes

If yes, what is the estimated time per record to abstract data?
11

How many data elements will be collected for the measure?
15

Measure Testing Details

Reliability Testing Interpretation of Results
The overall split-sample reliability score of 0.8952 is interpreted to indicate high reliability. This value demonstrates that the practice performance rate has high reliability, and that the measurement error is reasonably reduced. Reliability coefficients of 0.75 or above reflect high precision between performance rates derived from the two samples (a reliability coefficient of greater than 0.90 represents excellent reliability).

Citation: Koo, T. K., & Li, M. Y. (2016). A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. Journal of chiropractic medicine, 15(2), 155–163. https://doi.org/10.1016/j.jcm.2016.02.012

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
Random Split Half Correlation

Reliability Testing Sample Size
Seventy-five (75) patients across seven (7) different sites satisfied the measure denominator and were chosen for performance score reliability testing. Each site had an average of ten (10) patients. Of 75 patients, 36, or 46%, were female, and 39 or 52% were male. Additionally, 10 patients (13%) were African American, 1 patient (1%) was Asian, 1 patient (1%) was of other race, 1 patient (1%) was of unknown race, and 62 patients (83%) were White.

Reliability Testing Statistical Result
A split sample method of calculating reliability was used, where provider performance was measured once using a randomly chosen subset of the initial 75 patient sample and then measured again using the second random sample exclusive of the first. The agreement between the two resulting performance scores (one for each subset) was compared across 7 sites. As the metric of agreement, split-half coefficient was calculated. The unadjusted split-half coefficient was 0.8103. Spearman-Brown prophecy formula was used to adjust the split-half coefficient to provide an estimate that approximates as if entire sample was used for reliability calculation. The adjusted coefficient was 0.8952.

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Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
Measure Score Validity

Validity Testing: Type of Validity Testing Analysis
Face Validity; Internal Consistency

Validity Testing Sample Size
Face Validity: Forty-one (41) subject matter experts (SMEs) were surveyed for input on face validity of the measure during a public comment period that ran from February 25, 2021 to March 19, 2021. Internal Consistency: Seven (7) sites encompassing seventy-five (75) patients were chosen to assess the internal consistency of the measure.

Validity Testing Statistical Result
Face Validity:

Face validity of the measure component specifications and the measure score was evaluated by surveying forty-one (41) subject matter experts (SMEs) via a web-based survey. Thirty-one (31) SMEs were physicians, three (3) were cancer researchers, two (2) were nurses, two (2) were patients, two (2) were pharmacists, and one (1) was a pharmaceutical representative.

The survey asked respondents about the appropriateness of the measure components (denominator, denominator exclusions, denominator exceptions, and numerator) given the intent of this measure. For each measure component, respondents indicated the extent to which they agreed with the stated specifications of the measure component on a 5-point Likert scale (5 = Strongly agree; 4 = Agree; 3 = Neutral; 2 = Disagree; 1 = Strongly disagree).

Of the SMEs surveyed, 24% (10 SMEs) strongly agreed and 68% (28 SMEs) agreed with the measure denominator. Twenty-two percent (9 SMEs) strongly agreed and 51% (21 SMEs) agreed with the denominator exclusions. Seventeen percent (7 SMEs) strongly agreed and 71% (29 SMEs) agreed with denominator exceptions. Thirty-two percent (13 SMEs) strongly agreed and 51% (21 SMEs) agreed with the numerator.

Additionally,

- 22% strongly agreed and 76% agreed that the measure is meaningful
- 24% strongly agreed and 59% agreed that the measure addresses a gap in care
- 44% strongly agreed and 54% agreed that the measure will improve care, and
- 41% strongly agreed and 49% agreed that the measure addresses a serious ailment with dangerous consequences.

Internal Consistency:

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A split sample method of calculating internal consistency was used, where provider performance was measured once using a randomly chosen subset of the initial 75 patient sample and then measured again using the second random sample exclusive of the first. The agreement between the two resulting performance scores (one for each subset) was compared across 7 sites. As the metric of agreement, split-half coefficient was calculated. The unadjusted split-half coefficient was 0.8103. The adjusted split-half coefficient, an estimate that approximates as if entire sample was used for reliability calculation, was 0.8952.

Validity Testing Interpretation of Results

Face Validity:

Overall, the agreement on the face validity of the measure was high:

- 92% of subject matter experts agreed on the denominator
- 73% of subject matter experts agreed on denominator exclusions
- 88% of subject matter experts agreed on denominator exceptions, and
- 83% of subject matter experts agreed on the numerator.

Additionally, an average of 92% of subject matter experts agreed that the measure is meaningful, addresses a gap in care, will improve care, and addresses a serious ailment with dangerous consequences.

Internal Consistency:

The overall split-sample coefficient of 0.8952 is interpreted to indicate high internal consistency. This value shows that a provider performs consistently on the measure regardless of which subset of their patients is chosen to calculate their measure performance.

Measure performance – Type of Score

Proportion

Measure Performance Score Interpretation

Higher score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have

For a Clinical Quality Measure (CQM) Registry submission method, the mean performance rate is 0.6049 and the standard deviation is 0.2790. The mean and standard deviation were calculated based on the sample of 75 patients across 7 sites. Standard deviation was weighted to account for different number of patients per site. The results indicate there is still an existing performance gap and there is an opportunity for improvement.

Benchmark, if applicable

Not applicable at this time. The benchmark will be established once more data is collected on the measure.

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Measure Contact Information

Measure Steward
Society for Immunotherapy of Cancer (SITC)

Measure Steward Contact Information
Peter Intile

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414-271-2456

Long-Term Measure Steward
N/A

Long-Term Measure Steward Contact Information
N/A

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Secondary Submitter Contact Information
N/A

Section 2: Preliminary Analysis – MUC2021-058 Appropriate intervention of immune-related diarrhea and/or colitis in patients treated with immune checkpoint inhibitors

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

Justification and Notes: The proposed measure does not address any of the specialty areas, clinical conditions, or topics identified as high-priority areas for future measure consideration within MIPS. The measure does address the broader Meaningful Measures area of safety. If included, this process measure would be the only quality measure in MIPS related to gastrointestinal toxicity resulting from

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use of immune checkpoint inhibitors.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes

Justification and Notes: The developer cited five clinical guidelines that support holding immunotherapy and administering corticosteroids (e.g., prednisone or methylprednisolone) and/or immunosuppressants (e.g., infliximab, vedolizumab) to reduce symptoms from grade 2+ diarrhea or colitis. These guidelines are from the National Comprehensive Cancer Network (2020, grade 2A), American Gastroenterological Association (2020), Oncology Nursing Society (2019), American Society of Clinical Oncology (2018, moderate strength), and the European Society for Medical Oncology (2017, level IV-V/grade B). At least three of these guidelines (NCCN, AGA, ESMO) were developed using an evidence-based process that includes review of existing literature. Appropriate treatment and avoidance of an immunotherapy-related gastrointestinal adverse event is estimated to result in $13,699 cost savings per patient (Ghate et al., 2018).

Does the measure address a quality challenge?
Yes/No: Yes

Justification and Notes: Immune checkpoint inhibitors can improve outcomes for advanced cancers, and 43% of cancer patients are eligible for these treatments (Haslam and Prasad, 2019). Some of the most common side effects associated with immune checkpoint inhibitor use are diarrhea and colitis, which occur in over 10% of patients (Champiat et al., 2016). Severe or immune-related diarrhea and colitis can lead to life-threatening complications if treatment is delayed or inappropriate (e.g., delayed reporting, nonadherence to antidiarrheals, failure to hold immunotherapy), but are reversible with early intervention (Acharya and Jeter, 2013; Oncology Nursing Society, 2019). The developer indicated that during measure testing, the mean performance rate was 0.6049, indicating opportunity for performance improvement in this area.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?
Yes/No: Yes

The MIPS quality program does not include any other measures related to adverse effects from use of immune checkpoint inhibitors. The developer noted that two similar measures exist – NQF #3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy and ONSQIR23 Assessment for and Management of Immune-Related Adverse Events During Cancer Treatment with Checkpoint Inhibitors (ICPi). NQF #3490 is currently used in CMS reporting, but it is a broader, facility-level outcome measure addressing hospital/ED admissions due to a range of chemotherapy side effects. ONSQIR23 specifically targets diarrhea and colitis from immune checkpoint inhibitor use and is used in the Premier Clinician Performance Registry MIPS QCDR, but ONSQIR23 targets grade 3+ diarrhea/colitis; the developer states that since the proposed measure also targets grade 2 colitis, it has greater potential for reducing hospital admissions. Finally, the developer states that this measure can be linked to MIPS cost measures including Total Per Capita Cost and Medicare Spending Per Beneficiary due to potential cost savings from prevention of adverse events.

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Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The developer shared that this measure is intended to be a registry measure, and CMS will need to generate HCPCS codes in order to report some of the required elements for the measure. The measure was tested for feasibility at six pilot sites; testing data indicated that the measure was feasible (with some data elements in defined EHR fields) and posed average burden to providers.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: Yes

Justification and Notes: The proposed measure is specified at the clinician/group level and has been tested in the ambulatory, hospital outpatient, and PPS-exempt cancer hospital settings, which aligns with the proposed program (MIPS). The measure has not been submitted for NQF endorsement but is fully developed. Testing demonstrated face validity and reliability for the measure (split-sample reliability score = 0.8952), and 92% of subject matter experts agreed that the measure was meaningful and would address a serious gap in care.

If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure been identified?

Yes/No: No

Justification and Notes: This measure is newly developed and is not yet in use. The developer shared that the Technical Expert Panel that provided input during measure development did not anticipate any unintended consequences with the measure. A member of the MAP Clinician workgroup noted some burden to characterize the grading for diarrhea/colitis.

PAC/LTC Core Concept?

N/A

Impact Act Domain

N/A

Hospice High Priority Areas

N/A

MAP Rural Health Advisory Group Input:

Relative priority/utility:

- The context of the measure was suggested to be appropriate for rural providers and geared towards outpatient for the rural populations.

Data collection issues:

- Concern raised for data availability for grading as it would be in progress note and would require chart abstraction.
- Integration of data from multiple patient care sites was noted as a concern.

Calculation issues:

- None identified.

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Unintended consequences:

- None identified.

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 3.2
1 – 0 votes
2 – 2 votes
3 – 8 votes
4 – 5 votes
5 – 0 votes

MAP Health Equity Advisory Group Input:

Relative priority/utility:

- No major equity implications were identified (either positive or negative).

Data collection issues:

- This measure may have a small denominator.

Calculation issues:

- None identified.

Unintended consequences:

- None identified.

Votes: Range is 1 – 5, where higher number has greater potential for positive impact on health equity.
Average: 3.4
1 – 0 votes
2 – 0 votes
3 – 14 votes
4 – 9 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking, contingent on NQF endorsement.

Summary: What is the potential value to the program measure set?

This newly developed measure addresses the Meaningful Measures area of patient safety. If included, this measure would be the only quality measure in MIPS addressing gastrointestinal adverse effects from the use of immune checkpoint inhibitors as part of cancer treatment.

Summary: What is the potential impact of this measure on quality of care for patients?

While immune checkpoint inhibitors can improve outcomes for advanced cancers, they are associated with side effects including immune-related diarrhea and colitis (Champiat et al., 2016). These toxicities can lead to life-threatening complications if treatment is delayed or inappropriate, but are reversible with early intervention (Acharya and Jeter, 2013; Oncology Nursing Society, 2019). Developer testing

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data demonstrated that only 60% of providers were providing appropriate treatment. Measurement in this area could inform quality improvement efforts related to recognition and management of immune-related adverse events. Conditional support for rulemaking is contingent on NQF endorsement.

Section 3: Public Comments

Mass Gene Hospital

This is for MUC2021-058. Early identification of adverse events such as colitis in the setting of immunotherapy administration is an important measure which can improve patient quality of life.

American Society of Clinical Oncology

This measure would be an important addition to the MIPS program. Currently there are no measures in the MIPS program that specifically targets immunotherapy. In addition, this measure addresses the important domain of Patient Safety. Diarrhea and colitis are the second-most commonly reported AEs (adverse events) with ICIs (immune checkpoint inhibitors), and symptoms typically develop within 6 to 8 weeks of starting treatment (NCCN Guidelines 2020). It can become life-threatening if not addressed in a timely manner.

College of American Pathologists

The College of American Pathologists supports this measure as an important consideration for managing patients as part of an individual care plan that includes genetic testing as clinically indicated, appropriate follow up, and personalized treatment.

Society for Immunotherapy of Cancer

The Society for Immunotherapy in Cancer (SITC) appreciates the opportunity to provide comment in support of “MUC2021-058: Appropriate intervention of immune-related diarrhea and/or colitis in patients treated with immune checkpoint inhibitors (SITC).”" SITC is the world’s leading member-driven organization specifically dedicated to improving cancer patient outcomes and quality of life by advancing the science, development and application of cancer immunology and immunotherapy. SITC strives to make cancer immunotherapy a standard of care which is accessible to all and the word “cure” a reality for cancer patients.

MUC2021-058 was developed by SITC with the purpose of addressing a gap in the field of immunotherapy care as it relates to patient safety. The introduction of immune checkpoint inhibitors (ICIs) into standard of care for many cancer types has resulted in a rapid paradigm shift in the cancer treatment landscape. As the field of oncology continues to adapt to increased ICI use it is critical that measures are in place to ensure quality delivery of care for patients. Currently, the MIPS program does not have any measures pertaining to cancer immunotherapy. As such, there is a gap in measuring the delivery of quality care surrounding cancer immunotherapy, and our society believes that MUC2021-058 will serve as a foundation of which future immunotherapy-focused measures will be built upon.

MUC2021-058 specifically addresses diarrhea and immune-related colitis, which represent the second-most commonly reported adverse event with ICI treatment. Symptoms typically develop within 6 to 8 weeks of starting treatment (NCCN Guidelines 2020) and can become life-threatening if not addressed in

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a timely manner. As developed, MUC2021-058 will help ensure that cancer patients being treated with ICIs are appropriately treated if diarrhea and/or immune-related colitis present and will represent an important step for the field in terms of overall patient care.

Of note, SITC conducted thorough feasibility testing in order to ensure that there is no undue burden on providers to obtain the appropriate data for MUC2021-058. SITC was initially concerned that data collection would be limited for immunotherapy patient care. The results of MUC2021-058 feasibility testing, however, clearly revealed that necessary data were not only available but also easily accessible for providers. Our testing results combined with the critical importance of ensuring this patient population is appropriately treated show that this measure's benefits and ease of use should support its incorporation into the MIPS program.

SITC fully supports MUC2021-058 and looks forward to seeing its potential impact benefit cancer patients. We thank you for the opportunity to provide comment in support of the measure.

American Gastroenterological Associate

The AGA supports the addition of measure MUC2021-058 to the MIPS program. Gastroenterologists are frequently asked to evaluate patients in this clinical condition, and a quality measure would provide a strict framework for management; medication changes would primarily be the responsibility of the oncology providers though a gastroenterologist would potentially be involved for assessment/diagnosis. Furthermore, this is a measure that is applicable to several specialties (e.g., gastroenterology, oncology) and fits the larger paradigm of cross-cutting measure, which are particularly relevant.

Measure MUC2021-058 is a process-oriented measure; the burdens of data collection seem consistent with other similar measures, though there may be challenges for data extraction related to lack of formal coding for the medications. However, this might be overcome by an electronic health record that could reliably extract medication lists and timing of start/stop administration.

Johnson & Johnson

Johnson & Johnson agrees with the recommendation of the Workgroup for conditional support for rulemaking, pending NQF endorsement. Johnson & Johnson supports patient-centered measures focused on appropriate management of adverse events that may reduce unnecessary utilization and improve quality of life (QOL) for patients taking checkpoint inhibitors. We further support optional reporting of this measure in the MIPS program for clinicians who administer checkpoint inhibitors and seek to improve their management of adverse events.

Society for Immunotherapy of Cancer

The Society for Immunotherapy in Cancer (SITC) appreciates the opportunity to provide comment in support of "MUC2021-058 Appropriate intervention of immune-related diarrhea and/or colitis in patients treated with immune checkpoint inhibitors (SITC)." SITC is the world's leading member-driven organization specifically dedicated to improving cancer patient outcomes by advancing the science, development and application of cancer immunology and immunotherapy. SITC strives to make cancer immunotherapy a standard of care and the word "cure" a reality for cancer patients everywhere.

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MUC2021-058 was developed by SITC with the purpose of addressing a gap in the field of immunotherapy care as it relates to patient safety. Specifically, the introduction of immune checkpoint inhibitors (ICIs) into standard of care for many cancer types has resulted in a rapid paradigm shift in the cancer treatment landscape. As stated in our previous open comment, the community continues to adapt to increased ICI usage and it is critical that there are systems in place to ensure safe and effective treatment. One concern is the onset of immune-related diarrhea and colitis – the second most commonly reported AEs (adverse events) with ICIs (immune checkpoint inhibitors). Symptoms typically develop within 6 to 8 weeks of starting ICI treatment (NCCN Guidelines 2020), and these AEs can become life-threatening if not addressed in a timely manner. As the MIPS program does not currently have any immunotherapy specific measures, the creation of a measure to ensure that ICI patients are appropriately treated would serve as an important step for the field to improve patient quality of care.

SITC greatly appreciated the feedback received throughout the multiple NQF working group meetings, including the Rural Workgroup, the Health Equity Workgroup, and the Clinician Workgroup. The discussions during these meetings drew attention to important questions about how MUC2021-058 will work in practice and the potential benefit it has to improve patient care. We are hopeful that any and all concerns were addressed, and we are encouraged by the positive results from the three working groups. We also believe the numerous public comment letters on the importance of the measure signify that the oncology community recognizes the importance and impact MUC2021-058 will have in practice

OCHIN, Inc.

This measure will be difficult to assess in an automated fashion. It looks like it would require manual review or natural language processing.

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MUC2021-063 Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Merit-based Incentive Payment System–Quality

Workgroup
Clinician

Measure Description
The percentage of adult patients 18 years and older who had an elective primary total hip arthroplasty (THA) or total knee arthroplasty (TKA) during the performance period AND who completed both a pre- and post-surgical care goal achievement survey and demonstrated that 75% or more of the patient's expectations from surgery were met or exceeded.

The pre- and post-surgical surveys assess the patient's main goals and expectations (i.e., pain, physical function and quality of life) before surgery and the degree to which the expectations were met or exceeded after surgery. The measure will be reported as two risk-adjusted rates stratified by THA and TKA.

Numerator
The total number of patients in the denominator who completed both a pre- and post-surgical care goal achievement (CGA) survey who demonstrated that 75% or more of the patient's expectations from surgery were met or exceeded.

Numerator Exclusions
N/A

Denominator
All adult patients age 18 and older who undergo an elective, primary THA or TKA during the performance period AND who have completed a pre-surgical care goal achievement (CGA) survey 0-90 days before surgery AND a post-surgical CGA survey 90-180 days after surgery.

Denominator Exclusions
Patients who meet the following criteria are excluded from the measure:

- A revision THA or TKA procedure
- A conversion THA or TKA procedure
- A fracture of the hip or knee at the time of the THA or TKA
- A malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a

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disseminated malignant neoplasm that overlaps the data measurement collection period or the THA or TKA procedure
- A simultaneous, bilateral THA or TKA procedure
- Transfer from another acute care facility for the THA or TKA procedure

For additional information, please refer to attachment: Care Goal Achievement PRO-PM MIF.

Denominator Exceptions
N/A

State of development
Fully Developed

State of Development Details
The following language has been updated and replaces the original paragraph that starts with "The clinician and clinician-group level were each tested... and ends with "This minimum led to few individual clinicians (4) being eligible.."

The clinician and clinician-group level were each tested. In applying a minimum requirement of 25 patients, three clinician-groups had large enough samples to calculate the CGA PRO-PM for each THA and TKA, separately. This minimum led to few individual clinicians (3) being eligible. Our data experts (i.e., psychometrician, statistician, measure developer) tried to conduct analysis on those three clinicians, but their analysis did not produce any significant statistical results. Consistently, we were unable to conduct risk adjustment analysis. Thus, with this very small sample size of clinicians (clinician-level) having 25 or more paired data sets, we were unable to conduct meaningful analysis nor produce statistically significant results.

For additional information on the limited clinician level testing results for this measure, please see the attachment: CGA PRO-PM Clinician-Level Testing Executive Summary for the Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA).

What is the target population of the measure?
All patients aged 18 years and older undergoing a primary, elective THA or TKA from all payers.

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Orthopedic surgery

Measure Type
Patient-Reported Outcome

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Administrative Data (non-claims);Electronic Health Record;Paper Medical Records;Patient Reported

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Data and Surveys

If applicable, specify the data source
N/A

If EHR or Chart-Abstracted data, description of parts related to these sources
The CGA pre-and post-surgical surveys are scheduled based on patient demographic and clinical data, which is stored in the patient record in the EHR, along with surgical scheduling information. Once completed, the scores of the pre- and post-surgical PROMs/PRO-PM are stored in the patient's EHR.

The data pulled from these sources are used to determine if the patient met the inclusion or exclusion criteria, the numerator or denominator criteria, and variables used for risk adjustment.

At what level of analysis was the measure tested?
Clinician; Group

In which setting was this measure tested?
Hospital outpatient department (HOD);Hospital inpatient acute care facility

What one healthcare domain applies to this measure?
Person-Centered Care

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
This quality measure can contribute to the MIPS Value Pathway (MVP) framework in the Quality Payment Program (QPP) by linking to the two cost measures "Elective Primary Hip Arthroplasty (COST_PHA_1)" and "Knee Arthroplasty (COST_KA_1)" and the "Use of certified EHR to capture patient reported outcomes" Improvement Activity to create a new MVP for orthopedic surgery.

The CGA PROMs and PRO-PM aligns with the "Elective Primary Hip Arthroplasty (COST_PHA_1)" and "Knee Arthroplasty (COST_KA_1)" measures, as setting more realistic patient expectations can result in better pre- and post-surgical care compliance, reduced complications and other THA and TKA-associated costs.

Both the "Elective Primary Hip Arthroplasty (COST_PHA_1) and "Knee Arthroplasty (COST_KA_1) measures support opportunities for improvement for elective primary hip and knee arthroplasty include appropriate use of institutional post-acute care (e.g., having patients receive post-procedure treatment in a home health or outpatient therapy setting), improving adherence to correct treatment guidelines, and increasing the use of optimal surgical techniques.

Although EHR measure is not specified as an eCQM, the CGA PROMS and PRO-PM can be implemented in an EHR, improves patient care, can facilitate patient-provider communication, improve quality of care, and track patient goals and expectations before and after THA and TKA surgery.

The Use of certified EHR to capture patient reported outcomes measure supports improving patient access, performing additional activities that enable capture of patient reported outcomes (e.g., home blood pressure, blood glucose logs, food diaries, at-risk health factors such as tobacco or alcohol use, etc.) or patient activation measures through use of certified EHR technology, containing this data in a separate queue for clinician recognition and review.

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CMIT ID
6104

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
Comment 1:

Measure Information - Evidence that the measure can be operationalized: Currently, measures submitted in May 2021 for pre-rulemaking that are recommended by the MAP in December 2021 for implementation would be included in the July 2022 Proposed Rule and if included in the November 2022 Final Rule, eligible clinicians would report the measure for Performance Year 2023. These examples follow the current submission timelines.

Example 1 – In some cases, surgery, the pre-surgical survey, and post-surgical survey will occur within the same Performance Year: On January 1, 2023, a patient completes a pre-surgical survey, then on April 1, 2023, the same patient undergoes surgery. Between July 1 -October 1, 2023, the patient completes a post-surgical survey.

Example 2 – In some cases, the pre-surgical survey may be completed in the year before the Performance Year with the surgery and the post-surgical survey occurring in the Performance Year: On October 1, 2022, a patient completes a pre-surgical survey, then on January 1, 2023, the same patient undergoes surgery. Between April 1 - July 1, 2023, the patient completes a post-surgical survey.

Example 3 – In some cases, the pre-surgical survey and the surgery may occur prior to the Performance Year and post-surgical survey will occur in the Performance Year

On July 1, 2022, the patient completes a pre-surgical survey, then on October 1, 2022, the same patient

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undergoes surgery. Between January 1 - April 1, 2023, the patient completes a post-surgical survey.

It is recommended that for those cases where the surgeries that occur toward the end of the Performance Year with the follow-up occurring during the next Performance Year be excluded from the denominator.

Comment 2:

Burden – Estimated time to complete the survey: During the cognitive testing period, patients were timed during their completion of the CGA surveys and the median time for the pre-surgical PROM was 1.5 minutes as was the completion of post-surgical PROM. Based on our interviews with patients, providers, and leadership overseeing PROMs at MGB, they all felt these completion times kept in line with minimal patient burden.

Comment 3:

Burden – Provider workflow analysis: The measure development team conducted retrospective analysis of THA and TKA cases to determine the feasibility of collecting and accessing the required data through the MGB EDW; such as, if individual data elements are available and if the form in which they exist is consistent with the intent of the PRO-PM. Based on these findings, feedback from providers during qualitative interviews and other key stakeholders including the Mass General Brigham (MGB) (formerly Partners Health Systems) Orthopedics & Neurosurgery Clinical Collaborative Committee Clinic, it was determined that workflows for currently implemented orthopedic PROMs were able to integrate new PROMs as seamlessly as possible and create little clinician burden.

Comment 4:

Burden – Data elements collected: All 25 data elements required to compute and risk-adjust the PRO-PM are available in structured fields within all EHRs used to test the measure. All data elements are captured accurately using nationally accepted terminology and are collected as part of process of requiring no additional data entry from clinician-groups and without any EHR user interface changes.

There are 17 data elements collected from the PROMs – 8 responses for the pre-surgical survey and 9 responses for the post-surgical survey.

There are 8 data elements collected outside of the PROMs, i.e., gender, age, BMI, etc.

Comment 5:

Risk Adjustment – Social determinants of health: While social determinants can be an important part of risk adjusting, for this measure, we identified other risk variables that are widely used in THA and TKA measure development and are almost unanimously collected for patients undergoing joint replacement surgery. The areas of risk adjustment we are using are age, gender, and BMI, which have all shown to impact THA and TKA outcomes. As our sample was homogenous, risk-adjusting for social determinants of health at this time would not yield useful results.

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Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?
No

If eCQM, enter Measure Authoring Tool (MAT) number
N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs
N/A

What other federal programs are currently using this measure?
N/A

Is this measure similar to and/or competing with a measure(s) already in a program?
Yes

Which measure(s) already in a program is your measure similar to and/or competing with?
NQF #2958 - Informed, Patient Centered (IPC) Hip and Knee Replacement Surgery

NQF #3559 - Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA)

How will this measure be distinguished from other similar and/or competing measures?
There are no existing PRO-PM measures related to CGA following TJA. It was established that through

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extensive literature reviews and an environmental scan, that while there are measures that focus on goal achievement, there were no PRO-PMs specific to care goal achievement for total hip replacement and total knee replacement patients. Furthermore, it was determined that there are no measures geared toward identifying centers of excellence for THA and TKA. There are measures which assess hip and knee function pre- and post-surgery, HOOS -JR and KOOS-JR (Lyman et al., 2016a; Lyman et al., 2016b), but these measures are not centered around patient experience or CGA. This measure, in comparison to NQF2958:

- Facilitates conversation between provider and patient, allowing providers to understand patient expectations before surgery and guide conversations about realistic surgical outcomes
- Includes risk adjustment in areas commonly known to impact THA and TKA outcomes, such as age, gender, and BMI
- Compliments existing outcome measures commonly collected and publicly reported to CMS
- This measure, in comparison to NQF3559:
- Facilitates conversation between provider and patient, allowing providers to understand patient expectations before surgery and guide conversations about realistic surgical outcomes
- Includes adult patients aged 18 and older, and is for all payers rather than Medicare FFS beneficiaries aged 65 years and older

How will this measure add value to the CMS program?

Currently, there are no PRO-PMs specific to care goal achievement related to total hip arthroplasty (THA) or total knee arthroplasty (TKA). As noted in Subsection General Characteristics Evidence of performance gap, the value of this measure is to fill the gap in total joint arthroplasty and enable patient-centered care for THA and TKA patients.

It is anticipated that this measure will enable and increase the patient-centered care experience THA and TKA patients.

This PRO-PM under development has several unique benefits:

- Facilitates conversation between provider and patient, allowing providers to understand patient expectations before surgery and guide conversations about realistic surgical outcomes
- Contributes to patient satisfaction after surgery
- Includes adult patients aged 18 and older, and is for all payers
- Includes risk adjustment in areas commonly known to impact THA and TKA outcomes, such as age, gender, and BMI

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

N/A

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Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure

This patient-reported outcome-based performance measure (PRO-PM) related to care goal achievement following a total hip arthroplasty (THA) or total knee arthroplasty (TKA) is designed to promote patient-centered care and enable care that is personalized and aligned with patient's goals. Specifically, the newly developed pre- and post-surgical patient-reported outcome measures (PROMs) assess the patient's main goals and expectations (i.e., pain, physical function and quality of life) before surgery (i.e., THA or TKA) and the degree to which the expectations were met or exceeded after surgery. Consistent with this notion, the measure enables clinician-groups to identify patient's goals and expectations for their surgery, incorporate the information into their conversation with patients which allows shared-decision making and management of unrealistic expectations; all of which have the potential to enhance patient satisfaction, improve clinical outcomes (both as reported by patients and by more traditional measures), increase health service efficiency, and improve health-related business metrics.

Patient-centered care is part of a shift in focus which has drawn increasing interest in recent years, highlighting the importance of incorporating patients' perspectives, expectations and goals into care delivery (IOM 2001; Berwick DM 2002). Consistently, patient expectations have been proven to impact patient outcomes (Dyche 2005). Literature suggests that providers' responsiveness to patient expectations is one of the main determinants of patient experience and satisfaction (Needleman et al., 2002; Schoenfelder et al., 2011; McKinley et al., 2002). Unfulfilled patient expectations are associated with poor satisfaction (McKinley et al., 2002) and poor overall health outcomes (Barry et al. 2000). Consequently, a growing body of evidence supports the importance of identifying and addressing patients' expectations (McKinley et al., 2002; Dyche 2005; Main et al. 2010; Snell et al. 2010). Nonetheless, previous studies have emphasized that clinicians frequently neglect to solicit information about patients' expectations, tending to underestimate or not recognize them, resulting in unmet expectations and lower satisfaction (Rozenblum et al. 2011; Topaz et al. 2016; Rozenblum et al. 2015). As such, clinician-groups must begin to develop and implement practical and effective measurements (e.g., PROMs and PRO-PMs) and interventions that create a culture where clinician groups actively assess and respond to patient expectations.

The PRO-PM addresses a gap in orthopedic measure development, as currently there are no PRO-PMs related to care goal achievement. This gap impacts both patient outcomes, health service efficiency and healthcare cost. The demand for THA and TKA procedures are expected to continue to rise substantially in the coming decades (Singh et al. 2019). With this increased demand for total joint arthroplasty (TJA) and a consistent need for outcome improvement, it is important to maintain care goal achievement.

National goals emphasize the importance of engaging patients in the care process and measuring their goals, experience and perspectives. More specifically, there is increased emphasis on evaluating patient reported outcomes especially in the area of joint replacement. Consistent with this notion, both the American Joint Replacement Registry and the American Association of Hip and Knee Surgeons, established guidelines related to the use of PROMs in TJA (AJRR 2018; AAHKS 2016). PROMs have become increasingly emphasized in the transition from volume-based to value-based orthopedic care (Makhni et al, 2019). Studies showed the importance of measuring PROMs following THA and TKA (SooHoo et al. 2009; Makhni 2019). For example, a study conducted by SooHoo and colleagues identified that 81 percent of patients achieved a minimally clinically important difference of three

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PROMs three months following THA and TKA (SooHoo et al. 2009; Makhni et al 2019). Consistent with this notion, PROMs and PRO-PMs are currently one of the Centers for Medicare & Medicaid Service's (CMS) priorities (CMS 2021).

Therefore, we have developed two PROMs and a PRO-PM related to care goal achievement following a THA or TKA, which assess and manage patient goals and expectations. The importance of the measure was assessed with stakeholders in qualitative assessment (i.e., interviews and focus groups) throughout the measure development process. Patients and providers saw great value in the new PRO-PM. They indicated that completing PROMs before and after surgery to measure patient's expectations and perceived outcomes were a good approach for assessing goal achievement and that the measure is important in improving quality of care. The stakeholders also thought that the measure would improve communication among patients and providers and consequently, enhance patient satisfaction and health outcomes. Payers' interviews also supported these findings and added that this PRO-PM will enable new national benchmark related to care goal achievement and possibly incentivize efforts to implement the necessary improvements to practice quality.

For full citations, please refer to attachment: Care Goal Achievement PRO-PM References.

Evidence that the measure can be operationalized

The following language has been updated and replaces the original paragraph that starts with "The minimum number of paired data sets... and ends with "...using an EHR in a clinician-group setting is feasible."

The minimum number of paired data sets needed for inclusion in our measure is 25 per clinician/clinician group. By analyzing rates at the clinician-group level, many more patients and providers are included in the measure, as few individual clinicians in our samples collected over 25 paired data sets in the time frame. Of the 33 total clinicians included in the data, only three clinicians (9%) had large enough samples to meet the requirement above, two for THA and one for TKA. Our data experts (i.e., psychometrician, statistician, measure developer) tried to conduct analysis on those three clinicians, but their analysis did not produce any significant statistical results. Consistently, we were unable to conduct risk adjustment analysis. Thus, with this very small sample size of clinicians (clinician-level) having 25 or more paired data sets, we were unable to conduct meaningful analysis nor produce statistically significant results.

For additional information on the limited clinician level testing results for this measure, please see the attachment:

CGA PRO-PM Clinician-Level Testing Executive Summary for the Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA).

Group-level analysis also prevented a sampling bias. The minimum requirement of 25 paired data sets per clinician would introduce a sampling bias, as only high-volume clinicians would be included in the measure. There were three clinician-groups that did not meet the 25-paired data set minimum requirement.

Based on the aforementioned items the measure development team recommend reporting this PRO-PM only at the clinician-group level. Moreover, the team has demonstrated that the operationalization and

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testing of the CGA PRO-PM, in a real use case scenario, using an EHR in a clinician-group setting is feasible.

How is the measure expected to be reported to the program?
Clinical Quality Measure (CQM) Registry

Feasibility of Data Elements
Patient/family-reported information: electronic;Patient/family-reported information: paper

Evidence of Performance Gap
Our findings suggest that there is a significant performance gap and opportunities for improvement related to care goal achievement (CGA) following THA or TKA. The mean scores for THA patients were 56.0% using the unadjusted CGA and 56.2% using the adjusted CGA. By comparison, the mean scores for TKA patients were 39.7% using the unadjusted CGA and 41.3% using the adjusted CGA. By either the adjusted or unadjusted figures, the CGA score among both the hip and knee patients were very low; demonstrating a significant performance gap related to CGA following THA or TKA. Our findings demonstrated that many (N= 86 [44%] of THA patients and n= 114 [60%] of TKA patients) of the patients reported that their expectations/goals were not met and that there is variation in performance between clinician groups. Importantly, none of the clinician groups showed good care goal achievement (i.e., achieving the threshold of 75% of meeting and/or exceeding care goal achievement). Thus, our finding reveals high numbers and percentages (~50%) of hip and knee patients whose expectations/goals from the surgery were not met and indicates that there is substantial room for improvement related to CGA and health outcomes.

During information gathering sessions, the project stakeholders (e.g., TEP members, orthopedic co-investigators and measure experts) identified the measure as important for better evaluation of the quality of routine total joint replacement surgery and found value in the CGA PRO-PM. In addition, the project stakeholders indicated that there is a measurement gap (an absence of measures) related to care goal achievement following THA or TKA. The importance of the CGA PRO-PM has further been assessed with patients, providers, and payers in the qualitative assessment portions of our testing. In interviews and focus groups that were conducted throughout the measure development process, patients (n= 89) indicated that it is important to measure their goals and expectations as related to their total joint surgery. Providers (n=37) also agreed that it is important to be able to measure their patients' goals and expectations, as well as the achievement of them. The providers also thought that there is an absence of measures that assess care goal achievement following THA or TKA and that the measure would improve communication among patients and providers and consequently, enhance patient satisfaction and health outcomes. Payers' interviews also supported these findings and added that this PRO-PM might enable a new national benchmark related to care goal achievement and possibly incentivize efforts to implement the necessary improvements to practice quality. As a testimony for the value and feasibility of the newly developed measure, the Mass General Brigham (MGB) (formerly Partners Health Systems) Orthopedics & Neurosurgery Clinical Collaborative Committee recognized this need and formally approved the implementation and testing of the CGA PROMs and PRO-PM via Epic's PROMs platform across participating test sits (i.e., 6 clinician-groups).

Consistent with our quantitively and qualitative findings, studies have demonstrated that there is consensus among healthcare providers that it is important to ask patients about their expectations,

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however few providers reported doing so (Rozenblum et al., 2011; Rozenblum et al. 2015; Topaz et al. 2016). These findings reflect a gap, or "blind spot", between the importance providers attribute to addressing patient expectations and the providers' performance (Rozenblum et al., 2011). These studies also found that healthcare providers with greater awareness towards care goal achievement were more than twice as likely to ask patients about their expectations and goals than providers with lower awareness.

As mentioned elsewhere, the PRO-PM related to care goal achievement following THA or TKA addresses a gap in orthopedic measure development, as currently there are no PRO-PMs related to care goal achievement. This gap impacts both patient outcomes, health service efficiency and healthcare cost. The demand for THA and TKA procedures are expected to continue to rise substantially in the coming decades and are projected to reach 4.85 million total procedures - 1,429,000 THA and 3,416,000 TKA by 2040 (Singh et al. 2019), costing Medicare more than $50 billion USD annually (Wilson et al. 2008). Although the majority of total joint arthroplasty (TJA) [specifically THA and TKA] recipients report excellent results, up to 30% of patients have suboptimal outcomes (Nilsdotter et al. 2003). With this increased demand for TJA and a consistent need for outcome improvement, it is important to maintain care goal achievement.

In summary, this PRO-PM related to care goal achievement following a THA or TKA will add value to the area noted by the gap analysis above, as currently there are no PRO-PMs related to care goal achievement. The measure will assist clinician-groups to identify patient's goal and expectations for their surgery, incorporating this information into their conversation and potentially addressing unrealistic expectations. Clinician-groups will be enabled to assess if, and to what extent, their patient's goals were addressed after the surgery, which in turn will encourage patients to be more engaged in their care and be part of the decision-making process; all of which is aligned with CMS initiative to assist providers and clinician groups in ensuring that care is both personalized and aligned with patient goals (IOM 2001). Finally, this PRO-PM will enable a new national benchmark related to care goal achievement and a good measure for CMS consideration in the Merit-based Incentive Payment System (MIPS) Quality Payment Program (QPP).

For full citations, please refer to attachment: Care Goal Achievement PRO-PM References.

Unintended Consequences

The benefits of this performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Through engagement with our stakeholders, including the PROMs implementation team at MGB, the development team confirmed that this PRO-PM will not result in increased document burden for clinicians, early findings show there has been not undue burden on patients or providers and that the measure itself has been very easy to incorporate into the process of care at MGB.

A potential unintended consequence which is true for all PROMs and PRO-PMs (not only for those under development by the BWH team) is that provider groups who are not utilizing an integrated care delivery system may not have access to the entirety of EHR data elements necessary for this measure and, as a result, are unable to use web-based PROMs or PRO-PMs.

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Outline the clinical guidelines supporting this measure

The PRO-PM, Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA), meets the evidence requirement that the outcome can be linked to at least one process of care. National goals emphasize the importance of engaging patients in the care process and measuring their goals, experience and perspectives. Specifically, there is increased focus on adopting and evaluating patient reported outcomes in the area of joint replacement. Consistent with this notion, leading organizations are promoting the use of PROMs and PRO-PMs by providing guidelines and recommendations. These guidelines are both evidence-based and consensus based.

These guidelines will support the adoption and use of the CGA PRO-PM. Here are some of the guidelines relevant to the CGA PRO-PM:

The American Joint Replacement Registry has created explicit guidelines for PROM development and use as part of their mission to improve care for patients with meaningful data (AJRR, 2018).

The American Association of Hip and Knee Surgeons (AAHKS) has placed emphasis on developing measures that evaluate preoperative and postoperative care (AAHKS, 2016). Specifically, they established guidelines related to the use of PROMs in TJA (AAHKS, 2016).

The American Academy of Orthopaedic Surgeons (AAOS) developed an evidence-based clinical practice guideline, which is endorsed by the American Society of Anesthesiologists and the American Association of Hip and Knee Surgeons in addition to other professional organizations. This guideline is specific to a risk adjustment variable, Body Mass Index (BMI) and demonstrates that there is strong evidence that high BMI is a risk factor for reduced outcomes improvement for TKA patients (AAOS, 2015).

Currently the Centers for Medicare & Medicaid Service's (CMS') Meaningful Measures Initiative is prioritizing that patient care has alignment with patient goals. Consistent with this notion, the CMS providing guidelines for PROMs/PRO-PMs development and, implementation and reporting.

The National Quality Forum (NQF) serves as a critically important foundation for initiatives to enhance healthcare value, make patient care safer, and achieve better outcomes. They established guidelines for PROM and PRO-PM development for measures used in payment and public reporting programs in the "Patient Reported Outcomes (PROs) in Performance Measurement" guide. (NQF, 2013)

For full citations, please refer to attachment: Care Goal Achievement PRO-PM References.

Were the guidelines graded?

Yes

If yes, who graded the guidelines?

As mentioned in "General Characteristics: Outline the clinical guideline(s) supporting this measure" section, there are guidelines that support the adoption and use of the CGA PRO-PM. While not all of the guidelines are graded, they are promoted by governing orthopedic associations. A relevant graded guideline for our measure is for BMI, which is a risk-adjusted factor. The American Academy of Orthopaedic Surgeons (AAOS) developed an evidence-based clinical practice guideline, which is endorsed by the American Society of Anesthesiologists and the American Association of Hip and Knee Surgeons in addition to other professional organizations. These guidelines demonstrated that there is strong evidence that high BMI is a risk factor for reduced outcomes improvement for TKA patients

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(AAOS, 2015).

If yes, what was the grade?
The guideline from the AAOS relevant to this measure, specifically the body mass index as a risk factor of post-surgical complication, was rated as “strong.”

Estimated Impact of the Measure: Estimate of Annual Denominator Size
5407

Estimate of Annual Improvement in Measure Score
An estimated annual volume of THA and TKA procedures across our participating 6 clinician-groups is 2414 THA and 2993 TKA (2019 numbers). The median adjusted THA PRO-PM score for participating clinician-groups (with at least n= 25 patients) was 54%. Clinician-Group F had an adjusted PRO-PM score lower than the median, 50.1%. In order to raise this score to the median, Clinician-Group F would need an estimated additional 39/1,000 patients.

The median adjusted TKA PRO-PM score for participating clinician-groups (with at least n=25 patients) was 44%. Clinician-Group A had a median adjusted score lower than 44%, at 28.6%. In order to raise this score to the median adjusted score, Clinician-Group A would need an estimated 154/1,000 patients. These are crude estimates based on our sample and 2019 estimated volumes.

Type of Evidence to Support the Measure
Clinical Guidelines;Systematic Review;Empirical data;Other: Outcome measure linked to processes of care

Is the measure risk adjusted, stratified, or both?
Risk adjusted;Stratified

Are social determinants of health built into the risk adjustment model?
Not Applicable

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
Estimated avoided costs are $18,000 per avoided major complication and $23,100 per avoided readmission.

Improved communication of expectations through standardized decision aids resulted in improved decision making and reduced average cost per patient with hip and knee osteoarthritis by 12 to 21% percent over 6 months.

Applied cost per major complication and per readmission from Luzzi et al. 2018 to estimate avoided costs attributable to improved outcomes. Note that because complications and readmissions are not mutually exclusive, these categories cannot be added.

For full citations, please refer to attachment: Care Goal Achievement PRO-PM References.

Cost Avoided Annually by Medicare/Provider
We expect cost savings attributable to more realistic patient expectations to accrue via the following mechanisms:

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1. More realistic patient expectations are associated with improved patient satisfaction, patient activation and shared-decision making; resulting in: a. Improved patient compliance with pre- and post-surgical care, reducing major complications, readmissions, as well as other costs (e.g., pain management) (Luzzi 2018). b. Improved patient participation in activities such as rehab or physical therapy resulting in better outcomes. 2. Reduction in inappropriate/unnecessary TJA surgeries resulting in lower net cost per patient (e.g., cost savings attributable to not having surgery are partially offset by higher physical therapy costs) (Ghomrawi et al 2011); as a secondary effect fewer surgeries results in fewer surgical complications further reducing costs. To date we have estimated national cost savings associated with avoided/averted major complications or readmissions (these are not mutually exclusive categories and therefore can't be added). We estimate post-acute healthcare cost savings of $609,000/year from avoided complications and possibly as much as $2.9 million/year from avoided readmissions. For full citations, please refer to attachment: Care Goal Achievement PRO-PM References.

Source of Estimate

The following assumptions were made based on references, or best professional judgement:

1. The estimated number of annual THAs and TKAs (498,000 and 1.06 million respectively) from Singh et al, 2019.

2. The rate of 90-day major complications and 90-day readmissions for patients with costs greater than the 75th percentile (Snyder et al., 2019). Higher rates of poor outcomes are correlated with unrealistic patient expectations.

3. Subtract "usual" rate of major complications and readmissions that should not be attributable to unrealistic patient expectations (none).

4. Using Best Professional Judgement, assumed that no more than 10% of THAs and TKAs with poor outcomes can be attributed to patients with unrealistic expectations.

5. Using Ghomrawi et al., 2011, estimated percentage of patients with "seriously unrealistic" expectations, which we defined as patient with expectations for outcome are higher than those of their surgeon, and also think the probability of complications = zero (68% of THAs; 53% of TKAs). Patients with "seriously unrealistic" expectations are at highest risk for poor outcome.

6. Using Best Professional Judgement and previous sources Calculate number of major complications and readmissions associated with patients with seriously unrealistic expectations. (About 1.4% of all THAs and 2.6% of all TKAs respectively)

7. Using Best Professional Judgement Assumed surgeon exposure to their patients' care goal achievement PRO-PM improves communication and more realistic patient expectations resulting in a 5% reduction in major complications and readmissions.

8. Using Best Professional Judgement Calculate reduction in number of major complications and readmissions attributable to more realistic patient expectations.

9. Applied cost per major complication and per readmission from Luzzi et al. 2018 to estimate avoided costs attributable to improved outcomes. Note that because complications and readmissions are not mutually exclusive, these categories cannot be added.

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For full citations, please refer to attachment: Care Goal Achievement PRO-PM References.

Year of Cost Literature Cited
Cost per major complication and per readmission taken from Luzzi et al. 2018 in 2015 dollars; inflated to 2020 dollars using Bureau of Labor Statistics' (BLS) Producer Price Index for General Medical and Surgical Hospitals (BLS 2020).

For full citations, please refer to attachment: Care Goal Achievement PRO-PM References.

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

If yes, choose all methods of obtaining patient/caregiver information
Standard Technical Expert Panel (TEP) inclusive of patient/caregiver representatives;Focus groups;One-on-one interviews;Surveys

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
Patients were engaged a total of 4 times with regard to the various phases of measure development. Once during conceptualization, once during alpha testing, once during beta testing, and once at the conclusion of specification.

Some patients (n=425) were engaged a 5th time via a REDCap survey specific to the impact of COVID-19 on their care goals and expectations. Patients were asked to select a statement that best described the way in which COVID-19 impacted their goals and expectations for surgery and outcomes of surgery for the three domains of the care goal achievement survey (pain relief, physical activity, and quality of life).

Total Number of Patients and/or Caregivers Consulted
89

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
1:2

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
81

Burden for Patient: Does the measure require survey data from the patient?
Yes

If yes, what is the estimated time to complete the survey?
2

If yes, what is the frequency of requests for survey data per year?
2

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If yes, are the survey data to be collected during or outside of a visit?
Prior to visit;During visit;After visit

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
One-on-one interviews;Standard TEP;Other: Public Comment

Total Number of Clinicians/Providers Consulted
37

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
35

Burden for Provider: Was a provider workflow analysis conducted?
Yes

If yes, how many sites were evaluated in the provider workflow analysis?
6

Did the provider workflow have to be modified to accommodate the new measure?
Yes

If yes, how would you describe the degree of effort?
1 (little to no effort)

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
25

Measure Testing Details

Reliability Testing Interpretation of Results
CGA PRO-PM Reliability

CGA PRO-PM Data Element Reliability:

The results of the chart review demonstrate strong agreement between manual reviewers themselves, related to the data elements included in the measure calculation. Additionally, the alignment between manual reviewers and EDW data elements was strong overall. Importantly, gaps between manual chart review and EDW may be due to the comprehensive list of codes associated with the measure calculation.

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CGA PRO-PM Score Reliability:

Overall, the tests of the CGA PRO-PM reliability related to data elements showed positive results. Based on literature and experts' opinions, the very small sample size of clinician groups that were included in the analysis led to the poor score reliability of the PRO-PM. The BWH team and measure developer experts do not believe that these results show that the CGA PRO-PM has poor reliability, but only show that the sample size is small, and no conclusions can be drawn.

Given that the CGA PROMs/PRO-PM have been fully operationalized in a real use case scenario, into Epic, an electronic health record (EHR) system at Mass General Brigham (MGB), the BWH measure development team has the advantage to continue to collect data and to further evaluate the measure score reliability.

CGA PROMs Reliability:

The Cronbach's a results for the pre- and post-CGA PROM surveys for both joints, were all well above the a priori threshold of 0.7. These results show strong internal consistency reliability for the pre- and post-CGA PROMs. As for test-retest reliability, most or all of the 8 items exhibited moderate reliability or better, for both the pre- and post-CGA PROMs. Of the items that did not reach the exact threshold, many were quite close to it. Taken together, these results show that the pre- and post-CGA PROMs surveys are reliable.

Type of Reliability Testing

Measure Score Reliability;Data Element Reliability

Reliability Testing: Type of Testing Analysis

Signal to Noise;ICC (Intraclass correlation coefficient);Test-Retest;Internal Consistency;Signal to Noise;ICC (Intraclass correlation coefficient);Test-Retest;Internal Consistency

Reliability Testing Sample Size

CGA PROM sample size For the pre-CGA PROM, our unpaired samples included 556 hip patients and 592 knee patients. For the post-CGA PROM, our unpaired samples included 292 hip patients and 296 knee patients. CGA PRO-PM sample size For the CGA PRO-PM, our paired samples (i.e., patients that completed both the pre and post CGA surveys and met the inclusions and exclusions criteria), included 181 hip patients and 172 knee patients. A minimum of 25 cases per clinician-group were required for inclusion in the measure. For the CGA PRO-PM, we piloted at 6 clinician groups. Of these groups, 3 had sufficient hip patients and 3 had sufficient knee patients for PRO-PM calculation (minimum 25 patients). In addition to testing at the clinician-group level, we also tested at the clinician level. Considering sample size bias, minimum required data sets, and other factors, we found that when analyzing rates at the clinician-group level, many more patients and providers were eligible to be included in the measure, therefore we are not using clinician-level data.;PRO-PM Sample: For our PRO-PM testing, which focused on paired data sets (measured pre- and post-surgically on the same patients), our sample included 196 THA patients and 191 TKA patients, which were subsets of the unpaired groups from the PROMs sample. This cohort served for both the measure score reliability and data element reliability testing. PRO-PM Data Element Testing (Chart Review) Sample: A total of 80 patients (40 THA and 40 TKA) from Mass General Brigham (MGB) (formerly Partners Health Systems; PHS) from 2020-2021 were randomly sampled for data element testing. PROMs Sample: For our PROMs testing, which focused on unpaired

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data sets, our sample included 728 THA patients and 823 TKA patients for the presurgical sample, and 314 THA patients and 337 TKA patients for the postsurgical sample. For additional information about the sample size and the patient characteristics, please see the attachment: CGA PRO-PM Peer-Reviewed Journal Article.

Reliability Testing Statistical Result

Please review the following new paragraph that comes after the "2. Even among these three clinician groups, two exhibited very similar performance, even in a bootstrapped simulation," and before "CGA PROMs Reliability CGA PROMs Internal Consistency Reliability."

As mentioned in the “Evidence that the measure can be operationalized section and “State of Development Details” section, we also attempted to test the PRO-PM results on the clinician level. Of the 33 total clinicians included in the data, only three clinicians (9%) had large enough samples to meet the requirement above, two for THA and one for TKA. Our data experts (i.e., psychometrician, statistician, measure developer) tried to conduct analysis on those three clinicians, but their analysis did not produce any significant statistical results. Consistently, we were unable to conduct risk adjustment analysis. Thus, with this very small sample size of clinicians (clinician-level) having 25 or more paired data sets, we were unable to conduct meaningful analysis nor produce statistically significant results.

For additional information on the limited clinician level testing results for this measure, please see the attachment:

CGA PRO-PM Clinician-Level Testing Executive Summary for the Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA).

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?

Yes

If yes, specify the number of cases and the percentage of providers

A minimum of 25 cases per clinician-group were required for inclusion in the measure. Of six clinician groups, 50% (3) had sufficient patients for THA and 50% (3) had sufficient patients for TKA. Two clinician groups qualified for both joints. This minimum case requirement was harmonized with other relevant measure that we reviewed (i.e., NQF3559)

Type of Validity Testing

Measure Score Validity

Validity Testing: Type of Validity Testing Analysis

Correlation;Face Validity;Construct Validity;Structural Validity;Other: Known Groups Validity

Validity Testing Sample Size

PRO-PM Sample: For our PRO-PM testing, which focused on paired data sets (measured pre- and post-surgically on the same patients), our sample included 196 THA patients and 191 TKA patients, which were subsets of the unpaired groups from the PROMs sample. This cohort served for both the known-groups validity and discriminant validity testing. We piloted the CGA PRO-PM, at six (6) clinician-groups.

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A minimum of 25 cases per clinician-group were required for inclusion in the measure, as described in further detail in the Measure Information - Evidence that the measure can be operationalized section. Of these six clinician-groups, 3 had sufficient hip patients and 3 had sufficient knee patients for PRO-PM calculation. PRO-PM Face Validity: A vote was conducted with the seven (7) members of the development team's technical expert panel (TEP). PROMs Sample: For our PROMs testing, which focused on unpaired data sets, our sample included 728 THA patients and 823 TKA patients for the presurgical sample, and 314 THA patients and 337 TKA patients for the postsurgical sample.

Validity Testing Statistical Result

The following new information should follow the paragraph ending with "We did not statistically test these differences because of the small n's," and before "CGA PROMs Validity PROMs Face Validity."

As mentioned in other sections, we also attempted to test the PRO-PM results on the clinician level. Of the 33 total clinicians included in the data, only three clinicians (9%) had large enough samples to meet the requirement above, two for THA and one for TKA. Our data experts (i.e., psychometrician, statistician, measure developer) tried to conduct analysis on those three clinicians, but their analysis did not produce any significant statistical results.

Consistently, we were unable to conduct risk adjustment analysis. Thus, with this very small sample size of clinicians (clinician-level) having 25 or more paired data sets, we were unable to conduct meaningful analysis nor produce statistically significant results.

For additional information on the limited clinician level testing results for this measure, please see the attachment: CGA PRO-PM Clinician-Level Testing Executive Summary for the Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA).

Validity Testing Interpretation of Results

CGA PRO-PM Validity:

The confirmation of face validity of the PRO-PM by TEP endorsement (i.e., voting) supports the claim that the CGA PRO-PM measured what it was intended to measure. Thus, the stakeholders confirmed that the PRO-PM had face validity.

As expected, the known groups validity test was inconclusive due to the small N, but the tool performed well on the discriminant validity test. Although the N is small, the difference in mean CGA PRO-PM scores for THA compared to TKA was large, a difference of 16.5 percentage points (for both unadjusted means and case mix adjusted means). The higher means for THA support the validity of the CGA PRO-PM, since in general recovery from THA proceeds faster and more effectively than for TKA (Ethgen, 2004).

Given that the CGA PROMs/PRO-PM have been fully operationalized in a real use case scenario, into Epic, an electronic health record (EHR) system at Mass General Brigham (MGB), the BWH measure development team has the advantage to continue to collect data and to further evaluate the measure score validity.

CGA PROMs Validity:

The confirmation of face validity of the PROMs by TEP endorsement (i.e., voting) support the claim that

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the CGA PROMs measured what it was intended to measure. The uni-dimensionality of the PROM's items that was found by the EFA shows that the items on the PROMs all measured the same construct (i.e., have structural validity). For known groups validity, we hypothesized that the pre-CGA PROM would not be correlated strongly with functioning (HOOS-PS/KOOS-PS), but the post-CGA PROM would be correlated positively with functioning. Our findings were consistent with these hypotheses.

For full citations, please refer to attachment: Care Goal Achievement PRO-PM References.

Measure performance – Type of Score
Proportion;Proportion

Measure Performance Score Interpretation
Higher score is better;Higher score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have
After adjusting for case mix by age and gender, the results for mean and standard deviation are below:

Mean, adjusted CGA PRO-PM Score THA: 56.2%

Standard Deviation: 7.9%

Mean, adjusted CGA PRO-PM Score TKA: 41.3%

Standard Deviation: 11.8%

Benchmark, if applicable
Not applicable;Not applicable

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Section 2: Preliminary Analysis – MUC2021-063 Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

Justification and Notes: This measure aligns with the goals of the CMS Meaningful Measures 2.0 to "prioritize outcomes and patient reported measures." Person-centered care is achieved through the feedback provided by patients to their care team on their goals and expectations of their joint replacement surgery through completion of pre- and post-surgical surveys. The measure contributes to an efficient use of patient resources and supports program goals by focusing on improved patient-reported outcomes while not duplicating other measures currently in the MIPS program.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes

Justification and Notes: This patient reported outcome measure (PROM) aims to increase patient satisfaction by providing an opportunity for clinicians to incorporate feedback received from patients into a shared decision-making model. Successful implementation can lead to management of patient expectations, improved clinical outcomes, increased health service efficiency, and increased health-related business metrics. Research shows that while providers are aware of the importance of incorporating patient perspectives into care delivery, their input is rarely sought out (Rozenblum et al. 2011; Topaz et al. 2016; Rozenblum et al. 2015). This PRO-PM measure/intervention will fill gaps in orthopedic measure development consistent with guidance provided by the American Joint Replacement Registry and the American Association of Hip and Knee Surgeons (AJRR 2018; AAHKS 2016)

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and has the potential to incur cost savings associated with complications and readmissions linked to poor patient satisfaction (Dyche, 2005).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: This measure identifies current performance gaps when patient survey responses are reported as two risk-adjusted rates stratified by THA and TKA procedures. The entities represented included six-clinician groups with a total of 33 individual clinicians. Using adjusted care goal achievement (CGA) rates, mean scores for THA patients were 56.2% and 41.3% for TKA patients. Low average scores among both patient groups indicates that many of the patients' goals and expectations were not met and there is variation among clinician groups. Overall, none of the clinician groups achieved a threshold of greater than 75% to meet or exceed patient goals and expectations.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?

Yes/No: Yes

Justification and Notes: The current program includes measures of similar target populations (NQF#2958 and NQF#3559), but not similar measure focus. The primary justification for utilization of this measure is that there are no existing PRO-PM measures related to CGA following total joint replacement. Additionally, there are no measures geared toward identifying centers of excellence for THA and TKA. Instead, previous measures are focused on assessment of hip and knee function pre- and post-surgery. Two areas of importance to highlight within this measure are the inclusion of age, gender, and BMI in the risk adjustment model, and the expansion of the patient population to include patients 18 years and older for all payers.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The feasibility of measurement reporting appears to be fair and is based on the capabilities and infrastructure of the clinician group. EHRs appear to be the main vehicle. In instances where a standard EHR is not used by the clinician group, a third-party vendor may be used. Data sources include administrative data, patient medical records (paper-based or electronic), and patient-reported data and surveys. For implementation of CGA PROMs through non-EHR or non-web-based administration, data can be compiled using practical programming applications.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: No

Justification and Notes: In the orthopedic care setting of TKAs and THAs, the level of analysis determined to be most appropriate is the clinician-group level rather than individual-level clinicians. This is because clinician groups provide more stable assessments, individual clinicians were not able to reach large enough sample sizes for CGA PRO-PM calculations, and sampling bias becomes a threat when high-volume individual-level clinicians are overrepresented in the data.

The NQF Scientific Methods Panel raised several concerns regarding the reliability and validity of the

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measure specification submitted for measure endorsement in the Fall 2021. While reliability testing conducted at the patient level was sufficient (The overall agreement between the reviewers and the electronic data warehouse ranged from 89.9-99.2 percent). However, the developer performed reliability testing of the accountable entity (i.e., measure score) using a signal-to-noise ratio (SNR) approach (0.00118 for THA and 0.00004 for TKA). NQF SMP members noted that reliability testing is sufficient at the patient or encounter (i.e., data element) level, yet inadequate at the clinician-group practice level due to small sample size, low variability of scores across practices, and no assessment of nonresponse bias. Further, SMP members also raised concerns with the empirical validity testing and interpretation due to the small sample sizes overall and for the risk adjustment model, testing methodology, apparent homogenous populations, lack of population variability (including social risks), and inconclusive results during measure known groups testing. The SMP did not pass the measure on reliability and validity

If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure been identified?
Yes/No: N/A

Justification and Notes: This measure has not been shown to increase burden on patients or providers and the measure has proven to be easily incorporated into the process of care.

One potential unintended consequence, as a by-product of an unintegrated care delivery system, is that the underutilization of all EHR data elements may prevent the measurement data from being captured at its fullest extent.

PAC/LTC Core Concept?
N/A

Impact Act Domain
N/A

Hospice High Priority Areas
N/A

MAP Rural Health Advisory Group Input:
Relative priority/utility:

- A concern was raised regarding patient expectations related to goal achievement. Patients from rural communities may have different expectations from surgery than the general population.

Data collection issues:

- The data collection tools of paper versus electronic health record were discussed, and it was expressed that the paper tool would be more common in rural communities.

Calculation issues:

- Concern was raised regarding risk adjustment for BMI and the impact on rural communities.

Unintended consequences:

- Concerns were raised about patient selection in rural settings as a potential unintended negative consequence for the measure and should be monitored.

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 3.6

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1 – 0 votes
2 – 2 votes
3 – 3 votes
4 – 6 votes
5 – 2 votes

MAP Health Equity Advisory Group Input:

Relative priority/utility:

- This is an important patient reported outcome measure.

Data collection issues:

- Challenges identified with the completion of both the pre and post surveys due to loss to follow-up for disadvantaged populations.

Calculation issues:

- The Advisory Group recommended this measure be stratified to assess performance based on population subgroups.
- It was noted the measure is risk adjusted by age, gender, BMI (biological) but no details on other risk adjustment factors (e.g., SES); the developer noted that measure is not stratified by race, ethnicity, or other factors.

Unintended consequences:

- The Advisory Group noted that there is a disparity as to who receives THA and TKA and has access to the surgery. This disparity and the use of this measure could foster further patient selection.
- It was noted that the denominator may not include populations who are unable to return for the post survey.

Votes: Range is 1 – 5, where higher number has greater potential for positive impact on health equity.
Average: 2.6
1 – 2 votes
2 – 9 votes
3 – 9 votes
4 – 4 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:

Do Not Support for Rulemaking

Summary: What is the potential value to the program measure set?

This measure aligns with the goals of the CMS Meaningful Measures 2.0 to “prioritize outcomes and patient reported measures.” Person-centered care is achieved through the feedback provided by patients to their care team on their goals and expectations of their joint replacement surgery through completion of pre- and post-surgical surveys. However, the measure did not pass the NQF SMP for sufficient reliability and validity of the measure specifications.

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Summary: What is the potential impact of this measure on quality of care for patients?

The measure aims to increase patient satisfaction by providing an opportunity for clinicians to incorporate feedback received from patients into a shared decision-making model. Successful implementation will lead to management of unrealistic expectations, improved clinical outcomes, increased health service efficiency, and increased health-related business metrics.

This PRO-PM measure/intervention will fill gaps in orthopedic measure development consistent with guidance provided by the American Joint Replacement Registry and the American Association of Hip and Knee Surgeons (AJRR 2018; AAHKS 2016) and has the potential to incur cost savings associated with complications and readmissions linked to poor patient satisfaction (Dyche, 2005).

The primary justification for utilization of this measure is that there are no existing PRO-PM measures related to CGA following total joint replacement. Additionally, there are no measures geared toward identifying centers of excellence for THA and TKA. Instead, previous measures are more focused on assessment of hip and knee function pre- and post-surgery. Two areas of importance to highlight within this measure are the inclusion of risk adjustment areas, such as age, gender, and BMI, and the expansion of the patient population to include patients 18 years and older for all payers. The MAP Clinician workgroup also acknowledged the importance of stratifying the measure to assess performance on this measure based on population subgroups.

Section 3: Public Comments

Federation of American Hospitals

The Federation of American Hospitals (FAH) supports the development and implementation of patient-reported outcomes performance measures (PRO-PMs) but we also believe that additional questions and work remain before their widespread use such as the degree to which multiple PRO-PMs could lead to survey fatigue for patients, the potential impact additional PRO-PMs may have on the reporting of well-established measures such as HCAHPs and CG-CAHPS, what level of data collection burden for an individual PRO-PM is acceptable for a practice or other healthcare provider, and the degree to which duplicate data collection and reporting burden can be reduced with multiple groups (i.e., clinicians, practices, hospitals) implementing the same or similar measures. In addition, any measure used for accountability purposes must be evidence-based, reliable, and valid and we do not believe that this measure meets those requirements.

Based on the information available, the PROM and PRO-PM were only tested in one health system and the measure was calculated using data from three clinicians. The FAH strongly urges the Centers for Medicare & Medicaid Services (CMS) and the developer to demonstrate the reliability and validity of both the PROM and PRO-PM with multiple practices and across various patient populations. The PROMs for each procedure appear to have been created during the development of the PRO-PM but the information on the methods, modes, or languages of administration, patient characteristics of those completing the survey, or the tools' ability to produce reliable and valid results is insufficient. In addition, the measure should demonstrate that it produces reliable and valid scores and be risk-adjusted using a robust set of clinical and social risk factors such as frailty and health literacy. The developers were unable to collect a sufficient set of data on which reliability could be assessed nor was the

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information provided on the validity of the PRO-PM sufficient. The developer also did not adequately justify why social risk factors should not be considered nor were they able to evaluate the validity of the risk adjustment model. These unanswered questions raise significant concerns on the measure's ability to ensure that results will be comparable across practices and could contribute to inequities in care due to the lack of survey availability in multiple languages, the unreliable performance scores, inadequate validity testing, the limited variables are included in the PRO-PM's risk adjustment model, and absence of information on how the model performed.

The feasibility of requiring practices to collect these data and identifying and minimizing the additional workload and time required must also be prioritized. For example, the measure specifies that the PROM should be collected within 0-90 days pre-operative and up to 180 days post-operatively and information on the data collection processes used by the practices is needed so that we can understand the degree of burden this one PRO-PM may create. For example, what impact did implementation of the measure have on clinical workflows, what additional staff resources were required, and what additional costs were encountered? These same questions must also be asked and evaluated from the patient's perspective. For example, did the questions seem relevant and was the point in time during which these additional data were collected appropriate?

In addition, CMS included another PRO-PM for the same procedures in the Measures Under Consideration (MUC) list – MUC2021-107, Clinician-Level and Clinician Group-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA and TKA) PRO-PM. While each measure addresses important outcomes, the denominators and denominator exclusions differ significantly, which will likely increase implementation burden and produce performance scores that may be confusing to end users since different populations are captured. While we believe that the measures may use different data sources, the attribution approach must also be aligned. It is also important to understand the potential burden that may be placed on practices to implement and patients to be responsive to all of the surveys required for both measures. The FAH believes that there is significant risk for individuals to prioritize the completion of one survey over another and therefore lead to negative unintended consequences on response rates for these measures or other PRO-PMs such as HCAHPS or CG-CAHPS. Analysis of response rates for HCAHPS from 2008 (33%) to 2017 (26%) revealed a percentage change of -22% overall and an average 0.8 percentage point drop per year (FAH, 2019). This erosion of participation from patients will likely only increase as PRO-PMs become more prevalent.

The FAH believes that feasibility, reliability, and validity of the PROMs and PRO-PM must be demonstrated and endorsement by the National Quality Forum should be achieved prior to implementation of this measure in the Merit-based Incentive Payment System. As a result, the FAH requests that the highest level of MAP recommendation be "Do Not Support."

Reference:

Federation of American Hospitals. Modernizing the HCAHPS Survey. Released June 2019. Available at: https://www.fah.org/fah-ee2-uploads/website/documents/Modernizing_HCAHPS_-Recommendations_from_PELs.pdf.

American Medical Association

The American Medical Association (AMA) supports the assessment of patient-reported outcomes (PRO)

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but believes that the burden of data collection to the practice, hospital, and patient must be adequately addressed and any measure considered for the Merit-based Incentive Payment System (MIPS) must be feasible, reliable, and valid. We do not believe that this measure meets these minimum expectations.

This measure was only tested in one health system with data from only three clinicians, which is insufficient to ensure that this measure can be implemented widely and drive meaningful improvements in patient outcomes. It must be tested across multiple physician practices and hospitals to assess the feasibility and potential data collection burden both of the PRO survey and measure. Specifically, the degree to which participating testing sites had to coordinate data collection across the ambulatory and inpatient settings, who was responsible for collecting the survey and any other required data elements, whether integration of this measure required new or revised staffing, and any other changes to clinical workflows or business operations should be documented and released for public comment and input. Robust assessments of unintended consequences to clinical care and day-to-day operations based on the integration of the survey and measure should also be assessed.

It is our understanding that the PRO survey was created during the development of this measure, but testing was only completed using patients from the single health system and we could not determine the characteristics of the patient population(s) surveyed or the methods, modes, and languages of administration that were available. As a result, we do not believe that the survey itself has been adequately tested for reliability and validity. It is critically important that the developer demonstrate that the tool on which this measure is based captures what it is intended to capture and is widely available and usable by all individuals, regardless of their language, education, or other characteristics.

In addition, evaluating the feasibility and effectiveness with administering this survey to patients should be prioritized. This assessment from the patient's perspective should include whether the timing and number of surveys was appropriate and did not result in survey fatigue. For example, if these data were collected on the morning of the surgery, could stress and anxiety have impacted responses, or would the addition of this survey lead them to be less likely to complete other surveys such as HCAHPS or CG-CAHPS? We believe that it is critical to understand the potential impact and burden that could be experienced.

Not only should feasibility assessments be conducted across a variety of practices, hospitals, and patient populations, the same approach should be taken when testing the measure for reliability and validity. The minimum acceptable thresholds when assessing measure score reliability should be 0.7 and empirical validity testing and not just face validity testing should be conducted. It is also critical that a broad set of clinical and social risk factors (e.g., frailty, health literacy) are included within the risk adjustment model. We do not believe that this measure meets any of these expectations since the reliability results were impacted by the number of test sites and denominator counts, the risk adjustment model was not tested, and the validity testing was insufficient.

CMS included another measure for the same procedures in the Measures Under Consideration (MUC) list – MUC2021-107, Clinician-Level and Clinician Group-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA and TKA) Patient-Reported Outcome-Performance Measure. While each measure addresses important and slightly different outcomes, the denominators and denominator exclusions are not aligned, which will likely increase implementation burden and produce performance scores that may be confusing to end users since different populations are captured. In addition, the attribution approach

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used by each measure and which variables, particularly social risk factors, in the risk model must also be aligned. It is also critical to understand the potential burden that may be placed on practices to implement and patients to be responsive to all of the surveys required for both measures.

CMS must assess the potential long-term impact on patients, clinicians, and hospitals as more and more patient-reported outcome performance measures are implemented. In the meantime, the AMA believes that additional testing and implementation both of the PRO survey and measure are needed prior to the consideration of this measure. As a result, the AMA requests that the highest level of MAP recommendation be "Do Not Support."

The Coalition to Transform Advanced Care

We support this measure as it is one of the first to focus on the patient's goals and whether they were achieved by the medical intervention. As such it adds value in gathering and honoring that information and should improve patient outcomes by better clarifying expectations before surgery and outcomes afterwards. However, we recommend that a similar measure be also developed/considered for use for anyone with serious illness to ensure that similar patient goals and expectations are identified and, hopefully, met.

This measure could be used for QI, certification, accreditation, payment, and public reporting purposes.

As this will be done via survey, the only implementation issues we anticipate would be the administration of the survey and then the analysis of its results.

American College of Surgeons

On behalf of the over 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Measures Application Partnership (MAP). The ACS is a scientific and education association of surgeons founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. ACS has a vested interest in CMS' MAP and the CMS Measures Under Consideration (MUC) list because of our dedication to improving the assessment of surgical care value for surgical patients. With our 100-year history in developing quality programs to optimize the delivery of surgical services, we believe that we can offer valuable insight to the MAPs deliberations.

As the Medicare programs transition toward Value-Based Health Care (VBHC), ACS believes it is important to define value based on what matters to the patient. ACS has long-supported measures that incentivized shared decision making with patient goal identification because patient-centered value is about the judgment applied by a patient and their family for care that meets their goals at an affordable price. We strongly support measures that discuss patient goals prior to care, then assess whether the patient goals were met following care for value assessment. Therefore, ACS supports the Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA) PROM measure. We encourage CMS to consider how this type of measure may apply to other areas of surgical care. When considering surgical workflow, orthopedics may have a unique ability to capture pre- and post-care based on how the patient is assessed prior to and following elective surgery for hip and knee. Orthopedic patients have measurable functional status which lends itself to pre-habilitation and rehabilitation. Therefore, functional status and patient flows may optimize the ability to track PROMS from preop to post recovery. More work is needed in defining 'how to' for other surgical conditions and differing patient workflows.

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We also believe that a patient's interpretation of their care is relative to their personal values for quality, safety, access, inclusiveness, price, trustworthiness, appropriateness and so forth. We encourage the consideration of PROMs that address these values in addition to patient goal identification. We also ask CMS to explore transparently reporting on how a patient values care for a specific condition. We believe this could become a useful tool for other patients who are seeking a reasonable place for their care.

Johnson & Johnson

Johnson & Johnson does not agree with the Workgroup's recommendation to oppose support for rulemaking. Johnson & Johnson supports meaningful patient-centered care planning measures that promote comprehensive, shared decision making and we agree with the development of patient-reported outcome performance measures that close gaps in CMS priority measure development areas. Johnson & Johnson encourages a "potential for mitigation" decision by the map, with the recommendation that the measure steward refine and revise the measure specifications to ensure sufficient reliability and validity. Johnson & Johnson further encourages measure developers to continue to consider measures that allow for holistic care planning around treatment and supportive care for surgical episodes and patient-reported outcome measures.

Johnson & Johnson supports the MAP Clinician Workgroup's acknowledgement of the inclusion of risk adjustment areas, such as age, gender, and BMI, and the expansion of the patient population to all patients 18 years and older. Johnson & Johnson also encourages the measure steward to include socio-economic and other demographic data collection in the measure specifications to allow stratifying the measure to assess performance by population subgroups.

American Medical Association

No, do not support this measure for inclusion in the program.

American Society of Anesthesiologists

ASA supports the development and implementation of measures that are cross-disciplinary in nature and assess physicians and other clinicians for the care they provide to the patient. This measure includes pre- and post-surgical survey assessments of the patient's main goals and expectations (e.g., pain, physical function, and quality of life) before surgery and the degree to which the expectations were met or exceeded after surgery. The measure would be reported as two risk-adjusted rates stratified by THA and TKA. We were unable to access the full measure specifications. If anesthesiologists were not included in the initial measure specifications for this measure, we ask that the measure developer consider the role of anesthesiologists as part of the surgical care team that work with patients on their goals. Anesthesiologists have developed and been a part of numerous care pathways, including those encouraged by the Perioperative Surgical Home, to reduce length of stay, improve pain management, and assess patient goals. Limiting patient goals or attributing this measure to one clinician or their group does not meet the larger health care goal of better care coordination and patient-centered care.

ASA recognizes that the NQF MAP process uses specific algorithms that push certain measures into specific recommendation categories instead of using a more nuanced approach to why a measure may be clinically valid, necessary, and integral to improving patient care. Although the Scientific Methods Panel should assess and make measure recommendations for the MAP to consider, the decision to recommend a measure for a quality program should rely on defensible yet attainable testing standards

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in addition to expert review. With nearly half of all MIPS measures approaching topped out status, NQF and CMS should support measures in a way that is scientifically sound but not hampered by arbitrary testing protocols that elevate statistics above clinical significance and patient needs.

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MUC2021-107 Clinician-Level and Clinician Group-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA and TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM)

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Merit-based Incentive Payment System–Quality

Workgroup
Clinician

Measure Description
The measure will estimate a clinician- and clinician group-level, risk-standardized improvement rate for patient-reported outcomes (PROs) following elective primary THA/TKA for Medicare fee-for-service (FFS) patients 65 years of age or older. Substantial clinical benefit (SCB) improvement will be measured by the change in score on the joint-specific patient-reported outcome measure (PROM) instruments, measuring hip or knee pain and functioning, from the preoperative assessment (data collected 90 to 0 days before surgery) to the postoperative assessment (data collected 300 to 425 days following surgery).

Numerator
The numerator is the risk-adjusted proportion of patients undergoing an elective primary THA/TKA who meet or exceed a SCB threshold of improvement between preoperative and postoperative assessments on joint-specific PROMs as follows:

For THA patients, meeting or exceeding a 22-point increase in score on the Hip dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR)1, and

For TKA patients, meeting or exceeding a 20-point increase in score on the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR)2.

Numerator Exclusions
N/A

Denominator
The cohort (target population) includes Medicare FFS patients 65 years of age and older undergoing elective primary THA/TKA procedures. The measure requires patients be enrolled in Medicare FFS Part A and Part B for the 12 months prior to the date of the index admission and enrolled in Part A during the

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index admission, be discharged alive from their admission, and not have more than two THA or TKA procedure codes on their index hospitalization claim.

Denominator Exclusions

Denominator exclusion: 1) Patients with staged procedures, defined as two or more elective primary THA or TKA procedures performed on the same patient during distinct hospitalizations during the measurement period, are excluded from the measure. The recovery from one procedure may negatively impact recovery from the other procedure therefore, staged procedures are excluded from the measure. Therefore, at this time, the measure focuses on patients receiving unilateral or simultaneous bilateral (not staged) THA/TKA procedures.

2) Patients who die within 300 days of the procedure are excluded as they are unable to complete PROM data in alignment with the postoperative PROM collection timeframe. 3) Patients that leave against medical advice are excluded from this measure.

Denominator Exceptions

N/A

State of development

Fully Developed

State of Development Details

Fully Developed:

This PRO-PM was tested on eligible procedures performed between July 1, 2016 and June 30, 2018 with complete preoperative and postoperative PRO data. Data element internal consistency and test-retest reliability results as reported in the literature by PROM developers demonstrate that the HOOS, JR and the KOOS, JR are sufficiently reliable and exceed accepted norms for reliability testing. The responsiveness, external construct validity, and floor and ceiling effects results from the literature demonstrate that these PROMs are valid and meaningful measures for assessing PROs following THA/TKA procedures.

For measure score reliability, we assessed signal to noise reliability and results indicate excellent reliability. To assess empirical measure score validity, we compared the THA/TKA PRO-PM risk-standardized improvement rates (RSIRs) to the National Quality Forum (NQF) endorsed clinician- and clinician group-level risk-standardized complication rate (RSCR) measure. Comparison of THA/TKA PRO-PM RSIRs to RSCRs at the clinician- and clinician group-level showed correlation statistics that were low and non-significant but, consistent with our a priori hypothesis that lower complications would yield higher improvement rates, suggested this inverse correlation.

Potential response bias due to non-response of PROs was addressed using stabilized inverse probability weighting. The comparison of RSIRs for risk-adjusted model of SCB improvement with stabilized inverse probability weighting and without stabilized inverse probability weighting revealed only a small impact on the measure results; however, we expect that non-response bias will be a factor for the THA/TKA PRO-PM, and we retained response bias adjustment for the measure results.

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What is the target population of the measure?
Medicare Fee for Service

The cohort for this measure is Medicare FFS patients 65 years of age and older undergoing an elective primary THA/TKA procedure at a non-federal short-term acute care hospital.

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Orthopedic surgery

Measure Type
Patient-Reported Outcome

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Claims Data;Other: EDB, MBSF, American Community Survey data

If applicable, specify the data source
N/A

If EHR or Chart-Abstracted data, description of parts related to these sources
Medicare administrative claims data will be used for identifying eligible elective primary THA/TKA procedures and for identifying comorbid conditions for risk adjustment. Medicare Part A inpatient data and Medicare Part B inpatient claim and claim line data from the IDR are used to match patients to clinicians and clinician groups who billed for the procedure. The Medicare EDB will be used to assess Medicare FFS enrollment and identify patient race, and the MBSF will be used to determine dual eligibility status. The AHRQ SES index score is derived from American Community Survey data.

At what level of analysis was the measure tested?
Clinician; Group

In which setting was this measure tested?
Hospital inpatient acute care facility

What one healthcare domain applies to this measure?
Person-Centered Care

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
This measure complements the process eCQMs (CMS 66 and CMS 56), supporting PRO collection for the elective, primary THA/TKA population. Both measures help support CMS's goal of more patient-centered care and measures that use the patient voice.

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CMIT ID
N/A

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?
No

If eCQM, enter Measure Authoring Tool (MAT) number
N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

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Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs
N/A

What other federal programs are currently using this measure?
N/A

Is this measure similar to and/or competing with a measure(s) already in a program?
Yes

Which measure(s) already in a program is your measure similar to and/or competing with?
NQF # 2653: Average change in functional status following total knee replacement surgery (Developed by MN Community Measurement for the MIPS Program)

How will this measure be distinguished from other similar and/or competing measures?
This PRO-PM differs from NQF #2653 in cohort, outcome, and risk adjustment.

Cohort: This PRO-PM includes both THA and TKA procedures, as clinical experts agree that clinician-level processes are shared across these procedures. It includes only primary, not revision, procedures, based upon clinical input that revision procedures are more complicated to perform, and patient-reported outcomes may be influenced by the initial surgery. The target population is Medicare FFS beneficiaries 65 years of age and older. NQF #2653 includes only TKA procedures, includes knee replacement revisions as well as primary procedures, and includes all adults 18 years of age and older.

Outcome: This PRO-PM collects PROs with the HOOS, JR for THA patients and the KOOS, JR for TKA patients. The timing of PRO data collection is 90 – 0 days prior to and 300 – 425 days following surgery. The numerator measures SCB improvement for each patient from preoperative to postoperative assessment with a binary outcome (Yes/No), and the measure produces a risk-standardized improvement rate that elucidates for clinicians and clinician groups the risk-adjusted proportion of patients with improvement and those without improvement. In contrast, NQF #2653 collects PRO data with the Oxford Knee Score three months prior to and 9 – 15 months following surgery and measures average change in knee function score. The outcome definition of SCB, with a defined threshold for change in PROM score, allows patients with poorer baseline PRO scores more room to improve and thus a greater opportunity to achieve SCB. This was identified by the hospital-level THA/TKA PRO-PM development TEP members as a specific benefit of measuring SCB versus average change; measuring SCB incentivizes providers to offer and perform THA/TKA procedures on even those with poor PRO

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scores. Furthermore, the TEP and PWG convened during development of the hospital-level THA/TKA PRO-PM stated concerns with measuring an average change score because hospitals with all average outcomes would look similar to hospitals whose patients either did very well or very poorly (bimodal distributed outcomes), thus providing potentially misleading information to consumers and patients. This concern, likewise, applies to clinicians and clinician groups.

Risk Adjustment: The risk model for this PRO-PM includes important risk variables supported by the hospital-level THA/TKA PRO-PM development TEP and other expert clinical consultants including health literacy, other musculoskeletal pain, and chronic narcotic use which are not included in NQF #2653; these risk variables were identified and tested based upon input from orthopedic professional societies including the American Association of Hip and Knee Surgeons and American Academy of Orthopedic Surgeons through public comment (Centers for Medicare & Medicaid Services, CJR Final Rule 2015, Section III.D.3.A).

How will this measure add value to the CMS program?

The benefits of this PRO-PM over NQF #2653 include the following:

1. This PRO-PM reflects outcomes for both THA and TKA recipients (rather than TKA recipients only), allowing for measurement of a greater number of patients and providers to provide CMS with broader influence on quality improvement. This approach aligns with the typical provision of orthopedic care, delivered to patients undergoing THA/TKA procedures by the same providers and staff.
2. This PRO-PM assesses improvement in patient-reported pain and function using a binary outcome that elucidates for providers and patients the risk-adjusted proportion of patients with and without improvement (a clear, understandable metric that patients support); this is preferable to measuring an average change score, as NQF #2653 does, which cannot distinguish between providers with mostly average outcomes from providers whose patients either did very well or very poorly. In addition, using a SCB to define the measure outcome ensures that the measure does not penalize clinicians who operate on those patients with the worst baseline pain and function (often those with higher social risk or non-white race).
3. NQF Measure #2653 uses an average change score adjusted for the baseline PROM score – this fundamentally equates to measuring post-operative PROM scores, which may incentivize surgeons to operate on those with the least severe symptoms at baseline and potentially avoid patients with the most severe pain and functional limitations at baseline. This would likely result in worsening disparities over time.
4. This PRO-PM uses a more robust and stakeholder-driven risk model and methodology to address non-response bias, anticipated to produce a measure with greater face validity with stakeholders. Specifically, this measure includes key clinical risk variables for a PRO-PM identified by clinical experts and supported by orthopedic professional societies, such as health literacy, back pain, and contralateral leg pain. These ensure accurate assessment of the index THA/TKA procedure and account for concomitant comorbidities such as chronic back or contralateral joint disease that can interfere with PROM interpretation. In addition, this measure accounts for non-response bias. We have seen no evidence of NQF #2653

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analytically addressing non-response bias. Non-response bias is a critical potential threat to the validity of PRO-PMs and failure to account for it may lead to worsening disparities.

5. Of note, this measure is harmonized with related measures including NQF #3559 Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Knee Arthroplasty (THA/TKA), NQF #3439 Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS) Eligible Clinicians and Eligible Clinician Groups, and NQF #1550 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA). Use of the harmonized hospital-level and clinician-and clinician group-level PRO-PMs may increase participation and acceptance of the measure.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure

Elective primary THA/TKA procedures are well-suited for patient-reported outcome (PRO) measurement. Unlike procedures that are intended to promote survival, these procedures are specifically intended to improve function and reduce pain, outcomes best reported by patients, making PROs a meaningful outcome metric to assess for this population. THA/TKAs are important, effective procedures performed on a broad population. Patient-reported outcomes for these procedures (pain, mobility, and quality of life) can be measured in a scientifically sound way 3-15 and are influenced by a range of improvements across the full spectrum of care pre-, peri-, and postoperatively 16-23.

The goal of the clinician-level THA/TKA PRO-PM is to incentivize patient-centered care and promote clinician-level accountability for improving patients' health and reducing the burden of their recovery.

Evidence that the measure can be operationalized

The primary data sources for development and testing of this measure were PRO data collected with PROMs and additional patient and provider-reported risk variable data collected through the Center for Medicare and Medicaid Innovation (CMMI) Comprehensive Care for Joint Replacement (CJR) payment model. This model is an ongoing proof of concept for broad, prospective collection of PRO data, implementing real-world data collection and data submission for risk adjustment and measure calculation. Data from Medicare Parts A and B claims were used for identifying eligible elective primary THA/TKA procedures and for identifying comorbid conditions for risk adjustment. Medicare Part A inpatient data and Medicare Part B inpatient claim and claim line data from the Integrated Data Repository (IDR) are used to match patients to clinicians and clinician groups who billed for the

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procedure. The Medicare Enrollment Database (EDB) was used to assess Medicare FFS enrollment and identify patient race, and the Master Beneficiary Summary File (MBSF) was used to determine dual eligibility status. The Agency for Healthcare Research and Quality (AHRQ) socioeconomic status (SES) index score was derived from American Community Survey data.

The CJR voluntary PRO and risk variable data is a strong proof of concept that the measure can be operationalized; complete pre- and post-operative PRO and risk variable data for 1,254 eligible clinicians and 526 eligible clinician groups were available in the initial 24 months of data collection in CJR.

How is the measure expected to be reported to the program?

Claims;Other: PRO data and provider-reported risk variable data will be submitted and linked with administrative claims data

Feasibility of Data Elements

Patient/family-reported information: electronic;Patient/family-reported information: paper

Evidence of Performance Gap

The variation in RSIRs for clinicians and clinician groups suggests that there are meaningful differences in performance measure scores across clinicians and clinician groups. For clinicians, the interquartile range (56.04 – 73.48%) represents a difference of 17.44 percentage points, and the difference between the 10th and 90th percentiles (47.78% and 79.13%, respectively) is 31.35 percentage points. Likewise, for clinician groups, the interquartile range (58.21 – 73.42%) indicates a difference of 15.21 percentage points, and the difference between the 10th and 90th percentiles (48.50% and 79.74%, respectively) is 30.94 percentage points. This variation indicates an important quality gap among clinicians and clinician groups.

Variation in performance was also evaluated by calculating the median odds ratio (MOR) for all clinicians and clinician groups in the dataset (n=232 and 170, respectively). The MOR represents the median increase in odds of the patient outcome (a SCB improvement in PROM score from preoperative to postoperative assessment) if a procedure on a single patient was performed by a higher performing clinician or clinician group compared to a lower performing clinician or clinician group. It is calculated by taking all possible combinations of clinicians and clinician groups, always comparing the higher performing clinicians and clinician groups to the lower performing clinicians and clinician groups. The MOR is interpreted as a traditional odds ratio would be.

The MOR values indicate that a patient is 1.98 times more likely to achieve SCB improvement if their elective primary THA/TKA procedure was performed by a higher performing clinician and 1.97 times more likely if performed by a higher performing clinician group than by a lower performing clinician or clinician group, respectively. This suggests almost a two-fold increase in the likelihood of SCB improvement by higher performing clinicians and clinician groups compared to lower performing clinicians and clinician groups.

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Unintended Consequences

The measure developer has not identified unintended consequences for this measure if it is implemented.

Outline the clinical guidelines supporting this measure

This measure aligns with federal promotion of patient-centered approaches to health care quality improvement and with orthopedic and medical society recommendations for PRO data collection for improved orthopedic care. The National Quality Strategy (NQS), led by the AHRQ, has identified patient centeredness as one of its six priorities for addressing a range of health care quality concerns32. Similarly, the National Academy of Medicine (previously known as the Institute of Medicine) has identified patient-centeredness as one of its quality domains33. Both the American Academy of Orthopedic Surgeons and the American College of Rheumatology have expressed support for the collection of PRO data in clinical practice to improve outcomes34, 35. This measure would encourage more widespread use of PROs in clinical outcome measurement and increase the focus on patient centeredness in improving healthcare quality.

Were the guidelines graded?

No

If yes, who graded the guidelines?

N/A

If yes, what was the grade?

N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size

Estimated eligible denominator size: over 786,000 procedures per year (PRO data collection is voluntary, and there will likely be some number of non-respondents, impacting the denominator size)

Estimate of Annual Improvement in Measure Score

Until the measure is implemented, it is challenging to estimate annual improvement in absolute terms. A recent study using American Joint Replacement Registry (AJRR) data on THA/TKA patients for whom PRO data were collected with the HOOS, JR and KOOS, JR instruments reported that 79% of patients undergoing THA and 70% of patients undergoing TKA achieved substantial clinical benefit at one-year follow-up36. Given the wide variation in RSIRs in the development and testing samples (Clinician RSIRs ranged from 18.34% to 88.58%; Clinician group RSIRs ranged from 20.86% – 85.95%), we anticipate a considerable potential for improvement in measure performance overtime.

Type of Evidence to Support the Measure

Clinical Guidelines;Empirical data

Is the measure risk adjusted, stratified, or both?

Risk adjusted

Are social determinants of health built into the risk adjustment model?

Yes

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Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
N/A; Costs avoided are not a primary metric of this measure.

Cost Avoided Annually by Medicare/Provider
N/A; Costs avoided are not a primary metric of this measure. However, patients achieving substantial clinical benefit will generally have lower post-operative pain and higher physical function than patients not achieving this improvement, which will likely result in lower downstream medical costs, including fewer revision procedures and pain management services.

Source of Estimate
N/A; Costs avoided are not a primary metric of this measure. However, patients achieving substantial clinical benefit will generally have lower post-operative pain and higher physical function than patients not achieving this improvement, which will likely result in lower downstream medical costs, including fewer revision procedures and pain management services.

Year of Cost Literature Cited
N/A

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

If yes, choose all methods of obtaining patient/caregiver information
Standard Technical Expert Panel (TEP) inclusive of patient/caregiver representatives;Working groups

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
To date, the PWG, comprised of six patients who formerly underwent THA and/or TKA procedures, were engaged a total of two times. One meeting occurred at the conclusion of conceptualization and beginning of measure specification, and the other meeting occurred during specification and at the beginning of field testing. A third meeting is planned for June 2021.

The TEP, on which there are five patients, has met a total of three times to date: once at the conclusion of conceptualization and at the beginning of specification, and twice throughout specification and field testing. A fourth meeting to review final measure results is planned for Summer 2021.

Total Number of Patients and/or Caregivers Consulted
11

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
11:21

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
11

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Burden for Patient: Does the measure require survey data from the patient?
Yes

If yes, what is the estimated time to complete the survey?
3

If yes, what is the frequency of requests for survey data per year?
2

If yes, are the survey data to be collected during or outside of a visit?
Prior to visit;During visit

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Working groups;Standard TEP;Other: Ongoing clinical expert consultant

Total Number of Clinicians/Providers Consulted
21

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
21

Burden for Provider: Was a provider workflow analysis conducted?
Yes

If yes, how many sites were evaluated in the provider workflow analysis?
3

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
83

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Measure Testing Details

Reliability Testing Interpretation of Results

Measure Score Reliability: The signal-to-noise reliability scores of 0.87 and 0.92 for clinicians and clinician groups, respectively, indicate excellent reliability.

Data Element Reliability: The reliability results from the literature demonstrate that the HOOS, JR and the KOOS, JR PROM instruments are sufficiently reliable and exceed accepted norms for reliability testing. Test-retest reliability for the HOOS and KOOS domains, from which the HOOS, JR and KOOS, JR questions were drawn, respectively, provided evidence of good reliability.

Type of Reliability Testing

Measure Score Reliability;Data Element Reliability

Reliability Testing: Type of Testing Analysis

Signal to Noise; Test-Retest

Reliability Testing Sample Size

For measure score reliability, we identified the 232 clinicians and 170 clinician groups with at least 25 THA/TKA patients with PRO data during the measurement period and assessed signal-to-noise reliability to describe how well the measure can distinguish performance of one clinician or clinician group from another using the combined dataset.

Reliability Testing Statistical Result

Measure Score Reliability: The signal-to-noise ratio was 0.87 for clinicians (range: 0.79 – 0.97) and 0.92 for clinician groups (range: 0.79 – 0.99), indicating excellent reliability.

Data Element Reliability for the HOOS, JR and the KOOS, JR PROMs (conducted by PROM developers): The developers of the HOOS, JR1, assessed internal consistency reliability using the PSI in two data cohorts. Internal consistency of the HOOS, JR on the PSI was 0.86 - in the Hospital for Special Surgery (HSS) cohort and 0.87 in the Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE-TJR) cohort. Results of a principal component analysis conducted on the standardized residuals indicated that the six HOOS, JR items existed in a single dimension1. Additional validation studies indicated that the test-retest reproducibility of the HOOS via ICCs ranged from 0.75-0.9727-30.

Similarly, the developers of the KOOS, JR2 assessed internal consistency via the PSI in two data cohorts. Internal consistency of the KOOS, JR on the PSI were 0.84 in the HSS cohort and 0.85 in the FORCE-TJR cohort. An additional validation study indicated that the test-retest reproducibility of the KOOS ranged from 0.75-0.9331.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?

Yes

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If yes, specify the number of cases and the percentage of providers
25 100%

Type of Validity Testing
Measure Score Validity; Data Element Validity

Validity Testing: Type of Validity Testing Analysis
Correlation; Face Validity

Validity Testing Sample Size
19429

Validity Testing Statistical Result
Measure Score Validity:

The correlation statistics for these RSIR to RSCR comparisons were low, non-significant but, consistent with our a priori hypothesis that lower complications would yield higher improvement rates, negatively correlated (corr for clinician-level measure results = -0.043; corr for clinician group-level measure results = -0.009). This may be due to the small numbers of statistically significant RSCR outliers (1 clinician in the better performance bucket, 5 clinicians in the worse performance bucket, 10 clinician groups in the better performance bucket, and 7 clinician groups in the worse performance bucket) available in the data sample. We recognize that the complication measure assesses the occurrence of rare outcomes and that this will impact correlation of complication rates to patient improvement rates.

Data Element Validity:

Data element validity results are reported for validity testing conducted during the development and testing of the joint-specific PROMs on which this THA/TKA PRO-PM is based. Validity testing included analysis of responsiveness, external validity, and floor and ceiling effects. The validity results from the literature demonstrate that the HOOS, JR and the KOOS, JR PROM instruments are valid and meaningful measures for assessing patient-reported outcomes following THA/TKA procedures.

Face Validity:

Face validity was assessed qualitatively with stakeholder groups. To date, all six members of the Patient Working Group (PWG) strongly supported the measure concept and its face validity. All four members of the Clinical Working Group (CWG) supported the measure. In the Technical Expert Panel (TEP), all twenty clinical experts, patients, and additional stakeholders supported the measure specifications after discussions regarding clinician attribution, risk model results, non-response bias, social risk factor analyses, reliability, and measure updates. Face validity will be assessed quantitatively using a Likert scale survey with the TEP and CWG in the spring or summer of 2021.

Validity Testing Interpretation of Results
Measure Score Validity:

The measure score validity results directionally and conceptually support measure face validity but are

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quantitatively low and statistically non-significant. These results are likely influenced and potentially limited by the fact that the data were collected and submitted as part of a hospital payment model, the moderate responses rates in the data sample (due to the collection incentives provided in the payment model), and the low variation in complication outcomes making statistically significant differences difficult to detect. We acknowledge that the testing dataset is limited, and we plan to retest the measure score validity in a larger dataset.

Data Element Validity:

The reliability results from the literature demonstrate that the HOOS, JR and the KOOS, JR PROM instruments are sufficiently valid.

Face Validity:

To date, this measure sustains overwhelming qualitative support of face validity from various stakeholder groups. Face validity will be formally (quantitatively) assessed with stakeholders in the spring and summer of 2021.

Measure performance – Type of Score

Proportion

Measure Performance Score Interpretation

Higher score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have

The performance rate is the RSIR. This is calculated as the ratio of a clinician's or clinician group's "predicted" number of patients with substantial clinical improvement to "expected" number of patients with substantial clinical improvement multiplied by the overall observed improvement rate. The RSIR accounts for patient characteristics and comorbidities. Patients with substantial clinical improvement are defined as patients undergoing an elective primary THA or TKA who meet or exceed a patient-defined SCB threshold of improvement from preoperative to postoperative assessments on joint-specific PROMs.

Clinician RSIRs ranged from 18.34% to 88.58% and the mean RSIR was 64.22% (standard deviation [SD] 13.13). Clinician group RSIRs ranged from 20.86% – 85.95% and the mean RSIR was 64.75% (SD 12.64). The variation in RSIRs suggests that there are meaningful differences in performance measure scores across clinicians and clinician groups. The interquartile range represents a difference of 17.44 percentage points for clinician RSIRs and 15.21 percentage points for clinician groups, and the difference between the 10th and 90th percentiles (47.78% and 79.13% for clinicians and 48.50% and 79.74% for clinician groups, respectively) is 31.35 percentage points for clinicians and 30.94 percentage points for clinician groups. This variation indicates an important quality gap among clinicians and clinician groups.

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Benchmark, if applicable
N/A

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Section 2: Preliminary Analysis – MUC2021-107 Clinician-Level and Clinician Group-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA and TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM)

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

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Justification and Notes: This patient-reported outcome measure addresses the quality priority of patient-centered care in the CMS Meaningful Measures 2.0 framework. The use of the joint-specific patient-reported outcome measure (PROM) instruments incorporate shared decision making in orthopedic surgery with the potential to improve patient health outcomes.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes

Justification and Notes: The measure/intervention uses patient-reported outcomes to gather feedback on pain and joint function after THAs and TKAs to impact outcomes that are important to patients. Feedback from a Technical Expert Panel and a Patient Working Group established continued support for additional post-surgical surveys to monitor recovery and encourage high-quality care.

Does the measure address a quality challenge?
Yes/No: Yes

Justification and Notes: 30 million Americans are affected by degenerative joint disease, which is commonly treated with elective THAs and TKAs (CDC, 2019). These procedures decrease pain and improve function during the approximately 1 million osteoarthritis-related hospitalizations per year (Guccione et al., 1994). More specifically, approximately 6 million American 65 years or older suffer from osteoarthritis, contributing to Medicare costs exceeding 15 billion dollars annually (Miller et al., 2011). The frequency and high cost of these procedures provides a solid foundation for the creation of patient-reported outcome measure development (Liebs et al., 2013).

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?
Yes/No: Yes

Justification and Notes: The measure developer compares this submitted measure to the NQF-endorsed measure (#2653): Average change in functional status following total knee replacement surgery. This measure captures both THA and TKA in the measured population. The developers have reported that this measure is actively used in the MIPS program, but NQF has not been able to confirm using the CMS CMIT tool. MIPS has several other measures that examine functional status and patient-reported outcomes after knee or hip replacement on the clinician/group level and that are focused on the ECQM priority: CMIT ID 5876, CMIT ID 5828, and CMIT ID 5833.

Another measure being submitted for MAP consideration this cycle is NQF# 3638 (Care Goal Achievement). NQF# 3638 is in consideration for use in the MIPS program and assesses whether patient expectations from surgery were met or exceeded. This measure captures improvement following THA and TKA.

Can the measure be feasibly reported?
Yes/No: Yes

Justification and Notes: The data reported for this measure is pulled from Medicare Parts A and B claims data, Patient-reported survey data, the Medicare Enrollment Database (EDB), the Master Beneficiary Summary File (MBSF), and the American Community Survey data.

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Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?
Yes/No: Yes

Justification and Notes: The measure is tested at the level of individual clinicians and clinician-group practices serving Medicare Fee For Service beneficiaries aged 65 years and older. Like similar measures with this clinical quality focus, a threshold of 25 cases were deemed appropriate for high measure result reliability. Meaningful differences in performance measure scores were identified across clinicians and clinician groups. The developer demonstrates above average measure score reliability with signal-to-noise reliability scores of 0.87 and 0.92 for clinicians and clinician groups. Measure score validity results were quantitatively low and statistically non-significant.

> This measure is currently under consideration by the NQF CDP Standing Committee. This measure was recently reviewed by the NQF SMP who noted that this measure uses the same measure specifications as the NQF-endorsed (NQF # 3559) hospital-level risk-standardized improvement rate (RSIR) following elective primary THA/TKA with the following exception, however this measure attributes the outcome to a clinician or clinician group. The NQF SMP provided moderate rates for reliability and validity.

If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure been identified?
Yes/No: N/A

Justification and Notes: This measure is not currently in use and the developer as not reported any discovered unintended consequences.

PAC/LTC Core Concept?
N/A

Impact Act Domain
N/A

Hospice High Priority Areas
N/A

MAP Rural Health Advisory Group Input:
Relative priority/utility:

- The measure was noted to be applicable to rural providers.

Data collection issues:

- Concerns were raised regarding the challenges of obtaining high response rates for follow up, as rural providers with resource limitations may be specifically challenged.

Calculation issues:

- Concerns raised regarding the calculation of the average (change score) of the measure. The developer clarified during the MAP Clinician workgroup meeting that the calculation uses improvement based on clinical benefit rather than an average.

Unintended consequences:

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- Concerns were raised regarding lessened recovery for patients due to physical/manual occupations in rural communities.

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 3.3
1 – 0 votes
2 – 3 votes
3 – 5 votes
4 – 7 votes
5 – 0 votes

MAP Health Equity Advisory Group Input:

Relative priority/utility:

- This measure looks at a threshold level of improvement.

Data collection issues:

- Challenge with collecting the data pre op and post op due to complexity and access barriers for certain populations of patients (i.e., non-English speaking patients).
- Burden to collect data will likely be distributed unevenly across practices.

Calculation issues:

- Lack of stratification was identified as a priority for this measure, particularly stratification for language.
- Potential selection bias of the population

Unintended consequences:

- The Advisory Group noted a concern that the measure may be benefit practices that serve more English-speaking, less socially disadvantaged patients, for whom administering these measures are easier.

Votes: Range is 1 – 5, where higher number has greater potential for positive impact on health equity.
Average: 2.6
1 – 3 votes
2 – 8 votes
3 – 6 votes
4 – 5 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking, pending NQF endorsement.

Summary: What is the potential value to the program measure set?

This patient-reported outcome measure addresses the quality priority of patient-centered care in the CMS Meaningful Measures 2.0 framework. The use of the joint-specific patient-reported outcome measure (PROM) instruments incorporate shared decision making in orthopedic surgery and with the potential to improves patient health outcomes.

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Summary: What is the potential impact of this measure on quality of care for patients?
The measure/intervention uses patient-reported outcomes to gather feedback on pain and joint function after THAs and TKAs to impact outcomes that are important to patients. Feedback from a Technical Expert Panel and a Patient Working Group established continued support for additional post-surgical surveys to monitor recovery and encourage high-quality care.

30 million Americans are affected by degenerative joint disease, which is commonly treated with elective THAs and TKAs (CDC, 2019). These procedures decrease pain and improve function during the approximately 1 million osteoarthritis-related hospitalizations per year (Guccione et al., 1994). More specifically, approximately 6 million American 65 years or older suffer from osteoarthritis, contributing to Medicare costs exceeding 15 billion dollars annually (Miller et al., 2011). The frequency and high cost of these procedures provides a solid foundation for the creation of patient-reported outcome measure development (Liebs et al., 2013).

Section 3: Public Comments

Federation of American Hospitals

The Federation of American Hospitals (FAH) supports the development and implementation of patient-reported outcomes performance measures (PRO-PMs) but we also believe that additional questions and work remain before their widespread use such as the degree to which multiple PRO-PMs could lead to survey fatigue for patients, the potential impact that additional PRO-PMs may have on the reporting of well-established measures such as HCAHPs and CG-CAHPS, what level of data collection burden for an individual PRO-PM is acceptable for a clinician, hospital, or other healthcare provider, and the degree to which duplicate data collection and reporting burden can be reduced with multiple groups (i.e., clinicians, practices, hospitals) implementing the same or similar measures.

Specifically, the FAH notes that multiple data points beyond the typical clinical variables are required to ensure that the measure results are adequately risk adjusted. The FAH supports the inclusion of these data points, but we are concerned that there is insufficient information on how these data are collected and what additional workload and time will be required. For example, several of the data elements needed for risk adjustment are derived from patient-reported surveys, which must be collected within 0-90 days pre-operative. No information was provided on the processes used by the clinicians and practices such as whether it required coordination with the hospital or if the burden of the additional data collection was placed on hospital staff on the day of surgery. To what extent did these requirements impact clinical workflows and were additional staff resources required? What additional costs might an individual clinician and practice encounter as a result of implementation of this PRO-PM?

Alternatively, from the patient's perspective, did the additional questions seem relevant and was the point in time during which these additional data were collected appropriate? It would also be useful to understand whether there is a potential for individuals to prioritize the completion of one survey over another and therefore lead to negative unintended consequences on response rates for other PRO-PMs such as HCAHPS or CG-CAHPS?

Furthermore, if this measure is implemented in the Merit-based Incentive Payment System (MIPS) and a

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similar measure in the Hospital Inpatient Quality Reporting Program, clinicians, practices and hospitals would be collecting and reporting on the same data but it is unclear if CMS sought to identify ways to mitigate the potential for duplicate data collection and reporting or addressed the concern that the duplication of effort could further increase the number of surveys or information that patients must provide. The FAH believes that these questions must be addressed and urges CMS to take the time to develop solutions to these questions prior to implementation of this measure in MIPS.

In addition, the FAH strongly supports the inclusion of health literacy in the risk adjustment model but recommends that CMS continue to consider the extent to which this measure ensures that results will be comparable across practices and does not contribute to inequities in care due to the lack of adequate risk adjustment for social risk factors.

In addition, CMS included another PRO-PM for the same procedures in the Measures Under Consideration (MUC) list – MUC2021-063, Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA). While each measure addresses important outcomes, the denominators and denominator exclusions differ significantly, which will likely increase implementation burden and produce performance scores that may be confusing to end users since different populations are captured. The FAH believes that the risk models used for these two measures should be aligned and that MUC2021-063 should include factors such as health literacy similar to this PRO-PM's risk adjustment model. While we believe that the measures may use different data sources, the attribution approach must be aligned. It is also important to understand what the potential burden that may be placed on practices to implement and patients to be responsive to all of the surveys required for both measures. The FAH believes that there is significant risk for individuals to prioritize the completion of one survey over another and therefore lead to negative unintended consequences on response rates for these measures or other PRO-PMs such as HCAHPS or CG-CAHPS. Analysis of response rates for HCAHPS from 2008 (33%) to 2017 (26%) revealed a percentage change of -22% overall and an average 0.8 percentage point drop per year (FAH, 2019). This erosion of participation from patients will likely only increase as PRO-PMs become more prevalent.

The FAH believes that these questions must be addressed and endorsement by the National Quality Forum should be achieved prior to implementation of this measure in the Merit-based Incentive Payment System. As a result, the FAH requests that the highest level of MAP recommendation be "Do Not Support with Potential for Mitigation."

Reference:

Federation of American Hospitals. Modernizing the HCAHPS Survey. Released June 2019. Available at: https://www.fah.org/fah-ee2-uploads/website/documents/Modernizing_HCAHPS_-Recommendations_from_PELs.pdf

American Medical Association

The American Medical Association (AMA) supports the assessment of patient-reported outcomes but believes that the burden of data collection to the clinician, practice, and patient and the lack of alignment with MUC2021-063: Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA) must be adequately addressed prior to implementation of this measure in the

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Merit-Based Incentive Payment System (MIPS).

The AMA supports the additional refinement made to the attribution approach. Specifically, other measures have experienced a similar issue of assigning patients to clinicians not primarily responsible for the procedure or episode such as physician assistants. We appreciate that this inaccurate attribution was identified, and steps were taken to address the issue and we urge CMS to consider adopting this approach for other quality and cost measures in MIPS.

The current measure specifications for the numerator and risk variables require multiple data elements from additional patient-reported surveys beyond those used to assess the patient-reported outcome of interest. Furthermore, this information is expected to be collected between 90 to 0 days prior to surgery. The AMA supports the inclusion of many of these variables within the risk model given their relevance to how patients may or may not be able to achieve improvement but questions whether the CMS adequately assessed the feasibility and potential data collection burden to the clinician, practice, and patient. Specifically, the limited information on feasibility does not provide any detail on how the testing sites coordinated data collection across settings or on whom the responsibility of the additional items was placed. This question is particularly important since the specifications require clinicians and practices to collect data for one measure from 90 days pre-operatively to up to 425 days post-operatively, which the hospital is also likely collecting at the same time. The inclusion of this measure in addition to the one at the hospital-level further raises our concerns over how the duplication of effort in collecting these data required for the measure numerator and risk adjustment variables. Any information that CMS released on this measure does not address these concerns and the AMA urges CMS to complete additional testing around the feasibility of data collection and reduction of reporting burden prior to implementing this measure in MIPS.

Perhaps even more importantly, we would have expected to see an assessment from the patient's perspective on whether the timing and number of items solicited throughout this process were appropriate and does not result in survey fatigue, particularly now that they may have the hospital and clinician requesting the same data. For example, would the number of surveys throughout the pre-, intra-, and post-operative timeframes lead them to be less likely to complete other surveys such as HCAHPS or CG-CAHPS? CMS should also examine if whether the timing of data collection is appropriate such as if the pre-operative PRO-PM data were collected on the morning of the surgery, could stress and anxiety have impacted responses? We believe that it is critical to understand the potential impact and burden that could be experienced. While it may seem reasonable for one measure, if this measure is an example of how future measures could be specified, what is the potential long-term impact on patients, hospitals, clinicians, and practices as more and more PRO-PMs are implemented?

CMS included another measure for the same procedures in the Measures Under Consideration (MUC) list – MUC2021-063: Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA). While each measure addresses important and slightly different outcomes, the denominators and denominator exclusions are not aligned, which will likely increase implementation burden and produce performance scores that may be confusing to end users since different populations are captured. In addition, the attribution approach used by each measure and which variables, particularly social risk factors, in the risk model must be aligned. It is also critical to understand the potential burden that may be placed on practices to implement and patients to be responsive to all of

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the surveys required for both measures.

CMS must assess the potential long-term impact on patients, clinicians, and hospitals as more and more patient-reported outcome performance measures are implemented. In the meantime, the AMA believes that additional information on these concerns must be addressed prior to the implementation of this measure. As a result, the AMA requests that the highest level of MAP recommendation be "Do Not Support with Potential for Mitigation."

Mass General Brigham

Mass General Brigham supports inclusion of a Patient Reported Outcome Measure (PROM) in CMS quality reporting programs and specifically supports a THA/TKA PROM. We are concerned, though, that many survey responses will not be captured 300 days after surgery. With our many years of PROM collection experience and multiple survey modes, we have seen patient recovery plateau and survey response rate drop precipitously well before 300 days after surgery. Mass General Brigham urges CMS to expand the post-surgery survey period to include surveys starting 180 days after surgery, if not earlier.

MGB also strongly encourages CMS to consider in developing this measure that there is not a single PROM of consensus in THA/TKA inpatient or outpatient populations. Mass General Brigham has extensive experience in collection of the HOOS-PS and the KOOS-PS and recommends that the -PS versions be included as acceptable instruments. This measure should allow for flexibility of PROM choice and favor/allow PROMs with score crosswalk capability. For example, pain reduction and the regaining of physical function are separate goals for some patients after these surgeries and should be considered as separate measures.

CMS earlier this year requested comment on using a PROM in different settings such as Outpatient, ASC, and Inpatient surgeries. Mass General Brigham requests that CMS consider site-of-service for surgery patient reported outcome performance measures (PRO-PMs). We understand the usefulness of an aligned set of PRO-PMs across all settings where TKA/THA are performed, but risk adjustment comparing patients at different sites of care is flawed. Adjusting for case-mix alone may not capture the potential for some settings to treat healthier, less-complex patients. Further, even though younger, healthier patients may have their surgery in an ASC, those patients will likely have higher pre-surgery scores and are thus less likely to achieve the minimal clinically important difference (MCID) after surgery. CMS should consider equivalent measures where comparison across settings can occur, while each measure would allow for examination of potential differences in quality of care and room for improvement in those patients specific to each setting.

Johnson & Johnson

Johnson & Johnson supports the recommendation of the workgroup to conditionally move forward with support for rulemaking. Johnson & Johnson supports meaningful patient-centered care planning measures that promote comprehensive, shared decision making and we agree with the development of patient-reported outcome performance measures that close gaps in CMS priority measure development areas. Johnson & Johnson supports the feedback from the Technical Expert Panel and a Patient Working Group to encourages measure developers to continue to consider measures that evaluate quality of life associated with post-surgical complications and management to encourage high-quality care.

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American Medical Association

The American Medical Association (AMA) continues to be concerned with the burden of data collection to the clinician, practice, and patient produced by this one measure as outlined in our previous comments. In summary, we do not believe that the complexity and number of data elements and patient-reported surveys required to calculate this measure have been adequately evaluated for feasibility of data collection by a practice or the burden to patients. As a result, the AMA requests that the highest level of MAP recommendation be "Do Not Support with Potential for Mitigation."

American Society of Anesthesiologists

ASA has been a leading proponent of shared accountability measures where physicians and other clinicians who contribute to the care of a patient receive appropriate credit. We are disappointed that measure development appears to reflect current trends of siloing care and measurement instead of allowing patient-reported outcomes to be attributed to each member of the patient's care team. Although this measure has many positive features that lend itself to better care coordination, patient-centered care, it nonetheless continues a trend of assigning performance to the clinician and their group (not across the care team). We believe that CMS and the MAP should redouble their efforts to further encourage cross-disciplinary measurement focused on improving patient care and enhancing communication and quality improvement activities between specialties. ASA supports this measure for what it seeks to improve, but we encourage hospitals, physicians, and others to share data on this measure with all members of the patient's care team.

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MUC2021-135 Dermatitis – Improvement in Patient-Reported Itch Severity

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Merit-based Incentive Payment System–Quality

Workgroup
Clinician

Measure Description
The percentage of patients, aged 18 years and older, with a diagnosis of dermatitis where at an initial (index) visit have a patient reported itch severity assessments performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit.

Numerator
Patients who achieve an assessment score that is reduced by 2 or more points (minimal clinically important difference) from the initial (index) assessment score.

Numerator Exclusions
N/A

Denominator
All patients aged 18 years and older, with a diagnosis of dermatitis with an initial (index visit) NRS, VRS, or ItchyQuant assessment score of greater than or equal to 4 who are returning for a follow-up visit.

Denominator Exclusions
N/A

Denominator Exceptions
N/A

State of development
Fully Developed

State of Development Details
Beta testing was conducted on the fully developed specification. Testing included critical data element validity, performance score reliability, feasibility testing and workflow burden assessment.

What is the target population of the measure?
All Payer

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Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Dermatology ;General practice;Internal medicine;Primary care

Measure Type
Patient-Reported Outcome

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Administrative Data (non-claims);Electronic Health Record;Paper Medical Records;Standardized Patient Assessments;Patient Reported Data and Surveys;Registries;Hybrid

If applicable, specify the data source
N/A

If EHR or Chart-Abstracted data, description of parts related to these sources
N/A

At what level of analysis was the measure tested?
Clinician

In which setting was this measure tested?
Ambulatory/office-based care

What one healthcare domain applies to this measure?
Chronic Conditions

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
There are two improvement activities that are linked to these measures; both IA_AHE_3 and IA_PSPA_8 promote the use of PRO tools and the use of patient safety tools, respectively, which when reported together can align scope and reduce reporting burden. ;There are two improvement activities that are linked to these measures; both IA_AHE_3 and IA_PSPA_8 promote the use of PRO tools and the use of patient safety tools, respectively, which when reported together can align scope and reduce reporting burden. ;There are two improvement activities that are linked to these measures; both IA_AHE_3 and IA_PSPA_8 promote the use of PRO tools and the use of patient safety tools, respectively, which when reported together can align scope and reduce reporting burden.

CMIT ID
N/A

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Never Submitted

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NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
https://assets.ctfassets.net/1ny4yoiyrqia/2X7u75SzQ3OiCQyUalm73R/9fec006f9433e92a90de72ea230abe36/AAD_10_Dermatitis_PRO_Improvement_Itch_Severity_2021.pdf

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?
No

If eCQM, enter Measure Authoring Tool (MAT) number
N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

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Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
Measure currently used in a CMS program being submitted as-is for a new or different program

Range of years this measure has been used by CMS Programs
MIPS reporting as a QCDR measure (2020 – current)

What other federal programs are currently using this measure?
Merit-based Incentive Payment System–Quality

Is this measure similar to and/or competing with a measure(s) already in a program?
No

Which measure(s) already in a program is your measure similar to and/or competing with?
N/A

How will this measure be distinguished from other similar and/or competing measures?
N/A

How will this measure add value to the CMS program?
N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure
Various types of dermatitis are chronically pruritic and are tremendously burdensome. Atopic dermatitis (AD) is a chronic skin disease in which pruritus is responsible for much of the disease burden and morbidity borne by patients. It is estimated that in the U.S. alone, 31.6 million people have symptoms of AD, with 17.8 million meeting the criteria for AD. The effects of this disease are substantial; with direct costs estimated to be between $1 and $4 billion.

Other types of dermatitis, such as contact dermatitis and seborrheic dermatitis (SD) are also chronic, pruritic conditions which greatly affect patients. Approximately 6 million people in the U.S. have SD with direct and indirect costs estimated to be $230 million.

These various forms of dermatitis also greatly impact the quality-of-life patients have. In one study looking at the patient burden in adults with moderate to severe AD, 85% reported problems with the frequency of their itch and 41.5% reported itching for 18 hours or more a day. With this persistence of itching, 55% of patients showed AD-related sleep disturbance 5 days a week or more and 21.8% showed clinically relevant anxiety or depression.

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In another study, investigators quantified pruritic burden in a cross-sectional analysis investigating chronic pruritus and pain. They demonstrated that the quality-of-life impact was due to the severity of the symptom, rather than whether the symptom was pain or pruritus. Moreover, they elucidated a mean health utility score of 0.87 from CP patients, meaning that on average, a patient would give up 13% of their life expectancy to live without pruritus. Additionally, studies of CP have shown patients to have a 17% higher mortality risk as well as being strongly associated with poorer general health.

Moreover, data from the National Ambulatory Medical Care Survey (1999-2009) found that a total of 77 million patient visits for itch were made during the 11-year time period. This was an average of 7 million visits per year, which represented approximately 1% of all outpatient visits. Also, further analysis showed that although the majority visits (58.6%) were for new instances of itch, almost a third (32%) were for chronic pruritus.

This measure aims to improve pruritus in patients who carry a large burden with this disease; by assessing itch and aiming to make the symptom more manageable.

Evidence that the measure can be operationalized
This measure has been in used in the American Academy of Dermatology's (AAD) Qualified Clinical Data Registry (QCDR) DataDerm since 2020.

How is the measure expected to be reported to the program?
Clinical Quality Measure (CQM) Registry

Feasibility of Data Elements
ALL data elements are in defined fields in a combination of electronic sources;Patient/family-reported information: electronic;Patient/family-reported information: paper

Evidence of Performance Gap
Aggregate performance score for the measure was 54.9%, indicating a gap in care and opportunities for improvement.

Additionally, the workflow burden and usability results indicated a lack of consistent itch screening with a validated tool prior to testing the measure, suggesting that there is a gap in care associated with itch assessment that would be addressed with the implementation of the measure.

Unintended Consequences
N/A

Outline the clinical guidelines supporting this measure
Evidence-based guideline: Guidelines of care for the management of atopic dermatitis

Section 1. Diagnosis and assessment of atopic dermatitis

Recommendation: It is recommended that clinicians ask general questions about itch, sleep, impact on daily activity, and persistence of disease, and currently available scales be

used mainly when practical.

This measure enhances compliance of the guideline by routinely assessing pruritus in dermatitis

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patients. For patients with moderate and severe pruritus symptoms, the measure looks to reduce pruritus burden by a minimal clinically important difference (2 or more points).

Were the guidelines graded?
Yes

If yes, who graded the guidelines?
American Academy of Dermatology

If yes, what was the grade?
C

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Unable to determine

Estimate of Annual Improvement in Measure Score
Not applicable

Type of Evidence to Support the Measure
Clinical Guidelines; Systematic Review

Is the measure risk adjusted, stratified, or both?
None

Are social determinants of health built into the risk adjustment model?
Not Applicable

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
Not applicable

Cost Avoided Annually by Medicare/Provider
Not applicable

Source of Estimate
Not applicable

Year of Cost Literature Cited
Not applicable

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

If yes, choose all methods of obtaining patient/caregiver information
Standard Technical Expert Panel (TEP) inclusive of patient/caregiver representatives

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
Patients were involved throughout the development of the measure specification on all workgroup

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development calls from conceptualization to finalization.

Total Number of Patients and/or Caregivers Consulted
3

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
1:3

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
3

Burden for Patient: Does the measure require survey data from the patient?
Yes

If yes, what is the estimated time to complete the survey?
1

If yes, what is the frequency of requests for survey data per year?
2

If yes, are the survey data to be collected during or outside of a visit?
During visit

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Standard TEP

Total Number of Clinicians/Providers Consulted
11

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
17

Burden for Provider: Was a provider workflow analysis conducted?
Yes

If yes, how many sites were evaluated in the provider workflow analysis?
3

Did the provider workflow have to be modified to accommodate the new measure?
Yes

If yes, how would you describe the degree of effort?
2

Does the measure require manual abstraction?
Yes

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If yes, what is the estimated time per record to abstract data?
0

How many data elements will be collected for the measure?
3

Measure Testing Details

Reliability Testing Interpretation of Results
Reliability results for the measure were average and demonstrate a sufficient level of reliability to detect real difference in performance scores.

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
Signal to Noise

Reliability Testing Sample Size
In total 1,271 records from 901 unique patient encounters were submitted through a secure data platform for analysis.

Reliability Testing Statistical Result
Reliability scores range from 0.0 to 1.0. There is no consensus for a cut-off for minimum reliability level. Values above 0.7, however, are generally considered sufficient to ascertain statistically significant differences between a group of physicians (or clinics) and the mean. The reliability performance score was .69.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
Data Element Validity

Validity Testing: Type of Validity Testing Analysis
Other: Crude agreement, prevalence-adjusted kappa (PAK), Cohen´s kappa values and corresponding confidence intervals were also calculated for each critical data element.

Validity Testing Sample Size
A randomly selected sample of 79 records from the participating sites.

Validity Testing Statistical Result
Cohen's kappa coefficient (1), a statistic that measures inter-rater agreement for qualitative items, was used to determine reliability. Cohen´s kappa represents chance-corrected proportional agreement.

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Landis and Koch (2) proposed the following parameters as standards for strength of agreement for the kappa coefficient: 0=Poor, 0.01-0.20=Slight, 0.21-0.40=Fair, 0.41-0.60=Moderate, 0.61-0.80=Substantial and 0.81-1.0=Almost perfect (high). These categories are informal.

Date of birth and encounter date, which are required elements for performance score calculation, were also not subjected to validity testing and are presumed to be valid.

Data Element: Dx Dermatitis

Kappa: 0.87

Kappa 95% CI: 0.76 – 0.98

Prevalence Adjusted Kappa: 0.87

Prevalence Adjusted Kappa 95% CI: 0.77 – 0.98

Overall Agreement: 93.7%

Data Element: Assessment Tool

Kappa: 0.56

Kappa 95% CI: 0.39 – 0.74

Prevalence Adjusted Kappa: 0.72

Prevalence Adjusted Kappa 95% CI: 0.60 – 0.84

Overall Agreement: 81.0%

Data Element: PRO Score

Kappa: 1.00

Kappa 95% CI: n/a

Prevalence Adjusted Kappa: 1.00

Prevalence Adjusted Kappa 95% CI: n/a

Overall Agreement: 100.0%

1. Cohen J. A coefficient of agreement for nominal scales. Educational and psychological measurement. 1960;20(1):37-46.

2. Landis JR, Koch GG. The measurement of observer agreement for categorical data. biometrics. 1977:159-174

Validity Testing Interpretation of Results

Agreement statistics (kappa and prevalence adjusted kappa) indicate at least “Substantial” agreement abstractors’ findings of documentation in the medical record and the data submitted by the practice site

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for all critical data elements needed to calculate performance for the quality measures tested.

Measure performance – Type of Score
Proportion

Measure Performance Score Interpretation
Higher score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have
Mean Performance Rate: 54.9%

Std Dev: n/a

Benchmark, if applicable
N/A

Measure Contact Information

Measure Steward
American Academy of Dermatology

Measure Steward Contact Information
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Long-Term Measure Steward
N/A

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N/A

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847-240-1862

Section 2: Preliminary Analysis – MUC2021-135 Dermatitis – Improvement in Patient-Reported Itch Severity

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?

Yes/No: Yes

Justification and Notes: CMS has indicated their top priority for measure selection in the MIPS program is patient-reported outcome measures; as such, this measure fits that objective. If included in the program, the measure would be only the second outcome measure in the Dermatology Measure Set. The other measure is a clinical outcome measure of psoriasis disease activity level; although somewhat related, this Measure Under Consideration distinguishes itself as a patient-reported outcome and being more generally applicable to all dermatitis cases.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?

Yes/No: Yes

Justification and Notes: Chronic pruritis, the symptom assessed in this patient reported outcome, has a "quality of life impact comparable to that of chronic pain", a considerable burden of disease (Klini et al, 2011). Left unresolved, it can lead to "develop of symptoms of depression, global distress, and impairment of sleep" (Zachariae et al, 2008). A TEP convened by the developer included 3 patients, all three of whom indicated the measure result would help them make decisions about their care. However, the guideline on which this measure is based was only given a "C", indicating a "recommendation based on consensus, opinion, case studies, or disease-oriented evidence.". Note that the guideline indicates that the minimal clinically important difference is of 3 to 4 points using the scales identified in the measure; however, the measure gives credit to improvements of 2 or more points.

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: One study by Fuxench et al estimated that 6.6. million people in the United States meet the criteria for moderate to severe atopic dermatitis, the most common driver of health care visits for dermatitis, though other types of dermatitis are also common. There are over 4.5 million ambulatory health care visits for chronic pruritis in the United States every year (Shive et al, 2013). A TEP convened by the developer found that 11 of 11 providers consulted agreed that the measure was actionable to improve quality of care. In the measure's current implementation as a MIPS QCDR measure, the average performance rate is 54.9%, indicating a substantial gap in care.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?

Yes/No: Yes

Justification and Notes: The broad clinical incidence of dermatitis suggests this measure would be

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applicable and usable by most clinicians using the Dermatology MIPS measure set. There are no patient-reported outcome measures in the Dermatology measure set, and only one other outcome measure in the set, assessing disease activity level in psoriasis patients. Although psoriasis patients also experience chronic pruritis as a symptom, this measure distinguishes itself as patient-reported and focused on the symptom.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure is in current use as part of the American Academy of Dermatology QCDR. The Academy conducted a burden analysis, noting that although the clinical workflow would have to be modified to calculate the measure, as the numerator must be manually abstracted (comparing two scores on the severity assessment tools), the time to abstract per record was minimal. All data elements used to calculator the denominator is available through electronic coding, such as CPT or ICD-10.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: Yes

Justification and Notes: The measure is specified for use in outpatient dermatology clinical practices, at the individual clinician level; this is consistent with MIPS program objectives, and consistent with the parameters for the reliability and validity testing that was conducted.

If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure been identified?

Yes/No: No

Justification and Notes: The measure is in current use in the MIPS QCDR, and no negative unintended issues or implementation challenges have been identified.

PAC/LTC Core Concept?

N/A

Impact Act Domain

N/A

Hospice High Priority Areas

N/A

MAP Rural Health Advisory Group Input:

Relative priority/utility:

- No concerns raised for this measure.

Data collection issues:

- None identified.

Calculation issues:

- None identified.

Unintended consequences:

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- None identified.

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 4.3
1 – 0 votes
2 – 0 votes
3 – 0 votes
4 – 10 votes
5 – 4 votes

MAP Health Equity Advisory Group Input:

Relative priority/utility:

- The Health Equity Advisory Group noted that Dermatitis is an important clinical topic.

Data collection issues:

- Since this is a self-reported measure, data collection may be a problem for disadvantaged populations due to language and cultural barriers, as well as access issues.
- This measure does require two assessments, and the response rates may drop among disadvantaged population resulting in selection bias in the measure performance.

Calculation issues:

- The Advisory Group recommended this measure be stratified to assess performance based on population subgroups.

Unintended consequences:

- Disparity in diagnoses was identified as a potential issue.
- Response bias was identified as a potential issue.

Votes: Range is 1 – 5, where higher number has greater potential for positive impact on health equity.
Average: 2.8
1 – 0 votes
2 – 11 votes
3 – 8 votes
4 – 5 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking, pending NQF endorsement.

Summary: What is the potential value to the program measure set?

This Measure Under Consideration is a patient-reported outcome for a dermatitis symptom. This measure would be just the second outcome measure in the MIPS Dermatology set (and just the 12th measure overall), and as a patient-reported outcome, is consistent with CMS' Meaningful Measures Initiative. The MAP Clinician workgroup was encouraged to see another PRO proposed for this program.

Summary: What is the potential impact of this measure on quality of care for patients?

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Chronic pruritis, the symptom assessed in this patient reported outcome, has a significant impact on quality of life and is associated with depression and global distress, among other effects. Patients and providers on a technical expert panel agreed that the quality construct measured was actionable, and the measure result could be used to evaluate quality of care. The measure is supported by a clinical guideline, although the evidence supporting the guideline is somewhat weaker and the minimum clinical impact in the measure is lower than that recommended by the guideline.

In the measure's current implementation in a MIPS QCDR, the average performance rate is 54.9%, indicating a substantial gap in care. Incorporating this measure into MIPS would encourage adherence to the guideline, leading to better symptom control and improved quality of life for the millions affected by chronic pruritis.

Section 3: Public Comments

OCHIN, Inc.

Support Committee recommendation. Measures that look for improvement can be problematic in determining which score is the baseline score. It can also be difficult to reliably capture patient reported outcomes.

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MUC2021-136 Screening for Social Drivers of Health

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Merit-based Incentive Payment System–Quality

Workgroup
Clinician

Measure Description
Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety.

Numerator
Number of beneficiaries 18 and older screened for food insecurity, housing instability, transportation needs, utility assistance, and interpersonal violence.

Numerator Exclusions
N/A

Denominator
Number of beneficiaries 18 and older in practice (or population).

Denominator Exclusions
N/A

Denominator Exceptions
N/A

State of development
Field Testing

State of Development Details
•Using a standard, validated screening tool, AHC has screened nearly 1 million beneficiaries for HRSN in 21 states, with 33% of beneficiaries screened having at least one HRSN.

-Sources:

https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf

https://innovation.cms.gov/media/document/ahc-fact-sheet-2020-prelim-findings

•CMMI's Comprehensive Primary Care Plus (CPC+) model reported in 2020 that 86% of ~1,500 Track 1

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practices and 99% of ~1,500 Track 2 practices (together serving ~2.4M beneficiaries) are implementing DOH screening.

-Sources:

https://innovation.cms.gov/data-and-reports/2020/cpc-evaluation-annual-report-2

What is the target population of the measure?
All Payer

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Addiction medicine ;Allergy/immunology;Behavioral health;Cardiac electrophysiology;Cardiac surgery ;Cardiovascular disease (cardiology) ;Critical care medicine (intensivists);Dermatology ;Emergency medicine;Endocrinology;Family practice ;Gastroenterology ;General practice;General surgery ;Geriatric medicine;Gynecological oncology ;Hematology/oncology;Hospice and palliative care;Infectious disease;Internal medicine;Interventional pain management;Medical oncology;Nephrology ;Nursing Homes;Obstetrics/gynecology ;Osteopathic manipulative medicine ;Otolaryngology ;Pain management;Palliative care ;Pediatric medicine;Physical medicine and rehabilitation ;Podiatry ;Preventive medicine ;Primary care ;Psychiatry ;Public and/or population health;Pulmonary disease;Pulmonology ;Radiation oncology ;Rheumatology

Measure Type
Process

Is the measure a composite or component of a composite?
No

If Other, Please Specify
Social and Economic Determinants

What data sources are used for the measure?
Administrative Data (non-claims);Electronic Clinical Data (non-EHR);Standardized Patient Assessments;Patient Reported Data and Surveys

If applicable, specify the data source
N/A

If EHR or Chart-Abstracted data, description of parts related to these sources
N/A

At what level of analysis was the measure tested?
Clinician;Group;Facility;Other: Beneficiary, Population

In which setting was this measure tested?
Ambulatory/office-based care;Behavioral health clinic or inpatient psychiatric facility;Community hospital;Emergency department;Federally qualified health center (FQHC);Hospital outpatient department (HOD);Hospital inpatient acute care facility

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What one healthcare domain applies to this measure?
Equity

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
The measure correlate to specific MIPS Quality Improvement Activities as follows:

- Use QDCR data for ongoing practice assessment and improvements (IA_PSPA_7)
- Use of toolsets or other resources to close healthcare disparities in communities (IA_PM_6)
- Practice Improvements that Engage Community Resources to Support Patient Health (IA_CC_14)
- Provide Clinical-Community Linkages (IA_PM_18)

Source:

https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2021

The measure correlate to specific MIPS Quality Improvement Activities as follows:

- Use QDCR data for ongoing practice assessment and improvements (IA_PSPA_7)
- Use of toolsets or other resources to close healthcare disparities in communities (IA_PM_6)
- Practice Improvements that Engage Community Resources to Support Patient Health (IA_CC_14)
- Provide Clinical-Community Linkages (IA_PM_18)

Source:

https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2021

CMIT ID
N/A

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

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If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
In COVID-19's wake, food insecurity, housing instability, IPV, and other basic DOH have reached unprecedented levels – and revealed searing racial disparities. In 2021, 21% of Black individuals are projected to experience food insecurity experience food insecurity, compared to 11% of white individuals. Likewise, 22% of Asian, 22% of Black, and 20% of Latino renters are not caught up on rent, compared to 9% of white renters.

Secretary Becerra has pledged "to take a department-wide approach to the advancement of equity, consistent with President Biden's charge to federal departments and agencies, and this would include examination of ways to address the social determinants of health." In particular, he has noted the importance of collecting more robust DOH data to address the disparities exposed by COVID-19 and leveraging the data and experience from the CMMI Accountable Health Community (AHC) model, which has screened nearly one million beneficiaries.

CMS has recognized the importance of making DOH measures standard across programs, identifying the development and implementation of "measures that reflect social and economic determinants" as a key priority and measurement gap to be addressed through Meaningful Measures 2.0.

A growing set of constituencies have called on CMS to provide leadership in measuring and addressing DOH, citing various rationales for doing so. Healthcare experts have increasingly recognized that equity is unachievable without addressing DOH, calling for CMS to require program "participants to uniformly screen for and document drivers of health" and "build DOH measures into MIPS and all APMs." The Health Care Payment Learning & Action Network (LAN) – a group of public and private health care leaders providing thought leadership, strategic direction, and ongoing support to accelerate adoption of APMs – has identified promoting equity and addressing DOH as key facets of APM resiliency.

Likewise, physicians and other providers have called on CMS to create standard patient-level DOH measures – beyond socioeconomic status (SES), hierarchical condition category (HCC) score, or duals status – recognizing that these risk factors transcend specific subpopulations; drive demand for healthcare services; escalate physician burnout; and penalize physicians caring for those patients via worse Merit-based Incentive Payment System (MIPS) scores.

Sources:

https://www.feedingamerica.org/sites/default/files/2021-03/National%20Projections%20Brief_3.9.2021_0.pdf

https://www.cbpp.org/research/poverty-and-inequality/tracking-the-covid-19-recessions-effects-on-food-housing-and

https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization

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https://blueshieldcafoundation.org/sites/default/files/publications/downloadable/Investing%20in%20Health%20-%20A%20Federal%20Action%20Plan%20-January%202021_Final.pdf

https://www.healthaffairs.org/do/10.1377/hblog20201216.672904/full/

https://hcp-lan.org/2021-roadshow-deck/

https://physiciansfoundation.org/wp-content/uploads/2020/11/PF-QPP-Open-Comment-Submission-v.f_-.pdf

https://pubmed.ncbi.nlm.nih.gov/27942709/

https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf

https://pubmed.ncbi.nlm.nih.gov/30610144/

https://pubmed.ncbi.nlm.nih.gov/32897345/

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?
No

If eCQM, enter Measure Authoring Tool (MAT) number
N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

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What is the history or background for including this measure on the new measures under consideration list?
Measure currently used in a CMS program being submitted as-is for a new or different program

Range of years this measure has been used by CMS Programs
Accountable Health Communities Pilot (2017-2022)

What other federal programs are currently using this measure?
Not applicable

Is this measure similar to and/or competing with a measure(s) already in a program?
No

Which measure(s) already in a program is your measure similar to and/or competing with?
N/A

How will this measure be distinguished from other similar and/or competing measures?
N/A

How will this measure add value to the CMS program?
N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure
See attached document "Peer Reviewed Evidence and Relevant Research_MUC2021-136_The Physicians Foundation_5 27 21.pdf" with supporting evidence and research.

Evidence that the measure can be operationalized
•CMS has the opportunity to leverage and apply CMMI's 5+ years of data and experience with AHC. Using a standard, validated screening tool, AHC has screened nearly 1 million beneficiaries for HRSN in 21 states, with 33% of beneficiaries screened having at least one HRSN. AHC used screening, referral, and navigation data files extracted by NewWave (Centers for Medicare & Medicaid Services [CMS] Enterprise Portal contractor) and generated by Mathematica Policy Research (the AHC implementation contractor) using data submitted by bridge organizations.

Sources:

https://innovation.cms.gov/innovation-models/ahcm

https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf

https://innovation.cms.gov/media/document/ahc-fact-sheet-2020-prelim-findings

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A number of CMMI models and participating entities have incorporated DOH screening and navigation data into their quality frameworks and care management plans for beneficiaries. CMMI's Comprehensive Primary Care Plus (CPC+) model reported in 2020 that 86% of ~1,500 Track 1 practices and 99% of ~1,500 Track 2 practices (together serving ~2.4M beneficiaries) are implementing DOH screening. CMMI required that by Program Year 3, Track 2 practices would use an electronic screening tool to assess patients' health-related social needs and store an inventory of resources to meet patients' needs; notably, by Program Year 2, Track 1 practices were as likely as Track 2 practices to report implementing these DOH functions, even absent a requirement that they do so.

Source:

https://innovation.cms.gov/data-and-reports/2020/cpc-evaluation-annual-report-2

Likewise, annual evaluations of other current CMMI models, including the State Innovation Model and Next Generation ACOs, report that participants are investing in staffing and infrastructure to conduct DOH screening and navigation. The 2021 Comprehensive End-Stage Renal Disease Care Model evaluation, for example, reported that "[m]any beneficiaries are protein malnourished and don't eat enough fresh produce. Some beneficiaries go to the hospital to get meals." ESRD Seamless Care Organizations have begun to monitor food insecurity and provide food gift cards to both low-income beneficiaries and those above the poverty level, to address beneficiaries' non-adherence to nutritional guidelines and reduce the risk of increased utilization and costs.

Sources:

https://downloads.cms.gov/files/cmmi/sim-rd2-test-ar3.pdf

https://innovation.cms.gov/data-and-reports/2020/nextgenaco-thirdevalrpt-fullreport

https://innovation.cms.gov/data-and-reports/2021/cec-annrpt-py4

How is the measure expected to be reported to the program?
CQM

Feasibility of Data Elements
Some data elements are in defined fields in electronic sources; Patient/family-reported information: electronic; Patient/family-reported information: paper

Evidence of Performance Gap
CMS has already identified social and economic determinants as both a measurement priority and gap in Meaningful Measures 2.0. Other public and private organizations such as ASPE, NQF and NCQA have identified this as a critical gap.

Sources:

https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization

https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress

https://www.qualityforum.org/News_And_Resources/Press_Releases/2019/National_Quality_Forum_L

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eads_National_Call_to_Address_Social_Determinants_of_Health__through_Quality_and_Payment_Innovation.aspx

https://blog.ncqa.org/ncqa-releases-its-social-determinants-of-health-resource-guide/

Unintended Consequences
A potential unintended consequence of the measure is that health systems and hospitals will not be equipped to act on it due, in part, to the lack of community resources. This challenge was noted as a primary barrier to connecting beneficiaries to resources in the AHC Year 1 evaluation. There is a well-documented and well-tested catalog of additional tools, infrastructure, and investments that can be implemented to support practices in acting on this measure.

Sources:

https://fhop.ucsf.edu/sites/fhop.ucsf.edu/files/custom_download/Unintended%20consequences%20of%20screening%20for%20social%20determinants.pdf

https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt

https://nhchc.org/wp-content/uploads/2020/04/NHCHC_Community-Information-Exchange2.pdf

https://governor.nc.gov/news/north-carolina-creates-nation%E2%80%99s-first-statewide-infrastructure-connecting-healthcare-and-human

https://blueshieldcafoundation.org/sites/default/files/publications/downloadable/Investing%20in%20Health%20-%20A%20Federal%20Action%20Plan%20-January%202021_Final.pdf

Outline the clinical guidelines supporting this measure
Not applicable

Were the guidelines graded?
No

If yes, who graded the guidelines?
N/A

If yes, what was the grade?
N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Unable to determine

Estimate of Annual Improvement in Measure Score
Not applicable

Type of Evidence to Support the Measure
USPSTF (U.S. Preventive Services Task Force) Guidelines;Systematic Review;Empirical data

Is the measure risk adjusted, stratified, or both?
Stratified

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Are social determinants of health built into the risk adjustment model?
No

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
Extensive research exists demonstrating increased healthcare expenditures to patients including Medicare beneficiaries associated with DOH. The example below provides the annualized increase in annual healthcare expenditures (PMPY) associated with food insecurity across different disease categories across all payor types in the peer-reviewed literature:

- Diabetes Mellitus: $4,413.61
- Hypertension: $2,175.20
- Heart Disease: $5,144.05
- Overall: $1,863

Source:

https://www.gsfb.org/wp-content/uploads/2018/08/Berkowitz-S.-A.-Basu-S.-Meigs-J.-B.-Seligman-H.-K.-Food-Insecurity-and-Health-Care.pdf

The AHC Year 1 evaluation found that Medicare FFS beneficiaries in the Assistance Track intervention group had 9% fewer ED visits than those in the control group in the first year after screening. (No Medicaid utilization/cost data reported yet.)

Source:

https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt

Cost Avoided Annually by Medicare/Provider
Unable to determine – though the cost avoided annually is likely to be significant given the research demonstrating increased utilization, readmissions, cost and increased financial liability for providers caring for patients with increased social risk.

Source of Estimate
Sources:

https://www.gsfb.org/wp-content/uploads/2018/08/Berkowitz-S.-A.-Basu-S.-Meigs-J.-B.-Seligman-H.-K.-Food-Insecurity-and-Health-Care.pdf

Also see attached review of the research literature for additional cost studies related to DOH.

Year of Cost Literature Cited
Estimated expenditures in 2015 dollars

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

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If yes, choose all methods of obtaining patient/caregiver information
Surveys

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
Not applicable

Total Number of Patients and/or Caregivers Consulted
3162

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
Not applicable

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
2441

Burden for Patient: Does the measure require survey data from the patient?
Yes

If yes, what is the estimated time to complete the survey?
0

If yes, what is the frequency of requests for survey data per year?
1

If yes, are the survey data to be collected during or outside of a visit?
Prior to visit; During visit; After visit

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Surveys; Focus groups; Standard TEP

Total Number of Clinicians/Providers Consulted
10078

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
8800

Burden for Provider: Was a provider workflow analysis conducted?
Yes

If yes, how many sites were evaluated in the provider workflow analysis?
3224

Did the provider workflow have to be modified to accommodate the new measure?
Yes

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If yes, how would you describe the degree of effort?
3

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
0

Measure Testing Details

Reliability Testing Interpretation of Results
These results are the first to suggest that both the AHC and YCLS have high reliability and concurrent and predictive validity, supporting their use in healthcare settings, including by primary care physicians to engage in social risk-informed care.

Source:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7652127/#ref38

Type of Reliability Testing
Measure Score Reliability;Data Element Reliability

Reliability Testing: Type of Testing Analysis
IRR (Inter-rater reliability)

Reliability Testing Sample Size
1008

Reliability Testing Statistical Result
Within social domains, percentages reporting asocial risk tended to be higher by the AHC than the YCLS. Using unadjusted kappas, the AHC and YCLS items had substantial agreement for measures of food insecurity only. When examining the adjusted kappas that account for bias and prevalence, agreement between the AHC and YCLS items was substantial or higher (kappas > 0.60) for all social risksexcept housing quality (kappa = 0.52). The YCLS and CHW had substantial agreement (kappa 0.75) on housing.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

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Type of Validity Testing
Data Element Validity

Validity Testing: Type of Validity Testing Analysis
Internal Consistency;Predictive Validity;Other: Empirical validity (through AHC and CPC+ practice implementation across 3+ million beneficiaries over last ~ 5-year time frame) and Psychometric and Pragmatic Property Analysis (see https://pubmed.ncbi.nlm.nih.gov/31753276/)

Validity Testing Sample Size
Study 1: 1,008 ; Study 2: 30,098 ; Study 3: 60,000

Validity Testing Statistical Result
Study 1: A reported social risk on the AHC and YCLS measures was strongly associated with having fair or poor self-rated health

Source:

https://www.jfmpc.com/viewimage.asp?img=JFamMedPrimaryCare_2020_9_9_5026_296311_t6.jpg

tudy 2: HFSS questions 1 and 2 were most frequently endorsed among food-insecure families (92.5% and 81.9%, respectively). An affirmative response to either question 1 or 2 had a sensitivity of 97% and specificity of 83% and was associated with increased risk of reported poor/fair child health (adjusted odds ratio [aOR]: 1.56; P < .001), hospitalizations in their lifetime (aOR: 1.17; P < .001), and developmental risk (aOR: 1.60; P < .001).

Source:

https://pubmed.ncbi.nlm.nih.gov/20595453/

Study 3: Sensitivity of each two-item combination was high for the US population and high-risk demographic groups compared with the eighteen-item CFSM (Table 2). Sensitivity ranged from 96·4 % for items 2 and 3 for households with children and incomes <200 % of the federal poverty line, to 99·8 % for items 1 and 3 for Spanish-speaking households. (results for all combinations are available from the corresponding author upon request). Specificity was lower, ranging from 73·7 % for items 1 and 2 for households with children and incomes <100 % of the federal poverty line, to 94·5 % for items 2 and 3 for households with a respondent aged >60 years. Accuracy was high for all two-item combinations.

Source:

https://www.cambridge.org/core/journals/public-health-nutrition/article/brief-assessment-of-food-insecurity-accurately-identifies-highrisk-us-adults/81A4F5E162241E289A5181A10C056125

Validity Testing Interpretation of Results
Study 1: These results are the first to suggest that both the AHC and YCLS have concurrent and predictive validity, supporting their use in healthcare settings, including by primary care physicians to engage in social risk-informed care.

Source:

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https://www.jfmpc.com/viewimage.asp?img=JFamMedPrimaryCare_2020_9_9_5026_296311_t6.jpg

Study 2: A 2-item FI screen was sensitive, specific, and valid among low-income families with young children. The FI screen rapidly identifies households at risk for FI, enabling providers to target services that ameliorate the health and developmental consequences associated with FI.

Source:

https://pubmed.ncbi.nlm.nih.gov/20595453/

Study 3: The test characteristics of multiple two-item combinations of questions assessing food insecurity had adequate sensitivity (>97 %) and specificity (>70 %) for widespread adoption as clinical screening measures.

Source:

https://www.cambridge.org/core/journals/public-health-nutrition/article/brief-assessment-of-food-insecurity-accurately-identifies-highrisk-us-adults/81A4F5E162241E289A5181A10C056125

Measure performance – Type of Score
Proportion

Measure Performance Score Interpretation
Higher score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have
33%

Benchmark, if applicable
Not applicable

Measure Contact Information

Measure Steward
Other

Measure Steward Contact Information
Robert Seligson

4033 Lila Blue Lane

Raleigh, NC 27612

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919-306-0056

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Long-Term Measure Steward
N/A

Long-Term Measure Steward Contact Information
N/A

Primary Submitter Contact Information
N/A

Secondary Submitter Contact Information
N/A

Section 2: Preliminary Analysis – MUC2021-136 Screening for Social Drivers of Health

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

Justification and Notes: This measure assesses the percentage of patients screened for health-related social needs and is consistent with the MIPS priority to identify measures that support health equity, and the Meaningful Measures 2.0 priority to develop and implement measures that reflect social and economic determinants. There are no similar measures in MIPS.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes

Justification and Notes: Health outcomes are ~80% driven by socioeconomic factors, health behaviors, and the physical environment (Hood et al, 2017). Reviews have collected numerous studies identifying a causal relationship between poor health outcomes and homelessness (Stafford and Wood, 2017), food insecurity (Staren, 2020), and other needs screened for by the tool cited in this measure (Davidson et al, 2020). The process of screening itself is consistent with guidelines promulgated by the American Academy of Pediatrics, The American Academy of Family Physicians, and a recommendation by the U.S. Preventive Services Task Force. An evaluation of a program offering program navigation services to patients screened using this tool found a statistically significant decrease in ED visits, one example of interventions predicated on the screening to improving health outcomes.

Does the measure address a quality challenge?
Yes/No: Yes

Justification and Notes: The measure is conceptually related to a critical quality challenge. The developer notes that identifying and addressing social determinants of health has become a top nationwide priority for leaders in healthcare. According to Fraze et al (2019), just 16% of physician practices screened patients for all five social needs identified in this measure, and 33% of practices did not screen patients for any needs. In the 2017-2020 years of evaluation of a CMS program based on the measure's screening tool, 34% of beneficiaries screen were positive for at least one need, indicating a

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substantial unmet need for screening and a performance gap in the measure result.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?

Yes/No: Yes

Justification and Notes: There are no similar measures in MIPS or other federal quality programs. The concept of screening, either for disease (as in colorectal cancer screening) or for behavioral health issues (as in alcohol use or tobacco use) is well-established in the program, however.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: To report the measure, providers must collect the total number of patients and the number of patients who were screened for all five elements; the only demographic information needed is patient age. The screening tool data can be electronically collected and recorded; therefore, all these data points should be available to providers for reporting. The screening tool has been in use in 21 states across the US, with nearly one million patients screened. The MAP should consider that the measure specifications are not specific to a particular tool; other screening tools might introduce data collection and reporting issues that otherwise unanticipated here.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: No

Justification and Notes: The measure is specified and has been trialed in clinicians' offices, which is consistent with the MIPS program parameters. The MAP should note that although the reliability and validity has been examined for the screening tool, no such testing has been conducted or evaluated.

If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure been identified?

Yes/No: Yes

Justification and Notes: The developer notes one unintended consequence is that health systems and hospitals will not be equipped to act on identified needs. This could lead to frustration for both patients and providers as well as ethical challenges if these needs remain unmet even after referrals (Garg et al., 2016). One mitigant is that as implemented in MIPS, providers would presumably only choose to select this measure for reporting if they were comfortable with the implications.

PAC/LTC Core Concept?

N/A

Impact Act Domain

N/A

Hospice High Priority Areas

N/A

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MAP Rural Health Advisory Group Input:

Relative priority/utility:

- The measure was suggested to be applicable to rural communities.

Data collection issues:

- Concerns raised regarding standardized data sets and data collection for SDOH.
- However, the advisory group agreed that it is important to start the standard collection of this information. The developer commented that by introducing this measure into CMS programs, it will help drive standardization.

Calculation issues:

- None identified.

Unintended consequences:

- Concerns were raised regarding the capture of a positive screen without the appropriate resources available to support the patient needs.

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 3.5
1 – 0 votes
2 – 2 votes
3 – 4 votes
4 – 8 votes
5 – 1 vote

MAP Health Equity Advisory Group Input:

Relative priority/utility:

- This social driver measure is important as this is one of the first measures considered for Federal programs.
- Screening is important for advance equity.

Data collection issues:

- Need to ensure alignment regarding data capture and standardization, such as CMS SDOH Z codes could provide consistent standards.
- Lack of a fully developed federal data standard is holding back major investments in data systems for SDOH.

Calculation issues:

- This measure is particularly important/useful to stratify by disability.

Unintended consequences:

- Patient and provider frustrations and concerns about having to screen without having robust options (e.g., community resources, care navigators, etc.) to address the positive responses.

Votes: Range is 1 – 5, where higher number has greater potential for positive impact on health equity.
Average: 4.3
1 – 0 votes
2 – 1 vote
3 – 1 vote
4 – 12 votes
5 – 10 votes

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Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking, pending NQF endorsement.

Summary: What is the potential value to the program measure set?

This measure assesses the rate at which providers screen their adult patients for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety. As the first screening measure addressing social determinants of health and health care equity, this measure is consistent with CMS' Meaningful Measures 2.0 priority areas, and the priorities of the MIPS program to advance health equity.

Summary: What is the potential impact of this measure on quality of care for patients?

This measure addresses a significant performance gap, where even though approximately one-third of patients would screen positive for one or more social needs, 84% of physician offices do not screen for all five needs. This measure is consistent with recent guidelines from the American Academy of Family Physicians, the American Academy of Pediatrics, and the U.S. Preventive Services Task Force, which are inspired by research finding that health outcomes are largely driven by social determinants of health, and screening for health needs can help clinicians connect their patients to social services to ameliorate those needs.

Conditional Support for Rulemaking is recommended pending testing of the measure's reliability and validity, and NQF endorsement.

Section 3: Public Comments

Sacramento Native American Health Clinic

FQHC patients are generally lower on the socioeconomic and political ladder. Health outcomes DO NOT need to reflect that, yet they do. Many providers do not ask about these HRSN of patients and potentially miss important opportunities to intervene. If we collect this data, we can ask for more help and create a better case for policy changes. The additional time added to assess social needs would be offset by implementing interventions that bend towards equity.

Indiana University Health

Yes, we know 80% of patients' health conditions can be improved if we assist with social need gaps, rather than focusing on the health issue alone. This is really important to move forward with screening and assisting those patients further who screen positive.

The Physicians Foundation

In submitting these comments, the Physicians Foundation does so not only as the measure developer for MUC2021-134 (Screen Positive Rate for Social Drivers of Health) and MUC2021-134 (Screening for Social Drivers of Health), but also at the direction of physicians from 21 state and county medical societies across the country. As practicing physicians, we know that what our health care system measures and

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pays for—via diagnosis and billing codes, ""allowable services"" and myriad quality measures—is a reflection of both what and who it values. Further, we on the front lines of health care know that reducing total cost of care and achieving health equity are only achievable by addressing the social drivers of health—critical comorbidities such as food insecurity and housing instability. Yet, this is not how our system operates. Under federal payment and quality frameworks, the health care system codes, screens, measures and risk-adjusts for diabetes, but not for food insecurity—even though diabetics who are food insecure have worse health outcomes and cost on average $4,500 more per year than those with access to healthy food. A system that does not collect and act on food insecurity data cannot address rising health care costs or reduce racial disparities, especially given that Black Americans face the highest rates of both food insecurity and diabetes. The benefits of these SDOH measures certainly outweigh the burden of data collection or reporting. It is well-documented that the social drivers lead to physician burnout and effectively penalize physicians caring for affected patients via lower MIPS scores. A recent study found that SDOH were associated with 37.7% of variation in price-adjusted Medicare per beneficiary spending between counties in the highest and lowest quintiles of spending in 2017. Yet even with an ongoing pandemic that has painfully brought these issues to the fore, SDOH are still not included in any geographic adjustment or cost benchmarks. On behalf of physicians across the country, we strongly urge the MAP to recommend these measures consistent with CMS's stated commitment to identify new measures that are meaningful to patients and providers. These measures are well tested, including through the Accountable Health Communities model, which has screened nearly a million beneficiaries for SDOH in over 600 clinical practices. Further, the measures reflect the imperative to re-balance quality measures to focus on SDOH—which drive 70% of health outcomes and associated costs—and to bridge the realities of patients' lives and physician practice and the regulatory machinery of our health care system. With an Administration committed to operationalizing equity; a pandemic that has exacerbated rates of food insecurity, housing instability and other social drivers of health and the clinical disease burden linked to these factors; and the Medicare Trust Fund projected to be insolvent in five years, now is the moment to insist that these SDOH comorbidities be recognized and acted upon.

Citations:

https://physiciansfoundation.org/physician-and-patient-surveys/the-physicians-foundation-2020-physician-survey-part-3/https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/key-statistics-graphics.aspx/https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf/https://pubmed.ncbi.nlm.nih.gov/30610144/https://pubmed.ncbi.nlm.nih.gov/32897345/https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780864/https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7652127/https://www.commonwealthfund.org/sites/default/files/2019-07/ROI-EVIDENCE-REVIEW-FINAL-VERSION.pdf

Koss on Care LLC

Initial screen is important particularly to set baseline metrics, but screening without any follow-on intervention will not advance improvements for patients and families.

Screening needs to have accompanying socio-demographic metrics to also track and address disparities and inequities.

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Without an understanding of the level of screening for these known social determinants we cannot start to address major drivers of health and health outcomes.

As EHR increasingly facilitate & capture screen it should be reasonably cost effective.

Improved sharing of such data across providers could also reduce the burden.

Next Wave
This is an important first step in making Quality Measures in use truly patient-centric, by incorporating the patient's social needs as well as their clinical needs into care provided (""I am NOT just my condition""). Because these needs differ significantly by age, they should be reported by age/category (at minimum Over/Under 65).

Because this is the first use of Social Driver metrics, it provides an opportunity to learn and refine over time. Effort should be taken to capture some details beyond the bare minimum public reporting ratio to allow further research and refinement for the future, for example: Separate numerator and denominator, Medical vs. Surgical care. This could be accomplished by adding Z-codes to the claims data.

BHE Group
This measure is needed to initiate focus on SDOH at an entry level. However, it does not address the goal of integrating the screening result into the care plan, executing on it, and measuring the clinical impact of having it (or not having it) addressed. At minimum, a 2nd measure should also include % of results obtained through screening incorporated into the patient's care plan.

NewWave
Both MUC2021-136 (Driver of Health Screening Rate) and MUC2021-134 (Driver of Health Screen Positive Rate) are important baby-steps to begin measuring drivers. They are simple process measures that may be valuable in starting the measures we really need to be working toward. Knowing the rate of Screening and of those screened which had positive indicators of food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety will do little to improve the rate at which we implement programs that have a meaningful\measurable impact on effecting this QOL deteriorating drivers that rob value from any health care delivery received by effected individuals.

It is critical that these "conversation starter measures" are not considered an end in themselves but are in fact simple measures that we can do today with little controversy or change in the as is state of the care delivery system. Until we begin to measure the closed loop referral process and gather population level impacts and gaps the value of measures of drivers will be little more than the minimum, we must be doing to get started on the more important work to be done to address the blockers to better inter-sector and interoperable whole-person care that is called for by everyone.

Colorado Academy of Pediatrics
I would recommend outcome metrics and not process metrics.

The outcome metrics I would recommend is what % of eligible Medicaid enrollees are participating in SNAP and WIC. SNAP and WIC have been demonstrated to improve health outcomes, lower health costs and are currently under-enrolled. This metric would drive partnerships and innovation needed to

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maximize enrollment in these federal nutrition assistance programs. Screening can be harmful to some families and increase shame and fear. Promoting SNAP/WIC and facilitating enrollment/participation is a more strength-based approach.

American Occupational Therapy Association

AOTA supports MUC2021-134 Screen Positive Rate for Social Drivers of Health and MUC2021-136 Screening for Social Drivers of Health for both the IP-QRP and MIPS. These measures will help to ensure these items are monitored for patients. These important social drivers are areas that occupational therapy practitioners address with clients to improve outcomes.

Maryland Primary Care Program

Consider flexibility to the type of screening tool providers can use, many providers have tools already used in workflows and the measure should allow for flexibility to use already existing tools.

Consider how recent the screening needs to be performed (i.e., every visit? Within a year? etc.)

Blue Shield of California Foundation

The COVID-19 pandemic has exposed long-standing racial and economic injustices embedded in our health care system. This has led to a renewed commitment to improve health equity and address the drivers of health (DoH) that account for 80 percent of health outcomes and have a disproportionate impact on communities of color. These include stable, affordable housing; healthy food; reliable income; and interpersonal safety, among others.

Advancing health equity and addressing DoH will require changing how and what we measure in health care. Measurement matters because it equips providers with data to identify and address unmet needs and allows policymakers and payers to account for DoH in payment models.

We thus strongly encourage the Measure Applications Partnership to support for rulemaking both MUC2021-134 (Screen Positive Rate for Social Drivers of Health) and MUC2021-136 (Screening for Social Drivers of Health).

Despite the well-documented impact of DoH on health outcomes and costs and their impact on people of color, there are still no approved, standardized DoH measures in any Centers for Medicare &Medicaid Services' (CMS) programs. Even without such measures, the impact of DoH interventions are much referenced in the health care discourse and literature but remain functionally invisible in federal health care policymaking.

For example, a growing number of CMS Innovation Center models – Accountable Health Communities (AHC); Comprehensive Primary Care Plus; Maryland Total Cost of Care; State Innovation Models Round 2; and more – have screened millions of Medicare and Medicaid beneficiaries for DoH in thousands of inpatient and outpatient clinical settings across the country, but largely without the benefit of standard DoH screening tools or measures from CMS. As a result, CMS cannot systematically compare or use the data.

Recognizing the absence of DoH and race and ethnicity data as an issue, incoming CMS leadership in August 2021 cited the need for "patient-level demographic data and standardized social needs data" as a key element in its commitment to embedding equity in all models and demonstrations. The recently

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released CMS Innovation Center strategy report took this a step further by saying all new models will require participants to collect and report beneficiaries' demographic data and social needs data, when appropriate. Providers have joined the call for standardized, patient-level data collection for DoH, citing the impact of these drivers on patients, health care costs, and physician burnout.

These proposed DoH measures have been used in more than 600 clinical practices through the AHC model and have been subject to rigorous and independent validation. The AHC model found that 74% of navigation-eligible Medicare and Medicaid beneficiaries who were screened using these DoH measures opted in for navigation, nearly twice the projected estimate of 40%. Likewise, a large study in 2020 by Kaiser Permanente found that 85% of patients were in favor of health systems asking patients about social needs, and 88% were in favor of health systems helping to address those needs.

The introduction of the first DoH measures into core federal payment programs would be significant in its own right – making visible, when stratified by race and ethnicity, the social factors driving or inhibiting health, particularly for communities of color, including food insecurity, housing instability, transportation, utility needs, and interpersonal safety, including intimate partner violence. Only when these factors are brought to light and measured in a standardized way will we be able to align our collective resources and take action to achieve equitable health outcomes for all.

If approved, these DoH measures can be improved over time through CMS's annual measure review process and can provide the groundwork for comparable measures for the Medicaid and CHIP Child and Adult Core Sets and guidance for states in their efforts to standardize DoH data. Further, these initial DoH measures could lay the foundation for subsequent measures focused on ensuring patients secure the resources they need to be healthy and accelerating/enabling investments in community capacity. In particular, these DoH measures will provide crucial data on the prevalence of unmet social needs among beneficiaries and other learning to enable more effective public and private sector investments in the technical/IT infrastructure, community-based navigation workforce, and capacity building and sustainable sources of funding necessary to enable the equitable integration of healthcare and community social services.

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Stephanie L. Fitzpatrick, PhD

I am writing to express my overall support for the Centers for Medicare and Medicaid Services to add the two social care-related quality measures (MUC2021-136 and MUC2021-134) as new performance measures for Medicare public reporting and performance-based payment programs. Social determinants account for about 50% of health outcomes. Furthermore, it has been well-established that social risks (e.g., food insecurity, housing instability, and lack of transportation) exacerbate socioeconomic disparities in the prevalence of chronic conditions including diabetes [1] and cardiovascular disease. [2,3] Therefore, the addition of the 'driver of health screening measures' has major implications for population health, enhanced integrative care, and promoting health equity.

Currently, social risks screening is not systematically, nor consistently done in most health care settings. A recent study found that only 24% of hospitals and 16% of physician practices screened for all five of the major health-related social needs (i.e., food insecurity, housing instability, utility needs, transportation needs, and interpersonal violence).[4] Increasing social risks screening is key to understanding the prevalence of social risks in various patient populations, the impact on clinical outcomes and utilization at the population health level, and improving quality of care by adjusting treatment planning based on the presence of social risks (i.e., contextualized care). Screening also increases access to social services and community-based resources, which help alleviate the socioeconomic stressors that often take priority over chronic disease self-management.

Despite these benefits of screening, successful implementation of these two drivers of health screening measures would require moderate to major infrastructural changes, particularly at the health care and community levels. Therefore, a glide path approach to implementing these as performance measures may be ideal to allow clinics and hospitals to get resources in place and build strong relationships/partnerships with the community; similar to the staged approach for the EHR meaningful use. As currently worded, MUC2021-136 seems to imply that food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety must all be screened for each beneficiary. However, some health systems, including, FQHCs, do not have the bandwidth to screen or community services available to potentially address all of these risks. Therefore, I highly recommend this measure to be counted if any one of these risks are screened. Furthermore, screening from any provider (e.g., social workers, medical assistants, navigators, psychologists) should also count as most physicians will not have the time to do this screening, although they should be aware of these risks to inform care planning. In addition to training personnel to conduct trauma-informed and culturally sensitive social risks screening, patients should also be made aware that they may be screened for social risks, have the option to opt-out, and informed about how this data will be used, stored, and shared.

The MUC2021-134 measure, focused on reporting the number of positive social risks screens, could certainly have implications for increasing resources to particular geographic areas or health systems in which the prevalence of social risks among Medicare beneficiaries is high. However, these resources would need to also be spread to social services and community-based partners as they are the ones who usually receive the referrals and help patients address social risks. Without social services and the community, social healthcare fails.

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With that said, the MUC2021-134 measure is also incomplete. Reporting positive screens, but not the number of referrals to social services/community-based resources or documentation of follow-up on these social risks seems imperative for patient-centeredness, trust, and to actually move the needle in improving patient outcomes and advancing health equity. Screening on its own without a plan to address those risks is not good for patients or providers. Therefore, I highly recommend adding language to MUC2021-134 to also capture the number of positive screens with a referral to social services/ community-based resources and/or follow-up encounter with a provider.

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3. Berkowitz SA, Berkowitz TSZ, Meigs JB, Wexler DJ. Trends in food insecurity for adults with cardiometabolic disease in the United States: 2005-2012. PLoS One. 2017;12(6): e0179172.
4. Fraze TK, Brewster AL, Lewis VA, Beidler LB, Murray GF, Colla CH. Prevalence of Screening for Food Insecurity, Housing Instability, Utility Needs, Transportation Needs, and Interpersonal Violence by US Physician Practices and Hospitals. JAMA Netw Open. 2019;2(9): e1911514.

ZERO-The End of Prostate Cancer

On behalf of the all those managing prostate cancer and navigating prostate cancer care (now and in the future), ZERO - The End of Prostate Cancer submits these comments in support of identifying those who screen positive for specific social needs such as food insecurity, housing instability, transportation problems, utility help needs, or interpersonal safety in the Hospital IQR and the MIPS program. Research has shown that socioeconomic factors are a substantial driver in the racial/ethnic differences in prostate cancer across the cancer continuum from prevention to end-of-life care. Families managing a prostate cancer diagnosis and navigating prostate cancer care engage with several staff, providers, and administrators in the healthcare delivery system; and this process often proves to be very complex, and to be substantially influenced by the socioeconomic resources of the patient and on how well the care delivery system has integrated “social care” into medical care. Not surprisingly, generally racial/ethnic minority and low socioeconomic status patients have worse health outcomes as they navigate the healthcare/cancer care delivery system. To address this issue, there have been several recent efforts to facilitate the integration of screening and addressing patient social needs in health care delivery; yet there is no agreed upon standard tool for screening patients. Thus, it is critical that CMS facilitates the integration of standard measures and creates a pathway for identifying those with the social needs proposed in this new measure; and create financial incentives and risk models/frameworks that recognize the social factors that contribute to worse health outcomes and increased costs for patients. The integration of the proposed measures facilitates the consistent screening of patient social needs and incentivizes providers and health care delivery systems to navigate patients to address those social needs and to evaluate the impact of those efforts on patient health outcomes. These efforts are needed to identify and eliminate health disparities and work towards health equity.

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Academy of Nutrition and Dietetics

The Academy of Nutrition and Dietetics' (Academy) Strategic Plan has a focus area dedicated to the topic of food insecurity- Nutrition Security and Food Safety. Within that focus area, there are impact goals: Advocate for equitable access to safe and nutritious food and water, and Advance sustainable nutrition and resilient food system. Therefore, the Academy is focused on impacting the health and wellbeing of individuals impacted from food insecurity, a component of the quality measure.

A concern with this proposed measure is it is not outcomes based. What happens with care once the individual is screened? What interventions are proposed to improve care? These outcomes are important so that care is impacted, not just data collected.

Food insecurity and malnutrition are widespread and worsening issues in the United States. Both food insecurity and malnutrition are associated with negative health outcomes and higher spending on health care. Adults who are malnourished at the time of hospitalization or surgery are more likely to have worse hospitalization, surgery, and recovery outcomes. Registered dietitian nutritionists (RDNs) have a responsibility to identify and address nutrition and food insecurity.

The purpose of a food insecurity screen, which is a component of the Accountable Health Communities Health-Related Social Needs Screening Tool, is to quickly identify households at risk for food insecurity, allowing providers to target services and interventions that address the health and developmental consequences of food insecurity.

RDNs working in health care settings, e.g., hospitals, long-term care, residential care, or free-standing dialysis facilities actively address discharge planning needs directly or in collaboration with a social worker or care coordinator to achieve improved outcomes for patients/clients and the organization, e.g., avoid hospital readmission. In addition to RDNs working in health care settings, RDNs in community nutrition or population health conduct population health management to achieve improved clinical health outcomes of the community/population.

The Academy has created a Practice Tips: Addressing Food and Nutrition Security (https://www.eatrightpro.org/practice/quality-management/competence-case-studies-practice-tips) to help RDNs assist patients/clients with these issues and to improve the health of the community at large.

Institute for Healthcare Improvement (IHI)

Public Statement on 2021 CMS Measures Under Consideration: Drivers of Health

December 8, 2021

Today we know that social factors influence health outcomes. We also know that racial inequities in health outcomes persist because remedies often focus only on reducing disparities in clinical care and not on the drivers of health (DOH). In COVID-19's wake, food insecurity, housing instability, interpersonal violence, and other DOH have reached unprecedented levels and revealed massive racial inequities. In 2021, 21% of Black individuals are projected to experience food insecurity, compared to 11% of white individuals. Likewise, 20% of Asian, 28% of Black, and 18% of Latino renters are not caught up on rent, compared to 12% of white renters (references below.)

The challenge now is to figure out how to work on these drivers of health in a fundamentally different

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way. In this context, it is untenable for the health care system to continue to address DOH primarily through special pilots or initiatives, as the National Academies of Sciences, Engineering, and Medicine (NASEM) demonstrated in their report, "Integrating Social Care into the Delivery of Health Care: Moving Upstream to Improve the Nation's Health."

Consistent with recommendations in the NASEM report, we are pleased that CMS has included two beneficiary-level DOH measures (MUC2021-134: Screen Positive Rate for Social Drivers of Health and MUC2021-136: Screening for Social Drivers of Health) on the Measures Under Consideration list in the equity domain. These measures should be recommended by the Measure Applications Partnership (MAP) in this review cycle, as a reflection of HHS' and CMS' commitment to equity and addressing the health-related social needs of the millions of beneficiaries they serve.

These measures, stratified by race/ethnicity, are (1) crucial to identify racial disparities in DOH, including those driving health inequities; (2) will lay the foundation for health care institutions to help guide beneficiaries to the resources they need to be healthy; and (3) will lead to more accurate risk adjust payment models. Drivers of health screening are also crucial in creating the imperative for public and private investments in the workforce and technology needed to reliably connect beneficiaries to the resources they need. And, most importantly, these measures can help ensure those resources exist in the first place, through cross-sector and community-based partnerships.

In 1999, the Institute of Medicine published To Err is Human in part to "…reveal the often startling statistics of medical error." That report did not promise easy solutions, but it asserted that it was time to "…break the silence that has surrounded medical errors and their consequence." Similarly, it is time to make visible the reach and impact of DOH by enacting the first-ever DOH measures in federal payment programs.

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Texas Medical Association
December 9, 2021

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Dr. Dana Safran

CEO

National Quality Forum

Measure Applications Partnership

1099 14th Street NW, Suite 500

Washington, DC 20005

RE: Texas physicians support drivers of health quality measures

Dear Dr. Safran:

On behalf of our more than 55,000 Texas physician and medical student members, the Texas Medical Association (TMA) writes in response to the agency's pre-rulemaking process that seeks input on the List of Measures Under Consideration for December 1, 2021.

We are pleased to offer our strongest support for the following two measures and thus urge the agency to move them forward through the regulatory review process of the Measurement Application Partnership (MAP):

- Screen Positive Rate for Social Drivers of Health (MUC2021-134) and
- Screening for Social Drivers of Health (MUC2021-136).

At TMA, we recognize that social drivers of health have a profound impact on patients and the physicians who care for them, especially in the wake of COVID-19. These two measures signal that the Centers for Medicare & Medicaid Services (CMS) has begun to recognize and address the significant impact that social drivers of health have on health disparities, outcomes, and costs. Additionally, social drivers impact both physician well-being and the economics of clinical practice.

It is not surprising, for example, that in the CMS Innovation Center's Accountable Health Communities model evaluation, 34% of beneficiaries screened positive for a health-related social need and among that group, racial and ethnic minorities were over-represented. Likewise, numerous studies have now quantified the impact of patients' social risk on physician performance scores through the Merit-Based Incentive Payment System and its impact on the geographic variation in Medicare spending (37.7% when including both direct and indirect associations).

Physicians in Texas already are working to effectively identify and address their patients' health-related social needs. We do so recognizing that screening patients for social determinants of health is, as one of our colleagues recently observed, "just like when you use a screening tool or test to diagnose a medical condition. The diagnosis and the plan to address the problem can be enhanced by understanding some of the social needs, i.e., social determinants, that can get in the way, or may have already gotten in the way of making this person as healthy as they could be. This is not about ascribing fault as much as it is identifying factors that should be considered or addressed."

The challenge is that physicians are screening for and addressing their patients' social needs on their

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own. CMS has provided no guidance or incentives relative to standard quality measures that could inform risk-adjustment, cost benchmarks, financial incentives, and partnerships between physician practices and communities. We strongly support CMS advancing these measures through the MAP review process. These recommendations are essential to advance CMS' stated commitment to equity as well as enacting measures that matter to patients and physicians.

Regarding social determinants of health, it is TMA's policy to:

- Educate physicians about the social determinants of health for the purpose of assisting physicians to better understand their impact on patient health outcomes and well-being;
- Educate state and federal policymakers, business leaders, and governmental and commercial payers about the influence of social determinants of health on overall health care quality and health care costs;
- Collaborate with innovative public and private partnerships to address social determinants of health and advocate for their adoption by state policymakers; and
- Advocate that governmental and commercial payers modify existing performance and quality programs to reflect the higher expected health care utilization and costs associated with populations at greater risk of exposure to social determinants of health, and that these entities appropriately risk-adjust physician compensation to reflect these higher costs.

As such, we fully support MUC2021-134 and MUC2021-136. We appreciate the opportunity to comment on this matter. If you have any questions, please do not hesitate to contact Karen Batory, MPA, TMA vice president of population health and medical education, at Karen.Batory@texmed.org.

Sincerely,

E. Linda Villarreal, MD

President

Texas Medical Association

American Academy of Family Physicians

One unintended consequence of screening is not be equipped to act on identified needs. However, as the first screening measure addressing social determinants of health and health care equity, this measure is consistent with CMS' Meaningful Measures 2.0 priority areas, and the priorities of the MIPS program to advance health equity.

Missouri Hospital Association

The Missouri Hospital Association feels that the resources required to generate these data would be better used in the systematic capture of ICD-10 Z-codes related to SDOH in both electronic health records and uniform billing administrative claims data systems. CMS also should work with ICD-10 Cooperating Parties to include additional Z-codes currently in unrepresented domains of social vulnerability, such as access to reliable transportation.

Legacy Community Health

For the first time, CMS is considering two quality measures related to social risk screening as part of this

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year's 44 new Measures Under Consideration (MUCs) list. The two measures are:

Driver of Health Screening Rate: % beneficiaries 18 years and older screened for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-136) Driver of Health Screen Positive Rate: % beneficiaries 18 years and older who screen positive for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-134)

We have been screening for these measures for years and have found them to be a key driver in health outcomes. It would be helpful to have a standardized approach so that we can further our efforts of proving that social determinants of health are just as important to overall health as traditional healthcare.

Duke Margolis Center for Health Policy

The Duke-Margolis Center for Health Policy encourages the inclusion of measures addressing social drivers of health (SDoH) in CMS quality reporting programs. The impact of these drivers on health is well documented, and a growing number of efforts are under way to examine how health care providers and organizations can better identify and address individuals' SDoH-related needs. Among these efforts are those examining how to leverage value-based payment (VBP) models to better address SDoH.1 Our work has found VBP models have the potential to support the infrastructure and cross-sector relationships needed to identify and comprehensively address SDoH-related needs.2 However, the current dearth of SDoH-related quality measures makes it difficult to embed accountability for addressing SDoH into VBP models. Development and implementation of SDoH-related quality measures are needed if VBP efforts to meaningfully address SDoH are to be successful.

The addition of the MUC2021-136 and MUC2021-134 measures to the Hospital Inpatient Quality Reporting Program and Merit-based Incentive Payment System would reflect the emphasis needed on advancing SDoH-related quality measures, especially if they can be clearly linked to a strategy for supporting improvement in the SDOH risk factors reflected in such measures. Such a strategy should include more systematic collection and reporting of SDoH-related data, development of the infrastructure needed to support partnerships across sectors (e.g., health care, education, justice), and implementation of payment models that can support and sustain the delivery of SDoH-related services. The inclusion of SDOH-related quality measures in CMS quality reporting programs is one way to support progress in implementing such a strategy.

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Federation of American Hospitals

The Federation of American Hospitals (FAH) supports the development and implementation of measures that seek to address inequities in care and those factors that may directly or indirectly impact an individual's ability to achieve positive health outcomes. Regrettably, the FAH is unable to support the inclusion of this measure in the Merit-based Incentive Payment System (MIPS) for several reasons.

While the FAH supports the overall intent of this measure and MUC2021-134, Screen Positive Rate for Social Drivers of Health, we were unable to determine why the specific social drivers of health were selected, the degree to which they are aligned with the work of the Health Level 7 Gravity Project or the United States Core Data for Interoperability (USCDI), and whether the intended patient population is Medicare beneficiaries or those aged 18 years and older since the wording is not clear. In addition, the developer did not provide any evidence demonstrating that this process is linked to improvements in health outcomes nor has testing of the measure been completed.

Furthermore, the FAH requests that the Clinician Workgroup consider the degree to which this measure could be considered actionable. This measure assesses the rate of screens completed by a clinician or practices in the absence of any information on the degree to which a clinician or practice has been equipped with the necessary resources and tools to address the individual's needs. Any implementation of this measure is premature until these resources and tools are widely available.

The FAH believes that these questions and concerns must be addressed and endorsement by the National Quality Forum should be achieved prior to implementation of this measure in MIPS. As a result, the FAH requests that the highest level of MAP recommendation be "Do Not Support with Potential for Mitigation."

American Psychological Association

I am writing on behalf of the American Psychological Association (APA). As requested by the National Quality Forum (NQF), APA is providing comments on the draft measure specifications for the Screen Positive Rate for Social Drivers of Health (MUC2021-134) and Screening for Social Drivers of Health (MUC2021-136).

APA is the largest scientific and professional organization representing psychology in the United States. APA's membership includes over 122,000 researchers, educators, clinicians, consultants, and students. APA seeks to promote the advancement, communication, and application of psychological science and knowledge to benefit society and improve lives.

We appreciate the Physicians Foundation undertaking this important initiative to develop quality measures related to social determinants of health (SDOH). It has become increasingly clear that addressing SDOH within health care is critically important. One of the first steps in addressing SDOH is measurement and documentation, because you cannot adequately address an issue if you are unaware of the extent to which it exists. However, measuring SDOH has numerous barriers, including philosophical beliefs on the part of providers that it is not their place to be asking such questions, training barriers in not knowing how or what to ask patients, and practical barriers with challenges in identifying community-based interventions to address SDOH and ensuring patients receive these services once identified. Further, without establishing reimbursement mechanisms and incentives for measuring SDOH, provider behavior is unlikely to change. One method for implementing a standardized

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approach to measuring SDOH would be to collect data via a health risk assessment or screening tool, document it in the electronic health record (EHR), and map SDOH data onto existing IDC-10-CM Z codes for documenting conditions in the environments where people are born, live, learn, work, play and age. To that end, while we applaud initial efforts to move the field forward with the proposed measures as a means of addressing the aforementioned barriers, we wish to convey several specific comments regarding the measure specifications:

1. While not identified within the measure specifications on the MUC List document, it is our understanding that both measure 134 and 136 are meant to be based on administration of the AHC screening tool. However, the specification as currently written does not provide any cut-off score for screening positive for social drivers of health, nor does it provide any reliability or validity data on the AHC tool itself. Further the AHC tool contains 26-items, making it a relatively lengthy measure and calling into question the feasibility of implementation, particularly in practice settings that do not have an EHR with this scale already imbedded.
2. It is unclear how both measures add value, as the information gathered from each one could be combined in one measure that would, if expanded upon, have a greater impact on improving outcomes. For example, one screening measure for social drivers of health that included a follow-up action of providing referrals to patients who scored positive is the mechanism of change we should be promoting in programs such as MIPS. As currently written, MUC2021-136 rewards providers for simply screening for social drivers of health but requires no action on their part when someone screens positive. And MUC2021-134, as currently written, merely rewards providers who have a high volume of patients with food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety. In addition to not then requiring any follow-up action of referral to appropriate services when someone screens positive, why would we reward providers who report higher rates of providing services to those with greater social need? Higher rates more likely reflect the communities within which services are rendered as opposed to a quality action on the part of a provider or setting. While this data could assist in allocating resources to communities in need, this is not currently how MIPS measures are conceptualized or utilized within the program, making resource allocation an unlikely outcome.
3. Screening patients for social drivers of health is a responsibility that needs to be implemented across the provider spectrum, including clinical psychologists and clinical social workers. It will be imperative that the appropriate CPT codes for psychotherapy, assessment, and health and behavior interventions be included so that MIPS eligible psychologists and social workers can also report on these measures should they be accepted.

APA wishes to thank NQF for this opportunity to provide comments on the draft measure specifications for Screen Positive Rate for Social Drivers of Health (MUC2021-134) and Screening for Social Drivers of Health (MUC2021-136). If your staff have any questions, you are welcome to contact our Director of Operations and Innovation, Nicole Owings-Fonner, MA, PMP by email (nowings-fonner@apa.org).

Cordially,

C. Vaile Wright, PhD

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Senior Director, Health Care Innovation

American Psychological Association

American Medical Association

While the American Medical Association (AMA) supports the intent of this measure to begin to address the social drivers that can also impact an individual's health outcomes, we do not believe that the implementation of this process measure, in the absence of any resources or tools that would be widely and readily available to clinicians and practices, should be pursued at this time. Measures must be actionable and facilitate improvements in patient care. While clinicians and practices can identify and facilitate addressing social needs, they cannot and should not be held responsible for resolving them. Other strategies such as stratification of populations by race, ethnicity, and social drivers of health should be employed.

In addition, the developer did not provide any evidence to demonstrate that the collection of these data alone will drive improvements in health outcomes nor is it is clear why the developer selected the specific social drivers of health for this measure and MUC2021-134: Screen Positive Rate for Social Drivers of Health. The measure must be supported by evidence and should align with the work of the Health Level 7 Gravity Project and the United States Core Data for Interoperability (USCDI). We were also unable to determine which patients the measure intended to capture since the word "beneficiaries" is typically used when a measure applies to those individuals with Medicare Fee-for-Service, yet the denominator language also indicates that it would be any person 18 years and older. In addition, the measure itself is not yet tested. We believe that many of these discrepancies would be resolved if the measure was fully specified and demonstrated to be evidence-based, reliable, and valid.

Because we do not believe that this measure will result in effective change, we request that the highest level of MAP recommendation be "Do Not Support."

IU Health

As long as the screening process is not specific to the AHC screening tool. Many health systems and community organizations utilize PRAPARE and USDA Food insecurity Questions, to name a couple, as their screener of choice. There are several other evidence-based screeners in addition to the AHC tool that assess food insecurity, etc. and I want to ensure that this measure wouldn't align with a particular screening tool.

The Coalition to Transform Advanced Care

We support this measure and very much appreciate its addition to the MUC list. We believe this will begin to gather this important information in a more systematic way and help to help build better links to community services that address these needs.

Because this is a new area for measurement, we are not yet sure what application it will have but believe it will certainly inform QI efforts and could also be used for payment in value-based arrangements.

We see little implementation issues in gathering the information, which is what the measure requires, but hope that it will be the beginning of a more comprehensive way not only to screen for social drivers of health but to refer and then deliver any needed services. However, this is an important first step

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Reinvestment Partners

MUC2021-136 (Driver of Health Screening Rate) adds value by documenting patients' unmet social needs. This is crucial in advancing social equity and public health outcomes. This measure is an important tool understanding the severity of social drivers of health and lay the groundwork for addressing social drivers in clinical settings. If adopted, these measures would be easy to implement and would generate evidence for investments in social driver programs through healthcare.

findhelp

MUC2021-134 (Driver of Health Screen Positive Rate)

MUC2021-136 (Driver of Health Screening Rate)

Re: Comments for NQF public comment period on CMS MUCs

In response to the National Quality Forum (NQF) public comment period on Centers for Medicare & Medicaid Services' (CMS) measures under consideration (MUCs), please see below comments related to MUC2021-134 and MUC2021-136 on behalf of findhelp, a Public Benefit Corporation.

About findhelp

Founded in 2010, findhelp, a Public Benefit Corporation runs the largest social care network in the United States and has served more than eight million Americans. Our mission is to connect all people in need with the programs that serve them with dignity and ease. As part of fulfilling this mission, we will always maintain findhelp.org, a free and anonymous search tool for identifying free and reduced cost programs in every U.S. zip code. Our network is used by over 250 health systems, health plans, community health centers, and health departments in the United States to manage social care referrals, as well as tens of thousands of Community Based Organizations (CBOs). Findhelp's interoperable social care technology works with electronic health records (EHRs) and other platforms to help clinicians and other partners address the social needs of individuals in a seamless fashion.

Comments

Findhelp appreciates the opportunity to share feedback with NQF related to proposed quality measures specific to Social Drivers of Health (SDoH).

1. This measure recognizes social needs screening as an important clinical tool.

Recognizing the value of Social Drivers of Health (SDoH)

Screening for SDoH provides clinicians with actionable data on health-related social needs that may be impacting the whole person of their patients. Capturing SDoH risks and screening information can better inform provider organizations about the needs of their patients and communities. This information can help healthcare organizations connect patients to needed resources, prioritize partnerships with CBOs and vendors, and inform capacity planning.

For example, findhelp customer Boston Medical Center (BMC) developed the THRIVE SDoH Screening

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and Referral program to identify and address detrimental social factors preventing patients from thriving, such as unstable housing, food insecurity, financial instability, and other issues. Through the THRIVE screener, patients identify their social needs, and BMC staff refer them to both resources at BMC and in the community using the THRIVE Directory (powered by findhelp).

Governments at all levels make significant resources available to consumers related to their social needs. Such resources could include, but are not limited to, those used to address food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety.

Yet, a clinician's ability to support a patient is only as strong as his or her awareness of the patient's needs. Screening for food insecurity, housing instability, transportation problems, utility help needs, or interpersonal safety gives providers the opportunity to impact a patient's health in ways far beyond clinical interventions.

Unfortunately, connecting those resources to consumers who need them – including the nation's Medicare and Medicaid beneficiaries – can be challenging. We encourage CMS to make identifying social care needs and connecting these consumers to available resources a core part of their healthcare quality and health equity strategies moving ahead.

Incentivizing measurement of SDoH

In particular, we encourage CMS to adopt MUC2021-134 and MUC2021-136 into federal payment programs. These will be the first standard SDoH measures included in federal payment programs and will provide a starting point to incentivize healthcare providers to measure and report on patients' SDoH needs.

2. The benefits of the measure outweigh the burden of data collection and reporting.

Data collection is both valuable and feasible

We believe that not screening for SDoH represents a larger burden to providers than conducting the screenings. Not building SDoH measures into the health system increases the burden on physicians as SDoH are still part of their patients' clinical reality. As healthcare providers increasingly recognize the impact of SDoH on their patients and practices, especially in light of COVID, they have called for CMS to measure what matters.

While this screening work is happening around the country already, there is a strong need for a national standard for this process. In the absence of CMS SDoH measures, physician organizations (e.g., findhelp customers American Academy of Family Physicians and American Academy of Pediatrics) have developed ad hoc SDoH screening guidelines. More than 100 findhelp customers currently using our platform to screen patients for SDoH needs, and many more screen directly in their EHRs and care platforms.

CMS has already implemented these measures in a limited fashion, providing NQF and other stakeholders an opportunity to review the tangible impact to clinicians of undertaking the screening. The measure developer (the Physicians Foundation) submitted these SDoH measures because they are currently in use in the CMS Innovation Center's Accountable Health Communities model, where they

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have been effectively tested and implemented over 5 years with nearly a million CMS beneficiaries in 600 clinical sites and multiple practice settings across the country.

Interoperability of social care networks

After screening patients for SDoH needs, many healthcare provider organizations will want to facilitate the connection of their patients with needed services. To facilitate this vital next step, the technology exists to integrate social care referrals into EHRs or other platforms. Through platforms such as findhelp, healthcare systems, providers and CBOs are able to receive and exchange social care data from various sources within their own environment and systems of record.

January 13, 2022
MUC2021-134 (Driver of Health Screen Positive Rate)
MUC2021-136 (Driver of Health Screening Rate)
Re: Comments for NQF public comment period on CMS MUCs
In response to the National Quality Forum (NQF) public comment period on draft recommendations offered by the Measure Application Partnership (MAP) workgroups that convened last month, please see below comments related to MUC2021-134 and MUC2021-136 on behalf of findhelp, a Public Benefit Corporation. These comments were shared with the MAP prior to last month's meeting.

The MAP's initial recommendations related to MUC2021-134 and MUC2021-136 are a welcome development. Findhelp encourages the MAP to continue its support for the measures in the final recommendations to HHS.

Denver Regional Council of Governments

As the Project Director for one implementation of the CMMI Accountable Health Communities Alignment Track Model, I support this measure with limitations. Simply put, only screening for social needs will not work for the clinical staff or the patient. Screening for social needs and not addressing the need is the same as diagnosing someone with diabetes and then not providing a prescription for insulin or instructions on how to use it.

For this measure to be successful for the patient, the hospital must be required to connect the patient with a service that addresses the identified need. Additionally, any hospital that implements a program to achieve success on this measure should be required to partner with local community-based organizations to provide services to address the identified needs.

The burden to implement this measure far exceeds the cost of implementation, data collection, and reporting. The benefit to the patients with needs is obvious and the benefit to the hospital and clinical staff include increased trust and engagement from patients as well as better outcomes.

Kaiser Permanente

KP supports development and adoption of reliable, evidence-based, well-tested measures of social drivers of health. KP currently measures social drivers with a standard instrument for quality and performance improvement, and we have set aggressive targets to rapidly expand standard screening across the enterprise. Our unique experience with implementation of these measures at significant scale with our 12.5 million members enables us to contribute to the evidence base for these measures,

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including impact on health, care, cost, and equity, and we will continue to do so through our robust social health research and evaluation efforts over the next few years. We recognize these upstream measures are new in the measure development and review process and may present special challenges. We offer our support and collaboration, and request to stay informed and connected throughout the process.

Children's HealthWatch, Boston Medical Center
Measure Applications Partnership (MAP)

Currently selected 2021 MAP Measures Under Consideration (MUC)

Comments submitted

On behalf of Children's HealthWatch, we applaud the National Quality Forum (NQF) Measures Application Partnership's consideration of MUC 2021-136 (Driver of Health Screening Rate) and MUC 2021-134 (Driver of Health Screen Positive Rate). Children's HealthWatch seeks to improve the health and development of young children and their families by informing equitable policies that address and alleviate economic hardships and by dismantling systems of institutionalized discrimination and inequity at the root of these hardships. Our work begins with research through interviewing caregivers of young children on the frontlines of pediatric care, in urban emergency departments and primary care clinics in five cities: Boston, Minneapolis, Little Rock, Baltimore, and Philadelphia. Since 1998, we have interviewed over 75,000 caregivers of children under four years of age and analyzed the data to determine the impact of social risk factors (individual-level adverse social determinants of health) and public policies designed to address those social risk factors on the health and development of young children and the well-being of their families. Specifically, our research focuses on the following: nutrition, housing, health care, childcare, utilities, income and wealth, employment, Adverse Childhood Experiences and Experiences of Discrimination. Our research – in addition to that of others – shows that lack of access to basic needs is associated with poor child health and development, poor parental physical and mental health, higher child hospitalization rates, and learning and behavioral/emotional impairments. Health consequences are often compounded, as they are frequently experienced simultaneously, often as a result of limited income and resources.

How would adding this measure add value? How would the measure improve patient outcomes?

Based on decades of our research, and the research of others, we stress the importance and value of measuring of social risk factors to identify and address unmet social needs (social needs differ from social risks insofar as they convey the patient's preferences and priorities regarding the social risk) and enable policymakers and agencies such as CMS and other payers to incorporate them in value-based payment models. The measures under consideration (MUC 2021-136, MUC 2021-134) also offer a valuable opportunity to provide a foundation for comparable measures for the Medicaid Adult and Child Core Measure Set and guidance for states in their efforts to standardize these data.

Do the benefits of the measure outweigh the burden of data collection or reporting?

The benefits of measuring social risk factors far outweigh the burden of data collection and reporting. Numerous studies have shown relatively high acceptability of social needs screening and referral among both patients and providers (https://bit.ly/3rSik2v, https://bit.ly/3rOPlN5). Initial evaluation of the

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Accountable Health Communities (AHC) Model found that among navigation-eligible beneficiaries who reported unmet social needs, 41% had one unmet social need and nearly 60% reported having multiple unmet social needs. While research and implementation of social needs screening and intervention has grown substantially over the past decade, providers and health systems struggle with heterogeneous screening tools and interventions. This contributes to absence of consideration of unmet social needs in federal health care policymaking. The prospect of these two measures being utilized in Medicare public reporting and performance-based payment programs would be beneficial because they would both elevate the importance of these issues for health at the federal level and shed much needed light on social risk factors in a standardized way that allows for accurate comparison of data across settings and communities. Furthermore, if these measures are stratified by race and ethnicity and by age, policymakers and agencies will be prepared to effectively target resources and actions that advance health equity and address long-standing disparities in health outcomes.

For what purpose are you using the measure (e.g., QI, certification/recognition, regulatory/accreditation, payment, public reporting, disease surveillance)?

These measures (MUC 2021-136, MUC 2021-134) offer opportunities to be used for QI, maintenance of certification, payment, and public reporting.

We consider MUC 2021-134 to be an indicator of the identified risk of the population. Thus, the measure and specific screening tools included in the AHC questionnaire it relies on are not capable of disease surveillance or diagnosis of certain social risk factors precisely because the AHC questionnaire was designed as a screening tool and identifying social risk factors in clinical settings for diagnosis and intervention may require further assessment. In fact, our research has identified significant discordance among the AHC questionnaire housing questions and Children's HealthWatch housing questions. The two tools captured different housing-related risks and contributed to different health consequences, which were relevant to different subpopulations. These findings demonstrate that the choice of question is important to identifying the specific risk. We raise this point to underscore that any screening tool will inherently have limitations and thus further discussion with health providers and thoughtful linkages to interventions are critically important next steps. Thus, the AHC questionnaire does not measure all possible forms of social risk but instead is designed to capture specific domains currently identified as prevalent risk factors in health care and public health literature. Given the fact that there never will be, nor could there be a single social risk screening tool that identifies every health-related social need for every person, the evidence-based approach taken to develop the AHC tool along with its wide adoption over the past few years, indicates that it is the best option available for the purposes of accomplishing the goals of these measures.

We suggest creating a paired measure of improvement over time in the specific social risk factors dimensions as a better measure than simply a one-time measure of proportion, again stratified by race and ethnicity and age. This improvement measure is similar to what the NQF Measure Incubator project has developed for the forthcoming food insecurity measures (https://bit.ly/3pGLZt0). Further, also aligned with the NQF Measure Incubator project's forthcoming food insecurity measures, we suggest a paired measure on appropriate interventions that have occurred as a result of identification of unmet social needs on screening. Interventions need flexibility to adapt to local context, resources, and community needs, however, certain core principles and best practices can still be standardized. Without

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an intervention-focused measure, we miss opportunities to understand the landscape of programs and interventions that serve the needs of families, and coordinate strategies that target or improve interventions.

Any model of care that seeks to measure outcomes should focus measurement and evaluation on providers' and institutions' ability to effectively 1) measure and 2) address health related social risks or concern (e.g., food insecurity, housing instability, transportation). A recent report from the National Committee for Quality Assurance (NCQA) describe health care organizations' use of both process (i.e., the number of patients screened or referred) and outcome (i.e., improvement from a baseline, meeting quality targets, impact on health care utilization) measures to evaluate the impact of their overall strategy and specific interventions. This report also made note that the field currently focuses more on process measures for specific social needs rather than health outcomes and health care utilization outcomes. A broad set of outcome measures beyond process measures is an area for further exploration.

Are there implementation challenges?

Challenges do exist, including limited provider time to screen and intervene, lack of a multi-domain screening tool that encompasses any and all social risk factors individuals may experience, and ability of institutions to suitably identify needs and provide targeted resources. The CMS Innovation Center and its 5-year AHC Model, while still under way, is an encouraging approach that demonstrates the need and political will to address this critical gap. Beyond expansion of this model, the Improving Social Determinants of Health Act of 2021 is a promising legislative opportunity to address limited health care resources and challenges to implementation of effective value-based care. Supported by hundreds of professional health organizations and networks, health insurers, and community-based organizations, the Improving SDOH Act would enable health providers and systems to better coordinate, support, and align SDOH best practices and capacity building activities. In coordination with the Centers for Disease Control and Prevention, federal agencies such as CMS, and local public health departments, the Act would support these activities by ensuring that there are resources and policies in place to intervene effectively on unmet needs and their health correlates. Specifically, through increased funding opportunities, technical training, and evaluation assistance, scaled data collection and analysis, and identification and coordination of best practices, this act would increase the public health sector's capacity to engage with the health care sector and fully address SDOH priorities beyond temporary referrals and interventions. Efforts like these are important to ensure that health systems are not only supporting their patients in achieving holistic health, but that providers also have the systems and resources to do so in ways that are sustainable, evidence-based, and avoid harms to patients.

Do you recommend this measure?

Yes

Next Wave

This measure will assist in raising awareness of the importance of Social Drivers. Collecting this information using Z-codes in the claims system, particularly, if possible, through the electronic record will help build a foundation for future refinement.

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See also comments for this metric under the Hospital IQR.

Massachusetts Child and Adolescent Health Initiative
The Child and Adolescent Health Initiative is a multidisciplinary coalition in Massachusetts seeking to improve care and outcomes for children, with a primary focus on working with MassHealth (the state's Medicaid and CHIP agency) to assure that MassHealth insured children and their families get the care they need to optimize outcomes.

How would the measure add value?

Assessing health related social needs is an essential step in providing appropriate services to patients/beneficiaries. This assessment enables providers and their health care organizations to then ascertain whether the patient desires assistance in addressing identified needs and, if they do, link them to appropriate and effective services. The tally of needs in a population also points to the broader social needs in a community and can lead to interventions to address the root causes of those needs (what the World Health Organization considers the social determinants or social drivers of health). These are the two strategies being explored in the Accountable Health Communities (AHC) model by CMMI. Given the importance of social needs in influencing both short and long-term health, regular assessment by health care provider organizations in order to take action is a core element of high-quality care. Equity is also one of the core dimensions of care as defined by the National Academy of Medicine; key aspects of promoting equity in care include assessing and acting upon social needs and assuring those other aspects of care are not contingent upon the level of social need.

Asking about social needs requires sensitivity from the provider and candor from the respondent. In addition, as with any interview/survey/screening question, the precise way in which a question is worded produces different results. The cacophony of screening tools related to social needs produces confusion for patients, providers, health systems and others. The use of a consistent, valid, culturally appropriate set of screening questions will lower the burden on providers, produce more meaningful data, and also enable comparisons across providers and systems.

Although the specific information about the measure provided with this MUC list is quite limited, the measure used in the AHC correlates well with at least one other measure of social need for most of the dimensions. The assessment of housing taps different dimensions than the housing instability measure developed by Children's HealthWatch, but nonetheless appears useful.

We note that the specifications indicate the measure applies only to beneficiaries over 18. Understanding that this measure is being considered for use in Medicare programs at this time, we nonetheless note that most of these indicators of social need (food insecurity, housing quality and instability and utility challenges) apply to all the members of a family or household and not simply the person answering an assessment. The information obtained through these assessments should be linked to, and services provided for, those other household members—particularly children who are most vulnerable to the harmful impact of these types of adversity. Similarly, we would want performance measure reporting to be stratified, or reported separately, for children and adults. In addition, although this approval is in the context of Medicare, the measure may be appropriate to ultimately include in the Medicaid Adult and Child Core Measurement Sets and be accompanied by guidance for states in their efforts to standardize these data in both child and adult populations.

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- Do the benefits of the measure outweigh the burden of data collection or reporting?

Screening for social needs should be a routine part of care, particularly for, but not restricted to, primary care. Implementing screening for social needs imposes only marginal burden if systems are already established for other forms of screening (e.g., developmental screening in children, screening for depression in others). As with other forms of screening, screening for social needs only becomes useful for patients if the screening is confirmed by additional inquiry, if the patient desires follow up and if the patient is provided with an effective intervention.

Mechanisms for tracking who has been screened will require effort to establish. Such a mechanism should not be burdensome if fields in electronic health records capture that a screen was performed. Given the importance of assessing and addressing social needs, the benefits outweigh any such burden.

- For what purpose are you using the measure (e.g., QI, certification/recognition, regulatory/accreditation, payment, public reporting, disease surveillance)?

MassHealth requires that Accountable Care Organizations report on the proportion of each ACO's enrolled population that is screened for social needs, although the state does not specify a particular instrument for screening. The measure is now used for public reporting and may be used as part of payment purposes in the future. We recommend that this proposed measure be used for public reporting and as part of a payment system, and also that individual organizations use it for QI initiatives. Certification systems such as specialty board maintenance of certification programs could also incorporate this into their QI modules.

The implementation challenges are noted above; a mechanism for administration of the screening must be developed with appropriate privacy protections, availability in multiple languages, and sensitivity to the concerns of those without documentation. Nonetheless, many studies have confirmed that patients welcome these inquiries and view them as a positive indicator of provider concern, particularly if they lead to follow up conversations and action.

OCHIN, Inc.

These measures are essential to identify and remedy persistent structural inequality that adversely impacts patient outcomes. This enables the clinical team to identify structural barriers to improved health care and associated social and other services that could facilitate improved patient health status, including improved access to care (for example, transportation). Care teams would also be able to identify areas of need in their patients, and focus interventions and outreach based on this context.

These measures are needed for quality improvement activities, payment, research, and public health activities including disease surveillance and mitigation measures in order to address health care inequity. In light of the USCDI adoption of SDOH domains and elements, the suitability of this information can inform numerous clinical, public health, and policy needs to improve care overall equitably. Adding information on social complexity to payment discussions could provide valuable insight for value-based payment and care arrangements and risk-bearing contracts.

OCHIN network members have documented over 1 million individual patient screenings for SDOH. The screening, evaluation, and use of this information is complex, challenging, and hinges on preserving patient trust. This is a resource intensive process that requires adequate time, workflow design, patient

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engagement, and staff and clinician training. The benefits of the measures outweigh the burden of data collection and reporting to the extent providers are able to identify optimal workflows and staffing to collect the information with the goal of reducing cognitive burden and enhancing team-based approaches to care while preserving and safeguarding patient-clinician relationship and privacy.

OCHIN recommends that the measures for interpersonal safety domain be removed. Current approaches to addressing relationship safety and intimate partner violence (IPV) are moving away from screening towards a universal education and harm reduction approach. Futures Without Violence (FWV), the CMS partner for IPV prevention and education nationally, estimates that 1 in 3 women has experience IPV, but disclosure rates in practice are usually less than 10% (around 5-6% among OCHIN patients), indicating significant underreporting and calling the utility of collecting this data into question. Instead, FWV provides and promotes a framework called CUES that addresses confidentiality (including its limits in required reporting settings), universal education about healthy relationships, and support for any disclosure that includes warm handoff to appropriate resources. Given this disparate approach, I would recommend not including IPV in the current measures. I would be more supportive of a separate additional measure for IPV focused on the provision of universal patient education.

OCHIN has previously advocated for inclusion of SDOH in screening measures and data standards to begin with the domains of housing, food insecurity, and transportation as "core" domains appropriate for screening in most every community and patient panel. The addition of utility assistance aligns with research from the SIREN group at UCSF that finds these four domains (housing, food insecurity, transportation, and utility assistance) are the most impactful for screening and action in healthcare settings. Consequently, I see these as the appropriate domains to include in such measures at this time. In the future, other domains could either be optional based on appropriate community or clinic considerations or added as more evidence about the relationship between SDOH and health becomes available.

Premier, Inc.

Premier conceptually supports adoption of this measure. However, we would encourage CMS to work with stakeholders to develop a measure that appropriately assesses whether providers are administering screenings for social needs. For example, some providers may only conduct an initial screening on all patients to identify a subset of patients for whom a full social needs screening would be appropriate. Greater clarity is needed around how CMS is defining screenings, since there is no standardized tool. Finally, CMS should not move forward with the measure until it has received endorsement.

Society of Hospital Medicine

SHM believes identifying social drivers of health is a crucial step towards addressing healthcare disparities and prioritizing resources around social and environmental factors that impact patients' health and wellbeing. This measure would encourage consistent screening for social drivers of health, which may be helpful in raising the priority of these issues in health systems across the country. To better evaluate the measure, we ask for more detailed definitions of the social drivers listed in the numerator of the measure. Broadly we support this measure concept.

UniteUs/NowPow, a wholly owned subsidiary of UU

Overall, Unite Us supports including measure 134 in MIPS, hospital IRQ and other value-based payment

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programs if the proposed measure has been tested and meets NQF or CMS MERIT-based payment or other measure quality standards. Including these measures will encourage clinicians/clinical staff to screen and track social drivers of health. We recommend that additional measures should be considered that evaluate if beneficiaries who screened positive receive services to address their social drivers of health in a timely manner. Assessing without addressing does not improve quality in a meaningful way.

While we encourage the use of social driver measures, the Unite Us team have some concerns regarding the measure implementation, methodology and process. It is not clear whether all domains would need to be assessed (e.g., financial insecurity and housing and utilities, etc.) or any one of these domains could be assessed to meet the measure. It is unclear if 80% beneficiaries screened means 80% of people had at least one of these domains assessed (but some had financial insecurity assessed, some were assessed for transportation, or all were assessed for interpersonal violence and nothing else) or it means 80% of people had all of these domains assessed. The Unite Us team advocates for the latter approach, as it is a higher standard.

Health Care Without Harm
December 9, 2021

On behalf of Health Care Without Harm, which maintains a hospital member network of over 1,400 hospitals across the country, we strongly support the National Quality Forum Measure Applications Program (NQF MAP) working groups in recommending the following two Drivers of Health (DOH) measures under consideration:

MUC 2021-136; Driver of Health Screening Rate, and

MUC 2021-134; Driver of Health Screen Positive Rate

Health Care Without Harm is founded on the belief that: As the only sector with healing as its mission, health care has an opportunity, indeed a responsibility, to use its ethical, economic, and political influence to create ecologically sustainable, equitable and healthy communities. Founded over 25 years ago, Health Care Without Harm seeks to transform health care worldwide so that it reduces its environmental footprint, becomes a community anchor for sustainability and a leader in the global movement for environmental health and justice. We conduct research, model strategic interventions, and provide guidance and resources to spread and accelerate best practice in the field – with programs focused on climate and health, safer chemicals, and healthy food.

Health Care Without Harm has long recognized the impact that DOH have had on increasing rates of poor health outcomes, chronic disease, and death. Climate change, the COVID-19 pandemic and increasing economic and social inequities in our communities that are the result of decades of systemic racism only serve to exacerbate the situation.

For example, some sobering statistics regarding diet-related diseases and how food insecurity is impacting our nation's health, published in The Washington Post November 30th: 1) More than 100 million Americans — nearly half of all adults — suffer from diabetes or prediabetes; 2) About 122 million Americans have cardiovascular disease, which kills roughly 840,000 people each year; 3) More Americans are sick or suffer from major medical conditions than are healthy, and much of this is related to diet-related illness; 4) If you are a Black person, those numbers mean you probably will have an even

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worse outcome. 49.6 percent of Black adults are considered overweight if not obese. Black people are also 60 percent more likely to be diagnosed with diabetes than White people; 5) Americans who suffer from diet-related conditions such as heart disease, diabetes, cancer, and obesity are 12 times as likely to die after a COVID infection; 6) And in 2020, the year COVID-19 hit the United States, African Americans were disproportionately impacted by the virus, many due to those same underlying diseases of obesity and diabetes. In total, Black people experienced a 2.9-year decrease in life expectancy, causing the Black-White life expectancy gap to widen from 3.6 to 5 years. In a single year.

Statistics similarly alarming can be found regarding the health impacts of poor indoor air quality, air pollution, climate change, poor access to public transportation or living close to a freeway or port, housing instability, and exposure to toxic chemicals in the air, land, and water. And they are disproportionately affecting under-resourced communities of color. The frightening question is, how big and bad do the numbers have to get? What is the final tipping point before the federal government will declare a state of public health emergency and prioritize addressing the DOH with a systemic strategy? A coordinated, aligned national standards measurement process to screen for DOH as part of basic primary health care is absolutely critical to moving forward, and these two measures are a positive start.

The Physicians Foundation, which is directed by 21 state and county medical societies across the country, submitted these first-ever measures focused on screening patients for food insecurity, housing instability, transportation, utility needs, and interpersonal safety, including intimate partner violence. Their adoption would represent a crucial milestone as the first standardized federal measures to assess social need in the history of the U.S. health care system.

Despite the well-documented impact of DOH on health outcomes and costs and their impact on people of color, there are still no approved, standardized DOH measures in any Centers for Medicare and Medicaid Services' (CMS) programs. The impact of DOH interventions remain fairly invisible in federal health care policymaking, and the absence of standard DOH data or measures impedes efforts to achieve racial equity in health outcomes, given their profound impact on people and communities of color, especially in COVID's wake.

In enacting these first federal DOH measures, CMS could send a powerful signal to the health care sector and the communities they serve that there should be acknowledgement of how DOH impact peoples' health outcomes and an intention to address them in a coordinated strategy across the country. These initial DOH measures for screening could lay the foundation for additional measures focused on navigating beneficiaries to resources and connecting beneficiaries to the resources they need to be healthy.

When addressing issues such as food insecurity, housing instability, climate change, lack of transportation, and exposure to toxics in our air, land, and water, we cannot settle on solving for acute, short-term health impacts alone. We must devise long term solutions for these long term and entrenched challenges that require equitable investment and attention. Our collective environmental and economic health need to be prioritized, with regenerative systems that are protective of our environmental health and natural resources, and substantial investment in fair labor practices and living wage mandates.

It is our hope that CMS will do the right thing and approve these measures, creating a federal,

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standardized system to incorporate DOH factors into primary health care and begin to set the stage for long term effective intervention.

Signed by:

Gary Cohen, President, Health Care Without Harm & Practice Greenhealth

For more information, please contact: Emma Sirois, National Director, Healthy Food in Health Care Program, esirois@hcwh.org

MS State Department of Health

This measure will not only determine what the patient's basic needs are, but it was also help in determining what programs/services are lacking in that patient's community. It will also help determine what other social determinants are playing a positive or negative role in the patient's health (mental and physical). The benefits outweigh the burden of data collection because it will help to improve the overall health in communities in identifying service gaps and referring patients to services, they need. My program is in the process of screening for social determinants of health in working with expectant and parenting families. No current implementation challenges because the assessment is already built in the electronic health record database.

Phreesia

Phreesia applauds CMS's commitment to screening for social drivers of health and identifying the percent of beneficiaries who screen positive. However, there is no discussion of how the data should be collected. While the proposed IQR measure MUC2021-106 would require hospitals to train staff on health equity screenings, no measure included in the 2021 MUC List include an explicit reference to how such data should be collected. Furthermore, none of these data collection methods for social drivers or those in the equity domain specify the crucial importance of self-reported data from patients.

Self-reported data is fundamental to achieving higher quality care and an optimal patient experience. Experts agree that self-reported data is the most effective approach for data collection. Additionally, many health systems are now initiating or scaling SDOH screening, where self-reporting is crucial. Most are accomplishing this through verbal collection programs, though our experience shows that digital screening tools are by far more effective in accurately capturing patients' demographic and social needs information.

In general, failing to effectively capture patient demographic and social needs information has the potential to erode trust in the healthcare system among minority groups whose trust is already significantly low. However, when given the opportunity to input their own demographic data, we have found that patients are able to accurately provide key information and can play a key role in improving their own care by closing gaps in data. Phreesia encourages CMS to move providers to screening methods that include an explicit focus on patient self-reported data.

CyncHealth

The proposed measures are a step in the right direction. As a health information exchange (HIE), we recognize that these measures add value to both the community and providers. They allow for the community to become more aware of the social needs that are prevalent in the community, and for providers to have better data for reporting. This increased awareness and data allows for an

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improvement in cross-sector partnerships to occur that empowers providers and communities to collaborate and advocate for polices that support equity in their communities.

As an HIE, we would use the measures to do regulatory reporting on behalf of the providers we serve. The benefit of these measures will be determined by the effective implementation of the measure. The biggest challenge to implementation of these measures is a lack of standardization. There should be serious consideration given to adapt a universal screening tool, so that outcomes can be measurable and consistent across the board. A failure to adapt a standardize screening tool will result in inconsistent outcomes. Currently depressions screenings are standardized to the PHQ and that allows for measurable and consistent outcomes to be reported. The same level of standardization needs to be applied to these proposed measures. The consistency of measurable outcomes that standardization will provide will enable the development of a good tool and provide a real-world benefit that outweighs the burden of data collection or reporting.

National Produce Prescription Collaborative
December 9, 2021

To: Members of the NQF: Measure Applications Partnership

From: Members of the National Produce Prescription Collaborative (NPPC)

*SUBMITTED TWICE

*RE: Support for Driver of Health Screening Rate (MUC2021-136)

*Re: Driver of Health Screen Positive Rate (MUC2021-134)

As members of the National Produce Prescription Collaborative (NPPC), we are pleased to write in support of the Drivers of Health Measures currently being considered under the Measure Applications Partnership Considerations. We were thrilled that CMS accepted the “Drivers of Health Screening Rate” and the “Drivers of Health Screening Positive” measures as part of the 2021 CMS MUC list and recommend that you move them forward as part of the 2021-2022 Measure Applications Partnership (MAP) cycle.

Recognizing the nexus between hunger, nutrition insecurity and the structural inequities at the heart of these issues, Members of NPPC support screening for drivers of health, including food insecurity and believe the adoption of these measures would add tremendous value and represent a crucial milestone on the path towards health equity.

We appreciate that there is a current opportunity to enact the first-ever social DoH measures in the history of health reform. CMS recently included the DoH measures focused on screening patients for food insecurity, housing instability, transportation, utility needs, and interpersonal safety in its “measures under consideration” list this year. These measures (stratified by race/ethnicity) are well-tested in over 600 clinical sites across the country through the CMS Innovation Center’s Accountable Health Communities model. Adoption of these measures will go a long way to identify gaps in patient care and health outcomes that extend beyond the four walls of a health clinic and, with strengthened community-clinical connections, curb the growing national cost burden of diet-related disease through

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our federal health programs.

As you know, diseases linked to poor diet are the most frequent causes of death in the United States, and diet is the leading risk factor for premature death worldwide. Reducing even a fraction of this burden by improving people's diets would save countless lives. The COVID-19 pandemic has brought renewed focus to gaps in access and infrastructure that limit the ability of our federal health care and food assistance programs to address the issues of nutrition, food insecurity, and health. COVID-19 has also exposed the long-standing burden of diet-related chronic disease. Unfortunately, these diet-related diseases disproportionately affect low-income households, racial and ethnic minorities, and elderly people, highlighting the wounds of systemic racism and disparities in the US economy, food systems and healthcare systems.

While a growing number of CMS Innovation Center models are incorporating DoH screening and navigation on social needs, they use varied tools and approaches. As a result, CMS cannot systematically compare or use the data. The same is true for race and ethnicity data, which currently are measured or reported inconsistently across CMS programs. NPPC members and partners are developing and deploying programs and platforms and are seeking robust research capacity to support community-rooted health organizations in their efforts to address the lack of affordability and access to healthy food across the country.

If approved, this measure would apply to two key Medicare programs — the merit-based Incentive Payment System and the Hospital Inpatient Quality Reporting Program — and improve patient outcomes. At the same time, it would provide a crucial foundation for comparable measures to be adopted by the Medicaid Adult and Child Core Measure Set while providing critical guidance for states in their efforts to standardize DoH data. Furthermore, we see adoption of this measure as a pathway for Produce Prescription programs, which are demonstrating their value by improving the health outcomes of people struggling with diet-related diseases such as diabetes, high blood pressure, and kidney disease by increasing dietary quality and treating the stresses of food insecurity.

Evidence of Produce Prescription Programs

The Produce Prescription intervention began just over a decade ago. Today, more than 100 organizations administer them across the country.

A growing body of evidence, including 30 studies in peer-reviewed scientific and economic journals in the past 5 years, suggests that Produce Prescriptions improve intake of fruits and vegetables, improve overall dietary quality, reduce the gap between actual daily consumption and the national recommendations, lower weight, lower blood pressure, and lower Hemoglobin A1C — the biometric indicator used in diagnosing for diabetes and prediabetes.

Due to early promising results, Medicare Advantage plans have implemented Produce Prescriptions alongside other food and produce through the allotment for Special Supplemental Benefits for the Chronically Ill (SSBCI). From year one (2020) to year two (2021) plans offering these food and produce benefits have grown from 101 to 347, a 244% Medicaid managed care plans in several states have also implemented Produce Prescription programs through various flexibilities allowed using 1115 waivers. Having DOH measures available to screen for food insecurity will help these government-sponsored

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health plan practitioners deliver on the growing promise of food as medicine. For example:

In North Carolina, Reinvestment Partners and Blue Cross NC are launching an RCT that compares Produce Prescriptions and healthy food boxes for 6- or 12-month enrollment periods. Reinvestment Partners is also participating in an evaluation as part of Healthy Opportunity Pilots (under North Carolina's 1115 waiver). NC programs beneficiaries must have at least one qualifying physical or behavioral health condition and have one qualifying social risk factor. Of interest, partnering with insurers and providers, including 2 major health systems (Duke Health and Atrium Health, the state's largest provider network); 9 Federally Qualified Health Centers; 30+ county level WIC, DSS Offices, and health departments; and 100+ staff at a statewide care management agency (Community Care of North Carolina). The breadth of this program expansion is a demonstration that effective collaboration is possible in diverse healthcare settings and early research is showing promising impacts on food insecurity.

Likewise, Wholesome Wave's Fruit and Vegetable Prescription Program® (FVRx®), which ran in 12 states across the country, reached thousands of individuals who struggle with diet-related illness. FVRx reached 2300+ recipients in a 2016 Los Angeles pilot and was expanded to communities and health centers in Houston and Miami, Hartford and Sacramento and has helped more than 5,000 people. In the pilot, 93% of participants met produce-consumption guidelines by the program's conclusion, with a 128% increase in the number of cups of fruits and vegetables consumed. Among people at high risk of developing diabetes, those taking metformin lowered their risk of getting diabetes by 31% compared with those taking a placebo, while those who modified their diet and exercise regularly lowered their risk by 58% compared with those who didn't change their behaviors, a near doubling in risk reduction.

Additionally, the Washington State Department of Health has partnered with twelve health care systems and public health agencies and a large grocery chain to redeem over a million dollars in produce prescriptions from 2016 through 2020.

Having a Drivers of Health Screening Rate (MUC2021-136) that screens for food insecurity will provide vital insights to addressing nutrition insecurity for qualified patients enrolled in Medicare and help determine who will benefit from the intervention. This will be a vital step to adoption of Produce Prescription interventions within the healthcare system. The members of the National Produce Prescription Collaborative recommend including these measures among those the MAC moves forward for consideration.

About NPPC

The National Produce Prescription Collaborative (NPPC) is a group of produce prescription practitioners, researchers, and advocates, who gathered in 2019 to catalyze the vital role of food and nutrition in improving health and wellness by collectively leveraging the unique opportunities for Produce Prescriptions to achieve wellness by embedding and institutionalizing Produce Prescriptions within healthcare practice. Our respective organizations are actively working to bring new and innovative Produce Prescription models to communities across the country.

NPPC defines a Produce Prescription program as a medical treatment or preventative service for patients who are eligible due to a diet-related health risk or condition, food insecurity or other

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documented challenges in access to nutritious foods, and who are referred by a healthcare provider or health insurance plan. These prescriptions are fulfilled through food retail and enable patients to access healthy produce with no added fats, sugars, or salt, at low or no cost to the patient. When appropriately dosed, Produce Prescription programs are designed to improve healthcare outcomes, optimize medical spending, and increase patient engagement and satisfaction.

Harvard FXB Center for Health and Human Rights

I believe there is much value in collecting this data. However, I do wonder if there is a complimentary mechanism/data collection standard that could be implemented to understand if a referral or connection has been made to address those needs identified. Without this additional yet complimentary data collection, this data collection standard alone could also promote an ethical dilemma that emphasizes data collection over both resource connections and the investment in the community infrastructure to meet identified resource gaps. In 2016, "Dr. Alvin Garg, Dr. Renee Boynton-Jarret, and Dr. Paul Dworkin outlined in the JAMA Network that screening for any condition in isolation without the capacity to ensure referral and linkage to appropriate treatment is ineffective, and arguably unethical."

Also, with this standard, I hope that CMS will think about how this new data collection influences the social determinants of health industry. In the recent research article by Zachary Goldberg and Dr. David Nash "For Profit but Socially Determined: The Rise of the SDOH Industry," an emerging for-profit industry focused on social determinants of health has received over $2.4 billion dollars in funding and is valued at $18.5 billion dollars.

As studies show, racial/ethnic minorities are more prone to experience disparities in social determinants similar to traditional health disparities. Therefore, as SDOH technology platforms extract data, there is a higher likelihood of collecting more SDOH data or resource gap data on BIPOC communities. It is important to understand that BIPOC communities make this data valuable and, in turn, makes the technology platform/vendor platform. The market is even seeing SDOH technology companies participating in a monopoly to gain influence in this sector. These companies see extreme profit gain at the cost of BIPOC pain; that pain is revealed in BIPOC SDOH data. If one claims to be an advocate of racial justice, one cannot align with this approach--nor the technology vendors, health care systems, and other stakeholders that push this approach. This SDOH deficit data extraction approach ultimately furthers racial capitalism, which is established upon extracting social value and economic gain from the racial identity of others. Racial capitalism highlights the direct relationship between racial exploitation and capital gain, and many stakeholders see this currently in the SDOH sector. These technology companies will even publicly acknowledge the existence of structural racism while engaging in acts of profiteering off of structural racism.

Community members, especially BIPOC community members, are often least prioritized in these tech-forward SDOH interventions as most of these technology-forward approaches fail to see the patient/clients of social service organizations as the ultimate end user.

The primary reason for this predatory behavior stems from the healthcare sector's dictation of the return-on-investment case that is deemed most important. Often patients are seen as a high-risk group, and many health systems, health plans, and others are interested in the mere collection of this data to understand this population more. The data collection normally benefits stakeholders of power for

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health system focused analyses, like understanding the relationship between essential resource needs or resource care gaps (like food insecurity and housing insecurity) and healthcare metrics, like utilization and cost. Even more, this influx of a new data source can facilitate machine-based learning or predictive analyses that aim to reveal new learnings about the patient/client group. However, this machine-based learning or predictive analyses without an equity or anti-racist approach can have harmful effects marginalized communities. In Automating Inequality, Virginia Eubanks investigates how data mining, predictive risk modeling, and algorithms can actually be used to punish historically marginalized and socioeconomically disadvantaged individuals and groups. In the collection of SDOH data, patients are rarely fully informed nor provide consent on how data is used within a SDOH intervention and even more so after their intervention encounter.

We, as a sector, must ask ourselves as stakeholders in the SDOH space:

1. If patients and clients knew our approach to data use fully, would it yield more trust?
    a. If not, how do we create structures of good stewardship and trust around our clients'/patients' SDOH data?
2. How do we have processes of informed consent and informed refusal with the collection of SDOH data, particularly given the predatory/structurally racist nature that seems to be present in the SDOH industry currently?
3. Additionally, are we using SDOH data to create, reinforce, or further perpetuate bias?
    a. If so or if we are unsure, how do we create accountability structures to ensure the creation, reinforcement, perpetuation of bias does not occur (or at least limited)?

With the implementation of these new data collection standards, which I believe can be beneficial, I believe there is a need for further work to happen to ensure that the data collection is anti-racist. Without this equity/antiracism work, I fear how SDOH data will be used.

Social Interventions Research and Evaluation Network at the University of California, San Francisco
December 9, 2021

National Quality Forum

Measure Applications Partnership

Dear Measure Applications Partnership Committee Members,

As national leaders of the Social Interventions Research and Evaluation Network (SIREN), a center at the University of California, San Francisco dedicated to elevating and strengthening evidence related to programs and policies that can support health care systems to meaningfully deliver social care and as leading national experts in this evidence, we welcome the opportunity to comment on the social risk screening measures (MUC2021-134 and MUC2021-136) currently being considered through the MAP process.

We are excited to see federal level interest in quality measures related to social determinants of health (SDH) and social risks since these factors have been closely tied to health and health care utilization outcomes and equity. Incorporating feasible and impactful measures will help to signal the importance of assessing and addressing patients' socioeconomic risks as a critical part of a comprehensive strategy

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for improving care quality and outcomes.

We very much appreciate the potential advantages of increased recognition of patient-reported social risks in health care settings. Awareness of social risk may inform a range of interventions that have the potential to improve care quality, patient health, and reduce health costs. These interventions have been described in the 2019 National Academy of Sciences, Engineering, and Medicine report on Integrating Social Care into the Delivery of Health Care to Improve the Nation's Health. They include not only strategies to connect patients with social services, but also strategies to tailor or adjust medical care decision-making based on patients' social contexts and opportunities to strengthen data that informs community level investments and advocacy.

Recognizing the potential advantages of implementing quality measures in this area, we recommend moving forward with these measures with some modifications to address concerns detailed below. We also hope that this is just the first step in building out a robust set of quality metrics that measure, guide, and reward clinicians' and hospitals' work to improve patient outcomes by identifying and addressing social risks as part of high-quality clinical care.

Although we support moving forward with these measures, we share below some key concerns based on our knowledge of the research evidence and our experiences as practitioners (for Drs. Gottlieb and Lindau), as well as recommendations for how to address these concerns.

1. Could social risk screening cause harm that outweighs benefit?

Although there is abundant evidence that social factors strongly shape health and health care outcomes and inequities, it is not yet clear whether social screening (assessing) without subsequent interventions (addressing) actually improves outcomes. Studies have found that many patients understand how social conditions relate to health and well-being and believe that screening in health care settings is appropriate. At the same time, patients have voiced important concerns about potential negative consequences of sharing information about social adversity in health care settings, including concerns that the information could be used against them, worsen feelings of stigma, and exacerbate real or perceived bias/discrimination. Where, how, and by whom screening is conducted and data are used will influence patients' experience and the quality measures. On the whole, evidence suggests benefits outweigh risks in contexts where needs are assessed in ways that are patient-centered and minimize risks for stigmatization and discrimination. In the future, an additional patient-centered and patient-reported measure might be considered about the experience of screening.

2. Are there drawbacks to having measures related to screening without measures related to acting on identified needs?

Incentivizing screening through quality measures without also incentivizing action on identified concerns may lead health care organizations to attend to assessment over intervention, which may have benefit for calculating risk-adjusted payment but is unlikely to meaningfully change health outcomes. In a worst-case scenario, screening that does not yield risk-adjustment could result in 'creaming' or strategies to limit service to individuals or communities with higher socioeconomic risk. At the same time, although several NIH-funded randomized controlled trials with a diversity of urban and rural target populations (e.g., families with hospitalized children, dementia caregivers, older people with diabetes, adults, and

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children with cardiovascular disease risk) are ongoing, research has not yet provided clarity about what types and what intensity of actions are most likely to improve outcomes. Ideally the screening-focused QM will contribute to more innovation and evaluation in the intervention space. This learning should contribute to measure development around strategies to hold health care organizations accountable for acting on collected social data. One possibility is to consider revising the second proposed QM (#136) to reflect a measure of change in the screen positive rate.

3. Are these the right social domains to include in a social screening quality measure?

In 2014, the National Academies recommended routinely incorporating information about financial strain/insecurity in EHRs with follow up assessments conducted only as needed around basic material needs such as transportation, utilities, food, and housing. This recommendation is not reflected in the proposed measures. Though the four social risks related to socioeconomic security (food insecurity, housing instability, transportation problems, and utility security) included in the proposed measures may each be relevant to health and actionable, it may not be maximally efficient to screen for each of these until an overarching assessment of financial strain is conducted; on the other hand, unpublished data suggests that needs disclosure may be higher in response to individual topics. If these measures move forward as they are, in the future research on likelihood of disclosure should be revisited and the measures should be modified. Additional topics related to basic material needs also should be strongly considered, e.g., digital access (a topic of whose relevance to health disparities is rapidly changing), employment, legal needs, and childcare affordability/access.)

4. Interpersonal violence screening poses unique concerns and opportunities

Screening for interpersonal violence raises a number of unique concerns, including but not limited to the distinction between interpersonal violence and intimate partner violence. One consideration would be to require that if IPV is the only measure a health system is assessing, in order to meet the quality standard, they must also include at least one other driver of health measure from the list of other included domains.

5. The proposed measures would benefit from more detailed specifications.

We would like to highlight two areas that are not clear about these measures:

- It is our understanding that measure 136 (screening) is meant to only count beneficiaries screened for all five risks (vs. any of the five risks) and that the screening positivity measure (134) is meant to count beneficiaries with at least one of the needs (not only those who have all five). However, the way the measures are defined do not make this explicit.
- The measure definitions also do not specify whether clinicians and hospitals can use any screening tool or approach or whether there is a required set of questions or tools that should be used. Despite hoping for future standardization, we currently would recommend allowing flexibility in how different social domains are measured because since there are a variety of assessment tools already in use across the country.

We recommend that these definitions be clarified as the measures move forward in the process.

Summary

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In summary, based on our knowledge of the research evidence in this space, we recommend that these measures mover forward but with the following modifications:

- Clarify the definitions of the measures
- Provide guidance about how to conduct screening in a way that is patient centered, maximizes confidentiality, and minimizes risks of stigmatization and discrimination. Also consider adding measures of patient experience in the future.
- Ensure the measures provide clinicians and hospitals flexibility in the screening tools and approaches used.

In addition, in the future we recommend adding measures focused on the actions that providers and hospitals can take to improve patient outcomes based on screening information, since those actions are what will lead to benefits to beneficiaries.

We thank NQF for providing this opportunity to provide feedback about this important and growing part of high-quality patient care. Please reach out to laura.gottlieb@ucsf.edu if you have any questions about these comments.

Sincerely,

Caroline Fichtenberg, PhD, University of California, San Francisco

Taressa Fraze, PhD, University of California, San Francisco

Laura Gottlieb, MD, MPH, University of California, San Francisco

Danielle Hessler Jones, PhD, University of California, San Francisco

Stacy Lindau, MD MAPP, University of Chicago

North Carolina Medical Society

NCMS is North Carolina's oldest professional organization, including nearly 12,000 members and a network of influential partners extending from county medical societies and specialty societies across the state, to the state legislature and Department of Health and Human Services (NC DHHS).

Consistent with our mission "to provide leadership in medicine by uniting, serving and representing physicians and their health care teams to enhance the health of North Carolinians," NCMS has long recognized and committed to act on the social drivers of health (SDOH), which directly impact health outcomes and health care costs.

On this basis, NCMS strongly recommends that the Measurement Application Partnership (MAP) move forward two measures forward through the regulatory review process: Screen Positive Rate for Social Drivers of Health (MUC2021-134) and Screening for Social Drivers of Health (MUC2021-136).

NCMS's support for these measures is rooted in the recognition that the presence of SDOH fuels physician burnout, creates economic risk for physician practices under value-based payment models, and drives poor health outcomes for North Carolinians. This is especially so in COVID's wake: faced with the convergence of their patients' clinical and economic needs, front-line physicians and other health

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care providers have been taxed as never before.

We recognize the strong alignment between physicians and patients about the importance of addressing SDOH. Focus groups we have conducted with our partners show striking agreement among North Carolinians (across race, gender, income, political affiliation, and geography) on what they need to be healthy, with all the focus groups choosing to spend more money on food and housing than on health care. Focus groups with NCMS members echoed these findings, with 100% of participating physicians indicating that some, many, or all of their patients are affected by social conditions.

Our experience is that NC DHHS's requirement under Medicaid Transformation that all members be screened for food insecurity, housing instability, lack of transportation, and interpersonal violence has spurred crucial investments in the capacity necessary to address these issues. Specifically, this SDOH screening requirement spurred a public-private partnership to implement NCCARE360 – the first statewide, up to date, community resource database and closed loop referral platform, which is now live in all 100 of NC's counties – as well as investments in community health workers to support in connecting patients to community resources.

We view the proposed SDOH measures before the MAP as crucial to CMS recognizing the impact of these issues on patients and providers alike – and laying the foundation to invest in those community resources necessary for health.

Citations:

https://www.healthaffairs.org/do/10.1377/hblog20210429.335599/full/

Camden Coalition of Healthcare Providers
How would adding this measure add value? How would the measure improve patient outcomes?

Mandating the two process measures may lead to wider adoption of social needs screening in healthcare settings. While screening itself does not imply practices will have the resources to respond effectively to the social needs identified, it at least establishes a foundation for building processes within practices and the community to address health-related social needs. Collecting structured data on social determinants could bolster efforts to understand and address equity issues in the healthcare system, improve segmentation efforts, and may be a springboard for measuring the capacity of healthcare providers to respond to social needs, and identifying where gaps between social needs and resource availability in the community exist.

Do the benefits of the measure outweigh the burden of data collection or reporting?

The benefits of the measure will not necessarily outweigh the burden of data collection or reporting. This will depend on many practice-level factors, such as the ability to develop efficient screening workflows, the availability of staff who are trained and well-prepared to engage patients with complex social needs (especially around sensitive needs such as those related to interpersonal safety), the smooth integration of screening data into a practice's existing data systems, and the ease with which the data can be made available to clinicians at the point-of-care. Moreover, the interpersonal safety questions are proprietary, and from a practice's perspective, it may not be worth the cost of including those questions in their screener, especially if there are inadequate resources available to address any

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interpersonal safety issues a person is experiencing. We would recommend offering alternative questions related to interpersonal safety for practices who do not want to pay to use the four questions currently included in the AHC screener. Finally, with reimbursement, benefits may outweigh burden as long as practices are given flexibility in how social needs screening takes place and the reporting requirements are not cumbersome.

For what purpose are you using the measure (e.g., QI, certification/recognition, regulatory/accreditation, payment, public reporting, disease surveillance)?

The Camden Coalition is an Accountable Health Communities alignment track hub. The social needs screening data we collect are used for multiple purposes locally and regionally. For example, we share the data with health systems and other community partners for community health needs assessments and gaps analysis; we leverage the data to procure funding for various population health initiatives; we make the data available through our Health Information Exchange to inform clinical decision-making; and we share the data with researchers who study the intersection of social risk and health.

Are there implementation challenges?

Challenges include incorporating the screening tool into practice workflows, throughput, cost, potential need for extra staffing, and storing and accessing the data. If the screener is self-administered, challenges related to staffing might be reduced, but there are other challenges that need to be considered. An efficient workflow still needs to be established - for example, determining when during a visit a patient will receive the screener and who on staff will be responsible for introducing the screener to the patient. Language and literacy barriers present challenges as well and may require additional time and support from staff. Additionally, if a practice is doing more than collecting data and is going to establish workflows to respond to social needs, there are coordination costs associated with addressing those needs. There would need to be people on staff who can have the kinds of conversations that must take place when a patient expresses a social need. This may mean hiring a social worker, for example, or taking on the cost of training existing staff members.

AMITA

Social Screenings are important and help to drive change to impact patient outcomes BUT the burden of collecting and reporting the data do not outweigh the benefits in the ambulatory setting. With the large variance of EHRs and screening tools available, it will be difficult for small primary care practices to collect and report this data. Specialty practices have often been exempt from this type of reporting but should be obligated to report if it is moved to MUD. Also, if the measure is moved to development, a CPT II or similar place holder should be implemented to help capture the screening via claims. There are currently Z codes to help capture patients who screened positive, but those codes will not capture those who were screened and had no food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety.

NewWave

Both MUC2021-136 (Driver of Health Screening Rate) and MUC2021-134 (Driver of Health Screen Positive Rate) are important baby-steps to begin measuring drivers. They are simple process measures that may be valuable in starting the measures we really need to be working toward. Knowing the rate of Screening and of those screened which had positive indicators of food insecurity, housing instability,

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transportation problems, utility help needs, and interpersonal safety will do little to improve the rate at which we implement programs that have a meaningful\measurable impact on effecting this QOL deteriorating drivers that rob value from any health care delivery received by effected individuals.

It is critical that these "conversation starter measures" are not considered an end in themselves but are in fact simple measures that we can do today with little controversy or change in the as is state of the care delivery system. Until we begin to measure the closed loop referral process and gather population level impacts and gaps the value of measures of drivers will be little more than the minimum, we must be doing to get started on the more important work to be done to address the blockers to better inter-sector and interoperable whole-person care that is called for by everyone.

United Way of the Mid-South

We welcome this opportunity to submit our comments related to the proposed addition of two new proposed quality measures related to social risk screening:

- Driver of Health Screening Rate: % beneficiaries 18 years and older screened for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-136)
- Driver of Health Screen Positive Rate: % beneficiaries 18 years and older who screen positive for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-134).

In 2016, the United Way of the Mid-South (UWMS), based in Memphis, Tennessee, launched Driving The Dream (DTD), a resilient human services ecosystem that aligns and better integrates the local human services, represented by 82 agencies, with the goal of connecting under-resourced families to an array of supportive services as well as clinical healthcare to improve their overall health and wellbeing. As an organization, we have worked deeply in this space and understand the nuances and complexities of coordinating and aligning clinical care and social services. As a former state public health commissioner and practicing physician, I personally understand firsthand the social and economic challenges families face when it comes to promoting their own health and the health of their children and other family members.

Given this experience and exposure, UWMS believes the introduction of these measures is a critical step in bridging the gap between clinical services and social services that address the socioeconomic and environmental factors, which as evidence supports contributes to 50% of a person’s overall health and wellbeing. Adoption of these measures will provide standardized data that begin to provide insights into the depth and breadth of social barriers that contribute to poor health outcomes. Additionally, with the ability to disaggregate by demographic characteristics, it will make visible the social factors driving or inhibiting health, particularly for communities of color. Equipped with this data, human services providers can better direct existing resources to be responsive to gaps, while also more effectively making the case for additional services that may be needed.

While these measures are just a first step in terms of diagnosis, adoption of these measures has the potential to drive greater awareness among clinical providers regarding the interconnectivity of physical health and underlying socioeconomic conditions. That awareness has the potential to incentivize more

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formal partnerships between clinical care and social service providers, all with the ultimate goal of improving patient health and wellbeing.

We are in full support of the adoption of these measures, however, we do raise one potential implementation challenge, as it relates to screening. There are a number of social determinants of health screening tools that have been adopted and in use by both clinical providers as well as social service providers. Understanding if there are specific validated screening tools that must be used to screen and diagnose these conditions is a potential area for further exploration and discussion.

Should the review committee have any follow-up questions or additional discussion, we would be more than happy to further contribute insights and related guidance.

Sincerely,

Kenneth S. Robinson, M.D.

Signify Health
December 8, 2021

National Quality Foundation

Measures Application Partnership

RE: Measures Under Consideration 2021-134 and 2021-136

To Whom It May Concern:

We appreciate the opportunity to offer comments pertaining to the referenced MUCs. By way of background Signify Health is a value-based care company that brings together a unique combination of services to reduce the costs and improve the quality of health care provided to beneficiaries of public and private health plans. We are a leading provider of technology-enabled, in-home assessments, complex care management, and SDOH services. We believe deeply that health flourishes in safe homes and connected communities. Every day, across the U.S., we deploy the nation's largest mobile network of duly licensed clinicians to support people where they are – in their homes, residential facilities, and communities. We take the time to fully understand their lives and use these insights to connect them to the medical and social care they need most.

Our comments apply to both proposed Measures.

How would adding this measure add value? How would the measure improve patient outcomes?

The proposed measures for data collection and reporting represent the first and necessary step to assessing the scope and scale of social needs for a population and understanding its true impact on health outcomes. Subsequent analyses of the resulting data can assist community-based organizations, payers, providers, and policymakers in designing programs that are discrete, modifiable, meaningful, and impactful in addressing social determinants of health.

Do the benefits of the measure outweigh the burden of data collection or reporting?

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Yes, however financial incentives will likely be necessary in order to accomplish broad data collection efforts. In order to relieve the associated burden, CMS could consider creative/innovative ways to collect the SDOH data to reduce burden on hospital and physician care teams. However, it is important to recognize the obvious: not all populations seek care in the traditional health system. If a hospital or physician is the sole data collection site, we are missing out on a significant population with unmet SDOH needs that could exacerbate a clinical condition that results in a subsequent hospital admission. To ensure more comprehensive data collection, public and private payer (Medicaid, ACA, MA, Medicare Supplement private insured) enrollment processes could be expanded and utilized to collect **standardized data**. Government grants could also be made available to organizations such as the United Way and other community-based entities that interact with community-based organization to enlist their aid in collecting and submitting SDoH data.

For what purpose are you using the measure (e.g., QI, certification/recognition, regulatory/accreditation, payment, public reporting, disease surveillance)?

As an organization, Signify Health collects SDoH data on a limited basis. We utilize this information to design programs that improve access to community-based services and to improve health outcomes.

Are there implementation challenges?

Yes. From a technological perspective, ensuring the security and privacy of data collected as CBOs are not covered entities under HIPAA; and the absence of a standardized data set; and operationally ensuring appropriate and culturally sensitive training of staff necessary in order to build patient trust. Importantly, the need for financial support to cover the required additional resources, time, and effort to comply fully.

Thank you for your consideration.

Submitted on behalf of the Company by Manjula Julka, MD, VP Medical Affairs, Senior Population Health • OOCMO

About Fresh, Inc.
December 7, 2021

To: Members of the NQF: Measure Applications Partnership

From: About Fresh, Inc.

RE: Support for Driver of Health Screening Rate (MUC2021-136)

Thank you for the opportunity to provide comments on the 2021-2022 Recommendations for Measures Under Consideration. We were happy to hear that CMS accepted the “Drivers of Health Screening Rate” and the “Drivers of Health Screening Positive” measures as part of the 2021 CMS MUC list. We are writing now to recommend that you move those forward as part of the 2021-2022 Measure Applications Partnership (MAP) cycle. We are writing on behalf of About Fresh, Inc., a Boston-based nonprofit that partners with health systems and civic leaders to get healthy food to the people who need it most. Our team builds retail and technology solutions that empower households to access healthy food, and we uplift data, health insights, and community voice to meaningfully integrate food access into the delivery

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of quality care.

We are submitting this letter because it is time to adopt federal standards for screening patients for the lived circumstances, such as food security and housing stability, that widely accepted research tells us drive a majority of healthcare outcomes. Despite that research, CMS has to date taken only limited initial steps to address these DOH – such as allowing certain Medicare Advantage plans to spend chronically ill members' premiums on fresh produce and other DOH. Furthermore, despite the growing focus on DOH there are currently no standard food security or other DOH measures in any of the federal programs that determine how insurers and healthcare providers are paid. Among other consequences, the absence of standard DOH data and measures impede efforts to achieve racial equity in health outcomes. Given the disproportionate and profound impact of the DOH on people and communities of color, especially in COVID's wake, this represents a profound gap in our ability to understand and address the racial inequities in our healthcare system.

The Physicians Foundation (directed by 21 state and county medical societies across the country) has submitted to CMS two DOH measures focused on screening for food insecurity, housing instability, transportation, utility needs, and interpersonal safety. These measures represent the foundation for future measures focused on ensuring patients secure the resources they need to be healthy and enabling community investments required for health. These measures (stratified by race/ethnicity) are well-tested in over 600 clinical sites across the country through the CMS Innovation Center's Accountable Health Communities (AHC) model. AHC has now screened ~1 million beneficiaries, with 69% of those who are navigation-eligible reporting food insecurity (the highest reported need).

These DOH measures have gained significant traction and momentum in the healthcare sector. The Commonwealth Fund and the Blue Shield of California Foundation recently published a blog, focused on these measures as a crucial milestone on the path towards health equity. The Physicians Foundation also published a Modern Healthcare op-ed calling for the measures' adoption, given the profound impact of DOH on health outcomes and costs, as well as physician burden and burnout.

Including food insecurity as a quality measure in the major federal healthcare programs (Medicare and Medicaid) via these DOH measures is a crucial prerequisite for CMS, states, or commercial payers to pay for access to healthy food, not as a pilot or initiative, but as a standard health benefit. Absent such measures, the impact of DOH will remain functionally invisible in federal healthcare policy making.

Thank you for your consideration of these comments.

Sincerely,

Adam Shyevitch

Chief Program Officer

Josh Trautwein

Chief Executive Officer

[1] Hood, C. M., K. P. Gennuso, G. R. Swain, and B. B. Catlin. 2016. County health rankings: Relationships between determinant factors and health outcomes. American Journal of Preventive Medicine 50(2):129-

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About Fresh, Inc.
January 10, 2022

To: Members of the NQF: Measure Applications Partnership

From: About Fresh, Inc.

RE: Support for Driver of Health Screening Rate (MUC2021-136)

Thank you for the opportunity to provide comments on the 2022 draft recommendations offered by the Measure Applications Partnership (MAP) Clinician, Hospital, and Post-Acute Care/Long-Term Care (PAC/LTC) Workgroups.

We are writing to offer our strong endorsement of the MAP Workgroup's support for the SDOH measures for MIPS. In addition, we urge the Coordinating Committee to recommend both SDOH measures (screening and screen positive rate) for the Hospital Inpatient Quality Reporting Program (HIQRP).

Publication of hospitals' screen positive rate would (1) improve healthcare transparency; (2) enable more targeted, data-driven community investments; (3) signify hospitals' familiarity/expertise regarding these issues; and (4) inform and strengthen quality improvement activities, including those addressing healthcare inequities.

We are writing on behalf of About Fresh, Inc., a Boston-based nonprofit that partners with health systems and civic leaders to get healthy food to the people who need it most. Our team builds retail and technology solutions that empower households to access healthy food, and we uplift data, health insights, and community voice to meaningfully integrate food access into the delivery of quality care.

We are submitting this letter because it is time to adopt federal standards for screening patients for the lived circumstances, such as food security and housing stability, that widely accepted research tells us drive a majority of healthcare outcomes1. Despite that research, CMS has to date taken only limited initial steps to address these DOH – such as allowing certain Medicare Advantage plans to spend chronically ill members' premiums on fresh produce and other DOH. Furthermore, despite the growing focus on DOH there are currently no standard food security or other DOH measures in any of the federal programs that determine how insurers and healthcare providers are paid. Among other consequences, the absence of standard DOH data and measures impede efforts to achieve racial equity in health outcomes. Given the disproportionate and profound impact of the DOH on people and communities of color, especially in COVID's wake, this represents a profound gap in our ability to understand and address the racial inequities in our healthcare system.

The Physicians Foundation (directed by 21 state and county medical societies across the country) has submitted to CMS two DOH measures focused on screening for food insecurity, housing instability, transportation, utility needs, and interpersonal safety. These measures represent the foundation for future measures focused on ensuring patients secure the resources they need to be healthy and enabling community investments required for health. These measures (stratified by race/ethnicity) are

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well-tested in over 600 clinical sites across the country through the CMS Innovation Center's Accountable Health Communities (AHC) model. AHC has now screened ~1 million beneficiaries, with 69% of those who are navigation-eligible reporting food insecurity (the highest reported need).

These DOH measures have gained significant traction and momentum in the healthcare sector. The Commonwealth Fund and the Blue Shield of California Foundation recently published a blog, focused on these measures as a crucial milestone on the path towards health equity. The Physicians Foundation also published a Modern Healthcare op-ed calling for the measures' adoption, given the profound impact of DOH on health outcomes and costs, as well as physician burden and burnout.

Including food insecurity as a quality measure in the major federal healthcare programs (Medicare and Medicaid) via these DOH measures is a crucial prerequisite for CMS, states, or commercial payors to pay for access to healthy food, not as a pilot or initiative, but as a standard health benefit. Absent such measures, the impact of DOH will remain functionally invisible in federal healthcare policymaking.

Thank you for your consideration of these comments.

Sincerely,

Adam Shyevitch, Chief Program Officer

Josh Trautwein, Chief Executive Officer

Public Agenda

To: NQF Measures Application Partnership

From: Public Agenda

Re: MUC2021-134

Date: January 7, 2022

Unmet social needs in early childhood can have long-lasting and wide-ranging consequences, including increased risk for chronic health conditions, behavioral problems and poor academic performance. The American Academy of Pediatrics in 2016 called on its members to begin universally screening for social needs and facilitating connections to community resources as a part of routine care.

Yet little research has asked parents, particularly low-income parents, for their perspectives about social determinants of health and how screenings can be implemented successfully. To help fill this gap, Public Agenda, with funding support from United Hospital Fund, conducted focus group research with low-income parents in New York City to understand parents' perspectives on social needs screenings.

In 2019, Public Agenda released findings from this research in a report titled "It's About Trust: Low-Income Parents' Perspectives on How Pediatricians Can Screen for Social Determinants of Health." The report is available on Public Agenda's website at https://publicagenda.org/reports/its-about-trust-low-income-parents-perspectives-on-how-pediatricians-can-screen-for-social-determinants-of-health/

Findings from this research include:

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1. Parents in these focus groups cited a broad range of social stressors that affected their children's health and well-being, including some that screening tools for social determinants of health may not currently include, such as the challenges of single parenthood, neighborhood violence, bullying, and environmental pollution

2. These parents did not immediately identify pediatricians as sources of help with social stressors. Their reactions to the idea of pediatricians discussing these stressors were mixed. They saw some topics, such as nutrition, education and minor behavioral issues, as appropriate to discuss with pediatricians, but saw others as more sensitive, such as domestic violence, parents' mental health and legal issues.

3. Parents expressed concerns about discussing sensitive social needs with pediatricians. For example, parents shared concerns about being judged and discriminated against because of their families' social needs. Parents feared that sharing information about social needs could trigger intervention by a child welfare agency. Parents noted that long waits for short appointments meant prioritizing more pressing health needs that could make it difficult to discuss complex social needs in depth. Parents expressed frustration at the prospect of disclosing sensitive information without getting help might frustrate parents.

Despite the concerns they cited about discussing social needs with pediatricians, particularly their more sensitive needs, most parents in these focus groups responded enthusiastically when the moderators asked for their ideas about how pediatricians should approach discussing social determinants of health. Parents' recommendations for pediatricians included:

1. Build trust. Parents in the groups emphasized that talking openly about social determinants of health with pediatricians is a matter of building trusting relationships. While some parents said they would prefer discussing social determinants of health with pediatricians face to face and others said they would prefer a questionnaire, their overriding message was that they could only share information about sensitive topics in the context of a trusting relationship with their children's pediatricians.

2. Choose the right moment for parents. With long waits for short appointments, parents felt pediatricians should choose the right moment to start conversations about social needs. They emphasized that if they come to an office visit with a child who has a cold or other immediate concern, the pediatrician should address that concern and wait for another visit, when they might have the time and energy for the conversation, to bring up more sensitive, complex topics.

3. Not in front of the children. Parents said that if they were to discuss social determinants of health with their children's pediatricians, they would prefer to do so in private, not in front of their children. They said pediatric offices should create dedicated spaces where children can play, giving adults time and space to discuss sensitive, complex topics, as well as easing the burden of long waits for appointments with sick children or siblings.

4. Let parents choose to learn about helpful resources at their own initiation. Parents often said they wanted posters on waiting room or exam room walls and pamphlets they could take themselves. They said posters and pamphlets would let them choose to learn about social needs—particularly more sensitive ones—and about helpful resources on their own time, discreetly and at their initiation.

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5. Signal confidentiality and be transparent about what triggers reporting to child welfare. Parents in these groups understood that when a child is truly in danger, a pediatrician must share that information with the appropriate authorities. But they also wanted pediatricians to be transparent about what triggers reporting and what does not, so they would know which issues they could talk about openly. They also felt strongly that when they share sensitive information, it must be kept confidential.

6. Do not ask just for the sake of asking. These parents were very firm in their conviction that if pediatricians ask about sensitive issues, they should be willing and able to provide or suggest helpful resources. Parents wanted to avoid the double loss of disclosing sensitive information without receiving help. They said referrals to other organizations should come with an offer of guidance and a warm handoff.

7. Make clear that screening is standard protocol. It was very important to parents in these groups to be assured that everyone gets screened—whether face to face or with questionnaires—not just those who appear to be struggling, are enrolled in Medicaid or are low-income. Otherwise, parents said, they would feel judged or profiled.

8. Consider "letters of support" and other ways to be parents' allies. Parents in these groups indicated that the doctors have a unique authority and can be their allies in difficult situations. Parents specifically said it could be helpful for pediatricians to provide what they called "letters of support," for instance, when they face problems with the public housing authority or private landlords regarding peeling paint, pests or other environmental hazards. Some parents said pediatricians could vouch for them when they face legal difficulties or child welfare investigations.

Public Agenda would welcome the opportunity to share findings from this research in further detail or to answer any additional questions that committee members may have.

Yours,

David Schleifer, PhD

Vice President, Director of Research

Public Agenda

dschleifer@publicagenda.org

Morris-Singer Foundation

As a primary care physician and Co-Director of the Morris-Singer Foundation (MSF), I am writing in support of two recently-considered measures of social determinants of health (SDOH): Screening for Social Drivers of Health MUC2021-136 (MIPS and Hospital IQR).

The Morris-Singer Foundation is a family foundation committed to pioneering new ways of being and engaging as we address the complex problems of our time. We provide grants to support a range of programs, including several operating on the frontlines of health care. Two in particular give us a unique view into the minds of clinicians: the Relational Leadership Institute at Primary Care Progress and 3rd Conversation by X4 Health. Both programs convene clinicians and administrators in conversations and trainings with each other to supercharge relationality and human connection in our health systems.

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These rooms tell us without a doubt that clinicians are hungry for SDOH measures that help shift the practice of medicine from the normal litany of required measures, to measuring what matters for health.

That's why I strongly support the screening measures for social drivers of health for both MIPS and the Hospital IQR program (MUC2021-136). Taken together, these are the first-ever social drivers of health measures in any federal quality or payment program.

I strongly urge the MAP to recommend both these SDOH measures. The technical merits of measures are important, but they can also be an excuse for inaction.

We on the front lines of healthcare know that building strong relationships with our patients; addressing physician burnout; achieving better health for all; and reducing healthcare costs depend on our recognizing the realities of our patients' lives, those critical co-morbidities such as food insecurity or housing instability that have only escalated in the context of COVID.

Yet, under federal payment and quality frameworks, the healthcare system codes, screens, measures and risk-adjusts for diabetes, but not for food insecurity – even though diabetics who are food insecure have worse health outcomes and cost on average $4,500 more per year than those with access to healthy food.

Amazingly, there is not a single SDOH measure in any of the federal payment models. Not one.

It's past time for these measures – especially as we physicians continue to witness COVID's profound impact on the physical, psychological, and economic well-being of our patients. We can't keep asking clinicians to address health without also providing tools and reimbursement to understand the known drivers or determinants of health.

One question that has come up is whether these measures will incentivize providers to care for wealthier patients or frustrate patients and providers because they involve screening for SDOH but do not yet require action on the results. Not only do these completely hypothetical concerns reflect a striking degree of cynicism about my fellow physicians and health professionals –they are inconsistent with the evidence from testing of social needs screenings in clinical settings, which shows that providers will chose to screen their patients and will act on those results.

CMS's largest-ever primary care model, Comprehensive Primary Care Plus, did not include a SDOH screening requirement for about 1,200 practices in the model. But 86% of these practices screened their patients anyway – because they knew that's what their patients needed to be healthy. We must begin to include measures that will enable quality improvement and appropriate payments related for health.

The evidence makes clear that physicians are committed to helping their patients with these issues, and these SDOH measures are key in recognizing, supporting and incentivizing practices that choose to do so.

As burnout skyrockets in the pandemic era, helping medicine measure what matters will be a key strategy in preventing the mass exodus that will threaten our system.

Let us not make any excuses for inaction. I strongly urge the MAP to recommend both these SDOH

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measures to recognize – for the first time in a federal payment model – the thousands of physicians and other healthcare providers who work every day to understand what their patients need to be healthy and to address these needs.

Sincerely,

Andrew Morris-Singer, MD

Co-Director, Morris-Singer Foundation

Yale School of Public Health

Cancer incidence rates in Connecticut are well above the national average with the greatest overall burden on African Americans, Hispanic/Latinos, and those of low socioeconomic status (1). Recognizing the need for cancer control across the continuum, the Yale Cancer Disparities Firewall Project of the Yale Cancer Center (funded by Bristol-Meyer Squibb Foundation, co-sponsored by the Yale Cancer Center and Yale School of Public Health) uses an innovative approach to engage community residents prior to their need for cancer-specific services. In order to develop positive community relationships and facilitate institutional knowledge and trust, the Firewall Project offers “in-home” navigation to match high risk community members with social needs resources and providers as well as health education about cancer prevention and early detection and free cancer screenings. Our navigation services are distinct from conventional cancer navigation programs in three important ways: 1) a cancer diagnosis is not needed to qualify for or participate in Firewall programs, 2) conceptualized as wrap-around support, our project screens and assists community residents with social needs, and 3) our navigation services are provided telephonically and electronically allowing participants to receive resources or assistance in their home and community or other setting that is convenient for them.

Outcomes to date relevant to the collection of social determinants of health data as proposed: During a pilot project, 200 “healthy” people were offered social determinants of health screening at public events targeting specific neighborhoods or populations; 75 completed a telephonic SDOH screening and cancer risk factor intake survey. Among those with completed screenings 69% were identified as having one of more social need and significant percentages were referred to social services providers to help address food insecurity (42%), housing instability (39%), transportation challenges (32%), and utility assistance (29%). Approximately one third of the program participants were able to complete cancer screening visits or other medical appointments (including tobacco treatment visits) due, in part, to social needs support facilitated by the navigation program despite pandemic-related scheduling challenges in our state.

What we have learned: Even in times of uncertainty such as during a pandemic, screening for SDOH helped build trust among community members and improved potential points of engagement for health care as all of those who failed to complete intakes participated in conversations with community health educators about prevention, cancer screening or healthy lifestyles. Among those with identified social needs, those who screened positive for food insecurity and transportation challenges were able to be assisted in ways that helped them complete cancer screening or other medical visits. Whether patient outcomes were improved is something we would assess longitudinally. If screening rates are maintained or increased over time, however, one would expect overall health (e.g. earlier stage diagnoses, cancer risk awareness, broader availability of treatment options) to also improve. Additional follow up and

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analyses will be needed to determine statistical relationships between SDOH screening and health variables; however, the screening questions.

The SDOH screening questions were acceptable to participants and easy to administer using an electronic interface.

The measures have been used as part of research or pilot implementation programs focused on reducing cancer disparities in prevention and screening among underserved and racial/ethnic minoritized populations. Our selection of a screening tool was bolstered by CMS use of similar SDOH items in the Accountable Health Communities (AHC) demonstration projects (2,3). The SDOH screening assess social needs in five areas: food insecurity, housing instability, transportation challenges, utility payment challenges, and interpersonal safety (2,3). The screening items are also aligned with Healthy People 2030 SDOH goals and CMS' Meaningful Measures 2.0 initiative.

Implementation challenges at the health care system level include personnel and workflows for data collection, consistent data collection across the system and determining ways for data to be reported and proactively used by the health care system. At the provider level, implementation challenges include consideration of when SDOH screening questions should be asked within a visit workflow, by whom and appropriate follow up actions for patients who screen positive. Other implementation challenges include connecting patients with agencies that can help address social needs and communicating to patients and the public about how such screening data may be relevant to their health care and health outcomes. Despite such challenges, implementation of social needs screening may positively impact quality and health equity efforts by reducing the impact of unacknowledged and unaddressed social needs on health care outcomes.

This comment is issued as conditional support for rulemaking for MUC 2021-136 for IQR and MIPS pending NQF endorsement. In order for health care systems and providers to begin assessing and monitoring social needs and their impact on health, starting with screening is an important first step.

(1) State Cancer Profiles. Connecticut: Accessed at: https://statecancerprofiles.cancer.gov/quick-profiles/index.php?statename=connecticut. Created by statecancerprofiles.cancer.gov on 01/04/2022 1:46 pm.

(2) Centers for Medicare & Medicaid Services (CMS). The Accountable Health Communities

Health-Related Social Needs Screening Tool. Accessed on 1/4/22 at: https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.

(3) United States, U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. (2017, September 05). Accountable Health Communities Model. Link: https://innovation.cms.gov/initiatives/ahcm.

The ideas expressed here are those of the author and do not reflect the positions of the institutions with which she is affiliated.

Sakinah Suttiratana, PhD, MPH, MBA

Medical Sociologist/Chronic Disease Epidemiologist

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Cerner

With changes in regulatory requirements and a shift towards a value-based paradigm, it is now more important than ever to have complete data. As data becomes more complex, we have the ability to extract multifaceted insights and provide actionable analytics to organizations striving to satisfy the triple aim at the core of healthcare reform - promoting better health, providing better care, and reducing cost.

To excel in population health management, you need to understand how patient characteristics and contextual factors, external to the care delivery process, impact your patients. We help you to better understand how these characteristics affect segments of your patient population, optimize care delivery, understand variation in outcomes related to SBDH burden, excel in value-based care and achieve health equity.

Optum

Public Statement on 2021 CMS Measures Under Consideration: Drivers of Health

I applaud CMS for including the first measures specifically focused on the drivers of health (DOH) on the 2021 Measures Under Consideration (MUC) list – and the MAP for its thoughtful consideration of MUC2021-134 and MUC2021-136. These measures are particularly significant given that of all the potential Medicare measures under consideration by CMS this cycle, these are the only patient-level health equity or DOH measures.

I endorse the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision. Given the well-recognized impact of DOH health outcomes and cost and, in particular, their disproportionate impact on communities of color, this represents a significant and historic milestone for our healthcare system.

I further strongly urge the MAP Coordinating Committee to support the SDOH screening and the screen positive rate measures for the IQR, recognizing that both these measures are crucial. MUC21-134 (the screen positive rate) is especially important to both practicing physicians (like me) and to our patients given the imperative of transparency in reporting and the opportunity for such data to enable quality improvement activities, including addressing disparities.

What really matters to people is that health is more than medical care and that social drivers have outsized impact on health and healthcare costs. It is important to build models that care for people's physical, mental, and social needs, including home- and community-based care. To do so effectively and equitably, it is imperative to collect person-level DOH data– as essential step to improving patient outcomes, both by helping people access the resources they need to be healthy and enabling healthcare institutions to invest in and partner with communities.

Person-level DOH data is essential to quantify the health and economic implications of DOH and inform work on DOH-related billing codes, risk-adjustment, and cost benchmarks. For example, it is well-documented that a diabetic that is food insecure costs, on average, $4,500 more PMPY and has a greater risk of complications. Not knowing if a diabetic is food insecure is both an urgent safety and quality issue and a cost issue that must be understood – as well as key to understand and address health disparities.

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I look to CMS to drive learning and accountability on the impact of DOH at the federal level. Inclusion of these DOH measures in regulatory programs like MIPS and the HIQRP would create an unprecedented opportunity to fuel collaboration across public and private partners, address factors that drive inequity in health outcomes, and begin to close CMS's stated measurement gap on the "social and economic determinants."

Through CMS Innovation Center models such as Accountable Health Communities and Comprehensive Primary Care Plus (CPC+), CMS has amassed years of data and learning across millions of beneficiaries and thousands of practices and clinical sites across the country – demonstrating that implementation of DOH screening can be done reliably and consistently over time. Further, use of these measures has revealed that 34% of beneficiaries screened positive for at least one health-related social need and those who screen positive are disproportionately racial/ethnic minorities.

Building on this foundation – and recognizing that it is untenable to continue to defer collecting and reporting data on those factors that drive up to 80% of health outcomes and associated costs – it is now time for the MAP to recommend that CMS include the first-ever DOH measures in a regulatory program.

Citations:

https://www.gsfb.org/wp-content/uploads/2018/08/Berkowitz-S.-A.-Basu-S.-Meigs-J.-B.-Seligman-H.-K.-Food-Insecurity-and-Health-Care.pdf

University of Texas at Austin

It is incredibly important for hospital settings to screen for social determinants of health (SDH), particularly amongst Medicare patients. While the benefits outweigh the burden of data collection, hospitals will need to have the appropriate staff for assessing and addressing SDH, such as social workers and community health workers. Ideally, the social workers would be based in the hospital while community health workers would be engaged in transitional care post discharge. This will increase buy-in among hospital staff and ensure that there are appropriate responses to patient needs.

Health Hats

The Social Determinants of Health criteria don't include internet access. A major miss.

American College of Physicians

We understand that socioeconomic factors often determine one's health outcome and we recognize the importance of screening for the same. However, we believe that this measure is not ready for implementation. Moreover, we understand that the tool may have undergone testing and deemed valid, but the Performance Measure has not. Hence, we do not support this measure at either the individual clinician or hospital levels, until testing of the performance measure's reliability and validity has been conducted. While we support efforts to implement measures that would lead to the identification of SDOH, we also believe such performance measures should adopt a rigorous method for assessing their validity before including them in quality and reimbursement programs. We echo AMA's sentiment that these SDOH measures should only be implemented after adequate resources and tools have been provided to the clinicians and groups, to be able to address those needs once they are identified. Additionally, these measures should be aligned with other federal efforts to collect such data (e.g., using Z-codes). We would also like to see the measure revised to require the AHC HRSN and other validated

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instruments.

Duke-Margolis Center for Health Policy

The Duke-Margolis Center for Health Policy encourages the inclusion of measures addressing social drivers of health (SDoH) in CMS quality reporting programs. The impact of these drivers on health is well documented, and a growing number of efforts are under way to examine how health care providers and organizations can better identify and address individuals' SDoH-related needs. Among these efforts are those examining how to leverage value-based payment (VBP) models to better address SDoH.1 Our work has found VBP models have the potential to support the infrastructure and cross-sector relationships needed to identify and comprehensively address SDoH-related needs.2 However, the current dearth of SDoH-related quality measures makes it difficult to embed accountability for addressing SDoH into VBP models. Development and implementation of SDoH-related quality measures are needed if VBP efforts to meaningfully address SDoH are to be successful.

The addition of the MUC2021-136 and MUC2021-134 measures to the Hospital Inpatient Quality Reporting Program and Merit-based Incentive Payment System would reflect the emphasis needed on advancing SDoH-related quality measures, especially if they can be clearly linked to a strategy for supporting improvement in the SDOH risk factors reflected in such measures. Such a strategy should include more systematic collection and reporting of SDoH-related data, development of the infrastructure needed to support partnerships across sectors (e.g., health care, education, justice), and implementation of payment models that can support and sustain the delivery of SDoH-related services. The inclusion of SDOH-related quality measures in CMS quality reporting programs is one way to support progress in implementing such a strategy.

References:

1. Sandhu S, Saunders RS, McClellan MB, Wong, CA. (2020). Health Equity Should Be A Key Value in Value-Based Payment and Delivery Reform. Health Affairs Blog. Accessed December 3, 2021. http://www.healthaffairs.org/do/10.1377/hblog20201119.836369/full/
2. Crook HL, Zheng J, Bleser WK, Whitaker RG, Masand J, Saunders RS. (2021) How Are Payment Reforms Addressing Social Determinants of Health? Policy Implications and Next Steps. Accessed December 3, 2021. https://www.milbank.org/publications/how-are-payment-reforms-addressing-social-determinants-of-health-policy-implications-and-next-steps/

Legacy Community Health

We are excited to support this measure. For the first time, CMS is considering two quality measures related to social risk screening as part of this year's 44 new Measures Under Consideration (MUCs) list. The two measures are:
Driver of Health Screening Rate: % beneficiaries 18 years and older screened for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-136) Driver of Health Screen Positive Rate: % beneficiaries 18 years and older who screen positive for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-134)

We have screened for these measures for years and found them to be a key driver in health outcomes. It

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would be helpful to have a standardized approach so that we can further our efforts of proving that social determinants of health are just as important to overall health as traditional healthcare.

Optum

Patrick Conway, CEO, Care Solutions, Optum

Former Chief Medical Officer, Director of Center for Medicare and Medicaid Innovation, and Principal Deputy Administrator for Centers for Medicare and Medicaid Services (CMS)

Public Statement on 2021 CMS Measures Under Consideration: Drivers of Health

I applaud CMS for including the first measures specifically focused on the drivers of health (DOH) on the 2021 Measures Under Consideration (MUC) list – and the MAP for its thoughtful consideration of MUC2021-134 and MUC2021-136. These measures are particularly significant given that of all the potential Medicare measures under consideration by CMS this cycle, these are the only patient-level health equity or DOH measures.

I endorse the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision. Given the well-recognized impact of DOH health outcomes and cost and, in particular, their disproportionate impact on communities of color, this represents a significant and historic milestone for our healthcare system.

I further strongly urge the MAP Coordinating Committee to support the SDOH screening and the screen positive rate measures for the IQR, recognizing that both these measures are crucial. MUC21-134 (the screen positive rate) is especially important to both practicing physicians (like me) and to our patients given the imperative of transparency in reporting and the opportunity for such data to enable quality improvement activities, including addressing disparities.

What really matters to people is that health is more than medical care and that social drivers have outsized impact on health and healthcare costs. It is important to build models that care for people's physical, mental, and social needs, including home- and community-based care. To do so effectively and equitably, it is imperative to collect person-level DOH data– as essential step to improving patient outcomes, both by helping people access the resources they need to be healthy and enabling healthcare institutions to invest in and partner with communities.

Person-level DOH data is essential to quantify the health and economic implications of DOH and inform work on DOH-related billing codes, risk-adjustment, and cost benchmarks. For example, it is well-documented that a diabetic that is food insecure costs, on average, $4,500 more PMPY and has a greater risk of complications. Not knowing if a diabetic is food insecure is both an urgent safety and quality issue and a cost issue that must be understood – as well as key to understand and address health disparities.

I look to CMS to drive learning and accountability on the impact of DOH at the federal level. Inclusion of these DOH measures in regulatory programs like MIPS and the HIQRP would create an unprecedented opportunity to fuel collaboration across public and private partners, address factors that drive inequity in health outcomes, and begin to close CMS's stated measurement gap on the "social and economic determinants."

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Building on this foundation – and recognizing that it is untenable to continue to defer collecting and reporting data on those factors that drive up to 80% of health outcomes and associated costs – it is now time for the MAP to recommend that CMS include the first-ever DOH measures in a regulatory program.

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https://www.gsfb.org/wp-content/uploads/2018/08/Berkowitz-S.-A.-Basu-S.-Meigs-J.-B.-Seligman-H.-K.-Food-Insecurity-and-Health-Care.pdf

Child and Adolescent Health Initiative (Massachusetts)

The Child and Adolescent Health Initiative is a multidisciplinary coalition in Massachusetts seeking to improve care and outcomes for children, with a primary focus on working with MassHealth (the state's Medicaid and CHIP agency) to assure that MassHealth insured children and their families get the care they need to optimize outcomes.

Assessing health related social needs is an essential step in providing appropriate services to patients/beneficiaries. This assessment enables providers and their health care organizations to then ascertain whether the patient desires assistance in addressing identified needs and, if they do, link them to appropriate and effective services. The tally of needs in a population also points to the broader social needs in a community and can lead to interventions to address the root causes of those needs (what the World Health Organization considers the social determinants or social drivers of health). These are the two strategies being explored in the Accountable Health Communities (AHC) model by CMMI. Given the importance of social needs in influencing both short and long-term health, regular assessment by health care provider organizations in order to take action is a core element of high quality care. Equity is also one of the core dimensions of care as defined by the National Academy of Medicine; key aspects of promoting equity in care include assessing and acting upon social needs and assuring that other aspects of care are not contingent upon the level of social need.

Asking about social needs requires sensitivity from the provider and candor from the respondent. In addition, as with any interview/survey/screening question, the precise way in which a question is worded produces different results. The cacophony of screening tools related to social needs produces confusion for patients, providers, health systems and others. The use of a consistent, valid, culturally appropriate set of screening questions will lower the burden on providers, produce more meaningful data, and also enable comparisons across providers and systems.

Although the specific information about the measure provided with this MUC list is quite limited, the measure used in the AHC correlates well with at least one other measure of social need for most of the dimensions. The assessment of housing taps different dimensions than the housing instability measure

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developed by Children's HealthWatch, but nonetheless appears useful.

We note that the specifications indicate the measure applies only to beneficiaries over 18. Understanding that this measure is being considered for use in Medicare's MIPS programs at this time, we nonetheless note that most of these indicators of social need (food insecurity, housing quality and instability and utility challenges) apply to all the members of a family or household and not simply the person answering an assessment. Similarly the presence of interpersonal violence in a family will likely affect child well being. The information obtained through these assessments should be linked to, and services provided for, those other household members—particularly children who are most vulnerable to the harmful impact of these types of adversity. In addition, although this approval is in the context of Medicare, the measure may be appropriate to ultimately include in the Medicaid Adult and Child Core Measurement Sets and be accompanied by guidance for states in their efforts to standardize these data in both child and adult populations.

Screening for social needs should be a routine part of care, particularly for, but not restricted to, primary care. Implementing screening for social needs imposes only marginal burden if systems are already established for other forms of screening (e.g., developmental screening in children, screening for depression in others). As with other forms of screening, screening for social needs only becomes useful for patients if the screening is confirmed by additional inquiry, if the patient desires follow up and if the patient is provided with an effective intervention.

Mechanisms for tracking who has been screened will require effort to establish. Such a mechanism should not be burdensome if fields in electronic health records capture that a screen was performed. Given the importance of assessing and addressing social needs, the benefits outweigh any such burden.

MassHealth requires that Accountable Care Organizations report on the proportion of each ACO's enrolled population that is screened for social needs, although the state does not specify a particular instrument for screening. The measure is now used for public reporting and may be used as part of payment purposes in the future. We recommend that this proposed measure be used for public reporting and as part of a payment system, and also that individual organizations use it for QI initiatives. Certification systems such as specialty board maintenance of certification programs could also incorporate this into their QI modules.

The implementation challenges are noted above; a mechanism for administration of the screening must be developed with appropriate privacy protections, availability in multiple languages, and sensitivity to the concerns of those without documentation. Nonetheless, many studies have confirmed that patients welcome these inquiries and view them as a positive indicator of provider concern, particularly if they lead to follow up conversations and action.

Genesis Health Consulting

I am Veronica Gunn, a pediatrician and public health professional with more than 20 years of experience in clinical care, healthcare administration and public health leadership, having previously served as a state health officer. Currently, I am CEO of Genesis Health Consulting, a national firm that works with hospitals, health systems and networks to advance the health and wellbeing of children and families

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through an equity lens.

I greatly appreciate the inclusion of patient-level measures of social drivers of health (SDoH) for the very first time. Although equitability is one domain of quality, this is the first time I am aware that equity is being recognized in this CMS measure set.

Providers in all settings are exhausted with seeing these issues arise with their patients, especially given COVID's devastating impact. Food insecurity, housing instability, utility needs, etc. all make it extremely difficult for patients to achieve optimal health, and we know that our populations of color disproportionally experience these social and structural drivers of health.

And – as in my work – when that patient is a child, the burden is experienced by both the patient and the caregiver.

Having these measures validates the importance of screening for these needs, and allows providers recognition for reporting the results of screening.

As a physician, I would not adopt a screening practice without seeking the results of the screen. In the same manner, it is important that the committee acknowledges the importance of including BOTH measure MUC – 136 and MUC – 134 in the measure set.

According to a recent study in JAMA, 24% of hospitals are already screening for all 5 SDoH domains (food, housing, transportation, utilities, and IPV) – and 92% of hospitals are screening for one or more of the 5 SDoH domains specified in the measures. These SDoH measures would be a powerful and timely way to bring the latter institutions along towards a more complete approach to addressing their patients' SDoH needs. In addition, reporting of screen positive rates (MUC21-134) enables informed investments of both public and private resources in communities to support unmet needs.

Finally, from a practice standpoint, I would want to be able to establish a baseline prevalence of positive screens for my patient population before being required to report on those referred to navigation. Having a phased approach to measure development allows for adequate data collection to inform subsequent measures, and also enables clinicians time for planning, e.g., will I need to bring on or train additional staff members to ensure adequate navigation support?

I endorse the MAP Workgroup's support for these SDoH measures for MIPS, and strongly encourage the Coordinating Committee to recommend both measures – MUC21-134 and MUC21-136 – for the HIQRP.

American Heart Association

While the type of information collected in this measure would be valuable, this measure may be more appropriate if also reported at system or regional level.

The AHA supports the intent and importance of this measure, but has concerns about the data capture that would be required for this measure as it may not be collected in a hospital's electronic health record and may put additional burden on hospitals to be able to capture this information.

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Carolina Complete Health Network/North Carolina Medical Society

As a cardiologist and board member of the North Carolina Medical Society, I'm writing in support of MAP MUC-134 and 136. I serve as the President and Chief Medical Officer of Carolina Complete Health Network. This corporation is a first in kind joint venture between a large national payor, Centene Corporation, and the North Carolina Medical Society. Other investors in the enterprise include the North Carolina Community Health Center Association and individual community health centers serving the most vulnerable patients of North Carolina. This venture partners joined together to identify and address the gaps in healthcare that exist across NC by having the payor and provider work together to eliminate barriers to whole person health.

As the only provider-led entity in Medicaid Transformation in North Carolina, we hope to utilize data around the social drivers of health to create better individual care management support. However, to truly close the gaps in care quality, we need to pool this information and partner with community, municipal and state leaders in a community-based approach. The MAP MUC 136 hospital measure would allow this to be possible.

During my testimony in front of the MAP Hospital workgroup on 12/15/21, I referenced a scenario of high-risk acute myocardial infarction complicated by cardiogenic shock bringing a patient into hospital care. The treatment algorithm for this acute condition branches based on the patient's social drivers of health: having resources will save your life. There is no time to change the support available for the patient. High impact decisions, such as moving toward emergent cardiac transplant or left ventricular assist device use, are made based on social resources available to the patient at the time of the emergency.

Outside of clinical criteria, the social drivers of care are the deciding factor in who receives these supports. The health disparities associated with these heroic interventions, transplant and cardiac assist devices, are designed inside the current system. The care will not change unless we are able to go upstream: to assess the disparities on a longitudinal basis and build and complete an investment map for equity.

This increase in resources prior to emergency decisions around lifesaving care would create a new capacity to turn the tide on health disparities. Patients would receive available treatments knowing that the appropriate social support exists in their hospital and surrounding communities. While I agree that the hospital reporting might need clarifying score system for consumers (ex: hospital is located in a community at high, moderate or low probability of meeting social needs), it should not paralyze us from taking the needed action. Other reported outcomes that are heavily driven by social factors, for example acute MI, are already being released. Hospitalized patient outcomes are steeped in the social health of the patients in their communities. Let us take the bold step of recognizing this linkage for a more equitable future in healthcare.

North Carolina Medical Society

As North Carolina's oldest professional organization, including nearly 12,000 members and a network of county medical societies and specialty societies across the state, we note the significance of the MAP's consideration of the first-ever SDOH measures and the only patient-level health equity measures this review cycle.

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NCMS's support for these measures is rooted in the recognition that the presence of SDOH fuels physician burnout, creates economic risk for physician practices under value-based payment models, and drives poor health outcomes for North Carolinians. This is especially so in COVID's wake: faced with the convergence of their patients' clinical and economic needs, front-line physicians and other health care providers have been taxed as never before.

With this context, we register our strong endorsement of the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision.

Further, NCMS further urges the MAP Coordinating Committee to support not only the SDOH screening measure, but also the SDOH screen positive rate measures for the IQR. Representing the perspective of front-line physicians in a diversity of urban and rural practice settings, we recognize that the MAP's endorsement of both these measures are crucial.

We and others would anticipate significant variability in the SDOH screen positive rate for practices (via MIPS) and hospitals (via IQR) depending on the community context and patient population – and also understand that the measure's value is in spurring physicians and institutions to collect and make visible this data visible.

This data would be invaluable in enabling public and private institutions to make strategic investments to strengthen community capacity to meet patients' health-related social needs, thereby alleviating the challenges faced by patients and the associated burden of these issues on physicians.
Indeed, our experience is that NC DHHS's requirement under Medicaid Transformation that all members be screened for food insecurity, housing instability, lack of transportation, and interpersonal violence has spurred crucial investments in the capacity necessary to address these issues. Specifically, this SDOH screening requirement spurred a public-private partnership to implement NCCARE360 – the first statewide, up to date, community resource database and closed loop referral platform, which is now live in all 100 of NC's counties – as well as investments in community health workers to support in connecting patients to community resources.

Finally, it would be deeply demoralizing for practicing physicians to engage their patients around these crucial issues, only to then not have their institutions make the results of this SDOH screening public – reinforcing physicians' longstanding concerns regarding measurement burden that does not translate to value for providers or their patients.

We view the proposed SDOH measures before the MAP as crucial to CMS recognizing the impact of these issues on patients and providers alike – and to laying the foundation to invest in those community resources necessary for health. We urge the MAP Coordinating Committee to evidence its commitment to addressing equity and to addressing the realities of patients' lives and their impact on physicians by recommending to CMS both MUC2021-134 and MUC2021-136 for MIPS and the IQR.

Boston Children's Hospital
Dr. Kathleen Conroy

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Public Statement on 2021 CMS Measures Under Consideration:
MUC21-134 and MUC21-136

As a practicing pediatrician and the Clinical Chief of Boston Children's Hospital's primary care center, with deep experience in implementing screening for social determinants of health, I offer my enthusiastic support for the decision of MAP Clinician Workgroup to support both MUC2021-134 and MUC2021-136. Further, I encourage the MAP Coordinating Committee to recommend both these measures for Hospital Inpatient Quality Reporting Program.

At my own practice, which serves 22,000 children, we have been formally and universally screening the adult caregivers of these children for SDOH for over a decade – along with many of our peer institutions across the country. Like many clinicians, we adopted this practice because of the overwhelming evidence that screening is both acceptable to families and helps facilitate connections to needed social resources, like housing programs or SNAP benefits, which themselves are associated with positive impacts on child and adult health and well-being. Just like screening for depression and anxiety, screening for and addressing social determinants of heath has become a standard part of our clinical program.

More recently, in 2018, the Massachusetts Medicaid program introduced two quality measures through its current 1115 waiver that are nearly identical to MUC21-134 and 136. Although we were already screening, the need to report the percent of our patients screening positive for various needs across our clinic and our entire ACO population allowed us to understand two things: (1) who in our population was most likely to have needs and how these needs are changing over time and (2) whether our systems of screening and response were unintentionally inequitable.

This knowledge has become the foundation for both disparities-focused quality improvement programs and also the impetus for the creation of new community partnerships to be better address needs of certain populations. For this reason, I would argue that both MUC21-134 and 136 are crucial.

To those who may be surprised that these measures do not require navigation to resources, I would offer that Massachusetts similarly did not initially require navigation to resources. This has allowed healthcare organizations the opportunity to build their response systems after initially understanding their families' needs, and it has allowed them time to build data systems to record the social needs responses delivered to families. In my clinic, for example, we recognized that we were under-documenting our work with families once needs were identified and have improved this in anticipation of needing to ultimately report our response to positive screens.

Likewise, it is important that these proposed initial social determinants of measures specify the five target social determinants of health domains (linked to the Accountable Health Communities model), but do not require the use of a specific screening tool, enabling providers to exercise flexibility in this regard.

Given my own extensive, on-the-ground experience functionally implementing these specific SDOH measures – and recognizing that it is untenable for our healthcare system to continue to defer collecting

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and reporting data on food insecurity, housing instability, and other social factors that drive up to 80% of health outcomes and associated costs – I strongly recommend that the Coordinating Committee recommend MUC21-134 and 136 to CMS for implementation in MIPS and the HIQRP.

Johnson & Johnson
Johnson & Johnson agrees with the recommendation of the Workgroup of conditional support. It is important to routinely screen patients for social drivers of health that may impact access to diagnostics, treatment, and supportive care services. We appreciate the flexibility the measure offers for screening approaches but support future standardization of tools to ensure that providers have clear guidance and best practices for identifying patients at risk. While clinician and practice-level screening is important, it will not capture patients whose social drivers prevent them from accessing care entirely. Transportation, health literacy, education, and living situation, among other factors, significantly impair individuals from accessing care in the first place. We therefore encourage CMS and NQF to think about measures at other levels of analysis (e.g., surveillance measures) to understand how these social drivers impact Medicare populations more broadly.

Humana, Inc.
January 13, 2022

National Quality Forum
Measure Application Partnership
1099 14th St. NW, Suite 500
Washington, DC 20005

RE: 2021-2022 Recommendations for Measures Under Consideration

To Whom It May Concern:

This letter is in response to the National Quality Forum's Measure Application Partnership (MAP) comment opportunity on the 2021-2022 Recommendations for Measures Under Consideration. Humana applauds CMS for including the first measures focused on the social drivers of health (SDOH) on the Measures Under Consideration list, MUC21-134 and MUC21-136. These SDOH measures directly address the Centers for Medicare and Medicaid Services (CMS) Meaningful Measures 2.0's stated measurement gap/priority focused on the "social and economic determinants."

Humana Inc., headquartered in Louisville, Kentucky, is a leading health care company that offers a wide range of insurance products and health and wellness services that incorporate an integrated approach to lifelong well-being. As one of the nation's top contractors for Medicare Advantage (MA) with approximately 4.4 million members and Medicare Prescription Drug Plans (PDPs) with approximately 3.9 million members, we are distinguished by our nearly 35-year, long-standing, comprehensive commitment to Medicare beneficiaries across the United States. These beneficiaries – a large proportion of whom depend upon the Medicare Advantage program as their safety net and many in underserved areas – receive integrated, coordinated, quality, and affordable care through our plans.

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MUC21-134 and MUC21-136

In COVID-19's wake, food insecurity, housing instability, and other SDOH have reached unprecedented levels and revealed massive racial disparities. Yet, despite the well-documented impact of SDOH on health outcomes and costs and their disproportionate impact on communities of color, there are still no SDOH measures in the Quality Payment Program (or other CMS quality and payment programs), which is only more significant in light of COVID and HHS/CMS's commitment to equity.

We recognize that of the 44 potential Medicare measures under consideration by CMS this cycle, only three are tagged to the domain of "equity," including these two measures. We also note the MAP Health Equity Advisory Group's positive assessment of these measures.

With this context, we write to endorse the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 for inclusion in the Merit-based Incentive Payment System (MIPS) and encourage the MAP Coordinating Committee to accept this decision. We believe this is a historic milestone for our healthcare system.

Humana further strongly urges the MAP Coordinating Committee to support both MUC21-134 and MUC21-136 for the Hospital Inpatient Quality Reporting Program (HIQRP). We believe it is important to include both measures because, together, they will make visible the impact of health-related social needs on patients.

MUC21-134 (the screen positive rate) is especially important in that it creates the opportunity to reveal and address disparities, both with respect to SDOH and their impact on health outcomes and costs. This anticipated variability in screen positive rates – including SDOH disproportionate impact on diverse communities and communities of color – would be important in enabling public and private institutions to direct investments in communities.

From Humana's perspective, we have long been committed to addressing the impact of health-related social needs on our members and addressing SDOH in communities across the country. In 2020 alone, we completed 6.2 million SDOH screenings; this data and the overall SDOH screen positive rates of our members, which we have made public, has been invaluable in enabling us to partner effectively with dozens of other organizations in addressing needs among our members and in communities, including appropriately targeting our investments to address these issues.

While we agree that taking action on the result of the screening is important – and is something Humana itself is committed to doing – we recognize that the objective of this first phase of federal SDOH measures is focused on collecting standardized SDOH baseline data to support a data-driven approach to addressing these health-related social needs and inform potential future measures. In this regard, we believe – and have learned through our experience at Humana – that we cannot allow the perfect to be the enemy of the good in tackling the SDOH, but instead must prioritize learning and improvement over time.

On this basis, we encourage the MAP Coordinating Committee to enable CMS's commitment to

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addressing equity by recommending MUC2021-134 and MUC2021-136 for MIPS and the HIQRP.

We value this opportunity to provide comments and are pleased to answer any questions you may have. We hope that you consider our comments as constructive feedback aimed at ensuring that we continue to advance our shared goals of improving the delivery of coverage and services to Medicare beneficiaries and addressing health disparities, focused on improving the total health care experience of all Medicare beneficiaries.

Sincerely,

J. Nwando Olayiwola, MD, MPH, FAAFP
Chief Health Equity Officer & Senior Vice President
Humana, Inc.

Andrew Renda, MD, MPH
VP | Bold Goal & Population Health Strategy
Humana, Inc.

American Medical Association

While the American Medical Association (AMA) supports the intent of this measure to begin to address the social drivers that can also impact an individual's health outcomes, we continue to have concerns that this process measure will not lead to improved patient outcomes in the absence of any resources or tools that would be widely and readily available to clinicians and practices. In addition, this measure does not appear to be completely specified or tested. It must be supported by evidence and should align with the work of the Health Level 7 Gravity Project and the United States Core Data for Interoperability (USCDI). Because we do not believe that this measure will result in effective change and should be fully specified and demonstrated to be evidence-based, reliable, and valid prior to MAP consideration, we request that the highest level of MAP recommendation be "Do Not Support With Potential For Mitigation."

American Society of Anesthesiologists

ASA supports the recommendation of the MAP for conditional support for rulemaking. Patients with poor access to food and/or transportation cannot access our healthcare system easily for basic services, let alone elective surgeries. A key component for implementation of this measure, as well as MUC21-134, would rest upon sharing information between the hospital, physicians, and other healthcare professionals. For anesthesia, having this information available provides insights into the patient's daily life and perhaps their overall health maintenance and self-care. Even the preanesthesia work-up on the day of surgery is an opportune time to gather patient information that would inform clinical decisions, including postoperative pain management, risk of surgical site infection, possibility of readmission, and discharge to an appropriate post-acute care or home setting.

MUC21-136 could encourage anesthesiologists and other specialists to spot opportunities to improve patient safety and outcomes, especially when encountering patients who may have an acute surgical event without prior contact with health care personnel. For example, the case of a homeless patient receiving care in an ambulatory surgery center is instructive since that patient's care may result in an

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increased likelihood of a surgical site infection. Knowing this piece of information may encourage anesthesiologists to work with their surgical and facility colleagues to create a system for ensuring that appropriate care coordination and follow-up is provided. Such actions would likely prevent readmissions or other poor outcomes. Those colleagues, or even facility administrators, could consult with social workers as soon as the patient is scheduled for surgery. For certain patients, the surgeon and anesthesiologist could even schedule the patient as an inpatient. Regardless, we see opportunities for the measure to encourage anesthesiologists to strengthen their partnership with their surgical and perioperative colleagues to improve the patient's health, outcomes, and wellbeing.

Blue Shield of California Foundation

Blue Shield of California Foundation strongly supports MUC21-136, Screening for Social Drivers of Health, and MUC21-134, Screen Positive Rate for Social Drivers of Health, and urges the MAP Coordinating Committee to support both measures for rulemaking and inclusion in both MIPS and the Hospital IQR.

Nearly 90 percent of hospitals and health systems across the country are already conducting Driver of Health (DoH) screening to identify patients' unmet social needs, according to one recent study, including via a number of CMMI models, but without the benefit of any formal quality measures, guidance, or tools from CMS.

As evidenced in the momentum for these measures across the health sector, it is imperative that we begin to implement DoH measures into federal payment programs, especially in the wake of the deep health inequities revealed by our response to COVID. With this context, we applaud the MAP for its thoughtful deliberations on MUC21-134 and MUC21-136, two of only three equity measures under consideration by the MAP and CMS this year.

In particular, we applaud the leadership of the MAP Clinician Workgroup in supporting both MUC21-134 and MUC21-136, and applaud the Hospital Workgroup in likewise supporting MUC21-136 – and encourage the MAP Coordinating Committee to endorse these decisions. We are troubled, however, by the MAP Hospital Workgroup's vote on MUC21-134: "do not support with potential for mitigation."

First, the NQF MAP summary of the Workgroup's recommendation states that the "measure has not been evaluated for reliability or validity." Yet NQF's own preliminary analysis cites documentation that the screening tools and items used in the testing process to generate the data for both measures have been psychometrically evaluated and demonstrated evidence of reliability and validity.

Second, the Hospital Workgroup "expressed concern that the positive rate may be challenging for consumers to interpret when publicly reported." Through the lens of a commitment to equity, we find it remarkable that the Workgroup has determined that consumers would be unable to exercise their own judgment in interpreting important data about the degree to which their fellow consumers are impacted by social drivers of health. We believe a hospital's reporting of the screen positive rate will be important to patients for a number of reasons, including: (1) providing transparency; (2) enabling the targeting of hospital and community investments based on the social needs shown by the data; (3) signifying the hospital's understanding of the social drivers of health among its patient population; and (4) providing data for targeting quality improvement activities, including highlighting and addressing disparities in the social drivers of health for patients.

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Finally, we recognize that the measures are focused on screening beneficiaries for drivers of health, and do not require an action plan. At the same time, we believe these measures represent an important starting point for collecting DoH baseline data in a standard way to then support a data-driven approach to addressing these social drivers. We note that CMS's own CPC+ model demonstrates clinicians' appetite to engage in this screening and act on these results, even when not required: 86 percent of Track 1 practices reported that they screened patients for health-related social needs (though not required to do so) and 93 percent of physicians in those practices reported that they acted on those screening results.

The introduction of these first DoH measures into core federal payment programs would be significant in its own right: making visible, when stratified by race and ethnicity, the social factors driving or inhibiting health, particularly for communities of color, including food insecurity, housing instability, transportation, utility needs, and interpersonal safety, including intimate partner violence. Only when these factors are brought to light and measured in a standardized way will we be able to align our collective resources and take action to achieve equitable health outcomes for all. To achieve this goal, we strongly encourage the MAP Coordinating Committee to recommend to CMS MUC2021-134 and MUC2021-136 for both MIPS and the IQR.

Health Care Without Harm
January 11, 2022

On behalf of Health Care Without Harm, which maintains a hospital member network of over 1,400 hospitals across the country, we strongly support the National Quality Forum Measure Applications Program (NQF MAP) working groups in recommending the following two Drivers of Health (DOH) measures under consideration:

MUC 2021-136; Driver of Health Screening Rate, and
MUC 2021-134; Driver of Health Screen Positive Rate

Health Care Without Harm is founded on the belief that: As the only sector with healing as its mission, health care has an opportunity, indeed a responsibility, to use its ethical, economic and political influence to create ecologically sustainable, equitable and healthy communities. Founded over 25 years ago, Health Care Without Harm seeks to transform health care worldwide so that it reduces its environmental footprint, becomes a community anchor for sustainability and a leader in the global movement for environmental health and justice. We conduct research, model strategic interventions and provide guidance and resources to spread and accelerate best practice in the field – with programs focused on climate and health, safer chemicals, and healthy food.

Health Care Without Harm has long recognized the impact that DOH have had on increasing rates of poor health outcomes, chronic disease and death. Climate change, the COVID-19 pandemic and increasing economic and social inequities in our communities that are the result of decades of systemic racism only serve to exacerbate the situation.

For example, some sobering statistics regarding diet-related diseases and how food insecurity is

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impacting our nation's health, published in The Washington Post (November 30, 2021) :

- More than 100 million Americans — nearly half of all adults — suffer from diabetes or prediabetes. About 122 million Americans have cardiovascular disease, which kills roughly 840,000 people each year.
- More Americans are sick or suffer from major medical conditions than are healthy, and much of this is related to diet-related illness.
- If you are a Black person, those numbers mean you probably will have an even worse outcome. 49.6 percent of Black adults are considered overweight if not obese. Black people are also 60 percent more likely to be diagnosed with diabetes than White people.
- Americans who suffer from diet-related conditions such as heart disease, diabetes, cancer, and obesity are 12 times as likely to die after a COVID infection.
- And in 2020, the year COVID-19 hit the United States, African Americans were disproportionately impacted by the virus, many due to those same underlying diseases of obesity and diabetes. In total, Black people experienced a 2.9 year decrease in life expectancy, causing the Black-White life expectancy gap to widen from 3.6 to 5 years. In a single year.

Statistics similarly alarming can be found regarding the health impacts of poor indoor air quality, air pollution, climate change, poor access to public transportation or living close to a freeway or port, housing instability, and exposure to toxic chemicals in the air, land and water. And they are disproportionately affecting under-resourced communities of color. The frightening question is, how big and bad do the numbers have to get? What is the final tipping point before the federal government will declare a state of public health emergency and prioritize addressing the DOH with a systemic strategy? A coordinated, aligned national standards measurement process to screen for DOH as part of basic primary health care is absolutely critical to moving forward, and these two measures are a positive start.

The Physicians Foundation, which is directed by 21 state and county medical societies across the country, submitted these first-ever measures focused on screening patients for food insecurity, housing instability, transportation, utility needs, and interpersonal safety, including intimate partner violence. Their adoption would represent a crucial milestone as the first standardized federal measures to assess social need in the history of the U.S. health care system.

Despite the well-documented impact of DOH on health outcomes and costs and their impact on people of color, there are still no approved, standardized DOH measures in any Centers for Medicare and Medicaid Services' (CMS) programs. The impact of DOH interventions remain fairly invisible in federal health care policymaking, and the absence of standard DOH data or measures impedes efforts to achieve racial equity in health outcomes, given their profound impact on people and communities of color, especially in COVID's wake.

In enacting these first federal DOH measures, CMS could send a powerful signal to the health care sector and the communities they serve that there should be acknowledgement of how DOH impact peoples' health outcomes and an intention to address them in a coordinated strategy across the country. These initial DOH measures for screening could lay the foundation for additional measures focused on navigating beneficiaries to resources and connecting beneficiaries to the resources they need to be healthy.

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We urge the Coordinating Committee to recommend both SDOH measures (screening and screen positive rate) for the HIQRP. Hospitals' reporting the screen positive rate would be important to patients by (1) providing transparency; (2) targeting community investments based on data they provided; (3) signifying hospitals' familiarity/expertise regarding these issues; and (4) enabling quality improvement activities, including addressing disparities. And by reporting the screen positive rate for food insecurity, hospitals would be well-positioned to take action, including (for example) engaging community partners to tackle these issues.

When addressing issues such as food insecurity, housing instability, climate change, lack of transportation, and exposure to toxics in our air, land and water, we cannot settle on solving for acute, short-term health impacts alone. We must devise long term solutions for these long term and entrenched challenges that require equitable investment and attention. Our collective environmental and economic health need to be prioritized, with regenerative systems that are protective of our environmental health and natural resources, and substantial investment in fair labor practices and living wage mandates.

It is our hope that CMS will do the right thing and approve these measures, creating a federal, standardized system to incorporate DOH factors into primary health care and begin to set the stage for long term effective intervention.

Signed by:

Gary Cohen
President, Health Care Without Harm & Practice Greenhealth
www.noharm.org

Cambridge Health Alliance

As a family medicine physician practicing at the Cambridge Health Alliance in Cambridge, Massachusetts, I applaud CMS for considering the first measures specifically focused on the social drivers of health (MUC2021-134 and MUC2021-136) and the NQF MAP for its consideration of these measures. These measures are particularly significant given that of all the potential Medicare measures under consideration by CMS this cycle, these are the only patient-level health equity or DOH measures. For the past decade, I have been deeply involved in efforts by CHA and other health systems and community health centers in MA to screen patients for the social drivers of health. I have extensive experience implementing SDOH screening and navigation protocols at scale and have published on the resulting findings.

It is clear that food insecurity, for example, is not just a social factor, but a clinical co-morbidity that impacts quality care and drives health disparities.

Given COVID, SDOH screening has become only more critical to support our patients and to mitigate the frustration and burnout among primary care providers. Yet, we now do so without the benefit of any SDOH measures in any federal payment program, including MIPS. It is untenable for our federal payment programs to continue to exclude those factors that we know drive 80% of health outcomes in our patient populations.

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At CHA, my colleagues and I have screened thousands of patients in over a dozen primary care sites across our healthcare system; in doing so, we found that nearly 30% of our patients screen positive for food insecurity.

Had we not collected and share this data, we could not have developed effective strategies and community partnerships to address these challenges with our patients. In particular, this crucial data about our patient population – exactly the kind of foundational data that these SDOH measures will provide – then allowed us to design an electronic active referral to a community-based organization.

One question that has come up is whether these measures will, hypothetically, incentivize providers to treat fewer patients with social needs or to move way and care wealthier patients. But from the perspective of a physician who – like thousands of others across the country – is committed to serving patient populations that often face these challenges, these first-ever federal SDOH measures are essential to recognize practices (like mine) that are tackling these issues.

With this, I enthusiastically support the MAP Clinician Workgroup's decision to recommend both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision.

I further strongly urge the MAP Coordinating Committee to support the SDOH screening and the screen positive rate measures for the IQR, recognizing that both these measures are crucial. The latter measure is especially important to practicing physicians and to our patients, given the imperative of transparency in reporting and the opportunity for such data to enable quality improvement activities, including addressing disparities, as we have done at CHA.

Hogg Foundation for Mental Health

This is an important measure to consider to finally start including the impact of the social determinants in the ambulatory setting. The data generated will provide greater understanding and lead to more informed interventions by the clinical team and for social interventions. Extremely important for interdisciplinary team-based care. The benefits do outweigh the cost of data collection, especially when one considers this measures potential to track and monitor the quality of holistic health care outcomes. The challenge will be for all providers and team members to include and utilize this measure appropriately.

The Physicians Foundation

In submitting these comments, the Physicians Foundation does so not only as the measure developer for MUC2021-134 and MUC2021-134, but also an organization that takes its the direction of physicians from 21 state and county medical societies across the country.

In particular, we offer these comments from the perspective of practicing primary care physicians and specialists across the country. Every day, we encounter patients in our practices who show the physical toll of skipping meals to feed their children. Who have made impossible tradeoffs between refilling their heart medicine or buying food. Who carry the stress of spending weeks trying – and failing – to find a job, as bills pile up and they fear losing their home, as the rent or mortgage goes unpaid.

As our patients struggle to manage these risks in their day-to-day lives, we physicians bear the economic and psychic risk associated with these unaddressed social drivers of health. It is well-documented that these factors lead to physician burnout and effectively penalize physicians caring for affected patients via lower MIPS scores. A recent study in JAMA found that SDOH were associated with 37.7% of variation

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in price-adjusted Medicare per beneficiary spending between counties in the highest and lowest quintiles of spending in 2017. Yet even with an ongoing pandemic that has painfully brought these issues to the fore, SDOH are still not accounted for in geographic risk-adjustment or cost benchmarks.

We put forward these two first-ever SDOH measures (and the only patient-level equity measures this review cycle) because it is untenable – to patients and their physicians – for these challenges to be much-discussed in articles, speeches, and white papers, yet functionally invisible in our healthcare system's quality and payment frameworks.

We must start somewhere, and we must start now. Via CMS's own Accountable Health Communities model, the proposed SDOH screening measures – MUC21-134 and MUC21-136 – have been tested at scale over five years with 1M+ beneficiaries in over 600 clinical sites – with 40% of the screenings in hospital inpatient or ED settings and 54% in primary care practices. As documented in the AHC evaluation, these measures reliably identify: (1) beneficiaries with 1+ health-related social needs; (2) high cost/high use beneficiaries; and (3) racial/ethnic disparities.
Further, as well-documented in the NQF MAP's preliminary analysis, the screening tools and items used in the testing process to generate the data for both measures have been psychometrically evaluated and demonstrated evidence of both reliability and validity, including inter-rater reliability and concurrent and predictive validity (see sample citation below).

We appreciate the MAP's thoughtful and deliberate consideration of MUC21-134 and 136 and note the support for these measures across the Health Equity and Rural Health, Advisory Groups and Clinician Workgroup – and we strongly urge the Coordinating Committee to recognize this by accepting the recommendations of the Clinician Workgroup with respect to MIPS. It is especially important that those clinical practices that wish to collect and report on these SDOH measures have these important efforts recognized through the MIPS program.

We also urge the Coordinating Committee to accept the Hospital Workgroup's recommendation to offer conditional support to MUC21-134. We likewise recognize that Workgroup's questions regarding how CMS and consumers could or should interpret the screen positive rate results required by MUC21-136.

As CMS itself made clear in this discussion, hospitals would satisfy the performance threshold by reporting the screening rate and screen positive rate to CMS for patients who are 18 years or older at the time of admission. Performance is not determined based on the result of the screen positive rate; there is no requirement to demonstrate a rate reduction over time. Variability in this rate would, of course, depend on the institution's community context and patient population.
Hospitals' reporting of the SDOH screen positive rate is valuable to consumers for a number of reasons, including (1) providing transparency of data the institution has collected from those and other consumers who received care at the institution; (2) enabling public and private institutions – including the hospitals themselves – to target community investments based on data consumers provided; (3) allowing consumers to identify which hospitals have familiarity with and expertise in addressing these issues; and (4) enabling quality improvement activities, including making visible variation in health outcomes and costs potentially attributable to the prevalence of these underlying drivers of health and addressing disparities.

We agree that it is important to bridge patients who screen positive for health-related social needs to

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community navigation services and/or ensure there is an individualized action plan in place for these needs to be addressed. However, physicians are well aware that this is complex and resource-intensive work, which is dependent on the quality of the community resource landscape where their practices and/or health systems are located and their patients live. Hence, the objective of this first phase is focused on collecting DOH baseline data in a standard way to then support a data-driven approach to addressing these health-related social needs, including potential future measures focused on success in navigating patients to the resources they need to be healthy. To establish an SDOH navigation measure in the absence of practices and hospitals reporting baseline SDOH screening data is inadvisable.

Moreover, it must also be stressed that the validation of any screening tool used to collect data supporting a measure must include the result of the screen. Should the Coordinating Committee recommend the screening rate measure but reject the screen positive rate measure, it will impair the ability of CMS, the measure steward, and program participants to conduct additional validation of the screening rate measure post-implementation and over time.

We expect, and hope that, over time, these SDOH measures can and will be improved – and additional associated measures developed – with the benefit of the input of physicians, other healthcare providers, and health systems across the country and the data generated by these measures.

We also recognize, however, that given the profound challenges that COVID has wreaked on patients, physicians, and our healthcare system writ large – and the commitment to equity and the reduction in health disparities that CMS and healthcare institutions across the country have declared – that time is of the essence in enacting these first-ever SDOH measures (and the only patient-level equity or SDOH measures under review this cycle). We therefore strongly urge that the Coordinating Committee recommend to CMS MUC21-134 and MUC21-136 for both MIPS and the IQR.

Citation: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7652127/

Association of American Medical Colleges (AAMC)

The Clinician MAP Workgroup conditionally supported the Screening for Social Drivers of Health measure (MUC2021-136) for the Merit-based Incentive Payment System (MIPS), pending testing of the measure's reliability and validity in addition to NQF endorsement. The measure assesses the rate at which hospitals screen their adult patients for food insecurity, housing instability, transportation problems, utility needs, and interpersonal safety. The AAMC agrees with the MAP's recommendation. The AAMC fully supports efforts to screen patients for their health-related social needs and agrees that a quality measure consistent with guidelines could help improve and standardize screenings. That said, we believe this measure should be NQF endorsed prior to rulemaking to ensure that the measure is valid and reliable. The AAMC also believes greater clarity is needed regarding the denominator for this measure, and whether it would require a patient to be screened at certain intervals or at every interaction with every clinician regardless of how frequent. One suggestion is that the measure developers consider including a reasonable interval for screening - potentially every six months, if supported by the literature. Furthermore, we believe further study is needed regarding patient trust in sharing sensitive health-related social needs information with clinicians. Relatedly, whether it is appropriate to encourage all clinicians, regardless of specialty, to screen all of their patients through adoption of a quality measure without evidence that screening by all clinicians will be welcomed by the patients they treat. This is especially true when there are still structural challenges with translating the

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social needs information into actionable interventions for patients. We believe the NQF endorsement process is vital to ensuring this measure is appropriate for use in MIPS.

Kaiser Permanente (retired); NASEM Roundtable on Population Health (co-chair); Secretary, Board of Directors, CDC Foundation; Trustee, Blue Shield of CA Foundation

We know that racial inequities in health outcomes persist because remedies often focus only on reducing disparities in clinical care and not on the drivers of health. Some have suggested it is not feasible to do this at scale in the clinical setting. Two decades of work by Kaiser Permanente has demonstrated that this is not only feasible and effective, but embraced by clinicians and patients when the right tools and processes are put in place. Kaiser Permanente built its SDOH screening and followup on a clinical prevention platform that had already included, for example, screening for tobacco use, physical activity and domestic violence. As Kaiser Permanente's extensive community health investments deepened its understanding of how factors like food and housing security and personal safety shaped the health of individuals and entire communities, the system introduced more formal screening, referral and community partnerships to realize the full potential of identifying and addressing SDOH.

Now, many healthcare delivery systems across the country have committed to screen and address their patients' social needs – but are doing so without the benefit of any SDOH measures in any federal payment model, including Medicare or Medicaid. Indeed, a recent study in JAMA found that 24% of hospitals are already screening for all 5 SDOH domains (food, housing, transportation, utilities, and interpersonal safety) and 92% are screening for one or more of the 5 SDOH domains specified in the measures. At the same, a 2020 study conducted at Kaiser Permanente found that patients were in favor of health systems asking about social needs (85%) and helping to address those needs (88%).

With this context, I write to offer my support for the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision.

I further urge the MAP Coordinating Committee to support both MUC21-134 and MUC21-136 for the Hospital IQR, recognizing that, together, these measures reveal the impact of health-related social needs on patients and the opportunities to realign resources to invest where they are needed most.

It is important to note that both the SDOH measures under review today are critical to make visible the impact of these issues on the lives of patients and the disparities they spur. Given the disproportionate impact of SDOH on people of color, equity requires us to recognize providers for screening their patients and reporting the screen positive rate, to elucidate racial/ethnic disparities in DOH that, in turn, fuel disparities in health outcomes.

One key lesson we've learned in this work over the past twenty years is that we cannot allow the perfect to be the enemy of the good. The MAP Coordinating Committee has a crucial opportunity to support moving the first-ever SDOH measures into practice to enable learning and improvement over time. The data collected and learning from these foundational SDOH measures will be critical to improve the measures over time and to be thoughtful in developing the next set of measures focused on ensuring patients get the resources they need.

Finally, we are cognizant that there only 3 measures tagged to the domain of "equity" and these are the only patient-level SDOH measures or equity measures under review, making it all the more imperative that the MAP Coordinating Committee recommend them. In the wake of COVID, it is simply

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unacceptable to go yet another year without any federal payment program measures that recognize the profound impact of SDOH on the lives of our patients.

Citation: https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2751390
https://pubmed.ncbi.nlm.nih.gov/31898132/

Camden Coalition of Healthcare Providers

How would adding this measure add value? How would the measure improve patient outcomes?

Mandating the two process measures may lead to wider adoption of social needs screening in healthcare settings. While screening itself does not imply practices will have the resources to respond effectively to the social needs identified, it at least establishes a foundation for building processes within practices and the community to address health-related social needs. Collecting structured data on social determinants could bolster efforts to understand and address equity issues in the healthcare system, improve segmentation efforts, and may be a springboard for measuring the capacity of healthcare providers to respond to social needs, and identifying where gaps between social needs and resource availability in the community exist.

Do the benefits of the measure outweigh the burden of data collection or reporting?

The benefits of the measure will not necessarily outweigh the burden of data collection or reporting. This will depend on many practice-level factors, such as the ability to develop efficient screening workflows, the availability of staff who are trained and well-prepared to engage patients with complex social needs (especially around sensitive needs such as those related to interpersonal safety), the smooth integration of screening data into a practice's existing data systems, and the ease with which the data can be made available to clinicians at the point-of-care. Moreover, the interpersonal safety questions are proprietary, and from a practice's perspective, it may not be worth the cost of including those questions in their screener, especially if there are inadequate resources available to address any interpersonal safety issues a person is experiencing. We would recommend offering alternative questions related to interpersonal safety for practices who do not want to pay to use the four questions currently included in the AHC screener. Finally, with reimbursement, benefits may outweigh burden as long as practices are given flexibility in how social needs screening takes place and the reporting requirements are not cumbersome.

For what purpose are you using the measure (e.g., QI, certification/recognition, regulatory/accreditation, payment, public reporting, disease surveillance)?

The Camden Coalition is an Accountable Health Communities alignment track hub. The social needs screening data we collect are used for multiple purposes locally and regionally. For example, we share the data with health systems and other community partners for community health needs assessments and gaps analysis; we leverage the data to procure funding for various population health initiatives; we make the data available through our Health Information Exchange to inform clinical decision-making; and we share the data with researchers who study the intersection of social risk and health.

Are there implementation challenges?

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Challenges include incorporating the screening tool into practice workflows, throughput, cost, potential need for extra staffing, and storing and accessing the data. If the screener is self-administered, challenges related to staffing might be reduced, but there are other challenges that need to be considered. An efficient workflow still needs to be established - for example, determining when during a visit a patient will receive the screener and who on staff will be responsible for introducing the screener to the patient. Language and literacy barriers present challenges as well and may require additional time and support from staff. Additionally, if a practice is doing more than collecting data and is going to establish workflows to respond to social needs, there are coordination costs associated with addressing those needs. There would need to be people on staff who can have the kinds of conversations that must take place when a patient expresses a social need. This may mean hiring a social worker, for example, or taking on the cost of training existing staff members.

Carolina Complete Health

The COVID-19 pandemic and other recent events have exposed long-standing racial and economic injustices embedded in many American systems, including our health care system. Fortunately, the recent attention has either generated or renewed for many a commitment to improve health equity and address the social drivers of health (SDOH) that may account for up to 80 percent of health outcomes and have a demonstrably disproportionate impact on communities of color. Those drivers include stable, affordable housing; access to healthy food; availability of reliable income; and interpersonal safety, among others.

Because of the well-documented impact of these factors on health outcomes and costs, plus the disparate impact on people of color, we need standardized SDOH measures in Centers for Medicare and Medicaid Services (CMS) programs. Including such measures will assist CMS in realizing its pledge to collect more robust DOH data, move the needle on health equity, and address its stated measurement gap to “develop and implement measures that reflect social and economic determinants.”

Physicians and other healthcare providers have called on CMS to create standard patient-level SDOH measures – going beyond just socioeconomic status and duals status – recognizing these factors can drive physician burnout and impact providers caring for affected patients via increased financial risk through lower MIPS scores. The recent actions of the MAP groups to codify specific measures that will help to both identify and drive needed support for improvements in this vital area are appreciated. I continue to pledge my support for the MUC 134 and 136 measures before you.

The work of several CMS Innovation Center models like Accountable Health Communities, Comprehensive Primary Care Plus and others has demonstrated that screening for and acting upon these drivers of health is impactful for millions of Medicare and Medicaid beneficiaries, both in inpatient and outpatient settings. However, because this work has been done without the availability of standard SDOH measures or screening tools, CMS cannot systematically compare or use that wealth of data in a reliable fashion. The promise shown by these innovative efforts should not be minimized given the immense opportunity we have to improve overall outcomes and have meaningful impact on disparities amongst us. It should be encouraging to all that these proposed measures have been effectively implemented in AHC over 5 years now and across >1M CMS beneficiaries in 600 clinical sites and multiple practice settings across the country. It also should be reassuring that the AHC screening tool

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has been objectively shown to be reliable with concurrent and predictive validity.

The ideal convention would be use of the Social Driver of Health Screen Rate measure and the SDOH Screen Positive Rate measure in tandem. Given the disproportionate impact of SDOH on people of color, these measures account for actual screening that occurs but also recognizes providers for reporting the screen positive rate for their patients. Given the variability in the prevalence of SDOH across geographies and patient populations – as well as in clinical sites' capacity to provide patient navigation – the suggested approach for introducing such measures into the federal quality frameworks is critical.

While it is understandable that some entities may perceive being negatively and/or inappropriately burdened by sharing such data publicly, representing circumstances not fully under the entity's control, the reality is that many physicians and other health care entities serving in underserved settings have had to be compared against more ideally situated colleagues with the same quality measures despite caring for individuals who bore these often recognized but rarely addressed barriers to optimal outcomes. I experienced that directly in pediatric practice in East Winston-Salem, NC and in SE Wahsington, DC. So I strongly believe that implementation of these measures can increase the capacity of our systems to recognize needs, foster innovative support and more efficiently utilize available resources. Screening without sharing the results for action portends a risk that some might turn a blind eye and that others might just choose to move to more favorable settings. Allowing a true and transparent assessment of the populations served, the resources given and the actions that may be undertaken, gives us more global and reliable opportunities to truly shed light on and reverse the impacts of social inequities, deprived communities and even systemic racism. It is on this basis that I submit these public comments.

Respectfully Submitted on January 13, 2022,

William W. Lawrence Jr. MD, FAAP

Huntersville, NC

Unite Us/NowPow, a wholly owned subsidiary of Unite Us

Overall, Unite Us supports including measures 134 and 136 in MIPS, hospital IRQ and other value-based payment programs if the proposed measure has been tested and meets NQF or CMS MERIT-based payment or other measure quality standards. We are pleased to see that the Measure Applications Partnership (MAP) Clinician and Hospital Workgroups conditionally approved both measures for MIPs and 136 for IQR. We recommend that the MAP Workgroups also approve measure 134 for IQR.

We understand that a barrier to approval of measure 134 by the Hospital Workgroup was the concern of some members that public disclosure of rates of food insecurity and other health-related social and economic needs could negatively impact a hospital's business. Importantly, thousands of hospitals already publicly reporting these kinds of data through their Community Health Needs Assessments. These assessments commonly include rates of health-related socioeconomic conditions including food

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insecurity, unemployment, housing instability, transportation needs and poverty. Given the ubiquity of these conditions, it is unlikely that members of the public could or would meaningfully use publicly reported data on prevalent health-related socioeconomic conditions to decide whether or not to elect care at a given hospital or medical center.

In addition, hospitals play a critical role as both anchor institutions and data engines for communities. Public sharing of data about socioeconomic needs of people living in the primary service area enables data-driven community investments by hospitals and others and offers the opportunity to evaluate the impact of community investments on outcomes of shared importance to healthcare and community leaders. Transparently sharing social needs data empowers leaders to confront hard facts, develop targeted solutions to address unmet needs, and forge partnerships between healthcare, communities, philanthropy and government to improve health and well being.

We also note the measure does not require follow-up after needs have been identified. We recommend the creation of additional measures in the future that evaluate whether services to address social needs are provided in a timely manner. Assessing needs without addressing them will not improve quality.

Despite these concerns, we believe the measure is a positive first step towards considering and tracking social drivers of health. Including these measures will encourage clinicians and staff to screen and track social drivers of health.

Wholesome Wave on behalf of the National Produce Prescription Collaborative

National Produce Prescription Collaborative
January 13, 2022
To: Members of the NQF: Measure Applications Partnership
From: Members of the National Produce Prescription Collaborative (NPPC)
RE: Support for Driver of Health Screening Rate (MUC2021-136) and Driver of Health Screen Positive Rate (MUC2021-134)

As members of the National Produce Prescription Collaborative (NPPC), we are pleased to write additional comments in support of the Drivers of Health Measures currently being considered under the Measure Applications Partnership Considerations. We were thrilled that CMS accepted the “Drivers of Health Screening Rate” and the “Drivers of Health Screening Positive” measures as part of the 2021 CMS MUC list.

We greatly appreciated the MAP Workgroup’s strong support for the SDOH measures for MIPS. We ask that as the map process enters its final Coordinating Committee review on January 19, that the Coordinating Committee additional recommend both SDOH measures (screening and screen positive rate) for the HIQRP. Recognizing the nexus between hunger, nutrition insecurity and the structural inequities at the heart of these issues, Members of NPPC support screening for drivers of health, including food insecurity and believe the adoption of these measures would add tremendous value and represent a crucial milestone on the path towards health equity.

We appreciate that there is a current opportunity to enact the first-ever social DoH measures in the history of health reform. CMS recently included the DoH measures focused on screening patients for food insecurity, housing instability, transportation, utility needs, and interpersonal safety in its

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"measures under consideration" list. These measures (stratified by race/ethnicity) are well-tested in over 600 clinical sites across the country through the CMS Innovation Center's Accountable Health Communities model. Adoption of these measures will go a long way to identify gaps in patient care and health outcomes that extend beyond the four walls of a health clinic and, with strengthened community-clinical connections, curb the growing national cost burden of diet-related disease through our federal health programs.

Hospitals' reporting the screen positive rate would be important to patients by (1) providing transparency; (2) targeting community investments based on data they provided; (3) signifying hospitals' familiarity/expertise regarding these issues; and (4) enabling quality improvement activities, including addressing disparities. As you know, diseases linked to poor diet are the most frequent causes of death in the United States, and diet is the leading risk factor for premature death worldwide. Reducing even a fraction of this burden by improving people's diets would save countless lives. The COVID-19 pandemic has brought renewed focus to gaps in access and infrastructure that limit the ability of our federal health care and food assistance programs to address the issues of nutrition, food insecurity, and health. COVID-19 has also exposed the long-standing burden of diet-related chronic disease. Unfortunately, these diet- related diseases disproportionately affect low-income households, racial and ethnic minorities, and elderly people, highlighting the wounds of systemic racism and disparities in the US economy, food systems and healthcare systems.

While a growing number of CMS Innovation Center models are incorporating DoH screening and navigation on social needs, they use varied tools and approaches. As a result, CMS cannot systematically compare or use the data. The same is true for race and ethnicity data, which currently are measured or reported inconsistently across CMS programs. NPPC members and partners are developing and deploying programs and platforms and are seeking robust research capacity to support community-rooted health organizations in their efforts to address the lack of affordability and access to healthy food across the country.

Applying these measures to both the merit-based Incentive Payment System and the Hospital Inpatient Quality Reporting Program — would go a long way to improve patient outcomes. At the same time, it would provide a crucial foundation for comparable measures to be adopted by the Medicaid Adult and Child Core Measure Set while providing critical guidance for states in their efforts to standardize DoH data. Furthermore, by reporting the screen positive rate for food insecurity, hospitals would be well-positioned to take action, including (for example) implementing produce prescription programs, which are demonstrating their value by improving the health outcomes of people struggling with diet-related diseases such as diabetes, high blood pressure, and kidney disease by increasing dietary quality and treating the stresses of food insecurity.

Evidence of Produce Prescription Programs
The Produce Prescription intervention began just over a decade ago. Today, more than 100 organizations administer them across the country.

A growing body of evidence, including 30 studies in peer-reviewed scientific and economic journals in the past 5 years, suggests that Produce Prescriptions improve intake of fruits and vegetables, improve overall dietary quality, reduce the gap between actual daily consumption and the national

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recommendations, lower weight, lower blood pressure, and lower Hemoglobin A1C — the biometric indicator used in diagnosing for diabetes and prediabetes.

Due to early promising results, Medicare Advantage plans have implemented Produce Prescriptions alongside other food and produce through the allotment for Special Supplemental Benefits for the Chronically Ill (SSBCI). From year one (2020) to year two (2021) plans offering these food and produce benefits have grown from 101 to 347, a 244% Medicaid managed care plans in several states have also implemented Produce Prescription programs through various flexibilities allowed using 1115 waivers.

Having DOH measures available to screen for food insecurity will help these government-sponsored health plan practitioners deliver on the growing promise of food as medicine. For example: In North Carolina, Reinvestment Partners and Blue Cross NC are launching an RCT that compares Produce Prescriptions and healthy food boxes for 6- or 12-month enrollment periods. Reinvestment Partners is also participating in an evaluation as part of Healthy Opportunity Pilots (under North Carolina's 1115 waiver). NC programs beneficiaries must have at least one qualifying physical or behavioral health condition and have one qualifying social risk factor. Of interest, partnering with insurers and providers, including 2 major health systems (Duke Health and Atrium Health, the state's largest provider network); 9 Federally Qualified Health Centers; 30+ county level WIC, DSS Offices, and health departments; and 100+ staff at a statewide care management agency (Community Care of North Carolina). The breadth of this program expansion is a demonstration that effective collaboration is possible in diverse healthcare settings and early research is showing promising impacts on food insecurity.

Likewise, Wholesome Wave's Fruit and Vegetable Prescription Program® (FVRx®), which ran in 12 states across the country, reached thousands of individuals who struggle with diet-related illness. FVRx reached 2300+ recipients in a 2016 Los Angeles pilot and was expanded to communities and health centers in Houston and Miami, Hartford and Sacramento and has helped more than 5,000 people. In the pilot, 93% of participants met produce-consumption guidelines by the program's conclusion, with a 128% increase in the number of cups of fruits and vegetables consumed. Among people at high risk of developing diabetes, those taking metformin lowered their risk of getting diabetes by 31% compared with those taking a placebo, while those who modified their diet and exercised regularly lowered their risk by 58% compared with those who didn't change their behaviors, a near doubling in risk reduction.

Additionally, the Washington State Department of Health has partnered with twelve health care systems and public health agencies and a large grocery chain to redeem over a million dollars in produce prescriptions from 2016 through 2020.

Having a Drivers of Health Screening Rate (MUC2021-136) that screens for food insecurity will provide vital insights to addressing nutrition insecurity for qualified patients enrolled in Medicare, and help determine who will benefit from the intervention. This will be a vital step to adoption of Produce Prescription interventions within the healthcare system. The members of the National Produce Prescription Collaborative recommend including these measures among those the MAC moves forward for consideration.

About NPPC
The National Produce Prescription Collaborative (NPPC) is a group of produce prescription practitioners, researchers, and advocates, who gathered in 2019 to catalyze the vital role of food and nutrition in

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improving health and wellness by collectively leveraging the unique opportunities for Produce Prescriptions to achieve wellness by embedding and institutionalizing Produce Prescriptions within healthcare practice. Our respective organizations are actively working to bring new and innovative Produce Prescription models to communities across the country.

NPPC defines a Produce Prescription program as a medical treatment or preventative service for patients who are eligible due to a diet-related health risk or condition, food insecurity or other documented challenges in access to nutritious foods, and who are referred by a healthcare provider or health insurance plan. These prescriptions are fulfilled through food retail and enable patients to access healthy produce with no added fats, sugars, or salt, at low or no cost to the patient. When appropriately dosed, Produce Prescription programs are designed to improve healthcare outcomes, optimize medical spending, and increase patient engagement and satisfaction.

200 Massachusetts Ave NW, Suite 700 Washington, DC 20001

AHIP

On behalf of AHIP, thank you for the opportunity to comment on this measure. AHIP agree with the initial recommendation to conditionally support the Screening for Social Drivers of Health measure for both IQR and MIPS. AHIP believes that performance measurement is an underutilized tool to address healthcare disparities and supports the advancement of measure of health equity. Given the impact of social determinants of health on a person's health outcomes, screening for social risk factors in an important first step in promoting health equity and eliminating health disparities. We agree that screening for health needs can help providers connect patients to social services.

We suggest that CMS work with the measure steward to refine this measure to include specific screening tools or provide implementation guidance on which screening tools should be used to promote consistency in screening for social determinants across the healthcare sector. Additionally, we recommend that CMS and the measure steward work to ensure alignment with accepted data standards for SDOH. We would recommend that CMS and the measure steward look to the work of the Gravity Project to identify data standards. Ensuring consistency in the screening tools used and utilizing the work of the Gravity Project would align with work health care providers, electronic medical records companies, RHIOs, health insurance providers and government agencies are doing to address SDOH and could promote measure alignment across public and private payers.

University of Chicago, Section of General Internal Medicine

1. How would adding this measure add value? How would the measure improve patient outcomes?

As the National Program Office team at the University of Chicago we work with eight grantee organizations from the Merck Foundation funded Bridging the Gap: Reducing Disparities in Diabetes Care initiative. These organizations are transforming primary care through integrated medical and social care to improve diabetes care and outcomes. We have a national lens on integrated medical and social care activities to support chronic disease care. The initiative transforms primary care through the implementation of integrated strategies to address SDOH, with evolving payment models to support these transformations.

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The measures (MUC2021-134 (Screen Positive Rate for Social Drivers of Health) and MUC2021- 134 (Screening for Social Drivers of Health)) add value by providing an opportunity to change how and what we measure in health care. The opportunity to measure drivers of health (DoH) allows health care teams to have data to identify and address unmet needs and policymakers and payers to account for DoH in health care delivery and financing models. For example, grantees in the Bridging the Gap: Reducing Disparities in Diabetes Care initiative have utilized DoH screening at two levels: to understand individual patient needs and to assess the needs across their population. Health care teams have utilized screening to assist with resource allocation and to tailor care for individual patients. At the population level, grantees have harnessed this high-level to better inform the support services needed and to establish critical cross-sector partnerships.

These measures have the potential to improve patient outcomes by establishing approved, standardized DoH measures in Centers for Medicare and Medicaid Services' (CMS) programs. Standardized collection of DoH measures would allow CMS to systematically compare or use the data. DoH measures can provide insight into the social factors that facilitate or constrain optimal health, particularly for vulnerable populations (e.g., older adults, communities of color). Assessing these factors in a standardized way is an important first step towards improving equitable health outcomes.

2. Do the benefits of the measure outweigh the burden of data collection or reporting?

The benefits of these DoH measures outweigh the burden of data collection or reporting. These measures are well tested, including through the Accountable Health Communities model, which screened nearly a million beneficiaries for SDOH in over 600 clinical practices.

3. For what purpose are you using the measure (e.g., QI, certification/recognition,regulatory/accreditation, payment, public reporting, disease surveillance)?

The National Program Office at the University of Chicago has utilized positive DoH screening results to better understand the scope of social needs amongst the study population within our initiative, especially among medically high-risk populations. Grantees within the initiative utilize different screening tools and the standardization of DoH screening data has proved to be an area of difficulty in the evaluation process.

4. Are there implementation challenges?

To address implementation challenges it is imperative to plan for documentation of these measures during data collection and options for data extraction. Technical assistance may be needed to support best practices for data collection workflows and data extraction. In addition, providers in the Bridging the Gap: Reducing Disparities in Diabetes Care initiative have highlighted that screening for DoH should not be conducted without an appropriate pathway to address the needs screened for. As part of the implementation of screening for DoH, CMS and its partners should consider developing technical assistance to ensure best practices for DoH referrals.

OCHIN, Inc.

These measures are essential to identify and remedy persistent structural inequality that adversely impacts patient outcomes—and this is equally true whether patients are receiving care in ambulatory or in-patient settings. These measures create incentives for the clinical team to identify structural barriers

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to improved health care and associated social and other services that could facilitate improved patient health status, including improved access to care.

Clinicians and providers cannot address social determinants of health if this information is not collected and acted upon. Our nation's health care delivery models must embed incentives—such as quality measures--to improve care for patients facing the greatest barriers to health care and other structural inequities. The need does not change based on site of care since the patient faces the same social risks.

OCHIN is a nonprofit health information technology innovation and research network that serves over 1,000 community health care sites with 21,000 providers in 47 states serving nearly 6 million patients. The OCHIN network provides a continuous learning health system collaborative and offers technology solutions, informatics, evidence-based research, and policy insights. For two decades, OCHIN has advanced equitable health care solutions by leveraging the strength of our network's unique data set and the practical experience of our members to drive technology innovation at scale for patients and providers in underserved communities. To that end, OCHIN network members have documented over 1 million individual patient screenings for SDOH. The screening, evaluation, and use of this information is complex, challenging, and hinges on preserving patient trust. This is a resource intensive process that requires adequate time, workflow design, patient engagement, and staff and clinician training. The benefits of the measures outweigh the burden of data collection and reporting where flexibility is provided to optimize workflow and staffing needed to collect the information with the goal of reducing cognitive burden and enhancing team-based approaches to care while preserving and safeguarding patient-clinician relationship and privacy.

These measures are needed for quality improvement activities, payment, research, and public health activities including disease surveillance and mitigation measures in order to address health care inequity. In light of the USCDI adoption of SDOH domains and elements, the suitability of this information can inform numerous clinical, public health, and policy needs to improve care overall equitably. Adding information on social complexity to payment discussions could provide valuable insight for value-based payment and care arrangements and risk-bearing contracts.

We offered in our initial round of comments, as we do here, conditional support for these measures. OCHIN recommends that the measures for interpersonal safety domain be removed. Current approaches to addressing relationship safety and intimate partner violence (IPV) are moving away from screening towards a universal education and harm reduction approach. Futures Without Violence (FWV), the CMS partner for IPV prevention and education nationally, notes that while that 1 in 4 women experiences IPV in her lifetime, disclosure rates in practice are usually less than 10% (around 5-6% among OCHIN network members' patients), indicating significant underreporting and calling the utility of collecting this data into question. Instead, FWV provides and promotes a framework called CUES that addresses confidentiality (including its limits in required reporting settings), universal education about healthy relationships, and support for any disclosure that includes warm handoff to appropriate resources. Given this disparate approach, OCHIN recommends not including IPV in the current measures. OCHIN would, however, support a separate measure for IPV focused on the provision of universal patient education.

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OCHIN has previously advocated for inclusion of SDOH in screening measures and data standards to begin with the domains of housing, food insecurity, and transportation as "core" domains appropriate for screening in most every community and patient panel. The addition of utility assistance aligns with research from the SIREN group at University of California (San Francisco) that finds these four domains (housing, food insecurity, transportation, and utility assistance) are the most impactful for screening and action in healthcare settings. Consequently, these are the appropriate domains to include in such measures at this time. In the future, other domains could either be optional based on appropriate community or clinic considerations or added as more evidence about the relationship between SDOH and health becomes available.

NCQA

NCQA supports the implementation of a clinician-level measure of screening for social drivers of health. Incentivizing social need screening will help clinicians identify patients experiencing social risk factors which may be a barrier to their care; identification of need is a necessary first step in linking patients to the resources needed to address their social needs.

NCQA has the following concern to share regarding the specification of this measure:

1) Limitation of specifying use of a single screening tool: NCQA expresses concern that limiting the measure to one tool may penalize clinicians who are using other social need screening tools which are broadly implemented and considered acceptable. For example, clinicians may be using the PRAPARE tool, another broadly implemented social need screening tool among clinicians and practices. NCQA urges CMS to consider the implications of penalizing clinicians for use of tools other than the AHC screening, given that there is not yet consensus as to instruments considered gold standard for screening of social needs. Consider also whether requiring use of one specific tool may create unnecessary administrative burden on clinicians of switching to use of the AHC, when existing processes and infrastructure may be set up for use of another (for example, requirement from other payers such as state Medicaid).

MUC2021-134 Screen Positive Rate for Social Drivers of Health

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program

Merit-based Incentive Payment System–Quality

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Workgroup
Clinician

Measure Description
Percent of beneficiaries 18 years and older who screen positive for food insecurity, housing instability, transportation problems, utility help needs, or interpersonal safety.

Numerator
Number of beneficiaries 18 and older that screen positive for food insecurity, housing instability, transportation needs, utility assistance or interpersonal violence.

Numerator Exclusions
N/A

Denominator
Total number of beneficiaries 18 and older screened for food insecurity, housing instability, transportation needs, utility assistance or interpersonal violence.

Denominator Exclusions
N/A

Denominator Exceptions
N/A

State of development
Field Testing

State of Development Details
•Using a standard, validated screening tool, AHC has screened nearly 1 million beneficiaries for Health-Related Social Needs (HRSN) in 21 states, with 33% of beneficiaries screened having at least one HRSN.

Sources:

https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf

https://innovation.cms.gov/media/document/ahc-fact-sheet-2020-prelim-findings

CMMI's Comprehensive Primary Care Plus (CPC+) model reported in 2020 that 86% of ~1,500 Track 1 practices and 99% of ~1,500 Track 2 practices (together serving ~2.4M beneficiaries) are implementing DOH screening.

Sources:

https://innovation.cms.gov/data-and-reports/2020/cpc-evaluation-annual-report-2

What is the target population of the measure?
All Payer

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Addiction medicine ;Allergy/immunology;Behavioral health;Cardiac electrophysiology;Cardiac surgery

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;Cardiovascular disease (cardiology) ;Critical care medicine (intensivists);Dermatology ;Emergency medicine;Endocrinology;Family practice ;Gastroenterology ;General practice;General surgery ;Geriatric medicine;Gynecological oncology ;Hematology/oncology;Hospice and palliative care;Infectious disease;Internal medicine;Interventional pain management;Medical oncology;Nephrology ;Nursing Homes;Obstetrics/gynecology ;Osteopathic manipulative medicine ;Otolaryngology ;Pain management;Palliative care ;Pediatric medicine;Physical medicine and rehabilitation ;Podiatry ;Preventive medicine ;Primary care ;Psychiatry ;Public and/or population health;Pulmonary disease;Pulmonology ;Radiation oncology ;Rheumatology

Measure Type
Process

Is the measure a composite or component of a composite?
No

If Other, Please Specify
Social and Economic Determinants

What data sources are used for the measure?
Administrative Data (non-claims);Electronic Clinical Data (non-EHR);Standardized Patient Assessments;Patient Reported Data and Surveys

If applicable, specify the data source
N/A

If EHR or Chart-Abstracted data, description of parts related to these sources
N/A

At what level of analysis was the measure tested?
Clinician;Group;Facility;Other: Beneficiary, Population

In which setting was this measure tested?
Ambulatory/office-based care;Behavioral health clinic or inpatient psychiatric facility;Community hospital;Emergency department;Federally qualified health center (FQHC);Hospital outpatient department (HOD);Hospital inpatient acute care facility

What one healthcare domain applies to this measure?
Equity

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
The measure correlates to specific MIPS Quality Improvement Activities as follows:

- Use QDCR data for ongoing practice assessment and improvements (IA_PSPA_7)
- Use of toolsets or other resources to close healthcare disparities in communities (IA_PM_6)
- Practice Improvements that Engage Community Resources to Support Patient Health (IA_CC_14)
- Provide Clinical-Community Linkages (IA_PM_18)

Source:

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https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2021

CMIT ID
N/A

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
In COVID-19's wake, food insecurity, housing instability, IPV, and other basic DOH have reached unprecedented levels – and revealed searing racial disparities. In 2021, 21% of Black individuals are projected to experience food insecurity experience food insecurity, compared to 11% of white individuals. Likewise, 22% of Asian, 22% of Black, and 20% of Latino renters are not caught up on rent, compared to 9% of white renters.

Secretary Becerra has pledged "to take a department-wide approach to the advancement of equity, consistent with President Biden's charge to federal departments and agencies, and this would include examination of ways to address the social determinants of health." In particular, he has noted the importance of collecting more robust DOH data to address the disparities exposed by COVID-19 and leveraging the data and experience from the CMMI Accountable Health Community (AHC) model, which has screened nearly one million beneficiaries.

CMS has recognized the importance of making DOH measures standard across programs, identifying the development and implementation of "measures that reflect social and economic determinants" as a key priority and measurement gap to be addressed through Meaningful Measures 2.0.

A growing set of constituencies have called on CMS to provide leadership in measuring and addressing DOH, citing various rationales for doing so. Healthcare experts have increasingly recognized that equity

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is unachievable without addressing DOH, calling for CMS to require program "participants to uniformly screen for and document drivers of health" and "build DOH measures into MIPS and all APMs." The Health Care Payment Learning & Action Network (LAN) – a group of public and private health care leaders providing thought leadership, strategic direction, and ongoing support to accelerate adoption of APMs – has identified promoting equity and addressing DOH as key facets of APM resiliency.

Likewise, physicians and other providers have called on CMS to create standard patient-level DOH measures – beyond socioeconomic status (SES), hierarchical condition category (HCC) score, or duals status – recognizing that these risk factors transcend specific subpopulations; drive demand for healthcare services; escalate physician burnout; and penalize physicians caring for those patients via worse Merit-based Incentive Payment System (MIPS) scores.

Sources:

https://www.feedingamerica.org/sites/default/files/2021-03/National%20Projections%20Brief_3.9.2021_0.pdf

https://www.cbpp.org/research/poverty-and-inequality/tracking-the-covid-19-recessions-effects-on-food-housing-and

https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization

https://blueshieldcafoundation.org/sites/default/files/publications/downloadable/Investing%20in%20Health%20-%20A%20Federal%20Action%20Plan%20-January%202021_Final.pdf

https://www.healthaffairs.org/do/10.1377/hblog20201216.672904/full/

https://hcp-lan.org/2021-roadshow-deck/

https://physiciansfoundation.org/wp-content/uploads/2020/11/PF-QPP-Open-Comment-Submission-v.f_-.pdf

https://pubmed.ncbi.nlm.nih.gov/27942709/

https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf

https://pubmed.ncbi.nlm.nih.gov/30610144/

https://pubmed.ncbi.nlm.nih.gov/32897345/

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?
No

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If eCQM, enter Measure Authoring Tool (MAT) number
N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
Measure currently used in a CMS program being submitted as-is for a new or different program

Range of years this measure has been used by CMS Programs
Accountable Health Communities Pilot (2017-2022)

What other federal programs are currently using this measure?
Not applicable

Is this measure similar to and/or competing with a measure(s) already in a program?
No

Which measure(s) already in a program is your measure similar to and/or competing with?
N/A

How will this measure be distinguished from other similar and/or competing measures?
N/A

How will this measure add value to the CMS program?
N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

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Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure

See attached document "Peer Reviewed Evidence and Relevant Research_MUC2021-134_Physicians Foundation_5 27 21.pdf" with supporting evidence and research.

Evidence that the measure can be operationalized

•CMS has the opportunity to leverage and apply CMMI's 5+ years of data and experience with AHC. Using a standard, validated screening tool, AHC has screened nearly 1 million beneficiaries for HRSN in 21 states, with 33% of beneficiaries screened having at least one HRSN. AHC used screening, referral, and navigation data files extracted by NewWave (Centers for Medicare & Medicaid Services [CMS] Enterprise Portal contractor) and generated by Mathematica Policy Research (the AHC implementation contractor) using data submitted by bridge organizations.

Sources:

https://innovation.cms.gov/innovation-models/ahcm

https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf

https://innovation.cms.gov/media/document/ahc-fact-sheet-2020-prelim-findings

A number of CMMI models and participating entities have incorporated DOH screening and navigation data into their quality frameworks and care management plans for beneficiaries. CMMI's Comprehensive Primary Care Plus (CPC+) model reported in 2020 that 86% of ~1,500 Track 1 practices and 99% of ~1,500 Track 2 practices (together serving ~2.4M beneficiaries) are implementing DOH screening. CMMI required that by Program Year 3, Track 2 practices would use an electronic screening tool to assess patients' health-related social needs and store an inventory of resources to meet patients' needs; notably, by Program Year 2, Track 1 practices were as likely as Track 2 practices to report implementing these DOH functions, even absent a requirement that they do so.

Source:

https://innovation.cms.gov/data-and-reports/2020/cpc-evaluation-annual-report-2

Likewise, annual evaluations of other current CMMI models, including the State Innovation Model and Next Generation ACOs, report that participants are investing in staffing and infrastructure to conduct DOH screening and navigation. The 2021 Comprehensive End-Stage Renal Disease Care Model evaluation, for example, reported that "[m]any beneficiaries are protein malnourished and don't eat enough fresh produce. Some beneficiaries go to the hospital to get meals." ESRD Seamless Care Organizations have begun to monitor food insecurity and provide food gift cards to both low-income beneficiaries and those above the poverty level, to address beneficiaries' non-adherence to nutritional guidelines and reduce the risk of increased utilization and costs.

Sources:

https://downloads.cms.gov/files/cmmi/sim-rd2-test-ar3.pdf

https://innovation.cms.gov/data-and-reports/2020/nextgenaco-thirdevalrpt-fullreport

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https://innovation.cms.gov/data-and-reports/2021/cec-annrpt-py4

How is the measure expected to be reported to the program?
CQM

Feasibility of Data Elements
Some data elements are in defined fields in electronic sources;Patient/family-reported information: electronic;Patient/family-reported information: paper

Evidence of Performance Gap
CMS has already identified social and economic determinants as both a measurement priority and gap in Meaningful Measures 2.0. Other public and private organizations such as ASPE, NQF and NCQA have identified this as a critical gap.

Sources:

https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization

https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress

https://www.qualityforum.org/News_And_Resources/Press_Releases/2019/National_Quality_Forum_Leads_National_Call_to_Address_Social_Determinants_of_Health__through_Quality_and_Payment_Innovation.aspx

https://blog.ncqa.org/ncqa-releases-its-social-determinants-of-health-resource-guide/

Unintended Consequences
A potential unintended consequence of the measure is that health systems and hospitals will not be equipped to act on it due, in part, to the lack of community resources. This challenge was noted as a primary barrier to connecting beneficiaries to resources in the AHC Year 1 evaluation. There is a well-documented and well-tested catalog of additional tools, infrastructure, and investments that can be implemented to support practices in acting on this measure.

Sources

https://fhop.ucsf.edu/sites/fhop.ucsf.edu/files/custom_download/Unintended%20consequences%20of%20screening%20for%20social%20determinants.pdf

https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt

https://nhchc.org/wp-content/uploads/2020/04/NHCHC_Community-Information-Exchange2.pdf

https://governor.nc.gov/news/north-carolina-creates-nation%E2%80%99s-first-statewide-infrastructure-connecting-healthcare-and-human

https://blueshieldcafoundation.org/sites/default/files/publications/downloadable/Investing%20in%20Health%20-%20A%20Federal%20Action%20Plan%20-January%202021_Final.pdf

Outline the clinical guidelines supporting this measure
Not applicable

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Were the guidelines graded?
No

If yes, who graded the guidelines?
N/A

If yes, what was the grade?
N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Unable to determine

Estimate of Annual Improvement in Measure Score
Not applicable

Type of Evidence to Support the Measure
USPSTF (U.S. Preventive Services Task Force) Guidelines;Systematic Review;Empirical data

Is the measure risk adjusted, stratified, or both?
Stratified

Are social determinants of health built into the risk adjustment model?
No

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
Extensive research exists demonstrating increased healthcare expenditures to patients including Medicare beneficiaries associated with DOH. The example below provides the annualized increase in annual healthcare expenditures (PMPY) associated with food insecurity across different disease categories across all payor types in the peer-reviewed literature:

- Diabetes Mellitus: $4,413.61
- Hypertension: $2,175.20
- Heart Disease: $5,144.05
- Overall: $1,863

Source:

https://www.gsfb.org/wp-content/uploads/2018/08/Berkowitz-S.-A.-Basu-S.-Meigs-J.-B.-Seligman-H.-K.-Food-Insecurity-and-Health-Care.pdf

The AHC Year 1 evaluation found that Medicare FFS beneficiaries in the Assistance Track intervention group had 9% fewer ED visits than those in the control group in the first year after screening. (No Medicaid utilization/cost data reported yet.)

Source:

https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt

Cost Avoided Annually by Medicare/Provider
Unable to determine – though the cost avoided annually is likely to be significant given the research

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demonstrating increased utilization, readmissions, cost and increased financial liability for providers caring for patients with increased social risk.

Source of Estimate
Sources:

https://www.gsfb.org/wp-content/uploads/2018/08/Berkowitz-S.-A.-Basu-S.-Meigs-J.-B.-Seligman-H.-K.-Food-Insecurity-and-Health-Care.pdf

Also see attached review of the research literature for additional cost studies related to DOH.

Year of Cost Literature Cited
Estimated expenditures in 2015 dollars

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

If yes, choose all methods of obtaining patient/caregiver information
Surveys

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
Not applicable

Total Number of Patients and/or Caregivers Consulted
3162

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
Not applicable

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
2441

Burden for Patient: Does the measure require survey data from the patient?
Yes

If yes, what is the estimated time to complete the survey?
0

If yes, what is the frequency of requests for survey data per year?
1

If yes, are the survey data to be collected during or outside of a visit?
Prior to visit;During visit;After visit

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

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If yes, choose all methods that obtained clinician and/or provider input
Surveys;Focus groups;Standard TEP

Total Number of Clinicians/Providers Consulted
10078

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
8800

Burden for Provider: Was a provider workflow analysis conducted?
Yes

If yes, how many sites were evaluated in the provider workflow analysis?
3224

Did the provider workflow have to be modified to accommodate the new measure?
Yes

If yes, how would you describe the degree of effort?
3

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?

How many data elements will be collected for the measure?
0

Measure Testing Details

Reliability Testing Interpretation of Results
These results are the first to suggest that both the AHC and YCLS have high reliability and concurrent and predictive validity, supporting their use in healthcare settings, including by primary care physicians to engage in social risk-informed care.

Source:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7652127/#ref38

Type of Reliability Testing
Measure Score Reliability; Data Element Reliability

Reliability Testing: Type of Testing Analysis
IRR (Inter-rater reliability)

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Reliability Testing Sample Size
1008

Reliability Testing Statistical Result
Within social domains, percentages reporting a social risk tended to be higher by the AHC than the YCLS. Using unadjusted kappas, the AHC and YCLS items had substantial agreement for measures of food insecurity only. When examining the adjusted kappas that account for bias and prevalence, agreement between the AHC and YCLS items was substantial or higher (kappas > 0.60) for all social risksexcept housing quality (kappa = 0.52). The YCLS and CHW had substantial agreement (kappa 0.75) on housing.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
Data Element Validity

Validity Testing: Type of Validity Testing Analysis
Internal Consistency;Predictive Validity;Other: Empirical validity (through AHC and CPC+ practice implementation across 3+ million beneficiaries over last ~ 5-year time frame) and Psychometric and Pragmatic Property Analysis (see https://pubmed.ncbi.nlm.nih.gov/31753276/)

Validity Testing Sample Size
Study 1: 1,008 ; Study 2: 30,098 ; Study 3: 60,000

Validity Testing Statistical Result
Study 1: A reported social risk on the AHC and YCLS measures was strongly associated with having fair or poor self-rated health

Source:

https://www.jfmpc.com/viewimage.asp?img=JFamMedPrimaryCare_2020_9_9_5026_296311_t6.jpg

Study 2: HFSS questions 1 and 2 were most frequently endorsed among food-insecure families (92.5% and 81.9%, respectively). An affirmative response to either question 1 or 2 had a sensitivity of 97% and specificity of 83% and was associated with increased risk of reported poor/fair child health (adjusted odds ratio [aOR]: 1.56; P < .001), hospitalizations in their lifetime (aOR: 1.17; P < .001), and developmental risk (aOR: 1.60; P < .001).

Source:

https://pubmed.ncbi.nlm.nih.gov/20595453/

Study 3: Sensitivity of each two-item combination was high for the US population and high-risk demographic groups compared with the eighteen-item CFSM (Table 2). Sensitivity ranged from 96·4 % for items 2 and 3 for households with children and incomes <200 % of the federal poverty line, to 99·8 %

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for items 1 and 3 for Spanish-speaking households. (results for all combinations are available from the corresponding author upon request). Specificity was lower, ranging from 73·7 % for items 1 and 2 for households with children and incomes <100 % of the federal poverty line, to 94·5 % for items 2 and 3 for households with a respondent aged >60 years. Accuracy was high for all two-item combinations.

Source:

https://www.cambridge.org/core/journals/public-health-nutrition/article/brief-assessment-of-food-insecurity-accurately-identifies-highrisk-us-adults/81A4F5E162241E289A5181A10C056125

Validity Testing Interpretation of Results

Study 1: These results are the first to suggest that both the AHC and YCLS have concurrent and predictive validity, supporting their use in healthcare settings, including by primary care physicians to engage in social risk-informedcare.

Source:

https://www.jfmpc.com/viewimage.asp?img=JFamMedPrimaryCare_2020_9_9_5026_296311_t6.jpg

Study 2: A 2-item FI screen was sensitive, specific, and valid among low-income families with young children. The FI screen rapidly identifies households at risk for FI, enabling providers to target services that ameliorate the health and developmental consequences associated with FI.

Source:

https://pubmed.ncbi.nlm.nih.gov/20595453/

Study 3: The test characteristics of multiple two-item combinations of questions assessing food insecurity had adequate sensitivity (>97 %) and specificity (>70 %) for widespread adoption as clinical screening measures.

Source:

https://www.cambridge.org/core/journals/public-health-nutrition/article/brief-assessment-of-food-insecurity-accurately-identifies-highrisk-us-adults/81A4F5E162241E289A5181A10C056125

Measure performance – Type of Score

Proportion

Measure Performance Score Interpretation

Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have

33%

Benchmark, if applicable

Not applicable

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Measure Contact Information

Measure Steward
Other

Measure Steward Contact Information
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Raleigh, NC 27612

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919-306-0056

Long-Term Measure Steward
N/A

Long-Term Measure Steward Contact Information
N/A

Primary Submitter Contact Information
N/A

Secondary Submitter Contact Information
N/A

Section 2: Preliminary Analysis – MUC2021-134 Screen Positive Rate for Social Drivers of Health

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

Justification and Notes: This measure assesses the percentage of patients who screened positive for health-related social needs, which is consistent with the MIPS priority to identify measures that support health equity, and the Meaningful Measure 2.0 priority to develop and implement measures that reflect social and economic determinants. There are no similar measures in MIPS.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: No

Justification and Notes: Studies have shown that providers who care for patients with higher social risk scores tend to have lower performance scores in quality-of-care programs (e.g., this was observed in MIPS) (Khullar et al., 2020). However, the causal relationship is not clear. The conclusion of the cited MIPS study was that CMS should consider adding a strong scoring weight to the "Complex Patient Bonus", which gives clinicians a bonus based on the proportion of dual-eligible patients they serve.

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The measure ultimately seeks to bridge patients screened positive for health-related social needs with community navigation services and an individualized action plan from the beneficiary to resolve HRSNs identified by the screening. The MAP Clinician workgroup noted that this measure is an important first step to document screen positive rate for social drivers of health**.**

Does the measure address a quality challenge?
Yes/No: Yes

Justification and Notes: The measure is conceptually related to a critical quality challenge. The developer notes that identifying and addressing social determinants of health has become a top nationwide priority for leaders in healthcare. According to Fraze et al (2019), just 16% of physician practices screened patients for all five social needs identified in this measure, and 33% of practices did not screen patients for any needs. In the 2017-2020 years of evaluation of a CMS program based on the measure's screening tool, 34% of beneficiaries screened were positive for at least one need. The MAP Clinician workgroup acknowledged the volume of public comments noting that this measure is an important first step to document screen positive rates for social drivers of health.

Although the measure assesses the proportion of a clinician's patient population that has an unmet social need, the measure does not specifically address screening rates or follow-up after a positive screen.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?
Yes/No: Yes

Justification and Notes: There are no similar measures in MIPS or other federal quality programs. The concept of screening, either for disease (as in colorectal cancer screening) or for behavioral health issues (as in alcohol use or tobacco use) is well-established in the program, however. Can the measure be feasibly reported?
Yes/No: Yes

Justification and Notes: To report the measure, providers must collect the number of patients who were screened for all five elements, and the number who screened positive for at least one item; the only demographic information needed is patient age. The screening tool data can be electronically collected and recorded; therefore, all these data points should be available to providers for reporting. The screening tool has been in use in 21 states across the US, with nearly one million patients screened. The MAP should note that although the reliability and validity has been examined for the screening tool, no such testing has been conducted or evaluated.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?
Yes/No: Yes

Justification and Notes: The measure is specified and has been trialed in clinicians' offices, which is consistent with the MIPS program parameters. H**owever, the measure has not yet been submitted to NQF for evaluation of reliability, validity, and testing.**

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If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure been identified?
Yes/No: Yes

Justification and Notes: Because the measure itself has not been tested, no unintended consequences have yet been identified by stakeholders. However, three serious potential unintended consequences are evident from the measure concept. First, this measure directly incentivizes clinicians to treat fewer patients with social needs. Clinicians serving critical access areas or areas with low socioeconomic status would be incentivized to move away and care for a wealthier cohort. Second, clinicians may elect to screen only those patients who they expect are least likely to have a social need. Finally, screening for social needs where the provider might not be able to connect the patient with services that would remedy the need presents an ethical problem, and could lead to frustration for both patients and providers if these needs remain unmet even after referrals (Garg et al., 2016). One mitigant is that as implemented in MIPS, providers would presumably only choose to select this measure for reporting if they were comfortable with the implications.

PAC/LTC Core Concept?
N/A

Impact Act Domain
N/A

Hospice High Priority Areas
N/A

MAP Rural Health Advisory Group Input:
Relative priority/utility:

- The measure was suggested to be applicable to rural communities.

Data collection issues:

- Concerns raised regarding standardized data sets and data collection for SDOH. The developer responded that since the screening is standardized, then the positive indicator would also be standardized

Calculation issues:

- None.

Unintended consequences:

- There was some discussion on what the impact of a measure on payment to providers.
- Concerns were raised regarding the capture of a positive screen without the appropriate resources available to support the patient needs.

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 3.5
1 – 0 votes
2 – 2 votes
3 – 3 votes
4 – 7 votes
5 – 1 vote

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MAP Health Equity Advisory Group Input:

Relative priority/utility:

- This social driver measure is important as this is one of the first measures considered for Federal programs.
- Issue was raised as to how the results of the measure correlate to quality of care for this measure.

Data collection issues:

- Without standardization, there are concerns for variability of the measure to be able to compare across programs or entities. For example, some screens may include unmet behavioral health needs, where other may not.
- Results may not be comparable over time

Calculation issues:

- None identified.

Unintended consequences:

- Facilities with resources will potentially capture more "needs" in a disproportionate fashion and thus results of this measure may be difficult to interpret.

Votes: Range is 1 – 5, where higher number has greater potential for positive impact on health equity.
Average: 3.7
1 – 0 votes
2 – 4 votes
3 – 3 votes
4 – 10 votes
5 – 4 votes

Recommendation

Preliminary Analysis Recommendation:

Conditional Support, pending NQF endorsement

Summary: What is the potential value to the program measure set?

This measure assesses the percentage of patients who screened positive for health-related social needs. It would be the first in MIPS to specifically address screening for health equity, which is consistent with both the program goals and a Meaningful Measures priority. The MAP Clinician workgroup explored potential ambiguity on the definition of the measure as several workgroup members noted that providers should not be penalized for having a higher screen positive rate for social drivers of health. CMS and the developer clarified that MUC2021-134 and MUC2021-136 together *document* screening and *document* the positivity rate from the screening and does not compare providers based on differences in positive screening rates. Several MAP workgroup members encouraged CMS to examine MUC2021-134 and MUC2021-136 together, but the MAP Clinician workgroup noted that the current MIPS program allows providers to choose individual measures and thus these two measures may not always be selected together.

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Summary: What is the potential impact of this measure on quality of care for patients?

The measure ultimately seeks to bridge patients screened positive for health-related social needs with community navigation services and an individualized action plan from the beneficiary to resolve HRSNs identified by the screening. The MAP Clinician workgroup noted that this measure to document positive screen rates for social drivers of health is an important first step to addressing important social drivers of health outcomes.

Section 3: Public Comments

Indiana University Health

Yes, we know 80% of patients' health conditions can be improved if we assist with social need gaps, rather than focusing on the health issue alone. This is really important to move forward with screening and assisting those patients further who screen positive.

The Physicians Foundation

In submitting these comments, the Physicians Foundation does so not only as the measure developer for MUC2021-134 (Screen Positive Rate for Social Drivers of Health) and MUC2021-134 (Screening for Social Drivers of Health), but also at the direction of physicians from 21 state and county medical societies across the country.

As practicing physicians, we know that what our health care system measures and pays for—via diagnosis and billing codes, ""allowable services"" and myriad quality measures—is a reflection of both what and who it values. Further, we on the front lines of health care know that reducing total cost of care and achieving health equity are only achievable by addressing the social drivers of health—critical comorbidities such as food insecurity and housing instability.

Yet, this is not how our system operates. Under federal payment and quality frameworks, the health care system codes, screens, measures and risk-adjusts for diabetes, but not for food insecurity—even though diabetics who are food insecure have worse health outcomes and cost on average $4,500 more per year than those with access to healthy food. A system that does not collect and act on food insecurity data cannot address rising health care costs or reduce racial disparities, especially given that Black Americans face the highest rates of both food insecurity and diabetes.

The benefits of these SDOH measures certainly outweigh the burden of data collection or reporting. It is well-documented that the social drivers lead to physician burnout and effectively penalize physicians caring for affected patients via lower MIPS scores. A recent study found that SDOH were associated with 37.7% of variation in price-adjusted Medicare per beneficiary spending between counties in the highest and lowest quintiles of spending in 2017. Yet even with an ongoing pandemic that has painfully brought these issues to the fore, SDOH are still not included in any geographic adjustment or cost benchmarks.

On behalf of physicians across the country, we strongly urge the MAP to recommend these measures consistent with CMS's stated commitment to identify new measures that are meaningful to patients and providers. These measures are well tested, including through the Accountable Health Communities model, which has screened nearly a million beneficiaries for SDOH in over 600 clinical practices. Further,

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the measures reflect the imperative to re-balance quality measures to focus on SDOH—which drive 70% of health outcomes and associated costs—and to bridge the realities of patients' lives and physician practice and the regulatory machinery of our health care system.

With an Administration committed to operationalizing equity; a pandemic that has exacerbated rates of food insecurity, housing instability and other social drivers of health and the clinical disease burden linked to these factors; and the Medicare Trust Fund projected to be insolvent in five years, now is the moment to insist that these SDOH comorbidities be recognized and acted upon.

Citations:

https://physiciansfoundation.org/physician-and-patient-surveys/the-physicians-foundation-2020-physician-survey-part-3/

https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/key-statistics-graphics.aspx

https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.Pdf

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https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780864

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7652127/

https://www.commonwealthfund.org/sites/default/files/2019-07/ROI-EVIDENCE-REVIEW-FINAL-VERSION.pdf

Montefiore Health System
Yes, support for inclusion in the program

AMITA
Social Screenings are important and help to drive change to impact patient outcomes BUT the burden of collecting and reporting the data do not outweigh the benefits in the ambulatory setting. With the large variance of EHRs and screening tools available, it will be difficult for small primary care practices to collect and report this data. Specialty practices have often been exempt from this type of reporting but should be obligated to report if it is moved to MUD. Also, if the measure is moved to development, a CPT II or similar place holder should be implemented to help capture the screening via claims. There are currently Z codes to help capture patients who screened positive, but those codes will not capture those who were screened and had no food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety.

Blue Shield of California Foundation
The COVID-19 pandemic has exposed long-standing racial and economic injustices embedded in our health care system. This has led to a renewed commitment to improve health equity and address the drivers of health (DoH) that account for 80 percent of health outcomes and have a disproportionate

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impact on communities of color. These include stable, affordable housing; healthy food; reliable income; and interpersonal safety, among others.

Advancing health equity and addressing DoH will require changing how and what we measure in health care. Measurement matters because it equips providers with data to identify and address unmet needs and allows policymakers and payers to account for DoH in payment models.

We thus strongly encourage the Measure Applications Partnership to support for rulemaking both MUC2021-134 (Screen Positive Rate for Social Drivers of Health) and MUC2021-136 (Screening for Social Drivers of Health).

Despite the well-documented impact of DoH on health outcomes and costs and their impact on people of color, there are still no approved, standardized DoH measures in any Centers for Medicare &Medicaid Services' (CMS) programs. Even without such measures, the impact of DoH interventions are much referenced in the health care discourse and literature but remain functionally invisible in federal health care policymaking.

For example, a growing number of CMS Innovation Center models – Accountable Health Communities (AHC); Comprehensive Primary Care Plus; Maryland Total Cost of Care; State Innovation Models Round 2; and more – have screened millions of Medicare and Medicaid beneficiaries for DoH in thousands of inpatient and outpatient clinical settings across the country, but largely without the benefit of standard DoH screening tools or measures from CMS. As a result, CMS cannot systematically compare or use the data.

Recognizing the absence of DoH and race and ethnicity data as an issue, incoming CMS leadership in August 2021 cited the need for "patient-level demographic data and standardized social needs data" as a key element in its commitment to embedding equity in all models and demonstrations. The recently released CMS Innovation Center strategy report took this a step further by saying all new models will require participants to collect and report beneficiaries' demographic data and social needs data, when appropriate. Providers have joined the call for standardized, patient-level data collection for DoH, citing the impact of these drivers on patients, health care costs, and physician burnout.

These proposed DoH measures have been used in more than 600 clinical practices through the AHC model and have been subject to rigorous and independent validation. The AHC model found that 74% of navigation-eligible Medicare and Medicaid beneficiaries who were screened using these DoH measures opted in for navigation, nearly twice the projected estimate of 40%. Likewise, a large study in 2020 by Kaiser Permanente found that 85% of patients were in favor of health systems asking patients about social needs, and 88% were in favor of health systems helping to address those needs.

The introduction of the first DoH measures into core federal payment programs would be significant in its own right – making visible, when stratified by race and ethnicity, the social factors driving or inhibiting health, particularly for communities of color, including food insecurity, housing instability, transportation, utility needs, and interpersonal safety, including intimate partner violence. Only when these factors are brought to light and measured in a standardized way will we be able to align our collective resources and take action to achieve equitable health outcomes for all.

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If approved, these DoH measures can be improved over time through CMS's annual measure review process and can provide the groundwork for comparable measures for the Medicaid and CHIP Child and Adult Core Sets and guidance for states in their efforts to standardize DoH data. Further, these initial DoH measures could lay the foundation for subsequent measures focused on ensuring patients secure the resources they need to be healthy and accelerating/enabling investments in community capacity. In particular, these DoH measures will provide crucial data on the prevalence of unmet social needs among beneficiaries and other learning to enable more effective public and private sector investments in the technical/IT infrastructure, community-based navigation workforce, and capacity building and sustainable sources of funding necessary to enable the equitable integration of healthcare and community social services.

Citations:

https://blueshieldcafoundation.org/newsroom/press-releases/20210323/survey-documents-uneven-impact-covid-19-californias-communities

https://www.commonwealthfund.org/sites/default/files/2019-07/COMBINED_ROI_EVIDENCE_REVIEW_7.15.19.pdf

https://www.healthaffairs.org/do/10.1377/hblog20210812.211558/full/

https://innovation.cms.gov/strategic-direction

https://pubmed.ncbi.nlm.nih.gov/30610144/

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7652127/

https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt

https://pubmed.ncbi.nlm.nih.gov/31898132/

Stephanie L. Fitzpatrick, PhD

The MUC2021-134 measure, focused on reporting the number of positive social risks screens, could certainly have implications for increasing resources to particular geographic areas or health systems in which the prevalence of social risks among Medicare beneficiaries is high. However, these resources would need to also be spread to social services and community-based partners as they are the ones who usually receive the referrals and help patients address social risks. Without social services and the community, social healthcare fails.

With that said, the MUC2021-134 measure is also incomplete. Reporting positive screens, but not the number of referrals to social services/community-based resources or documentation of follow-up on these social risks seems imperative for patient-centeredness, trust, and to actually move the needle in improving patient outcomes and advancing health equity. Screening on its own without a plan to address those risks is not good for patients or providers. Therefore, I highly recommend adding language to MUC2021-134 to also capture the number of positive screens with a referral to social services/ community-based resources and/or follow-up encounter with a provider.

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Academy of Nutrition and Dietetics

The Academy of Nutrition and Dietetics' (Academy) Strategic Plan has a focus area dedicated to the topic of food insecurity- Nutrition Security and Food Safety. Within that focus area, there are impact goals: Advocate for equitable access to safe and nutritious food and water, and Advance sustainable nutrition and resilient food system. Therefore, the Academy is focused on impacting the health and wellbeing of individuals impacted from food insecurity, a component of the quality measure.

A concern with this proposed measure is it is not outcomes based. What happens with care once the individual is screened? What interventions are proposed to improve care? These outcomes are important so that care is impacted, not just data collected.

Food insecurity and malnutrition are widespread and worsening issues in the United States. Both food insecurity and malnutrition are associated with negative health outcomes and higher spending on health care. Adults who are malnourished at the time of hospitalization or surgery are more likely to have worse hospitalization, surgery, and recovery outcomes. Registered dietitian nutritionists (RDNs) have a responsibility to identify and address nutrition and food insecurity.

The purpose of a food insecurity screen, which is a component of the Accountable Health Communities Health-Related Social Needs Screening Tool, is to quickly identify households at risk for food insecurity, allowing providers to target services and interventions that address the health and developmental consequences of food insecurity.

RDNs working in health care settings, e.g., hospitals, long-term care, residential care, or free-standing dialysis facilities actively address discharge planning needs directly or in collaboration with a social worker or care coordinator to achieve improved outcomes for patients/clients and the organization, e.g., avoid hospital readmission. In addition to RDNs working in health care settings, RDNs in community nutrition or population health conduct population health management to achieve improved clinical health outcomes of the community/population.

The Academy has created a Practice Tips: Addressing Food and Nutrition Security (https://www.eatrightpro.org/practice/quality-management/competence-case-studies-practice-tips) to help RDNs assist patients/clients with these issues and to improve the health of the community at large.

Institute for Healthcare Improvement (IHI)

Public Statement on 2021 CMS Measures Under Consideration: Drivers of Health

December 8, 2021

Today we know that social factors influence health outcomes. We also know that racial inequities in health outcomes persist because remedies often focus only on reducing disparities in clinical care and not on the drivers of health (DOH). In COVID-19's wake, food insecurity, housing instability, interpersonal violence, and other DOH have reached unprecedented levels and revealed massive racial inequities. In 2021, 21% of Black individuals are projected to experience food insecurity, compared to 11% of white individuals. Likewise, 20% of Asian, 28% of Black, and 18% of Latino renters are not caught up on rent, compared to 12% of white renters (references below.)

The challenge now is to figure out how to work on these drivers of health in a fundamentally different

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way. In this context, it is untenable for the health care system to continue to address DOH primarily through special pilots or initiatives, as the National Academies of Sciences, Engineering, and Medicine (NASEM) demonstrated in their report, "Integrating Social Care into the Delivery of Health Care: Moving Upstream to Improve the Nation's Health."

Consistent with recommendations in the NASEM report, we are pleased that CMS has included two beneficiary-level DOH measures (MUC2021-134: Screen Positive Rate for Social Drivers of Health and MUC2021-136: Screening for Social Drivers of Health) on the Measures Under Consideration list in the equity domain. These measures should be recommended by the Measure Applications Partnership (MAP) in this review cycle, as a reflection of HHS' and CMS' commitment to equity and addressing the health-related social needs of the millions of beneficiaries they serve.

These measures, stratified by race/ethnicity, are (1) crucial to identify racial disparities in DOH, including those driving health inequities; (2) will lay the foundation for health care institutions to help guide beneficiaries to the resources they need to be healthy; and (3) will lead to more accurate risk adjust payment models. Drivers of health screening are also crucial in creating the imperative for public and private investments in the workforce and technology needed to reliably connect beneficiaries to the resources they need. And, most importantly, these measures can help ensure those resources exist in the first place, through cross-sector and community-based partnerships.

In 1999, the Institute of Medicine published To Err is Human in part to "…reveal the often startling statistics of medical error." That report did not promise easy solutions, but it asserted that it was time to "…break the silence that has surrounded medical errors and their consequence." Similarly, it is time to make visible the reach and impact of DOH by enacting the first-ever DOH measures in federal payment programs.

Citations:

https://www.feedingamerica.org/sites/default/files/2021-03/National%20Projections%20Brief_3.9.2021_0.pdf

https://www.cbpp.org/research/poverty-and-inequality/tracking-the-covid-19-economys-effects-on-food-housing-and

https://nam.edu/wp-content/uploads/2021/09/An-Equity-Agenda-for-the-Field-of-Health-Care-Quality-Improvement.pdf

https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556

https://www.nap.edu/cart/download.cgi?record_id=25467

https://www.medicaid.gov/federal-policy-guidance/downloads/sho21001.pdf

https://www.healthaffairs.org/do/10.1377/hblog20210414.379479/full/

Texas Medical Association
December 9, 2021

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Dr. Dana Safran

CEO

National Quality Forum

Measure Applications Partnership

1099 14th Street NW, Suite 500

Washington, DC 20005

RE: Texas physicians support drivers of health quality measures

Dear Dr. Safran:

On behalf of our more than 55,000 Texas physician and medical student members, the Texas Medical Association (TMA) writes in response to the agency's pre-rulemaking process that seeks input on the List of Measures Under Consideration for December 1, 2021.

We are pleased to offer our strongest support for the following two measures and thus urge the agency to move them forward through the regulatory review process of the Measurement Application Partnership (MAP):

- Screen Positive Rate for Social Drivers of Health (MUC2021-134) and
- Screening for Social Drivers of Health (MUC2021-136).

At TMA, we recognize that social drivers of health have a profound impact on patients and the physicians who care for them, especially in the wake of COVID-19. These two measures signal that the Centers for Medicare & Medicaid Services (CMS) has begun to recognize and address the significant impact that social drivers of health have on health disparities, outcomes, and costs. Additionally, social drivers impact both physician well-being and the economics of clinical practice.

It is not surprising, for example, that in the CMS Innovation Center's Accountable Health Communities model evaluation, 34% of beneficiaries screened positive for a health-related social need and among that group, racial and ethnic minorities were over-represented. Likewise, numerous studies have now quantified the impact of patients' social risk on physician performance scores through the Merit-Based Incentive Payment System and its impact on the geographic variation in Medicare spending (37.7% when including both direct and indirect associations).

Physicians in Texas already are working to effectively identify and address their patients' health-related social needs. We do so recognize that screening patients for social determinants of health is, as one of our colleagues recently observed, "just like when you use a screening tool or test to diagnose a medical condition. The diagnosis and the plan to address the problem can be enhanced by understanding some of the social needs, i.e., social determinants, that can get in the way, or may have already gotten in the way of making this person as healthy as they could be. This is not about ascribing fault as much as it is identifying factors that should be considered or addressed."

The challenge is that physicians are screening for and addressing their patients' social needs on their

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own. CMS has provided no guidance or incentives relative to standard quality measures that could inform risk-adjustment, cost benchmarks, financial incentives, and partnerships between physician practices and communities. We strongly support CMS advancing these measures through the MAP review process. These recommendations are essential to advance CMS' stated commitment to equity as well as enacting measures that matter to patients and physicians.

Regarding social determinants of health, it is TMA's policy to:

- Educate physicians about the social determinants of health for the purpose of assisting physicians to better understand their impact on patient health outcomes and well-being;
- Educate state and federal policymakers, business leaders, and governmental and commercial payers about the influence of social determinants of health on overall health care quality and health care costs;
- Collaborate with innovative public and private partnerships to address social determinants of health and advocate for their adoption by state policymakers; and
- Advocate that governmental and commercial payers modify existing performance and quality programs to reflect the higher expected health care utilization and costs associated with populations at greater risk of exposure to social determinants of health, and that these entities appropriately risk-adjust physician compensation to reflect these higher costs.

As such, we fully support MUC2021-134 and MUC2021-136. We appreciate the opportunity to comment on this matter. If you have any questions, please do not hesitate to contact Karen Batory, MPA, TMA vice president of population health and medical education, at Karen.Batory@texmed.org.

Sincerely,

E. Linda Villarreal, MD

President

Texas Medical Association

American Academy of Family Physicians

A major flaw of this measures is that no provision has been put in place to support physicians and other clinicians in underserved and rural practice. This measure directly incentivizes clinicians to treat fewer patients with high social needs including those in critical access areas or areas with low socioeconomic status.

Legacy Community Health

For the first time, CMS is considering two quality measures related to social risk screening as part of this year's 44 new Measures Under Consideration (MUCs) list. The two measures are:

Driver of Health Screening Rate: % beneficiaries 18 years and older screened for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-136) Driver of Health Screen Positive Rate: % beneficiaries 18 years and older who screen positive for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-134)

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We have been screening for these measures for years and have found them to be a key driver in health outcomes. It would be helpful to have a standardized approach so that we can further our efforts of proving that social determinants of health are just as important to overall health as traditional healthcare.

Missouri Hospital Association

The Missouri Hospital Association feels that the resources required to generate these data would be better used in the systematic capture of ICD-10 Z-codes related to SDOH in both electronic health records and uniform billing administrative claims data systems. CMS also should work with ICD-10 Cooperating Parties to include additional Z-codes currently in unrepresented domains of social vulnerability, such as access to reliable transportation.

Duke Margolis Center for Health Policy

The Duke-Margolis Center for Health Policy encourages the inclusion of measures addressing social drivers of health (SDoH) in CMS quality reporting programs. The impact of these drivers on health is well documented, and a growing number of efforts are under way to examine how health care providers and organizations can better identify and address individuals' SDoH-related needs. Among these efforts are those examining how to leverage value-based payment (VBP) models to better address SDoH.1 Our work has found VBP models have the potential to support the infrastructure and cross-sector relationships needed to identify and comprehensively address SDoH-related needs.2 However, the current dearth of SDoH-related quality measures makes it difficult to embed accountability for addressing SDoH into VBP models. Development and implementation of SDoH-related quality measures are needed if VBP efforts to meaningfully address SDoH are to be successful.

The addition of the MUC2021-136 and MUC2021-134 measures to the Hospital Inpatient Quality Reporting Program and Merit-based Incentive Payment System would reflect the emphasis needed on advancing SDoH-related quality measures, especially if they can be clearly linked to a strategy for supporting improvement in the SDOH risk factors reflected in such measures. Such a strategy should include more systematic collection and reporting of SDoH-related data, development of the infrastructure needed to support partnerships across sectors (e.g., health care, education, justice), and implementation of payment models that can support and sustain the delivery of SDoH-related services. The inclusion of SDOH-related quality measures in CMS quality reporting programs is one way to support progress in implementing such a strategy.

References:

1.Sandhu S, Saunders RS, McClellan MB, Wong, CA. (2020). Health Equity Should Be A Key Value in Value-Based Payment and Delivery Reform. Health Affairs Blog. Accessed December 3, 2021. http://www.healthaffairs.org/do/10.1377/hblog20201119.836369/full/

2.Crook HL, Zheng J, Bleser WK, Whitaker RG, Masand J, Saunders RS. (2021) How Are Payment Reforms Addressing Social Determinants of Health? Policy Implications and Next Steps. Accessed December 3, 2021. https://www.milbank.org/publications/how-are-payment-reforms-addressing-social-determinants-of-health-policy-implications-and-next-steps/

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Federation of American Hospitals

The Federation of American Hospitals (FAH) supports the development and implementation of measures that seek to address inequities in care and those factors that may directly or indirectly impact an individual's ability to achieve positive health outcomes. Regrettably, the FAH is unable to support the inclusion of this measure in the Merit-based Incentive Payment System (MIPS) for several reasons.

While the FAH supports the overall intent of this measure and MUC2021-136, Screening for Social Drivers of Health, we were unable to determine why the specific social drivers of health were selected, the degree to which they are aligned with the work of the Health Level 7 Gravity Project or the United States Core Data for Interoperability (USCDI), and whether the intended patient population is Medicare beneficiaries or those aged 18 years and older since the wording is not clear. In addition, the developer did not provide any evidence demonstrating that this process is linked to improvements in health outcomes nor has testing of the measure been completed.

Furthermore, the FAH requests that the Clinician Workgroup consider the degree to which this measure could be considered actionable and the resulting performance scores should be attributed to a clinician or practice. This measure assesses the rate of positive screens but does not appear to address the degree to which a clinician or practice has been equipped with the necessary resources and tools to address the individual's needs. In the absence of this information, the FAH does not believe that a rate of positive screens will reflect the quality of care provided by a clinician or practice.

The FAH believes that these questions and concerns must be addressed and endorsement by the National Quality Forum should be achieved prior to implementation of this measure in MIPS. As a result, the FAH requests that the highest level of MAP recommendation be "Do Not Support."

American Medical Association

While the American Medical Association (AMA) supports the intent of this measure to begin to address the social drivers that can also impact an individual's health outcomes, we do not believe that the implementation of this process measure, in the absence of any resources or tools that would be widely and readily available to hospitals, should be pursued at this time. Measures must be actionable and facilitate improvements in patient care and a measure that only reports the rate of positive screens does not represent the quality of care provided by a hospital. While all hospitals can identify and facilitate addressing social needs, they cannot and should not be held responsible for resolving them. Other strategies such as stratification of populations by race, ethnicity, and social drivers of health should be employed.

In addition, the developer did not provide any evidence to demonstrate that the collection of these data alone will drive improvements in health outcomes nor is it is clear why the developer selected the specific social drivers of health for this measure and MUC2021-136, Screening for Social Drivers of Health. The measure must be supported by evidence and should align with the work of the Health Level 7 Gravity Project and the United States Core Data for Interoperability (USCDI). We were also unable to determine which patients the measure intended to capture since the word "beneficiaries" is typically used when a measure applies to those individuals with Medicare Fee-for-Service, yet the denominator language also indicates that it would be any person 18 years and older. In addition, the measure itself is not yet tested. We believe that many of these discrepancies would be resolved if the measure was fully specified and demonstrated to be evidence-based, reliable, and valid.

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Because we do not believe that this measure will result in effective change, we request that the highest level of MAP recommendation be “Do Not Support.”

The Coalition to Transform Advanced Care

We support this measure and very much appreciate its addition to the MUC list. We believe this will begin to gather this important information in a more systematic way and help to help build better links to community services that address these needs.

Because this is a new area for measurement, we are not yet sure what application it will have but believe it will certainly inform QI efforts and could also be used for payment in value-based arrangements.

We see little implementation issues in gathering the information, which is what the measure requires, but hope that it will be the beginning of a more comprehensive way not only to screen for social drivers of health but to refer and then deliver any needed services. However, this is an important first step.

Reinvestment Partners

MUC2021-134 (Driver of Health Screen Positive Rate) adds value by documenting patients' unmet social needs. This is crucial in advancing social equity and public health outcomes. This measure is an important tool understanding the severity of social drivers of health and lay the groundwork for addressing social drivers in clinical settings. If adopted, these measures would be easy to implement and would generate evidence for investments in social driver programs through healthcare.

findhelp

MUC2021-134 (Driver of Health Screen Positive Rate)

MUC2021-136 (Driver of Health Screening Rate)

Re: Comments for NQF public comment period on CMS MUCs

In response to the National Quality Forum (NQF) public comment period on Centers for Medicare & Medicaid Services’ (CMS) measures under consideration (MUCs), please see below comments related to MUC2021-134 and MUC2021-136 on behalf of findhelp, a Public Benefit Corporation.

About findhelp

Founded in 2010, findhelp, a Public Benefit Corporation runs the largest social care network in the United States and has served more than eight million Americans. Our mission is to connect all people in need with the programs that serve them with dignity and ease. As part of fulfilling this mission, we will always maintain findhelp.org, a free and anonymous search tool for identifying free and reduced cost programs in every U.S. zip code. Our network is used by over 250 health systems, health plans, community health centers, and health departments in the United States to manage social care referrals, as well as tens of thousands of Community Based Organizations (CBOs). Findhelp’s interoperable social care technology works with electronic health records (EHRs) and other platforms to help clinicians and other partners address the social needs of individuals in a seamless fashion.

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Comments

Findhelp appreciates the opportunity to share feedback with NQF related to proposed quality measures specific to Social Drivers of Health (SDoH).

1. This measure recognizes social needs screening as an important clinical tool.

Recognizing the value of Social Drivers of Health (SDoH)

Screening for SDoH provides clinicians with actionable data on health-related social needs that may be impacting the whole person of their patients. Capturing SDoH risks and screening information can better inform provider organizations about the needs of their patients and communities. This information can help healthcare organizations connect patients to needed resources, prioritize partnerships with CBOs and vendors, and inform capacity planning.

For example, findhelp customer Boston Medical Center (BMC) developed the THRIVE SDoH Screening and Referral program to identify and address detrimental social factors preventing patients from thriving, such as unstable housing, food insecurity, financial instability, and other issues. Through the THRIVE screener, patients identify their social needs, and BMC staff refer them to both resources at BMC and in the community using the THRIVE Directory (powered by findhelp).

Governments at all levels make significant resources available to consumers related to their social needs. Such resources could include, but are not limited to, those used to address food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety.

Yet, a clinician's ability to support a patient is only as strong as his or her awareness of the patient's needs. Screening for food insecurity, housing instability, transportation problems, utility help needs, or interpersonal safety gives providers the opportunity to impact a patient's health in ways far beyond clinical interventions.

Unfortunately, connecting those resources to consumers who need them – including the nation's Medicare and Medicaid beneficiaries – can be challenging. We encourage CMS to make identifying social care needs and connecting these consumers to available resources a core part of their healthcare quality and health equity strategies moving ahead.

Incentivizing measurement of SDoH

In particular, we encourage CMS to adopt MUC2021-134 and MUC2021-136 into federal payment programs. These will be the first standard SDoH measures included in federal payment programs and will provide a starting point to incentivize healthcare providers to measure and report on patients' SDoH needs.

2. The benefits of the measure outweigh the burden of data collection and reporting.

Data collection is both valuable and feasible

We believe that not screening for SDoH represents a larger burden to providers than conducting the

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screenings. Not building SDoH measures into the health system increases the burden on physicians as SDoH are still part of their patients' clinical reality. As healthcare providers increasingly recognize the impact of SDoH on their patients and practices, especially in light of COVID, they have called for CMS to measure what matters.

While this screening work is happening around the country already, there is a strong need for a national standard for this process. In the absence of CMS SDoH measures, physician organizations (e.g., findhelp customers American Academy of Family Physicians and American Academy of Pediatrics) have developed ad hoc SDoH screening guidelines. More than 100 findhelp customers currently using our platform to screen patients for SDoH needs, and many more screen directly in their EHRs and care platforms.

CMS has already implemented these measures in a limited fashion, providing NQF and other stakeholders an opportunity to review the tangible impact to clinicians of undertaking the screening. The measure developer (the Physicians Foundation) submitted these SDoH measures because they are currently in use in the CMS Innovation Center's Accountable Health Communities model, where they have been effectively tested and implemented over 5 years with nearly a million CMS beneficiaries in 600 clinical sites and multiple practice settings across the country.

Interoperability of social care networks

After screening patients for SDoH needs, many healthcare provider organizations will want to facilitate the connection of their patients with needed services. To facilitate this vital next step, the technology exists to integrate social care referrals into EHRs or other platforms. Through platforms such as findhelp, healthcare systems, providers and CBOs are able to receive and exchange social care data from various sources within their own environment and systems of record.

January 13, 2022
MUC2021-134 (Driver of Health Screen Positive Rate)
MUC2021-136 (Driver of Health Screening Rate)
Re: Comments for NQF public comment period on CMS MUCs
In response to the National Quality Forum (NQF) public comment period on draft recommendations offered by the Measure Application Partnership (MAP) workgroups that convened last month, please see below comments related to MUC2021-134 and MUC2021-136 on behalf of findhelp, a Public Benefit Corporation. These comments were shared with the MAP prior to last month's meeting.

The MAP's initial recommendations related to MUC2021-134 and MUC2021-136 are a welcome development. Findhelp encourages the MAP to continue its support for the measures in the final recommendations to HHS.

Denver Regional Council of Governments

As the Project Director for one implementation of the CMMI Accountable Health Communities Alignment Track Model, I support this measure with limitations. Simply put, only screening for social needs will not work for the hospital, clinical staff, or the patient. screening for social needs and not addressing the need is the same as diagnosing someone with diabetes and then not providing a

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prescription for insulin or instructions on how to use it.

For this measure to be successful for the patient, the hospital must be required to connect the patient with a service that addresses the identified need. Additionally, any hospital that implements a program to achieve success on this measure should be required to partner with local community-based organizations to provide services to address the identified needs.

The burden to implement this measure far exceeds the cost of implementation, data collection, and reporting. The benefit to the patients with needs is obvious and the benefit to the hospital and clinical staff include increased trust and engagement from patients as well as better outcomes.

Discern Health on behalf of GSK

GlaxoSmithKline (GSK) appreciates this opportunity to submit comments on the MAP's MUC list. GSK supports efforts to use value-based care models to improve care delivery and health outcomes for Medicare beneficiaries.

GSK is a science-led global healthcare company. We have three world-leading businesses that research, develop and manufacture innovative pharmaceutical medicines, vaccines, and consumer healthcare products. GSK supports policy solutions that transform our healthcare system to one that rewards innovation, improves patient outcomes and achieves higher-value care.

GSK would like to offer the following comments:

GSK encourages the MAP to recommend immunization measures in quality programs such as the Merit-Based Incentive Payment System (MIPS) and Medicare Shared Savings Program (MSSP). Adult vaccines are a vital and underutilized preventative service, despite proven health and cost-savings benefits and strong recommendations from the Center for Disease Control's (CDC) Advisory Committee on Immunization Practices (ACIP).

The COVID-19 pandemic has reinforced the critical importance and value of vaccination- on both the individual and societal level. However, it has simultaneously disrupted the healthcare system, including access to vital preventative services like recommended vaccines. Earlier this year, GSK commissioned Avalere Health to quantify the impact. This report showed that over 17M adult vaccines were missed in 2020, essentially wiping away significant progress made previously on adult immunization (1). Furthermore, there is renewed urgency to build a comprehensive adult immunization infrastructure and embed awareness of recommended vaccines to reduce health, economic, and societal costs that would otherwise be avoided by timely vaccination.

Effective and clinically important performance measures can be a strong tool towards driving provider behavior change and improving quality of care (2). The Adult Immunization Status (AIS) and Prenatal Immunization Status (PRS) measures have the potential to be particularly impactful because provider recommendation is one of the most effective tactics to increase immunization rates. GSK supports CMS' goals of focusing on measures that are meaningful for patient outcomes and reducing overall costs to the healthcare system and believes the addition of the AIS and PRS measures accomplish those goals. Therefore, GSK encourages MAP to consider recommending both the AIS and PRS measures into MIPS and MSSP.

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There were legitimate, previous concerns about including the AIS and PRS measures into provider quality programs. However, new evidence has provided insights to alleviate those concerns. One concern was that the measures were developed for health plan reporting. New evidence that analyzed the AIS measure in medical groups shows that these types of immunization measures are feasible to use for provider accountability (3). Another concern was the potential gaps in data for providers, since patients receive vaccinations in a variety of different settings (e.g., pharmacies, workplaces, immunization sites). Advances in immunization information systems (IIS) due to the pandemic (4), as well as the electronic clinical data system (ECDS) method used to collect the AIS and PRS measures, makes it more feasible for providers to have full access to the patient data required to report immunization measures. Both IIS and the ECDS method encourages collection and sharing of data which ultimately advance health information sharing and improved patient care (5).

Thank you for this opportunity to comment on the 2021 MUC list. If you have any questions or GSK can provide additional insight, please do not hesitate to reach out to Halley Hetrick at halley.m.hetrick@gsk.com.

Sincerely,

Margaret Nowak Mann

VP US Public Policy

References:

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3: https://www.liebertpub.com/doi/abs/10.1089/pop.2021.0197

4: https://repository.immregistries.org/files/resources/60958446cdad0/adultlandscape_final.pdf

5: https://academic.oup.com/jamia/article/28/10/2226/6324040?guestAccessKey=592d303c-246e-4d6f-bc79-317abd866791

Kaiser Permanente

KP supports development and adoption of reliable, evidence-based, well-tested measures of social drivers of health. KP currently measures social drivers with a standard instrument for quality and performance improvement, and we have set aggressive targets to rapidly expand standard screening across the enterprise. Our unique experience with implementation of these measures at significant scale with our 12.5 million members enables us to contribute to the evidence base for these measures, including impact on health, care, cost, and equity, and we will continue to do so through our robust social health research and evaluation efforts over the next few years. We recognize these upstream measures are new in the measure development and review process and may present special challenges. We offer our support and collaboration, and request to stay informed and connected throughout the process.

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Camden Coalition of Healthcare Providers

How would adding this measure add value? How would the measure improve patient outcomes?

Mandating the two process measures may lead to wider adoption of social needs screening in healthcare settings. While screening itself does not imply practices will have the resources to respond effectively to the social needs identified, it at least establishes a foundation for building processes within practices and the community to address health-related social needs. Collecting structured data on social determinants could bolster efforts to understand and address equity issues in the healthcare system, improve segmentation efforts, and may be a springboard for measuring the capacity of healthcare providers to respond to social needs, and identifying where gaps between social needs and resource availability in the community exist.

Do the benefits of the measure outweigh the burden of data collection or reporting?

The benefits of the measure will not necessarily outweigh the burden of data collection or reporting. This will depend on many practice-level factors, such as the ability to develop efficient screening workflows, the availability of staff who are trained and well-prepared to engage patients with complex social needs (especially around sensitive needs such as those related to interpersonal safety), the smooth integration of screening data into a practice's existing data systems, and the ease with which the data can be made available to clinicians at the point-of-care. Moreover, the interpersonal safety questions are proprietary, and from a practice's perspective, it may not be worth the cost of including those questions in their screener, especially if there are inadequate resources available to address any interpersonal safety issues a person is experiencing. We would recommend offering alternative questions related to interpersonal safety for practices who do not want to pay to use the four questions currently included in the AHC screener. Finally, with reimbursement, benefits may outweigh burden as long as practices are given flexibility in how social needs screening takes place and the reporting requirements are not cumbersome.

For what purpose are you using the measure (e.g., QI, certification/recognition, regulatory/accreditation, payment, public reporting, disease surveillance)?

The Camden Coalition is an Accountable Health Communities alignment track hub. The social needs screening data we collect are used for multiple purposes locally and regionally. For example, we share the data with health systems and other community partners for community health needs assessments and gaps analysis; we leverage the data to procure funding for various population health initiatives; we make the data available through our Health Information Exchange to inform clinical decision-making; and we share the data with researchers who study the intersection of social risk and health.

Are there implementation challenges?

Challenges include incorporating the screening tool into practice workflows, throughput, cost, potential need for extra staffing, and storing and accessing the data. If the screener is self-administered, challenges related to staffing might be reduced, but there are other challenges that need to be considered. An efficient workflow still needs to be established - for example, determining when during a visit a patient will receive the screener and who on staff will be responsible for introducing the screener to the patient. Language and literacy barriers present challenges as well and may require additional time

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and support from staff. Additionally, if a practice is doing more than collecting data and is going to establish workflows to respond to social needs, there are coordination costs associated with addressing those needs. There would need to be people on staff who can have the kinds of conversations that must take place when a patient expresses a social need. This may mean hiring a social worker, for example, or taking on the cost of training existing staff members.

Children's HealthWatch, Boston Medical Center
Measure Applications Partnership (MAP)

Currently selected 2021 MAP Measures Under Consideration (MUC)

Comments submitted

On behalf of Children's HealthWatch, we applaud the National Quality Forum (NQF) Measures Application Partnership's consideration of MUC 2021-136 (Driver of Health Screening Rate) and MUC 2021-134 (Driver of Health Screen Positive Rate). Children's HealthWatch seeks to improve the health and development of young children and their families by informing equitable policies that address and alleviate economic hardships and by dismantling systems of institutionalized discrimination and inequity at the root of these hardships. Our work begins with research through interviewing caregivers of young children on the frontlines of pediatric care, in urban emergency departments and primary care clinics in five cities: Boston, Minneapolis, Little Rock, Baltimore, and Philadelphia. Since 1998, we have interviewed over 75,000 caregivers of children under four years of age and analyzed the data to determine the impact of social risk factors (individual-level adverse social determinants of health) and public policies designed to address those social risk factors on the health and development of young children and the well-being of their families. Specifically, our research focuses on the following: nutrition, housing, health care, childcare, utilities, income and wealth, employment, Adverse Childhood Experiences and Experiences of Discrimination. Our research – in addition to that of others – shows that lack of access to basic needs is associated with poor child health and development, poor parental physical and mental health, higher child hospitalization rates, and learning and behavioral/emotional impairments. Health consequences are often compounded, as they are frequently experienced simultaneously, often as a result of limited income and resources.

How would adding this measure add value? How would the measure improve patient outcomes?

Based on decades of our research, and the research of others, we stress the importance and value of measuring of social risk factors to identify and address unmet social needs (social needs differ from social risks insofar as they convey the patient's preferences and priorities regarding the social risk) and enable policymakers and agencies such as CMS and other payers to incorporate them in value-based payment models. The measures under consideration (MUC 2021-136, MUC 2021-134) also offer a valuable opportunity to provide a foundation for comparable measures for the Medicaid Adult and Child Core Measure Set and guidance for states in their efforts to standardize these data.

Do the benefits of the measure outweigh the burden of data collection or reporting?

The benefits of measuring social risk factors far outweigh the burden of data collection and reporting. Numerous studies have shown relatively high acceptability of social needs screening and referral among both patients and providers (https://bit.ly/3rSik2v, https://bit.ly/3rOPlN5). Initial evaluation of the

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Accountable Health Communities (AHC) Model found that among navigation-eligible beneficiaries who reported unmet social needs, 41% had one unmet social need and nearly 60% reported having multiple unmet social needs. While research and implementation of social needs screening and intervention has grown substantially over the past decade, providers and health systems struggle with heterogeneous screening tools and interventions. This contributes to absence of consideration of unmet social needs in federal health care policymaking. The prospect of these two measures being utilized in Medicare public reporting and performance-based payment programs would be beneficial because they would both elevate the importance of these issues for health at the federal level and shed much needed light on social risk factors in a standardized way that allows for accurate comparison of data across settings and communities. Furthermore, if these measures are stratified by race and ethnicity and by age, policymakers and agencies will be prepared to effectively target resources and actions that advance health equity and address long-standing disparities in health outcomes.

For what purpose are you using the measure (e.g., QI, certification/recognition, regulatory/accreditation, payment, public reporting, disease surveillance)?

These measures (MUC 2021-136, MUC 2021-134) offer opportunities to be used for QI, maintenance of certification, payment, and public reporting.

We consider MUC 2021-134 to be an indicator of the identified risk of the population. Thus, the measure and specific screening tools included in the AHC questionnaire it relies on are not capable of disease surveillance or diagnosis of certain social risk factors precisely because the AHC questionnaire was designed as a screening tool and identifying social risk factors in clinical settings for diagnosis and intervention may require further assessment. In fact, our research has identified significant discordance among the AHC questionnaire housing questions and Children's HealthWatch housing questions. The two tools captured different housing-related risks and contributed to different health consequences, which were relevant to different subpopulations. These findings demonstrate that the choice of question is important to identifying the specific risk. We raise this point to underscore that any screening tool will inherently have limitations and thus further discussion with health providers and thoughtful linkages to interventions are critically important next steps. Thus, the AHC questionnaire does not measure all possible forms of social risk but instead is designed to capture specific domains currently identified as prevalent risk factors in health care and public health literature. Given the fact that there never will be, nor could there be a single social risk screening tool that identifies every health-related social need for every person, the evidence-based approach taken to develop the AHC tool along with its wide adoption over the past few years, indicates that it is the best option available for the purposes of accomplishing the goals of these measures.

We suggest creating a paired measure of improvement over time in the specific social risk factors dimensions as a better measure than simply a one-time measure of proportion, again stratified by race and ethnicity and age. This improvement measure is similar to what the NQF Measure Incubator project has developed for the forthcoming food insecurity measures (https://bit.ly/3pGLZt0). Further, also aligned with the NQF Measure Incubator project's forthcoming food insecurity measures, we suggest a paired measure on appropriate interventions that have occurred as a result of identification of unmet social needs on screening. Interventions need flexibility to adapt to local context, resources, and community needs, however, certain core principles and best practices can still be standardized. Without

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an intervention-focused measure, we miss opportunities to understand the landscape of programs and interventions that serve the needs of families, and coordinate strategies that target or improve interventions.

Any model of care that seeks to measure outcomes should focus measurement and evaluation on providers' and institutions' ability to effectively 1) measure and 2) address health related social risks or concern (e.g., food insecurity, housing instability, transportation). A recent report from the National Committee for Quality Assurance (NCQA) describe health care organizations' use of both process (i.e., the number of patients screened or referred) and outcome (i.e., improvement from a baseline, meeting quality targets, impact on health care utilization) measures to evaluate the impact of their overall strategy and specific interventions. This report also made note that the field currently focuses more on process measures for specific social needs rather than health outcomes and health care utilization outcomes. A broad set of outcome measures beyond process measures is an area for further exploration.

Are there implementation challenges?

Challenges do exist, including limited provider time to screen and intervene, lack of a multi-domain screening tool that encompasses any and all social risk factors individuals may experience, and ability of institutions to suitably identify needs and provide targeted resources. The CMS Innovation Center and its 5-year AHC Model, while still under way, is an encouraging approach that demonstrates the need and political will to address this critical gap. Beyond expansion of this model, the Improving Social Determinants of Health Act of 2021 is a promising legislative opportunity to address limited health care resources and challenges to implementation of effective value-based care. Supported by hundreds of professional health organizations and networks, health insurers, and community-based organizations, the Improving SDOH Act would enable health providers and systems to better coordinate, support, and align SDOH best practices and capacity building activities. In coordination with the Centers for Disease Control and Prevention, federal agencies such as CMS, and local public health departments, the Act would support these activities by ensuring that there are resources and policies in place to intervene effectively on unmet needs and their health correlates. Specifically, through increased funding opportunities, technical training, and evaluation assistance, scaled data collection and analysis, and identification and coordination of best practices, this act would increase the public health sector's capacity to engage with the health care sector and fully address SDOH priorities beyond temporary referrals and interventions. Efforts like these are important to ensure that health systems are not only supporting their patients in achieving holistic health, but that providers also have the systems and resources to do so in ways that are sustainable, evidence-based, and avoid harms to patients.

Do you recommend this measure?

Yes

UniteUs/NowPow, a wholly owned subsidiary of UU

Overall, Unite Us supports including measure 134 in MIPS, hospital IRQ and other value-based payment programs if the proposed measure has been tested and meets NQF or CMS MERIT-based payment or other measure quality standards. Including these measures will encourage clinicians/clinical staff to screen and track social drivers of health. We recommend that additional measures should be considered

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that evaluate if beneficiaries who screened positive receive services to address their social drivers of health in a timely manner. Assessing without addressing does not improve quality in a meaningful way.

While we encourage the use of social driver measures, the Unite Us team have some concerns regarding the measure implementation, methodology and process. It is not clear whether all domains would need to be assessed (e.g., financial insecurity and housing and utilities, etc.) or any one of these domains could be assessed to meet the measure. It is unclear if 80% beneficiaries screened means 80% of people had at least one of these domains assessed (but some had financial insecurity assessed, some were assessed for transportation, or all were assessed for interpersonal violence and nothing else) or it means 80% of people had all of these domains assessed. The Unite Us team advocates for the latter approach, as it is a higher standard.

ZERO-The End of Prostate Cancer

On behalf of the all those managing prostate cancer and navigating prostate cancer care (now and in the future), ZERO - The End of Prostate Cancer submits these comments in support of identifying those who screen positive for specific social needs such as food insecurity, housing instability, transportation problems, utility help needs, or interpersonal safety in the Hospital IQR and the MIPS program. Research has shown that socioeconomic factors are a substantial driver in the racial/ethnic differences in prostate cancer across the cancer continuum from prevention to end-of-life care. Families managing a prostate cancer diagnosis and navigating prostate cancer care engage with several staff, providers, and administrators in the healthcare delivery system; and this process often proves to be very complex, and to be substantially influenced by the socioeconomic resources of the patient and on how well the care delivery system has integrated “social care” into medical care. Not surprisingly, generally racial/ethnic minority and low socioeconomic status patients have worse health outcomes as they navigate the healthcare/cancer care delivery system. To address this issue, there have been several recent efforts to facilitate the integration of screening and addressing patient social needs in health care delivery; yet there is no agreed upon standard tool for screening patients. Thus, it is critical that CMS facilitates the integration of standard measures and creates a pathway for identifying those with the social needs proposed in this new measure; and create financial incentives and risk models/frameworks that recognize the social factors that contribute to worse health outcomes and increased costs for patients. The integration of the proposed measures facilitates the consistent screening of patient social needs and incentivizes providers and health care delivery systems to navigate patients to address those social needs and to evaluate the impact of those efforts on patient health outcomes. These efforts are needed to identify and eliminate health disparities and work towards health equity.

Massachusetts Child and Adolescent Health Initiative

The Child and Adolescent Health Initiative is a multidisciplinary coalition in Massachusetts seeking to improve care and outcomes for children, with a primary focus on working with MassHealth (the state’s Medicaid and CHIP agency) to assure that MassHealth insured children and their families get the care they need to optimize outcomes.

How would the measure add value?

Assessing health related social needs is an essential step in providing appropriate services to patients/beneficiaries. This assessment enables providers and their health care organizations to then ascertain whether the patient desires assistance in addressing identified needs and, if they do, link them

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to appropriate and effective services. The tally of needs in a population also points to the broader social needs in a community and can lead to interventions to address the root causes of those needs (what the World Health Organization considers the social determinants or social drivers of health). These are the two strategies being explored in the Accountable Health Communities (AHC) model by CMMI. Given the importance of social needs in influencing both short and long-term health, regular assessment by health care provider organizations in order to take action is a core element of high-quality care. Equity is also one of the core dimensions of care as defined by the National Academy of Medicine; key aspects of promoting equity in care include assessing and acting upon social needs and assuring that other aspects of care are not contingent upon the level of social need.

The stand-alone value of the rate at which there is a positive screen for social needs, especially in the aggregate, is uncertain. An aggregate measure may be of value as an indicator of "risk" for either health outcomes or health care costs but would need to be validated and compared to other social risk indicators already in use.

The level of need of any particular indicator, such as food insecurity, may be of great value for a provider organization. Such information could prompt the provider to develop food supply programs such as pantries, to establish effective partnerships with community and governmental agencies, or to engage in public policy advocacy. But its value as a performance measure is unclear.

We would find great value in the use of a measure of change in the population level of a particular social need, such as food insecurity or housing instability. Such a measure has been developed in the NQF measure incubator project related to childhood food insecurity and is being incorporated into the maintenance of certification program of the American Board of Pediatrics.

We believe very few health care organizations have undertaken repeated measures of level of social need in their population and used such measures to assess the success of their programmatic efforts. We also recognize that the causes and solutions to many of these social needs are complex and lie outside the purview, and potentially the resources, of the health care system. Given that, we believe a measure of change in the positivity rate of a social need is best used for quality improvement at this time.

We note that the specifications indicate the measure applies only to beneficiaries over 18. Understanding that this measure is being considered for use in Medicare programs at this time, we nonetheless note that most of these indicators of social need (food insecurity, housing quality and instability and utility challenges) apply to all the members of a family or household and not simply the person answering an assessment. The information obtained through these assessments should be linked to, and services provided for, those other household members—particularly children who are most vulnerable to the harmful impact of these types of adversity. Similarly, we would want performance measure reporting to be stratified, or reported separately, for children and adults. In addition, although this approval is in the context of Medicare, the measure may be appropriate to ultimately include in the Medicaid Adult and Child Core Measurement Sets and be accompanied by guidance for states in their efforts to standardize these data in both child and adult populations.

Next Wave

This measure begins to close the loop for focusing in on addressing social needs. See also comments

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under MUC2021-136 for recommended details that could automatically be generated if collected electronically using ICD-10 Z-codes.

It could be captured by a composite ICD-10 Z-code if available, and/or the existence of detailed codes for WHICH needs are identified through the expanding number of health-related social need Z-codes.

In addition, for future social drivers, CMS should consider aligning the time frames for applying for any new ICD-10 Z-codes and creation of the MUC list to avoid implementation delays. E.g., it is already past the deadline for applying for ICD-10 codes to begin collection October 1, 2022, when this MUC list is being considered.

Premier, Inc.

Premier does not support adoption of this measure. While we are supportive of an overall screening approach, we are concerned that this measure will evaluate providers on factors that are outside of their control. Additionally, data collected through this measure will not be actionable and will not show directionality. For example, it is unclear what a higher positive screening rate means for a provider when compared against others. We instead encourage CMS to focus on the development of the "Screening for Social Drivers of Health" measure, which will better assess steps that providers are taking to evaluate the social needs of patients.

North Carolina Medical Society

NCMS is North Carolina's oldest professional organization, including nearly 12,000 members and a network of influential partners extending from county medical societies and specialty societies across the state, to the state legislature and Department of Health and Human Services (NC DHHS).

Consistent with our mission "to provide leadership in medicine by uniting, serving and representing physicians and their health care teams to enhance the health of North Carolinians," NCMS has long recognized and committed to act on the social drivers of health (SDOH), which directly impact health outcomes and health care costs.

On this basis, NCMS strongly recommends that the Measurement Application Partnership (MAP) move forward two measures forward through the regulatory review process: Screen Positive Rate for Social Drivers of Health (MUC2021-134) and Screening for Social Drivers of Health (MUC2021-136).

NCMS's support for these measures is rooted in the recognition that the presence of SDOH fuels physician burnout, creates economic risk for physician practices under value-based payment models, and drives poor health outcomes for North Carolinians. This is especially so in COVID's wake: faced with the convergence of their patients' clinical and economic needs, front-line physicians and other health care providers have been taxed as never before.

We recognize the strong alignment between physicians and patients about the importance of addressing SDOH. Focus groups we have conducted with our partners show striking agreement among North Carolinians (across race, gender, income, political affiliation, and geography) on what they need to be healthy, with all the focus groups choosing to spend more money on food and housing than on health care. Focus groups with NCMS members echoed these findings, with 100% of participating physicians indicating that some, many, or all of their patients are affected by social conditions.

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Our experience is that NC DHHS's requirement under Medicaid Transformation that all members be screened for food insecurity, housing instability, lack of transportation, and interpersonal violence has spurred crucial investments in the capacity necessary to address these issues. Specifically, this SDOH screening requirement spurred a public-private partnership to implement NCCARE360 – the first statewide, up to date, community resource database and closed loop referral platform, which is now live in all 100 of NC's counties – as well as investments in community health workers to support in connecting patients to community resources.

We view the proposed SDOH measures before the MAP as crucial to CMS recognizing the impact of these issues on patients and providers alike – and laying the foundation to invest in those community resources necessary for health.

Citations:

https://www.healthaffairs.org/do/10.1377/hblog20210429.335599/full/

Society of Hospital Medicine

SHM believes identifying social drivers of health is a crucial step towards addressing healthcare disparities and prioritizing resources around social and environmental factors that impact patients' health and wellbeing. We ask for more detailed information and definitions about the criteria for a positive screen to better assess this potential measure and whether to recommend it. We also strongly recommend consideration for how the measure may be implemented in federal programs and caution against using this measure to penalize providers. In the measure information, it seems CMS may propose this measure in the IQR and the MIPS. The MIPS scores providers, and adjusts their payments, based on performance on a set of measures and domains. We do not believe, for example, it would be appropriate for a high positive screen rate to result in reducing reimbursement for providers. We encourage careful consideration of these issues prior to recommending implementation of this measure.

Health Care Without Harm

December 9, 2021

On behalf of Health Care Without Harm, which maintains a hospital member network of over 1,400 hospitals across the country, we strongly support the National Quality Forum Measure Applications Program (NQF MAP) working groups in recommending the following two Drivers of Health (DOH) measures under consideration:

MUC 2021-136; Driver of Health Screening Rate, and

MUC 2021-134; Driver of Health Screen Positive Rate

Health Care Without Harm is founded on the belief that: As the only sector with healing as its mission, health care has an opportunity, indeed a responsibility, to use its ethical, economic, and political influence to create ecologically sustainable, equitable and healthy communities. Founded over 25 years ago, Health Care Without Harm seeks to transform health care worldwide so that it reduces its environmental footprint, becomes a community anchor for sustainability and a leader in the global movement for environmental health and justice. We conduct research, model strategic interventions, and provide guidance and resources to spread and accelerate best practice in the field – with programs

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focused on climate and health, safer chemicals, and healthy food.

Health Care Without Harm has long recognized the impact that DOH have had on increasing rates of poor health outcomes, chronic disease, and death. Climate change, the COVID-19 pandemic and increasing economic and social inequities in our communities that are the result of decades of systemic racism only serve to exacerbate the situation.

For example, some sobering statistics regarding diet-related diseases and how food insecurity is impacting our nation's health, published in The Washington Post November 30th: 1) More than 100 million Americans — nearly half of all adults — suffer from diabetes or prediabetes; 2) About 122 million Americans have cardiovascular disease, which kills roughly 840,000 people each year; 3) More Americans are sick or suffer from major medical conditions than are healthy, and much of this is related to diet-related illness; 4) If you are a Black person, those numbers mean you probably will have an even worse outcome. 49.6 percent of Black adults are considered overweight if not obese. Black people are also 60 percent more likely to be diagnosed with diabetes than White people; 5) Americans who suffer from diet-related conditions such as heart disease, diabetes, cancer, and obesity are 12 times as likely to die after a COVID infection; 6) And in 2020, the year COVID-19 hit the United States, African Americans were disproportionately impacted by the virus, many due to those same underlying diseases of obesity and diabetes. In total, Black people experienced a 2.9 year decrease in life expectancy, causing the Black-White life expectancy gap to widen from 3.6 to 5 years. In a single year.

Statistics similarly alarming can be found regarding the health impacts of poor indoor air quality, air pollution, climate change, poor access to public transportation or living close to a freeway or port, housing instability, and exposure to toxic chemicals in the air, land, and water. And they are disproportionately affecting under-resourced communities of color. The frightening question is, how big and bad do the numbers have to get? What is the final tipping point before the federal government will declare a state of public health emergency and prioritize addressing the DOH with a systemic strategy? A coordinated, aligned national standards measurement process to screen for DOH as part of basic primary health care is absolutely critical to moving forward, and these two measures are a positive start.

The Physicians Foundation, which is directed by 21 state and county medical societies across the country, submitted these first-ever measures focused on screening patients for food insecurity, housing instability, transportation, utility needs, and interpersonal safety, including intimate partner violence. Their adoption would represent a crucial milestone as the first standardized federal measures to assess social need in the history of the U.S. health care system.

Despite the well-documented impact of DOH on health outcomes and costs and their impact on people of color, there are still no approved, standardized DOH measures in any Centers for Medicare and Medicaid Services' (CMS) programs. The impact of DOH interventions remain fairly invisible in federal health care policymaking, and the absence of standard DOH data or measures impedes efforts to achieve racial equity in health outcomes, given their profound impact on people and communities of color, especially in COVID's wake.

In enacting these first federal DOH measures, CMS could send a powerful signal to the health care sector and the communities they serve that there should be acknowledgement of how DOH impact peoples' health outcomes and an intention to address them in a coordinated strategy across the country. These

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initial DOH measures for screening could lay the foundation for additional measures focused on navigating beneficiaries to resources and connecting beneficiaries to the resources they need to be healthy.

When addressing issues such as food insecurity, housing instability, climate change, lack of transportation, and exposure to toxics in our air, land, and water, we cannot settle on solving for acute, short-term health impacts alone. We must devise long term solutions for these long term and entrenched challenges that require equitable investment and attention. Our collective environmental and economic health need to be prioritized, with regenerative systems that are protective of our environmental health and natural resources, and substantial investment in fair labor practices and living wage mandates.

It is our hope that CMS will do the right thing and approve these measures, creating a federal, standardized system to incorporate DOH factors into primary health care and begin to set the stage for long term effective intervention.

Signed by:

Gary Cohen, President, Health Care Without Harm & Practice Greenhealth

For more information, please contact: Emma Sirois, National Director, Healthy Food in Health Care Program, esirois@hcwh.org

MS State Department of Health

This measure will not only determine what the patient's basic needs are, but it was also help in determining what programs/services are lacking in that patient's community. It will also help determine what other social determinants are playing a positive or negative role in the patient's health (mental and physical). The benefits outweigh the burden of data collection because it will help to improve the overall health in communities in identifying service gaps and referring patients to services, they need. My program is in the process of screening for social determinants of health in working with expectant and parenting families. No current implementation challenges because the assessment is already built in the electronic health record database.

Phreesia

Phreesia applauds CMS's commitment to screening for social drivers of health and identifying the percent of beneficiaries who screen positive. However, there is no discussion of how the data should be collected. While the proposed IQR measure MUC2021-106 would require hospitals to train staff on health equity screenings, no measure included in the 2021 MUC List include an explicit reference to how such data should be collected. Furthermore, none of these data collection methods for social drivers or those in the equity domain specify the crucial importance of self-reported data from patients.

Self-reported data is fundamental to achieving higher quality care and an optimal patient experience. Experts agree that self-reported data is the most effective approach for data collection. Additionally, many health systems are now initiating or scaling SDOH screening, where self-reporting is crucial. Most are accomplishing this through verbal collection programs, though our experience shows that digital screening tools are by far more effective in accurately capturing patients' demographic and social needs information.

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In general, failing to effectively capture patient demographic and social needs information has the potential to erode trust in the healthcare system among minority groups whose trust is already significantly low. However, when given the opportunity to input their own demographic data, we have found that patients are able to accurately provide key information and can play a key role in improving their own care by closing gaps in data. Phreesia encourages CMS to move providers to screening methods that include an explicit focus on patient self-reported data.

CyncHealth

The proposed measures are a step in the right direction. As a health information exchange (HIE), we recognize that these measures add value to both the community and providers. They allow for the community to become more aware of the social needs that are prevalent in the community, and for providers to have better data for reporting. This increased awareness and data allows for an improvement in cross-sector partnerships to occur that empowers providers and communities to collaborate and advocate for polices that support equity in their communities.

As an HIE, we would use the measures to do regulatory reporting on behalf of the providers we serve. The benefit of these measures will be determined by the effective implementation of the measure. The biggest challenge to implementation of these measures is a lack of standardization. There should be serious consideration given to adapt a universal screening tool, so that outcomes can be measurable and consistent across the board. A failure to adapt a standardize screening tool will result in inconsistent outcomes. Currently depressions screenings are standardized to the PHQ and that allows for measurable and consistent outcomes to be reported. The same level of standardization needs to be applied to these proposed measures. The consistency of measurable outcomes that standardization will provide will enable the development of a good tool and provide a real-world benefit that outweighs the burden of data collection or reporting.

National Produce Prescription Collaborative

December 9, 2021

To: Members of the NQF: Measure Applications Partnership

From: Members of the National Produce Prescription Collaborative (NPPC)

*SUBMITTED TWICE

*RE: Support for Driver of Health Screening Rate (MUC2021-136)

*Re: Driver of Health Screen Positive Rate (MUC2021-134)

As members of the National Produce Prescription Collaborative (NPPC), we are pleased to write in support of the Drivers of Health Measures currently being considered under the Measure Applications Partnership Considerations. We were thrilled that CMS accepted the “Drivers of Health Screening Rate” and the “Drivers of Health Screening Positive” measures as part of the 2021 CMS MUC list and recommend that you move them forward as part of the 2021-2022 Measure Applications Partnership (MAP) cycle.

Recognizing the nexus between hunger, nutrition insecurity and the structural inequities at the heart of

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these issues, Members of NPPC support screening for drivers of health, including food insecurity and believe the adoption of these measures would add tremendous value and represent a crucial milestone on the path towards health equity.

We appreciate that there is a current opportunity to enact the first-ever social DoH measures in the history of health reform. CMS recently included the DoH measures focused on screening patients for food insecurity, housing instability, transportation, utility needs, and interpersonal safety in its "measures under consideration" list this year. These measures (stratified by race/ethnicity) are well-tested in over 600 clinical sites across the country through the CMS Innovation Center's Accountable Health Communities model. Adoption of these measures will go a long way to identify gaps in patient care and health outcomes that extend beyond the four walls of a health clinic and, with strengthened community-clinical connections, curb the growing national cost burden of diet-related disease through our federal health programs.

As you know, diseases linked to poor diet are the most frequent causes of death in the United States, and diet is the leading risk factor for premature death worldwide. Reducing even a fraction of this burden by improving people's diets would save countless lives. The COVID-19 pandemic has brought renewed focus to gaps in access and infrastructure that limit the ability of our federal health care and food assistance programs to address the issues of nutrition, food insecurity, and health. COVID-19 has also exposed the long-standing burden of diet-related chronic disease. Unfortunately, these diet-related diseases disproportionately affect low-income households, racial and ethnic minorities, and elderly people, highlighting the wounds of systemic racism and disparities in the US economy, food systems and healthcare systems.

While a growing number of CMS Innovation Center models are incorporating DoH screening and navigation on social needs, they use varied tools and approaches. As a result, CMS cannot systematically compare or use the data. The same is true for race and ethnicity data, which currently are measured or reported inconsistently across CMS programs. NPPC members and partners are developing and deploying programs and platforms and are seeking robust research capacity to support community-rooted health organizations in their efforts to address the lack of affordability and access to healthy food across the country.

If approved, this measure would apply to two key Medicare programs — the merit-based Incentive Payment System and the Hospital Inpatient Quality Reporting Program — and improve patient outcomes. At the same time, it would provide a crucial foundation for comparable measures to be adopted by the Medicaid Adult and Child Core Measure Set while providing critical guidance for states in their efforts to standardize DoH data. Furthermore, we see adoption of this measure as a pathway for Produce Prescription programs, which are demonstrating their value by improving the health outcomes of people struggling with diet-related diseases such as diabetes, high blood pressure, and kidney disease by increasing dietary quality and treating the stresses of food insecurity.

Evidence of Produce Prescription Programs

The Produce Prescription intervention began just over a decade ago. Today, more than 100 organizations administer them across the country.

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A growing body of evidence, including 30 studies in peer-reviewed scientific and economic journals in the past 5 years, suggests that Produce Prescriptions improve intake of fruits and vegetables, improve overall dietary quality, reduce the gap between actual daily consumption and the national recommendations, lower weight, lower blood pressure, and lower Hemoglobin A1C — the biometric indicator used in diagnosing for diabetes and prediabetes.

Due to early promising results, Medicare Advantage plans have implemented Produce Prescriptions alongside other food and produce through the allotment for Special Supplemental Benefits for the Chronically Ill (SSBCI). From year one (2020) to year two (2021) plans offering these food and produce benefits have grown from 101 to 347, a 244% Medicaid managed care plans in several states have also implemented Produce Prescription programs through various flexibilities allowed using 1115 waivers. Having DOH measures available to screen for food insecurity will help these government-sponsored health plan practitioners deliver on the growing promise of food as medicine. For example:

In North Carolina, Reinvestment Partners and Blue Cross NC are launching an RCT that compares Produce Prescriptions and healthy food boxes for 6- or 12-month enrollment periods. Reinvestment Partners is also participating in an evaluation as part of Healthy Opportunity Pilots (under North Carolina's 1115 waiver). NC programs beneficiaries must have at least one qualifying physical or behavioral health condition and have one qualifying social risk factor. Of interest, partnering with insurers and providers, including 2 major health systems (Duke Health and Atrium Health, the state's largest provider network); 9 Federally Qualified Health Centers; 30+ county level WIC, DSS Offices, and health departments; and 100+ staff at a statewide care management agency (Community Care of North Carolina). The breadth of this program expansion is a demonstration that effective collaboration is possible in diverse healthcare settings and early research is showing promising impacts on food insecurity.

Likewise, Wholesome Wave's Fruit and Vegetable Prescription Program® (FVRx®), which ran in 12 states across the country, reached thousands of individuals who struggle with diet-related illness. FVRx reached 2300+ recipients in a 2016 Los Angeles pilot and was expanded to communities and health centers in Houston and Miami, Hartford and Sacramento and has helped more than 5,000 people. In the pilot, 93% of participants met produce-consumption guidelines by the program's conclusion, with a 128% increase in the number of cups of fruits and vegetables consumed. Among people at high risk of developing diabetes, those taking metformin lowered their risk of getting diabetes by 31% compared with those taking a placebo, while those who modified their diet and exercise regularly lowered their risk by 58% compared with those who didn't change their behaviors, a near doubling in risk reduction.

Additionally, the Washington State Department of Health has partnered with twelve health care systems and public health agencies and a large grocery chain to redeem over a million dollars in produce prescriptions from 2016 through 2020.

Having a Drivers of Health Screening Rate (MUC2021-136) that screens for food insecurity will provide vital insights to addressing nutrition insecurity for qualified patients enrolled in Medicare and help determine who will benefit from the intervention. This will be a vital step to adoption of Produce Prescription interventions within the healthcare system. The members of the National Produce Prescription Collaborative recommend including these measures among those the MAC moves forward

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for consideration.

About NPPC

The National Produce Prescription Collaborative (NPPC) is a group of produce prescription practitioners, researchers, and advocates, who gathered in 2019 to catalyze the vital role of food and nutrition in improving health and wellness by collectively leveraging the unique opportunities for Produce Prescriptions to achieve wellness by embedding and institutionalizing Produce Prescriptions within healthcare practice. Our respective organizations are actively working to bring new and innovative Produce Prescription models to communities across the country.

NPPC defines a Produce Prescription program as a medical treatment or preventative service for patients who are eligible due to a diet-related health risk or condition, food insecurity or other documented challenges in access to nutritious foods, and who are referred by a healthcare provider or health insurance plan. These prescriptions are fulfilled through food retail and enable patients to access healthy produce with no added fats, sugars, or salt, at low or no cost to the patient. When appropriately dosed, Produce Prescription programs are designed to improve healthcare outcomes, optimize medical spending, and increase patient engagement and satisfaction.

Harvard FXB Center for Health and Human Rights

I believe there is much value in collecting this data. However, I do wonder if there is a complimentary mechanism/data collection standard that could be implemented to understand if a referral or connection has been made to address those needs identified. Without this additional yet complimentary data collection, this data collection standard alone could also promote an ethical dilemma that emphasizes data collection over both resource connections and the investment in the community infrastructure to meet identified resource gaps. In 2016, “Dr. Alvin Garg, Dr. Renee Boynton-Jarret, and Dr. Paul Dworkin outlined in the JAMA Network that screening for any condition in isolation without the capacity to ensure referral and linkage to appropriate treatment is ineffective, and arguably unethical.”

Also, with this standard, I hope that CMS will think about how this new data collection influences the social determinants of health industry. In the recent research article by Zachary Goldberg and Dr. David Nash “For Profit but Socially Determined: The Rise of the SDOH Industry,” an emerging for-profit industry focused on social determinants of health has received over $2.4 billion dollars in funding and is valued at $18.5 billion dollars.

As studies show, racial/ethnic minorities are more prone to experience disparities in social determinants similar to traditional health disparities. Therefore, as SDOH technology platforms extract data, there is a higher likelihood of collecting more SDOH data or resource gap data on BIPOC communities. It is important to understand that BIPOC communities make this data valuable and, in turn, makes the technology platform/vendor platform. The market is even seeing SDOH technology companies participating in a monopoly to gain influence in this sector. These companies see extreme profit gain at the cost of BIPOC pain; that pain is revealed in BIPOC SDOH data. If one claims to be an advocate of racial justice, one cannot align with this approach--nor the technology vendors, health care systems, and other stakeholders that push this approach. This SDOH deficit data extraction approach ultimately furthers racial capitalism, which is established upon extracting social value and economic gain from the racial identity of others. Racial capitalism highlights the direct relationship between racial exploitation

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and capital gain, and many stakeholders see this currently in the SDOH sector. These technology companies will even publicly acknowledge the existence of structural racism while engaging in acts of profiteering off of structural racism.

Community members, especially BIPOC community members, are often least prioritized in these tech-forward SDOH interventions as most of these technology-forward approaches fail to see the patient/clients of social service organizations as the ultimate end user.

The primary reason for this predatory behavior stems from the healthcare sector's dictation of the return-on-investment case that is deemed most important. Often patients are seen as a high-risk group, and many health systems, health plans, and others are interested in the mere collection of this data to understand this population more. The data collection normally benefits stakeholders of power for health system focused analyses, like understanding the relationship between essential resource needs or resource care gaps (like food insecurity and housing insecurity) and healthcare metrics, like utilization and cost. Even more, this influx of a new data source can facilitate machine-based learning or predictive analyses that aim to reveal new learnings about the patient/client group. However, this machine-based learning or predictive analyses without an equity or anti-racist approach can have harmful effects marginalized communities. In Automating Inequality, Virginia Eubanks investigates how data mining, predictive risk modeling, and algorithms can actually be used to punish historically marginalized and socioeconomically disadvantaged individuals and groups. In the collection of SDOH data, patients are rarely fully informed nor provide consent on how data is used within a SDOH intervention and even more so after their intervention encounter.

We, as a sector, must ask ourselves as stakeholders in the SDOH space:

1. If patients and clients knew our approach to data use fully, would it yield more trust?
    a. If not, how do we create structures of good stewardship and trust around our clients'/patients' SDOH data?
2. How do we have processes of informed consent and informed refusal with the collection of SDOH data, particularly given the predatory/structurally racist nature that seems to be present in the SDOH industry currently?
3. Additionally, are we using SDOH data to create, reinforce, or further perpetuate bias?
    a. If so or if we are unsure, how do we create accountability structures to ensure the creation, reinforcement, perpetuation of bias does not occur (or at least limited)?

With the implementation of these new data collection standards, which I believe can be beneficial, I believe there is a need for further work to happen to ensure that the data collection is anti-racist. Without this equity/antiracism work, I fear how SDOH data will be used.

Social Interventions Research and Evaluation Network at the University of California, San Francisco
December 9, 2021

National Quality Forum

Measure Applications Partnership

Dear Measure Applications Partnership Committee Members,

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As national leaders of the Social Interventions Research and Evaluation Network (SIREN), a center at the University of California, San Francisco dedicated to elevating and strengthening evidence related to programs and policies that can support health care systems to meaningfully deliver social care and as leading national experts in this evidence, we welcome the opportunity to comment on the social risk screening measures (MUC2021-134 and MUC2021-136) currently being considered through the MAP process.

We are excited to see federal level interest in quality measures related to social determinants of health (SDH) and social risks since these factors have been closely tied to health and health care utilization outcomes and equity. Incorporating feasible and impactful measures will help to signal the importance of assessing and addressing patients' socioeconomic risks as a critical part of a comprehensive strategy for improving care quality and outcomes.

We very much appreciate the potential advantages of increased recognition of patient-reported social risks in health care settings. Awareness of social risk may inform a range of interventions that have the potential to improve care quality, patient health, and reduce health costs. These interventions have been described in the 2019 National Academy of Sciences, Engineering, and Medicine report on Integrating Social Care into the Delivery of Health Care to Improve the Nation's Health. They include not only strategies to connect patients with social services, but also strategies to tailor or adjust medical care decision-making based on patients' social contexts and opportunities to strengthen data that informs community level investments and advocacy.

Recognizing the potential advantages of implementing quality measures in this area, we recommend moving forward with these measures with some modifications to address concerns detailed below. We also hope that this is just the first step in building out a robust set of quality metrics that measure, guide, and reward clinicians' and hospitals' work to improve patient outcomes by identifying and addressing social risks as part of high-quality clinical care.

Although we support moving forward with these measures, we share below some key concerns based on our knowledge of the research evidence and our experiences as practitioners (for Drs. Gottlieb and Lindau), as well as recommendations for how to address these concerns.

6. Could social risk screening cause harm that outweighs benefit?

Although there is abundant evidence that social factors strongly shape health and health care outcomes and inequities, it is not yet clear whether social screening (assessing) without subsequent interventions (addressing) actually improves outcomes. Studies have found that many patients understand how social conditions relate to health and well-being and believe that screening in health care settings is appropriate. At the same time, patients have voiced important concerns about potential negative consequences of sharing information about social adversity in health care settings, including concerns that the information could be used against them, worsen feelings of stigma, and exacerbate real or perceived bias/discrimination. Where, how, and by whom screening is conducted and data are used will influence patients' experience and the quality measures. On the whole, evidence suggests benefits outweigh risks in contexts where needs are assessed in ways that are patient-centered and minimize risks for stigmatization and discrimination. In the future, an additional patient-centered and patient-reported measure might be considered about the experience of screening.

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7. Are there drawbacks to having measures related to screening without measures related to acting on identified needs?

Incentivizing screening through quality measures without also incentivizing action on identified concerns may lead health care organizations to attend to assessment over intervention, which may have benefit for calculating risk-adjusted payment but is unlikely to meaningfully change health outcomes. In a worst-case scenario, screening that does not yield risk-adjustment could result in 'creaming' or strategies to limit service to individuals or communities with higher socioeconomic risk. At the same time, although several NIH-funded randomized controlled trials with a diversity of urban and rural target populations (e.g., families with hospitalized children, dementia caregivers, older people with diabetes, adults, and children with cardiovascular disease risk) are ongoing, research has not yet provided clarity about what types and what intensity of actions are most likely to improve outcomes. Ideally the screening-focused QM will contribute to more innovation and evaluation in the intervention space. This learning should contribute to measure development around strategies to hold health care organizations accountable for acting on collected social data. One possibility is to consider revising the second proposed QM (#136) to reflect a measure of change in the screen positive rate.

8. Are these the right social domains to include in a social screening quality measure?

In 2014, the National Academies recommended routinely incorporating information about financial strain/insecurity in EHRs with follow up assessments conducted only as needed around basic material needs such as transportation, utilities, food, and housing. This recommendation is not reflected in the proposed measures. Though the four social risks related to socioeconomic security (food insecurity, housing instability, transportation problems, and utility security) included in the proposed measures may each be relevant to health and actionable, it may not be maximally efficient to screen for each of these until an overarching assessment of financial strain is conducted; on the other hand, unpublished data suggests that needs disclosure may be higher in response to individual topics. If these measures move forward as they are, in the future research on likelihood of disclosure should be revisited and the measures should be modified. Additional topics related to basic material needs also should be strongly considered, e.g., digital access (a topic of whose relevance to health disparities is rapidly changing), employment, legal needs, and childcare affordability/access.)

9. Interpersonal violence screening poses unique concerns and opportunities

Screening for interpersonal violence raises a number of unique concerns, including but not limited to the distinction between interpersonal violence and intimate partner violence. One consideration would be to require that if IPV is the only measure a health system is assessing, in order to meet the quality standard, they must also include at least one other driver of health measure from the list of other included domains.

10. The proposed measures would benefit from more detailed specifications.

We would like to highlight two areas that are not clear about these measures:

- It is our understanding that measure 136 (screening) is meant to only count beneficiaries screened for all five risks (vs. any of the five risks) and that the screening positivity measure (134) is meant to

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count beneficiaries with at least one of the needs (not only those who have all five). However, the way the measures are defined do not make this explicit.

- The measure definitions also do not specify whether clinicians and hospitals can use any screening tool or approach or whether there is a required set of questions or tools that should be used. Despite hoping for future standardization, we currently would recommend allowing flexibility in how different social domains are measured because since there are a variety of assessment tools already in use across the country.

We recommend that these definitions be clarified as the measures move forward in the process.

Summary

In summary, based on our knowledge of the research evidence in this space, we recommend that these measures mover forward but with the following modifications:

- Clarify the definitions of the measures
- Provide guidance about how to conduct screening in a way that is patient centered, maximizes confidentiality, and minimizes risks of stigmatization and discrimination. Also consider adding measures of patient experience in the future.
- Ensure the measures provide clinicians and hospitals flexibility in the screening tools and approaches used.

In addition, in the future we recommend adding measures focused on the actions that providers and hospitals can take to improve patient outcomes based on screening information, since those actions are what will lead to benefits to beneficiaries.

We thank NQF for providing this opportunity to provide feedback about this important and growing part of high-quality patient care. Please reach out to laura.gottlieb@ucsf.edu if you have any questions about these comments.

Sincerely,

Caroline Fichtenberg, PhD, University of California, San Francisco

Taressa Fraze, PhD, University of California, San Francisco

Laura Gottlieb, MD, MPH, University of California, San Francisco

Danielle Hessler Jones, PhD, University of California, San Francisco

Stacy Lindau, MD MAPP, University of Chicago

Koss on Care LLC

Initial screen is important particularly to set baseline metrics, but screening without any follow on intervention will not advance improvements for patients and families.

Screening needs to have accompanying socio-demographic metrics to also track and address disparities and inequities.

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Without an understanding of the level of screening for these known social determinants we cannot start to address major drivers of health and health outcomes.

As EHR increasingly facilitate & capture screen it should be reasonably cost effective.

Improved sharing of such data across providers could also reduce the burden.

Colorado Academy of Pediatrics

I would recommend outcome metrics and not process metrics.

The outcome metrics I would recommend is what % of eligible Medicaid enrollees are participating in SNAP and WIC. SNAP and WIC have been demonstrated to improve health outcomes, lower health costs and are currently under-enrolled. This metric would drive partnerships and innovation needed to maximize enrollment in these federal nutrition assistance programs. Screening can be harmful to some families and increase shame and fear. Promoting SNAP/WIC and facilitating enrollment/participation is a more strength based approach.

American Occupational Therapy Association

AOTA supports MUC2021-134 Screen Positive Rate for Social Drivers of Health and MUC2021-136 Screening for Social Drivers of Health for both the IP-QRP and MIPS. These measures will help to ensure these items are monitored for patients. These important social drivers are areas that occupational therapy practitioners address with clients to improve outcomes.

American Psychological Association

I am writing on behalf of the American Psychological Association (APA). As requested by the National Quality Forum (NQF), APA is providing comments on the draft measure specifications for the Screen Positive Rate for Social Drivers of Health (MUC2021-134) and Screening for Social Drivers of Health (MUC2021-136).

APA is the largest scientific and professional organization representing psychology in the United States. APA's membership includes over 122,000 researchers, educators, clinicians, consultants, and students. APA seeks to promote the advancement, communication, and application of psychological science and knowledge to benefit society and improve lives.

We appreciate the Physicians Foundation undertaking this important initiative to develop quality measures related to social determinants of health (SDOH). It has become increasingly clear that addressing SDOH within health care is critically important. One of the first steps in addressing SDOH is measurement and documentation, because you cannot adequately address an issue if you are unaware of the extent to which it exists. However, measuring SDOH has numerous barriers, including philosophical beliefs on the part of providers that it is not their place to be asking such questions, training barriers in not knowing how or what to ask patients, and practical barriers with challenges in identifying community based interventions to address SDOH and ensuring patients receive these services once identified. Further, without establishing reimbursement mechanisms and incentives for measuring SDOH, provider behavior is unlikely to change. One method for implementing a standardized approach to measuring SDOH would be to collect data via a health risk assessment or screening tool, document it in the electronic health record (EHR), and map SDOH data onto existing IDC-10-CM Z codes for documenting conditions in the environments where people are born, live, learn, work, play and age.

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To that end, while we applaud initial efforts to move the field forward with the proposed measures as a means of addressing the aforementioned barriers, we wish to convey several specific comments regarding the measure specifications:

4. While not identified within the measure specifications on the MUC List document, it is our understanding that both measure 134 and 136 are meant to be based on administration of the AHC screening tool. However, the specification as currently written does not provide any cut-off score for screening positive for social drivers of health, nor does it provide any reliability or validity data on the AHC tool itself. Further the AHC tool contains 26-items, making it a relatively lengthy measure and calling into question the feasibility of implementation, particularly in practice settings that do not have an EHR with this scale already imbedded.
5. It is unclear how both measures add value, as the information gathered from each one could be combined in one measure that would, if expanded upon, have a greater impact on improving outcomes. For example, one screening measure for social drivers of health that included a follow-up action of providing referrals to patients who scored positive is the mechanism of change we should be promoting in programs such as MIPS. As currently written, MUC2021-136 rewards providers for simply screening for social drivers of health but requires no action on their part when someone screens positive. And MUC2021-134, as currently written, merely rewards providers who have a high volume of patients with food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety. In addition to not then requiring any follow-up action of referral to appropriate services when someone screens positive, why would we reward providers who report higher rates of providing services to those with greater social need? Higher rates more likely reflect the communities within which services are rendered as opposed to a quality action on the part of a provider or setting. While this data could assist in allocating resources to communities in need, this is not currently how MIPS measures are conceptualized or utilized within the program, making resource allocation an unlikely outcome.
6. Screening patients for social drivers of health is a responsibility that needs to be implemented across the provider spectrum, including clinical psychologists and clinical social workers. It will be imperative that the appropriate CPT codes for psychotherapy, assessment, and health and behavior interventions be included so that MIPS eligible psychologists and social workers can also report on these measures should they be accepted.

APA wishes to thank NQF for this opportunity to provide comments on the draft measure specifications for Screen Positive Rate for Social Drivers of Health (MUC2021-134) and Screening for Social Drivers of Health (MUC2021-136). If your staff have any questions, you are welcome to contact our Director of Operations and Innovation, Nicole Owings-Fonner, MA, PMP by email (nowings-fonner@apa.org).

Cordially,

C. Vaile Wright, PhD

Senior Director, Health Care Innovation

American Psychological Association

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OCHIN, Inc.

These measures are essential to identify and remedy persistent structural inequality that adversely impacts patient outcomes. This enables the clinical team to identify structural barriers to improved health care and associated social and other services that could facilitate improved patient health status, including improved access to care (for example, transportation). Care teams would also be able to identify areas of need in their patients, and focus interventions and outreach based on this context.

These measures are needed for quality improvement activities, payment, research, and public health activities including disease surveillance and mitigation measures in order to address health care inequity. In light of the USCDI adoption of SDOH domains and elements, the suitability of this information can inform numerous clinical, public health, and policy needs to improve care overall equitably. Adding information on social complexity to payment discussions could provide valuable insight for value-based payment and care arrangements and risk-bearing contracts.

OCHIN network members have documented over 1 million individual patient screenings for SDOH. The screening, evaluation, and use of this information is complex, challenging, and hinges on preserving patient trust. This is a resource intensive process that requires adequate time, workflow design, patient engagement, and staff and clinician training. The benefits of the measures outweigh the burden of data collection and reporting to the extent providers are able to identify optimal workflows and staffing to collect the information with the goal of reducing cognitive burden and enhancing team-based approaches to care while preserving and safeguarding patient-clinician relationship and privacy.

OCHIN recommends that the measures for interpersonal safety domain be removed. Current approaches to addressing relationship safety and intimate partner violence (IPV) are moving away from screening towards a universal education and harm reduction approach. Futures Without Violence (FWV), the CMS partner for IPV prevention and education nationally, estimates that 1 in 3 women has experience IPV, but disclosure rates in practice are usually less than 10% (around 5-6% among OCHIN patients), indicating significant underreporting and calling the utility of collecting this data into question. Instead, FWV provides and promotes a framework called CUES that addresses confidentiality (including its limits in required reporting settings), universal education about healthy relationships, and support for any disclosure that includes warm handoff to appropriate resources. Given this disparate approach, I would recommend not including IPV in the current measures. I would be more supportive of a separate additional measure for IPV focused on the provision of universal patient education.

OCHIN has previously advocated for inclusion of SDOH in screening measures and data standards to begin with the domains of housing, food insecurity, and transportation as “core” domains appropriate for screening in most every community and patient panel. The addition of utility assistance aligns with research from the SIREN group at UCSF that finds these four domains (housing, food insecurity, transportation, and utility assistance) are the most impactful for screening and action in healthcare settings. Consequently, I see these as the appropriate domains to include in such measures at this time. In the future, other domains could either be optional based on appropriate community or clinic considerations or added as more evidence about the relationship between SDOH and health becomes available.

United Way of the Mid-South

We welcome this opportunity to submit our comments related to the proposed addition of two new

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proposed quality measures related to social risk screening:

- Driver of Health Screening Rate: % beneficiaries 18 years and older screened for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-136)
- Driver of Health Screen Positive Rate: % beneficiaries 18 years and older who screen positive for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-134).

In 2016, the United Way of the Mid-South (UWMS), based in Memphis, Tennessee, launched Driving The Dream (DTD), a resilient human services ecosystem that aligns and better integrates the local human services, represented by 82 agencies, with the goal of connecting under-resourced families to an array of supportive services as well as clinical healthcare to improve their overall health and wellbeing. As an organization, we have worked deeply in this space and understand the nuances and complexities of coordinating and aligning clinical care and social services. As a former state public health commissioner and practicing physician, I personally understand firsthand the social and economic challenges families face when it comes to promoting their own health and the health of their children and other family members.

Given this experience and exposure, UWMS believes the introduction of these measures is a critical step in bridging the gap between clinical services and social services that address the socioeconomic and environmental factors, which as evidence supports contributes to 50% of a person's overall health and wellbeing. Adoption of these measures will provide standardized data that begin to provide insights into the depth and breadth of social barriers that contribute to poor health outcomes. Additionally, with the ability to disaggregate by demographic characteristics, it will make visible the social factors driving or inhibiting health, particularly for communities of color. Equipped with this data, human services providers can better direct existing resources to be responsive to gaps, while also more effectively making the case for additional services that may be needed.

While these measures are just a first step in terms of diagnosis, adoption of these measures has the potential to drive greater awareness among clinical providers regarding the interconnectivity of physical health and underlying socioeconomic conditions. That awareness has the potential to incentivize more formal partnerships between clinical care and social service providers, all with the ultimate goal of improving patient health and wellbeing.

We are in full support of the adoption of these measures, however, we do raise one potential implementation challenge, as it relates to screening. There are a number of social determinants of health screening tools that have been adopted and in use by both clinical providers as well as social service providers. Understanding if there are specific validated screening tools that must be used to screen and diagnose these conditions is a potential area for further exploration and discussion.

Should the review committee have any follow-up questions or additional discussion, we would be more than happy to further contribute insights and related guidance.

Sincerely,

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Kenneth S. Robinson, M.D.

Signify Health
December 8, 2021

National Quality Foundation

Measures Application Partnership

RE: Measures Under Consideration 2021-134 and 2021-136

To Whom It May Concern:

We appreciate the opportunity to offer comments pertaining to the referenced MUCs. By way of background Signify Health is a value-based care company that brings together a unique combination of services to reduce the costs and improve the quality of health care provided to beneficiaries of public and private health plans. We are a leading provider of technology-enabled, in-home assessments, complex care management, and SDOH services. We believe deeply that health flourishes in safe homes and connected communities. Every day, across the U.S., we deploy the nation's largest mobile network of duly licensed clinicians to support people where they are – in their homes, residential facilities, and communities. We take the time to fully understand their lives and use these insights to connect them to the medical and social care they need most.

Our comments apply to both proposed Measures.

How would adding this measure add value? How would the measure improve patient outcomes?

The proposed measures for data collection and reporting represent the first and necessary step to assessing the scope and scale of social needs for a population and understanding its true impact on health outcomes. Subsequent analyses of the resulting data can assist community-based organizations, payers, providers, and policymakers in designing programs that are discrete, modifiable, meaningful, and impactful in addressing social determinants of health.

Do the benefits of the measure outweigh the burden of data collection or reporting?

Yes, however financial incentives will likely be necessary in order to accomplish broad data collection efforts. In order to relieve the associated burden, CMS could consider creative/innovative ways to collect the SDOH data to reduce burden on hospital and physician care teams. However, it is important to recognize the obvious: not all populations seek care in the traditional health system. If a hospital or physician is the sole data collection site, we are missing out on a significant population with unmet SDOH needs that could exacerbate a clinical condition that results in a subsequent hospital admission. To ensure more comprehensive data collection, public and private payer (Medicaid, ACA, MA, Medicare Supplement private insured) enrollment processes could be expanded and utilized to collect **standardized data**. Government grants could also be made available to organizations such as the United Way and other community-based entities that interact with community based organization to enlist their aid in collecting and submitting SDoH data.

For what purpose are you using the measure (e.g., QI, certification/recognition,

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regulatory/accreditation, payment, public reporting, disease surveillance)?

As an organization, Signify Health collects SDoH data on a limited basis. We utilize this information to design programs that improve access to community-based services and to improve health outcomes.

Are there implementation challenges?

Yes. From a technological perspective, ensuring the security and privacy of data collected as CBOs are not covered entities under HIPAA; and the absence of a standardized data set; and operationally ensuring appropriate and culturally sensitive training of staff necessary in order to build patient trust. Importantly, the need for financial support to cover the required additional resources, time, and effort to comply fully.

Thank you for your consideration.

Submitted on behalf of the Company by Manjula Julka, MD, VP Medical Affairs, Senior Population Health

• OOCMO

About Fresh, Inc.
December 7, 2021

To: Members of the NQF: Measure Applications Partnership

From: About Fresh, Inc.

Re: Driver of Health Screen Positive Rate (MUC2021-134)

Thank you for the opportunity to provide comments on the 2021-2022 Recommendations for Measures Under Consideration. We were happy to hear that CMS accepted the "Drivers of Health Screening Rate" and the "Drivers of Health Screening Positive" measures as part of the 2021 CMS MUC list. We are writing now to recommend that you move those forward as part of the 2021-2022 Measure Applications Partnership (MAP) cycle.

We are writing on behalf of About Fresh, Inc., a Boston-based nonprofit that partners with health systems and civic leaders to get healthy food to the people who need it most. Our team builds retail and technology solutions that empower households to access healthy food, and we uplift data, health insights, and community voice to meaningfully integrate food access into the delivery of quality care.

We are submitting this letter because it is time to adopt federal standards for screening patients for the lived circumstances, such as food security and housing stability, that widely accepted research tells us drive a majority of healthcare outcomes [1]. Despite that research, CMS has to date taken only limited initial steps to address these DOH – such as allowing certain Medicare Advantage plans to spend chronically ill members' premiums on fresh produce and other DOH. Furthermore, despite the growing focus on DOH there are currently no standard food security or other DOH measures in any of the federal programs that determine how insurers and healthcare providers are paid. Among other consequences, the absence of standard DOH data and measures impede efforts to achieve racial equity in health outcomes. Given the disproportionate and profound impact of the DOH on people and communities of

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color, especially in COVID's wake, this represents a profound gap in our ability to understand and address the racial inequities in our healthcare system.

The Physicians Foundation (directed by 21 state and county medical societies across the country) has submitted to CMS two DOH measures focused on screening for food insecurity, housing instability, transportation, utility needs, and interpersonal safety. These measures represent the foundation for future measures focused on ensuring patients secure the resources they need to be healthy and enabling community investments required for health. These measures (stratified by race/ethnicity) are well-tested in over 600 clinical sites across the country through the CMS Innovation Center's Accountable Health Communities (AHC) model. AHC has now screened ~1 million beneficiaries, with 69% of those who are navigation-eligible reporting food insecurity (the highest reported need).

These DOH measures have gained significant traction and momentum in the healthcare sector. The Commonwealth Fund and the Blue Shield of California Foundation recently published a blog, focused on these measures as a crucial milestone on the path towards health equity. The Physicians Foundation also published a Modern Healthcare op-ed calling for the measures' adoption, given the profound impact of DOH on health outcomes and costs, as well as physician burden and burnout.

Including food insecurity as a quality measure in the major federal healthcare programs (Medicare and Medicaid) via these DOH measures is a crucial prerequisite for CMS, states, or commercial payors to pay for access to healthy food, not as a pilot or initiative, but as a standard health benefit. Absent such measures, the impact of DOH will remain functionally invisible in federal healthcare policy making.

Thank you for your consideration of these comments.

Sincerely,

Adam Shyevitch

Chief Program Officer

Josh Trautwein

Chief Executive Officer

[1] Hood, C. M., K. P. Gennuso, G. R. Swain, and B. B. Catlin. 2016. County health rankings: Relationships between determinant factors and health outcomes. American Journal of Preventive Medicine 50(2):129-135. https://www.ajpmonline.org/article/S0749-3797(15)00514-0/fulltext

Public Agenda

To: NQF Measures Application Partnership

From: Public Agenda

Re: MUC2021-134

Date: January 7, 2022

Unmet social needs in early childhood can have long-lasting and wide-ranging consequences, including

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increased risk for chronic health conditions, behavioral problems and poor academic performance. The American Academy of Pediatrics in 2016 called on its members to begin universally screening for social needs and facilitating connections to community resources as a part of routine care.

Yet little research has asked parents, particularly low-income parents, for their perspectives about social determinants of health and how screenings can be implemented successfully. To help fill this gap, Public Agenda, with funding support from United Hospital Fund, conducted focus group research with low-income parents in New York City to understand parents' perspectives on social needs screenings.

In 2019, Public Agenda released findings from this research in a report titled "It's About Trust: Low-Income Parents' Perspectives on How Pediatricians Can Screen for Social Determinants of Health." The report is available on Public Agenda's website at https://publicagenda.org/reports/its-about-trust-low-income-parents-perspectives-on-how-pediatricians-can-screen-for-social-determinants-of-health/

Findings from this research include:

1. Parents in these focus groups cited a broad range of social stressors that affected their children's health and well-being, including some that screening tools for social determinants of health may not currently include, such as the challenges of single parenthood, neighborhood violence, bullying, and environmental pollution

2. These parents did not immediately identify pediatricians as sources of help with social stressors. Their reactions to the idea of pediatricians discussing these stressors were mixed. They saw some topics, such as nutrition, education and minor behavioral issues, as appropriate to discuss with pediatricians, but saw others as more sensitive, such as domestic violence, parents' mental health and legal issues.

3. Parents expressed concerns about discussing sensitive social needs with pediatricians. For example, parents shared concerns about being judged and discriminated against because of their families' social needs. Parents feared that sharing information about social needs could trigger intervention by a child welfare agency. Parents noted that long waits for short appointments meant prioritizing more pressing health needs that could make it difficult to discuss complex social needs in depth. Parents expressed frustration at the prospect of disclosing sensitive information without getting help might frustrate parents.

Despite the concerns they cited about discussing social needs with pediatricians, particularly their more sensitive needs, most parents in these focus groups responded enthusiastically when the moderators asked for their ideas about how pediatricians should approach discussing social determinants of health. Parents' recommendations for pediatricians included:

1. Build trust. Parents in the groups emphasized that talking openly about social determinants of health with pediatricians is a matter of building trusting relationships. While some parents said they would prefer discussing social determinants of health with pediatricians face to face and others said they would prefer a questionnaire, their overriding message was that they could only share information about sensitive topics in the context of a trusting relationship with their children's pediatricians.

2. Choose the right moment for parents. With long waits for short appointments, parents felt pediatricians should choose the right moment to start conversations about social needs. They

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emphasized that if they come to an office visit with a child who has a cold or other immediate concern, the pediatrician should address that concern and wait for another visit, when they might have the time and energy for the conversation, to bring up more sensitive, complex topics.

3. Not in front of the children. Parents said that if they were to discuss social determinants of health with their children's pediatricians, they would prefer to do so in private, not in front of their children. They said pediatric offices should create dedicated spaces where children can play, giving adults time and space to discuss sensitive, complex topics, as well as easing the burden of long waits for appointments with sick children or siblings.

4. Let parents choose to learn about helpful resources at their own initiation. Parents often said they wanted posters on waiting room or exam room walls and pamphlets they could take themselves. They said posters and pamphlets would let them choose to learn about social needs—particularly more sensitive ones—and about helpful resources on their own time, discreetly and at their initiation.

5. Signal confidentiality and be transparent about what triggers reporting to child welfare. Parents in these groups understood that when a child is truly in danger, a pediatrician must share that information with the appropriate authorities. But they also wanted pediatricians to be transparent about what triggers reporting and what does not, so they would know which issues they could talk about openly. They also felt strongly that when they share sensitive information, it must be kept confidential.

6. Do not ask just for the sake of asking. These parents were very firm in their conviction that if pediatricians ask about sensitive issues, they should be willing and able to provide or suggest helpful resources. Parents wanted to avoid the double loss of disclosing sensitive information without receiving help. They said referrals to other organizations should come with an offer of guidance and a warm handoff.

7. Make clear that screening is standard protocol. It was very important to parents in these groups to be assured that everyone gets screened—whether face to face or with questionnaires—not just those who appear to be struggling, are enrolled in Medicaid or are low-income. Otherwise, parents said, they would feel judged or profiled.

8. Consider "letters of support" and other ways to be parents' allies. Parents in these groups indicated that the doctors have a unique authority and can be their allies in difficult situations. Parents specifically said it could be helpful for pediatricians to provide what they called "letters of support," for instance, when they face problems with the public housing authority or private landlords regarding peeling paint, pests or other environmental hazards. Some parents said pediatricians could vouch for them when they face legal difficulties or child welfare investigations.

Public Agenda would welcome the opportunity to share findings from this research in further detail or to answer any additional questions that committee members may have.

Yours,

David Schleifer, PhD

Vice President, Director of Research

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Public Agenda

dschleifer@publicagenda.org

Optum

Patrick Conway, CEO, Care Solutions, Optum

Former Chief Medical Officer, Director of Center for Medicare and Medicaid Innovation, and Principal Deputy Administrator for Centers for Medicare and Medicaid Services (CMS)

Public Statement on 2021 CMS Measures Under Consideration: Drivers of Health

I applaud CMS for including the first measures specifically focused on the drivers of health (DOH) on the 2021 Measures Under Consideration (MUC) list – and the MAP for its thoughtful consideration of MUC2021-134 and MUC2021-136. These measures are particularly significant given that of all the potential Medicare measures under consideration by CMS this cycle, these are the only patient-level health equity or DOH measures.

I endorse the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision. Given the well-recognized impact of DOH health outcomes and cost and, in particular, their disproportionate impact on communities of color, this represents a significant and historic milestone for our healthcare system.

I further strongly urge the MAP Coordinating Committee to support the SDOH screening and the screen positive rate measures for the IQR, recognizing that both these measures are crucial. MUC21-134 (the screen positive rate) is especially important to both practicing physicians (like me) and to our patients given the imperative of transparency in reporting and the opportunity for such data to enable quality improvement activities, including addressing disparities.

What really matters to people is that health is more than medical care and that social drivers have outsized impact on health and healthcare costs. It is important to build models that care for people's physical, mental, and social needs, including home- and community-based care. To do so effectively and equitably, it is imperative to collect person-level DOH data– as essential step to improving patient outcomes, both by helping people access the resources they need to be healthy and enabling healthcare institutions to invest in and partner with communities.

Person-level DOH data is essential to quantify the health and economic implications of DOH and inform work on DOH-related billing codes, risk-adjustment, and cost benchmarks. For example, it is well-documented that a diabetic that is food insecure costs, on average, $4,500 more PMPY and has a greater risk of complications. Not knowing if a diabetic is food insecure is both an urgent safety and quality issue and a cost issue that must be understood – as well as key to understand and address health disparities.

I look to CMS to drive learning and accountability on the impact of DOH at the federal level. Inclusion of these DOH measures in regulatory programs like MIPS and the HIQRP would create an unprecedented opportunity to fuel collaboration across public and private partners, address factors that drive inequity in health outcomes, and begin to close CMS's stated measurement gap on the "social and economic

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determinants."

Through CMS Innovation Center models such as Accountable Health Communities and Comprehensive Primary Care Plus (CPC+), CMS has amassed years of data and learning across millions of beneficiaries and thousands of practices and clinical sites across the country – demonstrating that implementation of DOH screening can be done reliably and consistently over time. Further, use of these measures has revealed that 34% of beneficiaries screened positive for at least one health-related social need and those who screen positive are disproportionately racial/ethnic minorities.

Building on this foundation – and recognizing that it is untenable to continue to defer collecting and reporting data on those factors that drive up to 80% of health outcomes and associated costs – it is now time for the MAP to recommend that CMS include the first-ever DOH measures in a regulatory program.

Citations:

https://www.gsfb.org/wp-content/uploads/2018/08/Berkowitz-S.-A.-Basu-S.-Meigs-J.-B.-Seligman-H.-K.-Food-Insecurity-and-Health-Care.pdf

American College of Physicians

We understand that socioeconomic factors often determine one's health outcome and recognize the importance of screening for the same. However, there is a flaw in the measure specifications as this measure reports the percentage of patients who screened positive, rather than the percentage of patients with results of the screening reported. As currently worded, it would significantly disadvantage clinicians and hospitals who work in more disadvantaged areas where these HRSNs are more prominent. These issues came up during the MAP clinician work group meeting and the submitter acknowledged the error and promised to reword it prior to implementation. We do not support this measure at either the individual clinician or hospital levels, until the measure specifications have been revised to review this screen positive issue. These revised specifications would also have to undergo testing of the performance measure's reliability and validity. We understand that the tool may have undergone testing and deemed valid, but the Performance measure has not. While we support efforts to implement measures that would lead to the identification of SDOH, we also believe such performance measures should adopt a rigorous method for assessing their validity before including them in quality and reimbursement programs. We echo AMA's sentiment that these SDOH measures should only be implemented after adequate resources and tools have been provided to the clinicians and groups, to be able to address those needs once they are identified. Additionally, these measures should be aligned with other federal efforts to collect such data (e.g., using Z-codes).

Legacy Community Health

For the first time, CMS is considering two quality measures related to social risk screening as part of this year's 44 new Measures Under Consideration (MUCs) list. The two measures are:

Driver of Health Screening Rate: % beneficiaries 18 years and older screened for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-136) Driver of Health Screen Positive Rate: % beneficiaries 18 years and older who screen positive for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-134)

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We have screened for these measures for years and found them to be a key driver in health outcomes. It would be helpful to have a standardized approach so that we can further our efforts of proving that social determinants of health are just as important to overall health as traditional healthcare.

Child and Adolescent Health Initiative (Massachusetts)
Patrick Conway, CEO, Care Solutions, Optum
Former Chief Medical Officer, Director of Center for Medicare and Medicaid Innovation, and Principal Deputy Administrator for Centers for Medicare and Medicaid Services (CMS)

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I endorse the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision. Given the well-recognized impact of DOH health outcomes and cost and, in particular, their disproportionate impact on communities of color, this represents a significant and historic milestone for our healthcare system.

I further strongly urge the MAP Coordinating Committee to support the SDOH screening and the screen positive rate measures for the IQR, recognizing that both these measures are crucial. MUC21-134 (the screen positive rate) is especially important to both practicing physicians (like me) and to our patients given the imperative of transparency in reporting and the opportunity for such data to enable quality improvement activities, including addressing disparities.

What really matters to people is that health is more than medical care and that social drivers have outsized impact on health and healthcare costs. It is important to build models that care for people's physical, mental, and social needs, including home- and community-based care. To do so effectively and equitably, it is imperative to collect person-level DOH data– as essential step to improving patient outcomes, both by helping people access the resources they need to be healthy and enabling healthcare institutions to invest in and partner with communities.

Person-level DOH data is essential to quantify the health and economic implications of DOH and inform work on DOH-related billing codes, risk-adjustment, and cost benchmarks. For example, it is well-documented that a diabetic that is food insecure costs, on average, $4,500 more PMPY and has a greater risk of complications. Not knowing if a diabetic is food insecure is both an urgent safety and quality issue and a cost issue that must be understood – as well as key to understand and address health disparities.

I look to CMS to drive learning and accountability on the impact of DOH at the federal level. Inclusion of these DOH measures in regulatory programs like MIPS and the HIQRP would create an unprecedented opportunity to fuel collaboration across public and private partners, address factors that drive inequity

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in health outcomes, and begin to close CMS's stated measurement gap on the "social and economic determinants."

Through CMS Innovation Center models such as Accountable Health Communities and Comprehensive Primary Care Plus (CPC+), CMS has amassed years of data and learning across millions of beneficiaries and thousands of practices and clinical sites across the country – demonstrating that implementation of DOH screening can be done reliably and consistently over time. Further, use of these measures has revealed that 34% of beneficiaries screened positive for at least one health-related social need and those who screen positive are disproportionately racial/ethnic minorities.

Building on this foundation – and recognizing that it is untenable to continue to defer collecting and reporting data on those factors that drive up to 80% of health outcomes and associated costs – it is now time for the MAP to recommend that CMS include the first-ever DOH measures in a regulatory program.

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Genesis Health Consulting

I am Veronica Gunn, a pediatrician and public health professional with more than 20 years of experience in clinical care, healthcare administration and public health leadership, having previously served as a state health officer. Currently, I am CEO of Genesis Health Consulting, a national firm that works with hospitals, health systems and networks to advance the health and wellbeing of children and families through an equity lens.

I greatly appreciate the inclusion of patient-level measures of social drivers of health (SDoH) for the very first time. Although equitability is one domain of quality, this is the first time I am aware that equity is being recognized in this CMS measure set.

Providers in all settings are exhausted with seeing these issues arise with their patients, especially given COVID's devastating impact. Food insecurity, housing instability, utility needs, etc. all make it extremely difficult for patients to achieve optimal health, and we know that our populations of color disproportionally experience these social and structural drivers of health.

And – as in my work – when that patient is a child, the burden is experienced by both the patient and the caregiver.

Having these measures validates the importance of screening for these needs, and allows providers recognition for reporting the results of screening.

As a physician, I would not adopt a screening practice without seeking the results of the screen. In the same manner, it is important that the committee acknowledges the importance of including BOTH measure MUC – 136 and MUC – 134 in the measure set.

According to a recent study in JAMA, 24% of hospitals are already screening for all 5 SDoH domains (food, housing, transportation, utilities, and IPV) – and 92% of hospitals are screening for one or more of

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the 5 SDoH domains specified in the measures. These SDoH measures would be a powerful and timely way to bring the latter institutions along towards a more complete approach to addressing their patients' SDoH needs. In addition, reporting of screen positive rates (MUC21-134) enables informed investments of both public and private resources in communities to support unmet needs.

Finally, from a practice standpoint, I would want to be able to establish a baseline prevalence of positive screens for my patient population before being required to report on those referred to navigation.

Having a phased approach to measure development allows for adequate data collection to inform subsequent measures, and also enables clinicians time for planning, e.g., will I need to bring on or train additional staff members to ensure adequate navigation support?

I endorse the MAP Workgroup's support for these SDoH measures for MIPS, and strongly encourage the Coordinating Committee to recommend both measures – MUC21-134 and MUC21-136 – for the HIQRP.

American Heart Association

AHA seeks clarification on what the intent of this measure is, given that screening for social drivers is also captured in MUC2021-136.

The AHA is concerned that hospitals and providers who serve disadvantaged populations or practice in rural or low socioeconomic status communities might be unfairly penalized by this measure. While it is important to capture and address social drivers affecting patients' health, hospitals and providers treating disproportionate numbers of these patients ultimately require additional dedicated resources to implement such interventions. This measure may be more appropriate if reported at system or regional level.

The AHA agrees with the MAP's recommendation to not support this measure for rulemaking with potential for mitigation for the IQR program. However, the AHA does not agree with the MAP's recommendation for conditional support for rulemaking for the inclusion of this measure in the MIPs program. CMS should clarify how this measure is tied to the purposes of the IQR program to capture hospital quality of care as well as the MIPs program to capture physician quality of care.

Carolina Complete Health Network/North Carolina Medical Society

As a cardiologist and board member of the North Carolina Medical Society, I'm writing in support of MAP MUC-134 and 136. I serve as the President and Chief Medical Officer of Carolina Complete Health Network. This corporation is a first in kind joint venture between a large national payor, Centene Corporation, and the North Carolina Medical Society. Other investors in the enterprise include the North Carolina Community Health Center Association and individual community health centers serving the most vulnerable patients of North Carolina. This venture partners joined together to identify and address the gaps in healthcare that exist across NC by having the payor and provider work together to eliminate barriers to whole person health.

As the only provider-led entity in Medicaid Transformation in North Carolina, we hope to utilize data around the social drivers of health to create better individual care management support. However, to truly close the gaps in care quality, we need to pool this information and partner with community, municipal and state leaders in a community-based approach. The MAP MUC 136 hospital measure

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would allow this to be possible.

During my testimony in front of the MAP Hospital workgroup on 12/15/21, I referenced a scenario of high-risk acute myocardial infarction complicated by cardiogenic shock bringing a patient into hospital care. The treatment algorithm for this acute condition branches based on the patient's social drivers of health: having resources will save your life. There is no time to change the support available for the patient. High impact decisions, such as moving toward emergent cardiac transplant or left ventricular assist device use, are made based on social resources available to the patient at the time of the emergency.

Outside of clinical criteria, the social drivers of care are the deciding factor in who receives these supports. The health disparities associated with these heroic interventions, transplant and cardiac assist devices, are designed inside the current system. The care will not change unless we are able to go upstream: to assess the disparities on a longitudinal basis and build and complete an investment map for equity.

This increase in resources prior to emergency decisions around lifesaving care would create a new capacity to turn the tide on health disparities. Patients would receive available treatments knowing that the appropriate social support exists in their hospital and surrounding communities. While I agree that the hospital reporting might need clarifying score system for consumers (ex: hospital is located in a community at high, moderate or low probability of meeting social needs), it should not paralyze us from taking the needed action. Other reported outcomes that are heavily driven by social factors, for example acute MI, are already being released. Hospitalized patient outcomes are steeped in the social health of the patients in their communities. Let us take the bold step of recognizing this linkage for a more equitable future in healthcare.

NC Medical Society

As North Carolina's oldest professional organization, including nearly 12,000 members and a network of county medical societies and specialty societies across the state, we note the significance of the MAP's consideration of the first-ever SDOH measures and the only patient-level health equity measures this review cycle.

NCMS's support for these measures is rooted in the recognition that the presence of SDOH fuels physician burnout, creates economic risk for physician practices under value-based payment models, and drives poor health outcomes for North Carolinians. This is especially so in COVID's wake: faced with the convergence of their patients' clinical and economic needs, front-line physicians and other health care providers have been taxed as never before.

With this context, we register our strong endorsement of the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision.

Further, NCMS further urges the MAP Coordinating Committee to support not only the SDOH screening measure, but also the SDOH screen positive rate measures for the IQR. Representing the perspective of front-line physicians in a diversity of urban and rural practice settings, we recognize that the MAP's endorsement of both these measures are crucial.

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We and others would anticipate significant variability in the SDOH screen positive rate for practices (via MIPS) and hospitals (via IQR) depending on the community context and patient population – and also understand that the measure's value is in spurring physicians and institutions to collect and make visible this data visible.

This data would be invaluable in enabling public and private institutions to make strategic investments to strengthen community capacity to meet patients' health-related social needs, thereby alleviating the challenges faced by patients and the associated burden of these issues on physicians.

Indeed, our experience is that NC DHHS's requirement under Medicaid Transformation that all members be screened for food insecurity, housing instability, lack of transportation, and interpersonal violence has spurred crucial investments in the capacity necessary to address these issues. Specifically, this SDOH screening requirement spurred a public-private partnership to implement NCCARE360 – the first statewide, up to date, community resource database and closed loop referral platform, which is now live in all 100 of NC's counties – as well as investments in community health workers to support in connecting patients to community resources.

Finally, it would be deeply demoralizing for practicing physicians to engage their patients around these crucial issues, only to then not have their institutions make the results of this SDOH screening public – reinforcing physicians' longstanding concerns regarding measurement burden that does not translate to value for providers or their patients.

We view the proposed SDOH measures before the MAP as crucial to CMS recognizing the impact of these issues on patients and providers alike – and to laying the foundation to invest in those community resources necessary for health. We urge the MAP Coordinating Committee to evidence its commitment to addressing equity and to addressing the realities of patients' lives and their impact on physicians by recommending to CMS both MUC2021-134 and MUC2021-136 for MIPS and the IQR.

Boston Children's Hospital
Dr. Kathleen Conroy
Public Statement on 2021 CMS Measures Under Consideration:
MUC21-134 and MUC21-136

As a practicing pediatrician and the Clinical Chief of Boston Children's Hospital's primary care center, with deep experience in implementing screening for social determinants of health, I offer my enthusiastic support for the decision of MAP Clinician Workgroup to support both MUC2021-134 and MUC2021-136. Further, I encourage the MAP Coordinating Committee to recommend both these measures for Hospital Inpatient Quality Reporting Program.

At my own practice, which serves 22,000 children, we have been formally and universally screening the adult caregivers of these children for SDOH for over a decade – along with many of our peer institutions across the country. Like many clinicians, we adopted this practice because of the overwhelming evidence that screening is both acceptable to families and helps facilitate connections to needed social resources, like housing programs or SNAP benefits, which themselves are associated with positive impacts on child and adult health and well-being. Just like screening for depression and anxiety,

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screening for and addressing social determinants of heath has become a standard part of our clinical program.

More recently, in 2018, the Massachusetts Medicaid program introduced two quality measures through its current 1115 waiver that are nearly identical to MUC21-134 and 136. Although we were already screening, the need to report the percent of our patients screening positive for various needs across our clinic and our entire ACO population allowed us to understand two things: (1) who in our population was most likely to have needs and how these needs are changing over time and (2) whether our systems of screening and response were unintentionally inequitable.

This knowledge has become the foundation for both disparities-focused quality improvement programs and also the impetus for the creation of new community partnerships to be better address needs of certain populations. For this reason, I would argue that both MUC21-134 and 136 are crucial.

To those who may be surprised that these measures do not require navigation to resources, I would offer that Massachusetts similarly did not initially require navigation to resources. This has allowed healthcare organizations the opportunity to build their response systems after initially understanding their families' needs, and it has allowed them time to build data systems to record the social needs responses delivered to families. In my clinic, for example, we recognized that we were under-documenting our work with families once needs were identified and have improved this in anticipation of needing to ultimately report our response to positive screens.

Likewise, it is important that these proposed initial social determinants of measures specify the five target social determinants of health domains (linked to the Accountable Health Communities model), but do not require the use of a specific screening tool, enabling providers to exercise flexibility in this regard.

Given my own extensive, on-the-ground experience functionally implementing these specific SDOH measures – and recognizing that it is untenable for our healthcare system to continue to defer collecting and reporting data on food insecurity, housing instability, and other social factors that drive up to 80% of health outcomes and associated costs – I strongly recommend that the Coordinating Committee recommend MUC21-134 and 136 to CMS for implementation in MIPS and the HIQRP.

Humana, Inc.
January 13, 2022

National Quality Forum
Measure Application Partnership
1099 14th St. NW, Suite 500
Washington, DC 20005

RE: 2021-2022 Recommendations for Measures Under Consideration

To Whom It May Concern:

This letter is in response to the National Quality Forum's Measure Application Partnership (MAP)

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comment opportunity on the 2021-2022 Recommendations for Measures Under Consideration. Humana applauds CMS for including the first measures focused on the social drivers of health (SDOH) on the Measures Under Consideration list, MUC21-134 and MUC21-136. These SDOH measures directly address the Centers for Medicare and Medicaid Services (CMS) Meaningful Measures 2.0's stated measurement gap/priority focused on the "social and economic determinants."

Humana Inc., headquartered in Louisville, Kentucky, is a leading health care company that offers a wide range of insurance products and health and wellness services that incorporate an integrated approach to lifelong well-being. As one of the nation's top contractors for Medicare Advantage (MA) with approximately 4.4 million members and Medicare Prescription Drug Plans (PDPs) with approximately 3.9 million members, we are distinguished by our nearly 35-year, long-standing, comprehensive commitment to Medicare beneficiaries across the United States. These beneficiaries – a large proportion of whom depend upon the Medicare Advantage program as their safety net and many in underserved areas – receive integrated, coordinated, quality, and affordable care through our plans.

MUC21-134 and MUC21-136

In COVID-19's wake, food insecurity, housing instability, and other SDOH have reached unprecedented levels and revealed massive racial disparities. Yet, despite the well-documented impact of SDOH on health outcomes and costs and their disproportionate impact on communities of color, there are still no SDOH measures in the Quality Payment Program (or other CMS quality and payment programs), which is only more significant in light of COVID and HHS/CMS's commitment to equity.

We recognize that of the 44 potential Medicare measures under consideration by CMS this cycle, only three are tagged to the domain of "equity," including these two measures. We also note the MAP Health Equity Advisory Group's positive assessment of these measures.

With this context, we write to endorse the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 for inclusion in the Merit-based Incentive Payment System (MIPS) and encourage the MAP Coordinating Committee to accept this decision. We believe this is a historic milestone for our healthcare system.

Humana further strongly urges the MAP Coordinating Committee to support both MUC21-134 and MUC21-136 for the Hospital Inpatient Quality Reporting Program (HIQRP). We believe it is important to include both measures because, together, they will make visible the impact of health-related social needs on patients.

MUC21-134 (the screen positive rate) is especially important in that it creates the opportunity to reveal and address disparities, both with respect to SDOH and their impact on health outcomes and costs. This anticipated variability in screen positive rates – including SDOH disproportionate impact on diverse communities and communities of color – would be important in enabling public and private institutions to direct investments in communities.

From Humana's perspective, we have long been committed to addressing the impact of health-related social needs on our members and addressing SDOH in communities across the country. In 2020 alone, we completed 6.2 million SDOH screenings; this data and the overall SDOH screen positive rates of our

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members, which we have made public, has been invaluable in enabling us to partner effectively with dozens of other organizations in addressing needs among our members and in communities, including appropriately targeting our investments to address these issues.

While we agree that taking action on the result of the screening is important – and is something Humana itself is committed to doing – we recognize that the objective of this first phase of federal SDOH measures is focused on collecting standardized SDOH baseline data to support a data-driven approach to addressing these health-related social needs and inform potential future measures. In this regard, we believe – and have learned through our experience at Humana – that we cannot allow the perfect to be the enemy of the good in tackling the SDOH, but instead must prioritize learning and improvement over time.

On this basis, we encourage the MAP Coordinating Committee to enable CMS's commitment to addressing equity by recommending MUC2021-134 and MUC2021-136 for MIPS and the HIQRP.

We value this opportunity to provide comments and are pleased to answer any questions you may have. We hope that you consider our comments as constructive feedback aimed at ensuring that we continue to advance our shared goals of improving the delivery of coverage and services to Medicare beneficiaries and addressing health disparities, focused on improving the total health care experience of all Medicare beneficiaries.

Sincerely,

J. Nwando Olayiwola, MD, MPH, FAAFP
Chief Health Equity Officer & Senior Vice President
Humana, Inc.

Andrew Renda, MD, MPH
VP | Bold Goal & Population Health Strategy
Humana, Inc.

Johnson & Johnson

Johnson & Johnson agrees with the recommendation of the Workgroup of conditional support. It is important to routinely screen patients for social drivers of health that may impact access to diagnostics, treatment, and supportive care services. We appreciate the flexibility the measure offers for screening approaches but support future standardization of tools to ensure that providers have clear guidance and best practices for identifying patients at risk. While clinician and practice-level screening is important, it will not capture patients whose social drivers prevent them from accessing care entirely. Transportation, health literacy, education, and living situation, among other factors, significantly impair individuals from accessing care in the first place. We therefore encourage CMS and NQF to think about measures at other levels of analysis (e.g., surveillance measures) to understand how these social drivers impact Medicare populations more broadly.

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American Medical Association

The American Medical Association (AMA) agrees with the questions and concerns raised both by the Hospital and Clinician Workgroups and requests that the recommendations for this measure for use in MIPS be aligned with the recommendation for the IQR – Do Not Support With Potential For Mitigation.

American Society of Anesthesiologists

ASA supports the recommendation of the MAP to offer conditional support for rulemaking. We appreciated the MAP's discussion with CMS and the developer that clarified that MUC21-134 and MUC21-136 should not be used to penalize the physician or other clinician for reporting a higher positive rate for social drivers of health. The key to this measure, and MUC21-136, is to assess what can be done to improve patient care. As the MAP assesses and CMS implements these measures, careful attention should be paid to ensure all specialties can be appropriately assessed based upon how and when they encounter the patient. Disparity reduction cannot be addressed without first promoting transparency and data sharing between the facility and physicians as well as between physicians and other healthcare professionals.

As perioperative physicians, anesthesiologists can best contribute to the development of health equity measures by focusing on care coordination, surgical care, patient safety, and shared accountability measures. Many examples exist related to how anesthesia measures are carried out on a daily basis. However, our members also deliver care to patients in acute need and those who may encounter significant barriers to care. We believe this measure, in addition to MUC21-136, opens several opportunities for anesthesiologists to make positive changes within their local healthcare settings to enhance patient safety and improve patient outcomes

Blue Shield of California Foundation

Blue Shield of California Foundation strongly supports MUC21-136, Screening for Social Drivers of Health, and MUC21-134, Screen Positive Rate for Social Drivers of Health, and urges the MAP Coordinating Committee to support both measures for rulemaking and inclusion in both MIPS and the Hospital IQR.
Nearly 90 percent of hospitals and health systems across the country are already conducting Driver of Health (DoH) screening to identify patients' unmet social needs, according to one recent study, including via a number of CMMI models, but without the benefit of any formal quality measures, guidance, or tools from CMS.

As evidenced in the momentum for these measures across the health sector, it is imperative that we begin to implement DoH measures into federal payment programs, especially in the wake of the deep health inequities revealed by our response to COVID. With this context, we applaud the MAP for its thoughtful deliberations on MUC21-134 and MUC21-136, two of only three equity measures under consideration by the MAP and CMS this year.

In particular, we applaud the leadership of the MAP Clinician Workgroup in supporting both MUC21-134 and MUC21-136, and applaud the Hospital Workgroup in likewise supporting MUC21-136 – and encourage the MAP Coordinating Committee to endorse these decisions. We are troubled, however, by the MAP Hospital Workgroup's vote on MUC21-134: "do not support with potential for mitigation."

First, the NQF MAP summary of the Workgroup's recommendation states that the "measure has not been evaluated for reliability or validity." Yet NQF's own preliminary analysis cites documentation that

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the screening tools and items used in the testing process to generate the data for both measures have been psychometrically evaluated and demonstrated evidence of reliability and validity.

Second, the Hospital Workgroup "expressed concern that the positive rate may be challenging for consumers to interpret when publicly reported." Through the lens of a commitment to equity, we find it remarkable that the Workgroup has determined that consumers would be unable to exercise their own judgment in interpreting important data about the degree to which their fellow consumers are impacted by social drivers of health. We believe a hospital's reporting of the screen positive rate will be important to patients for a number of reasons, including: (1) providing transparency; (2) enabling the targeting of hospital and community investments based on the social needs shown by the data; (3) signifying the hospital's understanding of the social drivers of health among its patient population; and (4) providing data for targeting quality improvement activities, including highlighting and addressing disparities in the social drivers of health for patients.

Finally, we recognize that the measures are focused on screening beneficiaries for drivers of health, and do not require an action plan. At the same time, we believe these measures represent an important starting point for collecting DoH baseline data in a standard way to then support a data-driven approach to addressing these social drivers. We note that CMS's own CPC+ model demonstrates clinicians' appetite to engage in this screening and act on these results, even when not required: 86 percent of Track 1 practices reported that they screened patients for health-related social needs (though not required to do so) and 93 percent of physicians in those practices reported that they acted on those screening results.

The introduction of these first DoH measures into core federal payment programs would be significant in its own right: making visible, when stratified by race and ethnicity, the social factors driving or inhibiting health, particularly for communities of color, including food insecurity, housing instability, transportation, utility needs, and interpersonal safety, including intimate partner violence. Only when these factors are brought to light and measured in a standardized way will we be able to align our collective resources and take action to achieve equitable health outcomes for all. To achieve this goal, we strongly encourage the MAP Coordinating Committee to recommend to CMS MUC2021-134 and MUC2021-136 for both MIPS and the IQR.

Health Care Without Harm
January 11, 2022

On behalf of Health Care Without Harm, which maintains a hospital member network of over 1,400 hospitals across the country, we strongly support the National Quality Forum Measure Applications Program (NQF MAP) working groups in recommending the following two Drivers of Health (DOH) measures under consideration:

MUC 2021-136; Driver of Health Screening Rate, and
MUC 2021-134; Driver of Health Screen Positive Rate

Health Care Without Harm is founded on the belief that: As the only sector with healing as its mission, health care has an opportunity, indeed a responsibility, to use its ethical, economic and political

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influence to create ecologically sustainable, equitable and healthy communities. Founded over 25 years ago, Health Care Without Harm seeks to transform health care worldwide so that it reduces its environmental footprint, becomes a community anchor for sustainability and a leader in the global movement for environmental health and justice. We conduct research, model strategic interventions and provide guidance and resources to spread and accelerate best practice in the field – with programs focused on climate and health, safer chemicals, and healthy food.

Health Care Without Harm has long recognized the impact that DOH have had on increasing rates of poor health outcomes, chronic disease and death. Climate change, the COVID-19 pandemic and increasing economic and social inequities in our communities that are the result of decades of systemic racism only serve to exacerbate the situation.

For example, some sobering statistics regarding diet-related diseases and how food insecurity is impacting our nation's health, published in The Washington Post (November 30, 2021) :

- More than 100 million Americans — nearly half of all adults — suffer from diabetes or prediabetes.
- About 122 million Americans have cardiovascular disease, which kills roughly 840,000 people each year.
- More Americans are sick or suffer from major medical conditions than are healthy, and much of this is related to diet-related illness.
- If you are a Black person, those numbers mean you probably will have an even worse outcome. 49.6 percent of Black adults are considered overweight if not obese. Black people are also 60 percent more likely to be diagnosed with diabetes than White people.
- Americans who suffer from diet-related conditions such as heart disease, diabetes, cancer, and obesity are 12 times as likely to die after a COVID infection.
- And in 2020, the year COVID-19 hit the United States, African Americans were disproportionately impacted by the virus, many due to those same underlying diseases of obesity and diabetes. In total, Black people experienced a 2.9 year decrease in life expectancy, causing the Black-White life expectancy gap to widen from 3.6 to 5 years. In a single year.

Statistics similarly alarming can be found regarding the health impacts of poor indoor air quality, air pollution, climate change, poor access to public transportation or living close to a freeway or port, housing instability, and exposure to toxic chemicals in the air, land and water. And they are disproportionately affecting under-resourced communities of color. The frightening question is, how big and bad do the numbers have to get? What is the final tipping point before the federal government will declare a state of public health emergency and prioritize addressing the DOH with a systemic strategy? A coordinated, aligned national standards measurement process to screen for DOH as part of basic primary health care is absolutely critical to moving forward, and these two measures are a positive start.

The Physicians Foundation, which is directed by 21 state and county medical societies across the country, submitted these first-ever measures focused on screening patients for food insecurity, housing instability, transportation, utility needs, and interpersonal safety, including intimate partner violence.

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Their adoption would represent a crucial milestone as the first standardized federal measures to assess social need in the history of the U.S. health care system.

Despite the well-documented impact of DOH on health outcomes and costs and their impact on people of color, there are still no approved, standardized DOH measures in any Centers for Medicare and Medicaid Services' (CMS) programs. The impact of DOH interventions remain fairly invisible in federal health care policymaking, and the absence of standard DOH data or measures impedes efforts to achieve racial equity in health outcomes, given their profound impact on people and communities of color, especially in COVID's wake.

In enacting these first federal DOH measures, CMS could send a powerful signal to the health care sector and the communities they serve that there should be acknowledgement of how DOH impact peoples' health outcomes and an intention to address them in a coordinated strategy across the country. These initial DOH measures for screening could lay the foundation for additional measures focused on navigating beneficiaries to resources and connecting beneficiaries to the resources they need to be healthy.

We urge the Coordinating Committee to recommend both SDOH measures (screening and screen positive rate) for the HIQRP. Hospitals' reporting the screen positive rate would be important to patients by (1) providing transparency; (2) targeting community investments based on data they provided; (3) signifying hospitals' familiarity/expertise regarding these issues; and (4) enabling quality improvement activities, including addressing disparities. And by reporting the screen positive rate for food insecurity, hospitals would be well-positioned to take action, including (for example) engaging community partners to tackle these issues.

When addressing issues such as food insecurity, housing instability, climate change, lack of transportation, and exposure to toxics in our air, land and water, we cannot settle on solving for acute, short-term health impacts alone. We must devise long term solutions for these long term and entrenched challenges that require equitable investment and attention. Our collective environmental and economic health need to be prioritized, with regenerative systems that are protective of our environmental health and natural resources, and substantial investment in fair labor practices and living wage mandates.

It is our hope that CMS will do the right thing and approve these measures, creating a federal, standardized system to incorporate DOH factors into primary health care and begin to set the stage for long term effective intervention.

Signed by:

Gary Cohen
President, Health Care Without Harm & Practice Greenhealth
www.noharm.org

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Cambridge Health Alliance

As a family medicine physician practicing at the Cambridge Health Alliance in Cambridge, Massachusetts, I applaud CMS for considering the first measures specifically focused on the social drivers of health (MUC2021-134 and MUC2021-136) and the NQF MAP for its consideration of these measures.

These measures are particularly significant given that of all the potential Medicare measures under consideration by CMS this cycle, these are the only patient-level health equity or DOH measures. For the past decade, I have been deeply involved in efforts by CHA and other health systems and community health centers in MA to screen patients for the social drivers of health. I have extensive experience implementing SDOH screening and navigation protocols at scale and have published on the resulting findings.

It is clear that food insecurity, for example, is not just a social factor, but a clinical co-morbidity that impacts quality care and drives health disparities.

Given COVID, SDOH screening has become only more critical to support our patients and to mitigate the frustration and burnout among primary care providers. Yet, we now do so without the benefit of any SDOH measures in any federal payment program, including MIPS. It is untenable for our federal payment programs to continue to exclude those factors that we know drive 80% of health outcomes in our patient populations.

At CHA, my colleagues and I have screened thousands of patients in over a dozen primary care sites across our healthcare system; in doing so, we found that nearly 30% of our patients screen positive for food insecurity.

Had we not collected and share this data, we could not have developed effective strategies and community partnerships to address these challenges with our patients. In particular, this crucial data about our patient population – exactly the kind of foundational data that these SDOH measures will provide – then allowed us to design an electronic active referral to a community-based organization.

One question that has come up is whether these measures will, hypothetically, incentivize providers to treat fewer patients with social needs or to move way and care wealthier patients. But from the perspective of a physician who – like thousands of others across the country – is committed to serving patient populations that often face these challenges, these first-ever federal SDOH measures are essential to recognize practices (like mine) that are tackling these issues.

With this, I enthusiastically support the MAP Clinician Workgroup's decision to recommend both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision.

I further strongly urge the MAP Coordinating Committee to support the SDOH screening and the screen positive rate measures for the IQR, recognizing that both these measures are crucial. The latter measure is especially important to practicing physicians and to our patients, given the imperative of transparency in reporting and the opportunity for such data to enable quality improvement activities, including addressing disparities, as we have done at CHA.

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Hogg Foundation for Mental Health

As a family medicine physician practicing at the Cambridge Health Alliance in Cambridge, Massachusetts, I applaud CMS for considering the first measures specifically focused on the social drivers of health (MUC2021-134 and MUC2021-136) and the NQF MAP for its consideration of these measures.

These measures are particularly significant given that of all the potential Medicare measures under consideration by CMS this cycle, these are the only patient-level health equity or DOH measures. For the past decade, I have been deeply involved in efforts by CHA and other health systems and community health centers in MA to screen patients for the social drivers of health. I have extensive experience implementing SDOH screening and navigation protocols at scale and have published on the resulting findings.

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The Physicians Foundation
In submitting these comments, the Physicians Foundation does so not only as the measure developer for MUC2021-134 and MUC2021-134, but also an organization that takes its the direction of physicians from 21 state and county medical societies across the country.

In particular, we offer these comments from the perspective of practicing primary care physicians and specialists across the country. Every day, we encounter patients in our practices who show the physical toll of skipping meals to feed their children. Who have made impossible tradeoffs between refilling their heart medicine or buying food. Who carry the stress of spending weeks trying – and failing – to find a job, as bills pile up and they fear losing their home, as the rent or mortgage goes unpaid.

As our patients struggle to manage these risks in their day-to-day lives, we physicians bear the economic and psychic risk associated with these unaddressed social drivers of health. It is well-documented that these factors lead to physician burnout and effectively penalize physicians caring for affected patients via lower MIPS scores. A recent study in JAMA found that SDOH were associated with 37.7% of variation in price-adjusted Medicare per beneficiary spending between counties in the highest and lowest quintiles of spending in 2017. Yet even with an ongoing pandemic that has painfully brought these issues to the fore, SDOH are still not accounted for in geographic risk-adjustment or cost benchmarks.

We put forward these two first-ever SDOH measures (and the only patient-level equity measures this review cycle) because it is untenable – to patients and their physicians – for these challenges to be much-discussed in articles, speeches, and white papers, yet functionally invisible in our healthcare system's quality and payment frameworks.

We must start somewhere, and we must start now. Via CMS's own Accountable Health Communities model, the proposed SDOH screening measures – MUC21-134 and MUC21-136 – have been tested at scale over five years with 1M+ beneficiaries in over 600 clinical sites – with 40% of the screenings in hospital inpatient or ED settings and 54% in primary care practices. As documented in the AHC evaluation, these measures reliably identify: (1) beneficiaries with 1+ health-related social needs; (2) high cost/high use beneficiaries; and (3) racial/ethnic disparities.
Further, as well-documented in the NQF MAP's preliminary analysis, the screening tools and items used in the testing process to generate the data for both measures have been psychometrically evaluated and demonstrated evidence of both reliability and validity, including inter-rater reliability and concurrent and predictive validity (see sample citation below).

We appreciate the MAP's thoughtful and deliberate consideration of MUC21-134 and 136 and note the support for these measures across the Health Equity and Rural Health, Advisory Groups and Clinician Workgroup – and we strongly urge the Coordinating Committee to recognize this by accepting the recommendations of the Clinician Workgroup with respect to MIPS. It is especially important that those clinical practices that wish to collect and report on these SDOH measures have these important efforts recognized through the MIPS program.

We also urge the Coordinating Committee to accept the Hospital Workgroup's recommendation to offer conditional support to MUC21-134. We likewise recognize that Workgroup's questions regarding how CMS and consumers could or should interpret the screen positive rate results required by MUC21-136.

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As CMS itself made clear in this discussion, hospitals would satisfy the performance threshold by reporting the screening rate and screen positive rate to CMS for patients who are 18 years or older at the time of admission. Performance is not determined based on the result of the screen positive rate; there is no requirement to demonstrate a rate reduction over time. Variability in this rate would, of course, depend on the institution's community context and patient population.
Hospitals' reporting of the SDOH screen positive rate is valuable to consumers for a number of reasons, including (1) providing transparency of data the institution has collected from those and other consumers who received care at the institution; (2) enabling public and private institutions – including the hospitals themselves – to target community investments based on data consumers provided; (3) allowing consumers to identify which hospitals have familiarity with and expertise in addressing these issues; and (4) enabling quality improvement activities, including making visible variation in health outcomes and costs potentially attributable to the prevalence of these underlying drivers of health and addressing disparities.

We agree that it is important to bridge patients who screen positive for health-related social needs to community navigation services and/or ensure there is an individualized action plan in place for these needs to be addressed. However, physicians are well aware that this is complex and resource-intensive work, which is dependent on the quality of the community resource landscape where their practices and/or health systems are located and their patients live. Hence, the objective of this first phase is focused on collecting DOH baseline data in a standard way to then support a data-driven approach to addressing these health-related social needs, including potential future measures focused on success in navigating patients to the resources they need to be healthy. To establish an SDOH navigation measure in the absence of practices and hospitals reporting baseline SDOH screening data is inadvisable.

Moreover, it must also be stressed that the validation of any screening tool used to collect data supporting a measure must include the result of the screen. Should the Coordinating Committee recommend the screening rate measure but reject the screen positive rate measure, it will impair the ability of CMS, the measure steward, and program participants to conduct additional validation of the screening rate measure post-implementation and over time.

We expect, and hope that, over time, these SDOH measures can and will be improved – and additional associated measures developed – with the benefit of the input of physicians, other healthcare providers, and health systems across the country and the data generated by these measures.

We also recognize, however, that given the profound challenges that COVID has wreaked on patients, physicians, and our healthcare system writ large – and the commitment to equity and the reduction in health disparities that CMS and healthcare institutions across the country have declared – that time is of the essence in enacting these first-ever SDOH measures (and the only patient-level equity or SDOH measures under review this cycle). We therefore strongly urge that the Coordinating Committee recommend to CMS MUC21-134 and MUC21-136 for both MIPS and the IQR.

Citation: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7652127/

Association of American Medical Colleges (AAMC)
The Clinician MAP Workgroup conditionally supported the Screen Positive Rate for Social Drivers of Health measure (MUC2021-134) for MIPS, pending NQF endorsement. The AAMC recommends that the

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MAP revise its recommendation to do not support for rulemaking. We are concerned that in addition to the need for NQF review and endorsement, this measure simply is inappropriate for MIPS, whose objectives as part of the Quality Payment Program include "to educate, engage and empower patients as members of their care team…and to provide accurate, timely, and actionable performance data to clinicians, patients and other stakeholders." (https://qpp.cms.gov/about/qpp-overview) This measure does not assess quality of care delivered by a clinician or physician practice, but rather the percentage of patients treated who report a health-related social need. It is unclear how patients and consumers can interpret that information to make informed decisions about their care. For example, is a lower rate better? Additionally, it's unclear how an overall positivity rate is useful for quality improvement – it doesn't specify which health-related socials needs patients are screening positive for and thus does not inform potential actionable interventions.

Kaiser Permanente (retired); NASEM Roundtable on Population Health (co-chair); Secretary, Board of Directors, CDC Foundation; Trustee, Blue Shield of CA Foundation

We know that racial inequities in health outcomes persist because remedies often focus only on reducing disparities in clinical care and not on the drivers of health. Some have suggested it is not feasible to do this at scale in the clinical setting. Two decades of work by Kaiser Permanente has demonstrated that this is not only feasible and effective, but embraced by clinicians and patients when the right tools and processes are put in place. Kaiser Permanente built its SDOH screening and followup on a clinical prevention platform that had already included, for example, screening for tobacco use, physical activity and domestic violence. As Kaiser Permanente's extensive community health investments deepened its understanding of how factors like food and housing security and personal safety shaped the health of individuals and entire communities, the system introduced more formal screening, referral and community partnerships to realize the full potential of identifying and addressing SDOH.

Now, many healthcare delivery systems across the country have committed to screen and address their patients' social needs – but are doing so without the benefit of any SDOH measures in any federal payment model, including Medicare or Medicaid. Indeed, a recent study in JAMA found that 24% of hospitals are already screening for all 5 SDOH domains (food, housing, transportation, utilities, and interpersonal safety) and 92% are screening for one or more of the 5 SDOH domains specified in the measures. At the same, a 2020 study conducted at Kaiser Permanente found that patients were in favor of health systems asking about social needs (85%) and helping to address those needs (88%).

With this context, I write to offer my support for the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision.

I further urge the MAP Coordinating Committee to support both MUC21-134 and MUC21-136 for the Hospital IQR, recognizing that, together, these measures reveal the impact of health-related social needs on patients and the opportunities to realign resources to invest where they are needed most.

It is important to note that both the SDOH measures under review today are critical to make visible the impact of these issues on the lives of patients and the disparities they spur. Given the disproportionate impact of SDOH on people of color, equity requires us to recognize providers for screening their patients and reporting the screen positive rate, to elucidate racial/ethnic disparities in DOH that, in turn, fuel

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disparities in health outcomes.

One key lesson we've learned in this work over the past twenty years is that we cannot allow the perfect to be the enemy of the good. The MAP Coordinating Committee has a crucial opportunity to support moving the first-ever SDOH measures into practice to enable learning and improvement over time. The data collected and learning from these foundational SDOH measures will be critical to improve the measures over time and to be thoughtful in developing the next set of measures focused on ensuring patients get the resources they need.

Finally, we are cognizant that there only 3 measures tagged to the domain of "equity" and these are the only patient-level SDOH measures or equity measures under review, making it all the more imperative that the MAP Coordinating Committee recommend them. In the wake of COVID, it is simply unacceptable to go yet another year without any federal payment program measures that recognize the profound impact of SDOH on the lives of our patients.

Citation: https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2751390

https://pubmed.ncbi.nlm.nih.gov/31898132/

Karen L Smith, MD PA

The data derived from these events is critical to the understanding of the impact of social drivers on health outcome. It is imperative for the information to be collected, analyzed, and provided to the clinician at the point of care in order to affect a change in the individual patient via modification of the care delivery system. Currently there is very little information to suggest which variables are having impact and how great of an impact? If we are to truly affect a change the date must be aggregated beyond a single system or even a region.

Camden Coalition of Healthcare Providers

How would adding this measure add value? How would the measure improve patient outcomes?

Mandating the two process measures may lead to wider adoption of social needs screening in healthcare settings. While screening itself does not imply practices will have the resources to respond effectively to the social needs identified, it at least establishes a foundation for building processes within practices and the community to address health-related social needs. Collecting structured data on social determinants could bolster efforts to understand and address equity issues in the healthcare system, improve segmentation efforts, and may be a springboard for measuring the capacity of healthcare providers to respond to social needs, and identifying where gaps between social needs and resource availability in the community exist.

Do the benefits of the measure outweigh the burden of data collection or reporting?

The benefits of the measure will not necessarily outweigh the burden of data collection or reporting. This will depend on many practice-level factors, such as the ability to develop efficient screening workflows, the availability of staff who are trained and well-prepared to engage patients with complex social needs (especially around sensitive needs such as those related to interpersonal safety), the smooth integration of screening data into a practice's existing data systems, and the ease with which the data can be made available to clinicians at the point-of-care. Moreover, the interpersonal safety

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questions are proprietary, and from a practice's perspective, it may not be worth the cost of including those questions in their screener, especially if there are inadequate resources available to address any interpersonal safety issues a person is experiencing. We would recommend offering alternative questions related to interpersonal safety for practices who do not want to pay to use the four questions currently included in the AHC screener. Finally, with reimbursement, benefits may outweigh burden as long as practices are given flexibility in how social needs screening takes place and the reporting requirements are not cumbersome.

For what purpose are you using the measure (e.g., QI, certification/recognition, regulatory/accreditation, payment, public reporting, disease surveillance)?

The Camden Coalition is an Accountable Health Communities alignment track hub. The social needs screening data we collect are used for multiple purposes locally and regionally. For example, we share the data with health systems and other community partners for community health needs assessments and gaps analysis; we leverage the data to procure funding for various population health initiatives; we make the data available through our Health Information Exchange to inform clinical decision-making; and we share the data with researchers who study the intersection of social risk and health.

Are there implementation challenges?

Challenges include incorporating the screening tool into practice workflows, throughput, cost, potential need for extra staffing, and storing and accessing the data. If the screener is self-administered, challenges related to staffing might be reduced, but there are other challenges that need to be considered. An efficient workflow still needs to be established - for example, determining when during a visit a patient will receive the screener and who on staff will be responsible for introducing the screener to the patient. Language and literacy barriers present challenges as well and may require additional time and support from staff. Additionally, if a practice is doing more than collecting data and is going to establish workflows to respond to social needs, there are coordination costs associated with addressing those needs. There would need to be people on staff who can have the kinds of conversations that must take place when a patient expresses a social need. This may mean hiring a social worker, for example, or taking on the cost of training existing staff members.

Carolina Complete Health

The COVID-19 pandemic and other recent events have exposed long-standing racial and economic injustices embedded in many American systems, including our health care system. Fortunately, the recent attention has either generated or renewed for many a commitment to improve health equity and address the social drivers of health (SDOH) that may account for up to 80 percent of health outcomes and have a demonstrably disproportionate impact on communities of color. Those drivers include stable, affordable housing; access to healthy food; availability of reliable income; and interpersonal safety, among others.

Because of the well-documented impact of these factors on health outcomes and costs, plus the disparate impact on people of color, we need standardized SDOH measures in Centers for Medicare and Medicaid Services (CMS) programs. Including such measures will assist CMS in realizing its pledge to collect more robust DOH data, move the needle on health equity, and address its stated measurement gap to "develop and implement measures that reflect social and economic determinants."

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Physicians and other healthcare providers have called on CMS to create standard patient-level SDOH measures – going beyond just socioeconomic status and duals status – recognizing these factors can drive physician burnout and impact providers caring for affected patients via increased financial risk through lower MIPS scores. The recent actions of the MAP groups to codify specific measures that will help to both identify and drive needed support for improvements in this vital area are appreciated. I continue to pledge my support for the MUC 134 and 136 measures before you.

The work of several CMS Innovation Center models like Accountable Health Communities, Comprehensive Primary Care Plus and others has demonstrated that screening for and acting upon these drivers of health is impactful for millions of Medicare and Medicaid beneficiaries, both in inpatient and outpatient settings. However, because this work has been done without the availability of standard SDOH measures or screening tools, CMS cannot systematically compare or use that wealth of data in a reliable fashion. The promise shown by these innovative efforts should not be minimized given the immense opportunity we have to improve overall outcomes and have meaningful impact on disparities amongst us. It should be encouraging to all that these proposed measures have been effectively implemented in AHC over 5 years now and across >1M CMS beneficiaries in 600 clinical sites and multiple practice settings across the country. It also should be reassuring that the AHC screening tool has been objectively shown to be reliable with concurrent and predictive validity.

The ideal convention would be use of the Social Driver of Health Screen Rate measure and the SDOH Screen Positive Rate measure in tandem. Given the disproportionate impact of SDOH on people of color, these measures account for actual screening that occurs but also recognizes providers for reporting the screen positive rate for their patients. Given the variability in the prevalence of SDOH across geographies and patient populations – as well as in clinical sites' capacity to provide patient navigation – the suggested approach for introducing such measures into the federal quality frameworks is critical.

While it is understandable that some entities may perceive being negatively and/or inappropriately burdened by sharing such data publicly, representing circumstances not fully under the entity's control, the reality is that many physicians and other health care entities serving in underserved settings have had to be compared against more ideally situated colleagues with the same quality measures despite caring for individuals who bore these often recognized but rarely addressed barriers to optimal outcomes. I experienced that directly in pediatric practice in East Winston-Salem, NC and in SE Wahsington, DC. So I strongly believe that implementation of these measures can increase the capacity of our systems to recognize needs, foster innovative support and more efficiently utilize available resources. Screening without sharing the results for action portends a risk that some might turn a blind eye and that others might just choose to move to more favorable settings. Allowing a true and transparent assessment of the populations served, the resources given and the actions that may be undertaken, gives us more global and reliable opportunities to truly shed light on and reverse the impacts of social inequities, deprived communities and even systemic racism. It is on this basis that I submit these public comments.

Respectfully Submitted on January 13, 2022,

William W. Lawrence Jr. MD, FAAP

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Huntersville, NC

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Overall, Unite Us supports including measures 134 and 136 in MIPS, hospital IRQ and other value-based payment programs if the proposed measure has been tested and meets NQF or CMS MERIT-based payment or other measure quality standards. We are pleased to see that the Measure Applications Partnership (MAP) Clinician and Hospital Workgroups conditionally approved both measures for MIPs and 136 for IQR. We recommend that the MAP Workgroups also approve measure 134 for IQR.

We understand that a barrier to approval of measure 134 by the Hospital Workgroup was the concern of some members that public disclosure of rates of food insecurity and other health-related social and economic needs could negatively impact a hospital's business. Importantly, thousands of hospitals already publicly reporting these kinds of data through their Community Health Needs Assessments.

These assessments commonly include rates of health-related socioeconomic conditions including food insecurity, unemployment, housing instability, transportation needs and poverty. Given the ubiquity of these conditions, it is unlikely that members of the public could or would meaningfully use publicly reported data on prevalent health-related socioeconomic conditions to decide whether or not to elect care at a given hospital or medical center.

In addition, hospitals play a critical role as both anchor institutions and data engines for communities. Public sharing of data about socioeconomic needs of people living in the primary service area enables data-driven community investments by hospitals and others and offers the opportunity to evaluate the impact of community investments on outcomes of shared importance to healthcare and community leaders. Transparently sharing social needs data empowers leaders to confront hard facts, develop targeted solutions to address unmet needs, and forge partnerships between healthcare, communities, philanthropy and government to improve health and well being.

We also note the measure does not require follow-up after needs have been identified. We recommend the creation of additional measures in the future that evaluate whether services to address social needs are provided in a timely manner. Assessing needs without addressing them will not improve quality. Despite these concerns, we believe the measure is a positive first step towards considering and tracking social drivers of health. Including these measures will encourage clinicians and staff to screen and track social drivers of health.

AHIP

On behalf of AHIP, thank you for the opportunity to comment on this measure. Conceptually, we support the idea of the Screen Positive Rate measure as we would like to see equity measures that go beyond screening rates and promote action to address social risk. While we agree the information on who screens positive would be useful to physicians and hospitals so they can provide assistance, we believe this measure must be implemented carefully to avoid unfairly penalizing providers serving vulnerable populations.

While we support the confidential provision of this information to providers for the purposes of performance improvement, we would like more information on how this measure would be benchmarked for public reporting or payment before recommending its use for these purposes. We

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agree with the need to ensure patients are referred to needed services but do not believe this measure should be tied to payment or publicly reported until there is more information about how it performs. We also recommend that CMS work with the measure steward to refine this measure to include specific screening tools or provide implementation guidance on which screening tools should be used to promote consistency in screening for social determinants across the healthcare sector. Additionally, we recommend that CMS and the measure steward work to ensure alignment with accepted data standards for SDOH. We would recommend that CMS and the measure steward look to the work of the Gravity Project to identify data standards. Ensuring consistency in the screening tools used and utilizing the work of the Gravity Project would align with work health care providers, electronic medical records companies, RHIOs, health insurance providers and government agencies are doing to address SDOH.

OCHIN, Inc.

This measures are essential to identify and remedy persistent structural inequality that adversely impacts patient outcomes—and this is equally true whether patients are receiving care in ambulatory or in-patient settings. This measure creates incentives for the clinical team to identify structural barriers to improved health care and associated social and other services that could facilitate improved patient health status, including improved access to care.

Clinicians and providers cannot address social determinants of health if this information is not collected and acted upon. Our nation's health care delivery models must embed incentives—such as quality measures--to improve care for patients facing the greatest barriers to health care and other structural inequities. The need does not change based on site of care since the patient faces the same social risks.

Recommendations:
OCHIN supports the Coordinating Committee's conditional support for rulemaking with regard to MUC21-134 (MIPS).

OCHIN is a nonprofit health information technology innovation and research network that serves over 1,000 community health care sites with 21,000 providers in 47 states serving nearly 6 million patients. The OCHIN network provides a continuous learning health system collaborative and offers technology solutions, informatics, evidence-based research, and policy insights. For two decades, OCHIN has advanced equitable health care solutions by leveraging the strength of our network's unique data set and the practical experience of our members to drive technology innovation at scale for patients and providers in underserved communities. To that end, OCHIN network members have documented over 1 million individual patient screenings for SDOH. The screening, evaluation, and use of this information is complex, challenging, and hinges on preserving patient trust. This is a resource intensive process that requires adequate time, workflow design, patient engagement, and staff and clinician training. The benefits of the measures outweigh the burden of data collection and reporting where flexibility is provided to optimize workflow and staffing needed to collect the information with the goal of reducing cognitive burden and enhancing team-based approaches to care while preserving and safeguarding patient-clinician relationship and privacy.

These measures are needed for quality improvement activities, payment, research, and public health activities including disease surveillance and mitigation measures in order to address health care inequity. In light of the USCDI adoption of SDOH domains and elements, the suitability of this information can inform numerous clinical, public health, and policy needs to improve care overall

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equitably. Adding information on social complexity to payment discussions could provide valuable insight for value-based payment and care arrangements and risk-bearing contracts.

We offered in our initial round of comments, as we do here, conditional support for these measures. OCHIN recommends that the measures for interpersonal safety domain be removed. Current approaches to addressing relationship safety and intimate partner violence (IPV) are moving away from screening towards a universal education and harm reduction approach. Futures Without Violence (FWV), the CMS partner for IPV prevention and education nationally, notes that while that 1 in 4 women experiences IPV in her lifetime, disclosure rates in practice are usually less than 10% (around 5-6% among OCHIN network members' patients), indicating significant underreporting and calling the utility of collecting this data into question. Instead, FWV provides and promotes a framework called CUES that addresses confidentiality (including its limits in required reporting settings), universal education about healthy relationships, and support for any disclosure that includes warm handoff to appropriate resources. Given this disparate approach, OCHIN recommends not including IPV in the current measures. OCHIN would, however, support a separate measure for IPV focused on the provision of universal patient education.

OCHIN has previously advocated for inclusion of SDOH in screening measures and data standards to begin with the domains of housing, food insecurity, and transportation as "core" domains appropriate for screening in most every community and patient panel. The addition of utility assistance aligns with research from the SIREN group at University of California (San Francisco) that finds these four domains (housing, food insecurity, transportation, and utility assistance) are the most impactful for screening and action in healthcare settings. Consequently, these are the appropriate domains to include in such measures at this time. In the future, other domains could either be optional based on appropriate community or clinic considerations or added as more evidence about the relationship between SDOH and health becomes available.

University of Chicago, Section of General Internal Medicine

5. How would adding this measure add value? How would the measure improve patient outcomes?

As the National Program Office team at the University of Chicago we work with eight grantee organizations from the Merck Foundation funded Bridging the Gap: Reducing Disparities in Diabetes Care initiative. These organizations are transforming primary care through integrated medical and social care to improve diabetes care and outcomes. We have a national lens on integrated medical and social care activities to support chronic disease care. The initiative transforms primary care through the implementation of integrated strategies to address SDOH, with evolving payment models to support these transformations.

The measures (MUC2021-134 (Screen Positive Rate for Social Drivers of Health) and MUC2021- 134 (Screening for Social Drivers of Health)) add value by providing an opportunity to change how and what we measure in health care. The opportunity to measure drivers of health (DoH) allows health care teams to have data to identify and address unmet needs and policymakers and payers to account for DoH in health care delivery and financing models. For example, grantees in the Bridging the Gap: Reducing Disparities in Diabetes Care initiative have utilized DoH screening at two levels: to understand individual patient needs and to assess the needs across their population. Health care teams have utilized screening to assist with resource allocation and to tailor care for individual patients. At the population level,

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grantees have harnessed this high-level to better inform the support services needed and to establish critical cross-sector partnerships.

These measures have the potential to improve patient outcomes by establishing approved, standardized DoH measures in Centers for Medicare and Medicaid Services' (CMS) programs. Standardized collection of DoH measures would allow CMS to systematically compare or use the data. DoH measures can provide insight into the social factors that facilitate or constrain optimal health, particularly for vulnerable populations (e.g., older adults, communities of color). Assessing these factors in a standardized way is an important first step towards improving equitable health outcomes.

6. Do the benefits of the measure outweigh the burden of data collection or reporting?

The benefits of these DoH measures outweigh the burden of data collection or reporting. These measures are well tested, including through the Accountable Health Communities model, which screened nearly a million beneficiaries for SDOH in over 600 clinical practices.

7. For what purpose are you using the measure (e.g., QI, certification/recognition,regulatory/accreditation, payment, public reporting, disease surveillance)?

The National Program Office at the University of Chicago has utilized positive DoH screening results to better understand the scope of social needs amongst the study population within our initiative, especially among medically high-risk populations. Grantees within the initiative utilize different screening tools and the standardization of DoH screening data has proved to be an area of difficulty in the evaluation process.

8. Are there implementation challenges?

To address implementation challenges it is imperative to plan for documentation of these measures during data collection and options for data extraction. Technical assistance may be needed to support best practices for data collection workflows and data extraction. In addition, providers in the Bridging the Gap: Reducing Disparities in Diabetes Care initiative have highlighted that screening for DoH should not be conducted without an appropriate pathway to address the needs screened for. As part of the implementation of screening for DoH, CMS and its partners should consider developing technical assistance to ensure best practices for DoH referrals.

NCQA

While NCQA supports the implementation of a clinician-level measure of social need screening, we express concern as to the implementation of a screen-positive rate MIPS measure that is separate from the screening rate measure. Specifically, NCQA expresses the following concerns:

1) Disincentive to Screen Patients with High Likelihood of Screening Positive: In the MIPS program, clinicians are able to select the measures that they report. If a screen positive rate measure is reported separately from the screening rate measure, clinicians may choose only to report the screen positive rate measure. In such a scenario, there may be an incentive to focus screening efforts only on patients that are likely to screen negative, so as to have a low screen positive rate (high performance) on this measure. This would be a highly undesirable outcome, and could be an unintended consequence of this measure if reported separately from the screening rate measure.

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2) Interpretation of Screen Positive Rate as “lower is better”: In the measure materials, the interpretation of the measure performance is noted as “lower measure score is better.” While the goal of incentivizing clinicians to address social needs of patients and lower level of social need over time is worthwhile, interpreting performance on this measure as lower is better and tying clinician financial incentives to lower performance has important unintended consequences to consider. Notably, this would exacerbate concerns described above regarding incentivizing screening towards patients with low likelihood of screening positive. Clinicians should not be penalized for having a high rate of social needs among their patients; rather they should be incentivized to identify the level of social need and make efforts to address such needs through care coordination, linkage to services and patient-centered care plans. As currently specified, clinicians caring for populations with high levels of social needs may receive poorer performance on this measure, and by extension on their quality score in MIPS, equating to lower reimbursement. This could have the effect of reducing compensation for clinicians who serve patients with the highest level of need.

Duke-Margolis Center for Health Policy

The Duke-Margolis Center for Health Policy encourages the inclusion of measures addressing social drivers of health (SDoH) in CMS quality reporting programs. The impact of these drivers on health is well documented, and a growing number of efforts are under way to examine how health care providers and organizations can better identify and address individuals’ SDoH-related needs. Among these efforts are those examining how to leverage value-based payment (VBP) models to better address SDoH.1 Our work has found VBP models have the potential to support the infrastructure and cross-sector relationships needed to identify and comprehensively address SDoH-related needs.2 However, the current dearth of SDoH-related quality measures makes it difficult to embed accountability for addressing SDoH into VBP models. Development and implementation of SDoH-related quality measures are needed if VBP efforts to meaningfully address SDoH are to be successful.

The addition of the MUC2021-136 and MUC2021-134 measures to the Hospital Inpatient Quality Reporting Program and Merit-based Incentive Payment System would reflect the emphasis needed on advancing SDoH-related quality measures, especially if they can be clearly linked to a strategy for supporting improvement in the SDOH risk factors reflected in such measures. Such a strategy should include more systematic collection and reporting of SDoH-related data, development of the infrastructure needed to support partnerships across sectors (e.g., health care, education, justice), and implementation of payment models that can support and sustain the delivery of SDoH-related services. The inclusion of SDOH-related quality measures in CMS quality reporting programs is one way to support progress in implementing such a strategy.

References:

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2. Crook HL, Zheng J, Bleser WK, Whitaker RG, Masand J, Saunders RS. (2021) How Are Payment Reforms Addressing Social Determinants of Health? Policy Implications and Next Steps. Accessed December 3, 2021. https://www.milbank.org/publications/how-are-payment-reforms-addressing-social-determinants-of-health-policy-implications-and-next-steps/

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MUC2021-090 Kidney Health Evaluation

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Merit-based Incentive Payment System–Quality

Workgroup
Clinician

Measure Description
Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period

Numerator
Patients who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period

Numerator Exclusions
Not applicable

Denominator
All patients aged 18-75 years with a diagnosis of diabetes

Denominator Exclusions
Patients with a diagnosis of End Stage Renal Disease (ESRD); Patients with a diagnosis of Chronic Kidney Disease (CKD) Stage 5; Patients who have an order for or are receiving hospice or palliative care

Denominator Exceptions
N/A

State of development

Fully Developed

State of Development Details
Testing is complete. The parallel forms testing satisfies both the validity and reliability testing. NCQA notes that new measures typically don't have robust reliability testing initially. The plan-level measure was adopted by HEDIS and is already being reported by plans. These data should be able to supplement the testing data provided.

The development of this measure was the result of a large multidisciplinary, multi-stakeholder technical

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expert panel (TEP) drawing on expertise from governmental, private practice, and health care organization representatives. The TEP was comprised of clinical experts in kidney disease, diabetes, public health, primary care providers, researchers, persons diagnosed with kidney disease, and medical informaticists. Alpha testing was completed at two ambulatory test sites through completion of the NQF Feasibility Scorecard. Each test site provided information about data availability, data accuracy, data standards, workflow, and burden to collect and report data. All required data elements are able to be collected, although some data elements are not currently able to be captured in structured fields. Several data elements are currently being captured via free text. Barriers to feasibility are primarily related to the ability to capture data elements related to hospice and palliative care in an ambulatory setting. Without the ability to capture all applicable denominator exclusion data elements, the overall performance calculation may be impacted, as the denominator or eligible population would not be reduced by the number of patients for whom the measure is not applicable. Therefore, it could mean a lower calculated score. However, it is also possible that some patients who would have met the elements not captured also possess one or more of the other exclusions that are feasible, so they would be appropriately removed. Data elements critical to the calculation of the measure score are feasible and the measure is considered feasible for implementation. The measure was also tested in BONNIE and the measure logic performs as expected. The measure has 100% coverage and all 19 of the test cases are passing, within the BONNIE system. Validity testing was conducted using data element level testing through parallel forms. Two ambulatory test sites were selected with different electronic health record systems (EHRs). Testing is used to determine if data elements found through electronic data pulls can be confirmed by manual abstraction of the same data elements. The sample size for this analysis was 85 patients randomly selected at each site, 170 patients total. There are 18 physicians at site 1 and 1 physician at site 2. Testing was conducted at ambulatory sites and data elements that are present in inpatient data records for the denominator were excluded from this analysis (e.g. “Inpatient Encounter” and “Outpatient Consultation” which is conducted in an inpatient setting). In addition to providing the overall agreement rate for the denominator, exclusions, and numerator, we also calculated the Cohen’s kappa agreement, which provides an understanding of the share of cases where the manual and automated methods agreed after excluding agreement that would be expected by chance. Overall agreement is both testing sites pooled. Testing of the denominator indicated an overall agreement rate of 94%. Agreement is very high as expected. Cohen’s kappa agreement testing indicated an overall agreement rate of 78.71%, with a confidence interval between (66.14%, 91.27%); Kappa agreement for site 1 is 58.69%, with a confidence interval between (33.43%, 83.94%); Kappa agreement for site 2 is 92.65%, with a confidence interval between (82.62%, 100%). Testing for the exclusions indicated an overall agreement rate of 70%. Cohen’s kappa agreement testing indicated an overall agreement rate of 15.87%, with a confidence interval between (0.28%, 31.47%); Kappa agreement for site 1 is 45.21%, with a confidence interval between (22.63%, 67.80%); Kappa agreement for site 2 is 6.70%, with a confidence interval between (-6.82%, 20.23%). Exclusions include indicators often reported in inpatient settings such as palliative and/or hospice care. In many healthcare systems including ambulatory only, these elements are available for electronic reporting and agreement is expected to be higher. Agreement is high as expected. Testing for the numerator indicated an overall agreement rate of 68%. Cohen’s kappa agreement testing indicated an overall agreement rate of 1.33%, with a confidence interval between (-4.01%, 6.67%); Kappa agreement for site 1 is 3.84%, with a confidence interval between (-8.58%, 16.25%); Kappa agreement for site 2 is 0%, confidence interval for site 2 is not calculable as site 2’s EHR system indicates a numerator of exactly zero. There are several additional factors that are impacting the

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numerator agreement. First, between the two numerator elements, eGFR and UACR, it was more difficult to identify a UACR than EGFR presence regardless of method (manual or automated), and even more difficult to detect UACR with EHR/automated system than with manual extracts. Overall kappa agreement for EGFR is 23.02% with confidence interval between (10.83%, 35.21%), while overall kappa agreement for UACR is 2.79% with confidence interval between (-2.18%, 7.75%). The numerator for this measure requests presence of both EGFR and UACR, as a result, the agreement tends to be low. Second, the sites included in this study are part of a system that only provides ambulatory care and have more limitations in accessing laboratory data in discrete fields than is typically seen in other healthcare systems. Much of the testing is completed through smaller laboratories and results are often scanned into the EHR or the availability of data in discrete fields as received from the laboratory data is limited. This does not highlight an issue with the data flow from the EHR to the measure, but in the data transfer from the laboratory to the EHR where the level of granularity of the data is less specific and thereby more challenging to capture. However, we have confidence that the data in most large healthcare systems will be available in discrete fields and systems that have these barriers can develop appropriate data workflows and implement appropriate mapping and labelling of laboratory tests as specified in this measure. Many systems upon implementation of existing eCQMs have demonstrated the ability to make the necessary changes to enable electronic reporting. Finally, there is an aspirational aspect to this new measure in that the UACR test necessary for the numerator requires the use of a quantitative albumin test, which is recommended by clinical guidelines as part of the gold standard for screening and monitoring for kidney disease. Many providers and practices currently use a semi-quantitative albumin test that does not meet the requirements of this new measure. This was the case with Site 2 in our study, which explains the zero-numerator performance. With the implementation of this new measure, we intend to improve the use of the guideline-recommended set of tests and thus, improve the screening and monitoring of kidney disease in patients with diabetes.

What is the target population of the measure?

The target population is adults aged 18 – 75 years with a diagnosis of diabetes, identified by commercial, Medicare Advantage, or Medicare Fee-for-Service claims/encounter data or pharmacy data.

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure

Family practice ;General practice;Internal medicine

Measure Type

Process

Is the measure a composite or component of a composite?

No

If Other, Please Specify

N/A

What data sources are used for the measure?

Electronic Health Record

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If applicable, specify the data source
N/A

If EHR or Chart-Abstracted data, description of parts related to these sources
N/A

At what level of analysis was the measure tested?
Clinician;Group

In which setting was this measure tested?
Ambulatory/office-based care

What one healthcare domain applies to this measure?
Chronic Conditions

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
N/A

Alternate Measure ID
Not applicable

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
We would note that this measure is the physician-level equivalent of the measure, Kidney Health Evaluation for Patients with Diabetes that was adopted by HEDIS and is already being measured by health plans.

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Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?
Yes

If eCQM, enter Measure Authoring Tool (MAT) number
951

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
Yes

If eCQM, does any electronic health record (EHR) system tested need to be modified?
No

If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs
N/A

What other federal programs are currently using this measure?
N/A

Is this measure similar to and/or competing with a measure(s) already in a program?
Yes

Which measure(s) already in a program is your measure similar to and/or competing with?
Diabetes: Medical Attention for Nephropathy

How will this measure be distinguished from other similar and/or competing measures?
This measure would replace and improve upon the existing Healthcare Effectiveness Data and Information Set (HEDIS) medical attention for nephropathy measure. This measure is more specific than the HEDIS measure as the measure requires utilizing the estimated glomerular filtration rate (eGFR) and

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urine albumin creatinine ratio (uACR) tests to assess a patient's kidney health. In addition, a public comment period conducted from 4/01/19 to 4/30/19 included responses from patients who commented that this kidney health evaluation measure for two simple blood and urine tests is conceptually better than the existing nephropathy measure that NKF and NCQA seek to replace.

How will this measure add value to the CMS program?

The National Kidney Foundation (NKF) is focused on improving awareness about the importance of kidney health and the recognition of chronic kidney disease (CKD) as a major public health issue. Approximately 9 percent of American adults currently have CKD (NKF, 2019), and it is projected that by 2030 approximately 17 percent of Americans aged 30 years and older will have CKD (Saran et al., 2019; Hoerger et al., 2015). In the US from 2002-2016, the burden of CKD, defined as years of life lost, years living with disability, disability-adjusted life years, and deaths, outpaced changes in the burden of disease for other conditions (Bowe et al., 2018). Patients with CKD are readmitted to the hospital more frequently than those without diagnosed CKD (Saran et al., 2019). This public health issue is driven largely by the impact of diabetes—the most common comorbid risk factor for CKD (Saran et al., 2019; Bowe et al., 2018).

The intent of this process measure is to improve rates of guideline-concordant kidney health evaluation in patients with diabetes to more consistently identify and potentially treat or delay progression of CKD in this high-risk population. Annual kidney health evaluation in patients with diabetes to determine risk of CKD using estimated glomerular filtration rate (eGFR) and urine albumin creatinine ratio (uACR) is recommended by clinical practice guidelines and has been a focus of various local and national health care quality improvement initiatives, including Healthy People 2020 (United States Renal Data System, 2018).

References:

1. git

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure

Chronic kidney disease (CKD) stemming from diabetes occurs in almost 30% of patients with diabetes (Afkarian et al, 2016). CKD is diagnosed by the chronic presence of elevated urinary albumin-creatinine ratio albumin excretion (uACR) and low estimated glomerular

filtration rate (eGFR).

The following evidence statements are quoted from the referenced clinical guidelines:

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1) At least once a year, assess urinary albumin (e.g., spot urinary albumin-to-creatinine ratio) and estimated glomerular filtration rate (eGFR) in patients with type 1 diabetes with duration of =5 years and in all patients with type 2 diabetes regardless of treatment. (Evidence Grade = B) * (American Diabetes Association, 2020)
2) Patients with diabetes should be screened annually for chronic kidney disease. Initial screening should commence: 5 years after the diagnosis of type 1 diabetes; (Evidence Grade = A) * or From diagnosis of type 2 diabetes. (Evidence Grade = B) * Screening should include: Measurements of urinary albumin-creatinine ratio (ACR) in a spot urine sample; (Evidence Grade = B)* Measurement of serum creatinine and estimation of GFR. (Evidence Grade = B) * (National Kidney Foundation, 2007 and 2012)
1. *See end of the document for evidence classifications

References

1. Afkarian, M., Zelnick, L. R., Hall, Y. N., Heagerty, P. J., Tuttle, K., Weiss, N. S., & de Boer, I. H. (2016). Clinical Manifestations of Kidney Disease Among US Adults With Diabetes, 1988-2014. JAMA, 316(6), 602–610. https://doi.org/10.1001/jama.2016.10924
2. American Diabetes Association, Professional Practice Committee. (2020). Standards of Medical Care in Diabetes—2020. Retrieved from https://care.diabetesjournals.org/content/43/Supplement_1/S1
3. National Kidney Foundation. (2007). KDOQI™ Clinical practice guidelines and clinical practice recommendations for diabetes and chronic kidney disease. American Journal of Kidney Disorders, 49, S1-S180. Retrieved from https://www.kidney.org/sites/default/files/docs/diabetes_ajkd_febsuppl_07.pdf
4. National Kidney Foundation. (2012). KDOQI Clinical practice guidelines and clinical practice recommendations for diabetes and CKD: 2012 update. American Journal of Kidney Disorders, 60(5), 850-886. Retrieved from http://www.kidney.org/sites/default/files/docs/diabetes-ckd-update-2012.pdf

Evidence that the measure can be operationalized

The measure has been developed as an eCQM and is aligned with the national standards described in CMS' Blueprint for the CMS Measures Management System. It has been designed for seamless extraction from electronic data sources, including EHR, which are readily available to CMS through reporting in the Quality Payment Program. The measure also underwent alpha testing via completion of the NQF Feasibility Scorecard and is feasible to implement, as described in the State of Development Details section of the submission form.

How is the measure expected to be reported to the program?

eCQM;Clinical Quality Measure (CQM) Registry

Feasibility of Data Elements

ALL data elements are in defined fields in electronic health records (EHRs)

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Evidence of Performance Gap

According to Medicare and private insurance claims data, kidney evaluation using estimated glomerular filtration rate (eGFR) and urine albumin creatinine ratio (uACR) in patients with diabetes to determine risk of CKD remains suboptimal at 41.8% within Medicare data and 49% within private insurer data (Saran et al., 2019). Thus, there is still substantial room for improvement in evaluating kidney health among diabetes patients.

Reference:

1) Saran, R., Robinson, B., Abbott, K. C., Agodoa, L. Y. C., Bragg-Gresham, J., Balkrishnan, R.,… Shahinian, V. (2019). US Renal Data System 2018 Annual Data Report: Epidemiology of kidney disease in the United States. [Supplemental material]. American Journal of Kidney Diseases, 73(3)(suppl 1), Svii-Sxxii, S1-S772. doi:10.1053/j.ajkd.2019.01

Unintended Consequences

Not applicable

Outline the clinical guidelines supporting this measure

This clinical quality measure is based on two evidence-based clinical guidelines from the National Kidney Foundation (NKF), from 2007 and 2012, and the American Diabetes Association (ADA), from 2020. These guidelines explicitly recommended urine albumin-to-creatinine ratio (uACR) and estimated glomerular filtration rate (eGFR) laboratory testing in patients with diabetes. Kidney health evaluations, utilizing both eGFR and uACR tests, among diabetes patients provide an opportunity to improve identification and potential reversal of worsening kidney function. The intent of this process measure is to improve rates of guideline-concordant kidney health evaluation in patients with diabetes to identify and treat the progression of chronic kidney disease in this high-risk population.

References

2) American Diabetes Association, Professional Practice Committee. (2020). Standards of Medical Care in Diabetes—2020. Retrieved from https://care.diabetesjournals.org/content/43/Supplement_1/S1

3) National Kidney Foundation. (2007). KDOQI™ Clinical practice guidelines and clinical practice recommendations for diabetes and chronic kidney disease. American Journal of Kidney Disorders, 49, S1-S180. Retrieved from https://www.kidney.org/sites/default/files/docs/diabetes_ajkd_febsuppl_07.pdf

4) National Kidney Foundation. (2012). KDOQI Clinical practice guidelines and clinical practice recommendations for diabetes and CKD: 2012 update. American Journal of Kidney Disorders, 60(5), 850-886. Retrieved from http://www.kidney.org/sites/default/files/docs/diabetes-ckd-update-2012.pdf

Were the guidelines graded?

Yes

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If yes, who graded the guidelines?

1) At least once a year, assess urinary albumin (e.g., spot urinary albumin-to-creatinine ratio) and estimated glomerular filtration rate (eGFR) in patients with type 1 diabetes with duration of =5 years and in all patients with type 2 diabetes regardless of treatment. (Evidence Grade = B)* (American Diabetes Association, 2020), 2) Patients with diabetes should be screened annually for chronic kidney disease. Initial screening should commence: 5 years after the diagnosis of type 1 diabetes; (Evidence Grade = A)* or From diagnosis of type 2 diabetes. (Evidence Grade = B)* Screening should include: Measurements of urinary albumin-creatinine ratio (ACR) in a spot urine sample; (Evidence Grade = B)* Measurement of serum creatinine and estimation of GFR. (Evidence Grade = B)* (National Kidney Foundation, 2007 and 2012)

If yes, what was the grade?

B/B/B

Estimated Impact of the Measure: Estimate of Annual Denominator Size

Approximately 11 million Medicare beneficiaries, based on 27.7% prevalence of diabetes in the Medicare fee-for-service (FFS) population in 2018, will be impacted by the measure across MACRA programs.

Estimate of Annual Improvement in Measure Score

5-10%

Type of Evidence to Support the Measure

Clinical Guidelines

Is the measure risk adjusted, stratified, or both?

None

Are social determinants of health built into the risk adjustment model?

Not Applicable

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event

In 2016, Medicare spending was approximately $79 billion for CKD patients and $35 billion for ESRD patients, exceeding $114 billion combined (USRDS, 2018). CDC simulation studies showed that uACR screening for early detection of CKD was cost-effective in patients with diabetes, at $50 thousand per Quality-adjusted life-years (Hoerger et al., 2010).

Cost Avoided Annually by Medicare/Provider

The measure is both a new measure and process measure, the costs avoided annually by Medicare/Provider are unknowable without adoption of the measure and subsequent data on how organ-protective medications and other interventions are deployed by physicians in MIPS and the associated cost savings.

Source of Estimate

Hoerger, Thomas J., John S. Wittenborn, Joel E. Segel, Nilka R. Burrows, Kumiko Imai, Paul Eggers, Meda E. Pavkov, et al. 2010. “A Health Policy Model of CKD: 2. The Cost-Effectiveness of Microalbuminuria Screening.” American Journal of Kidney Diseases. 55 (3): 463–73. https://doi.org/10.1053/j.ajkd.2009.11.017.

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Year of Cost Literature Cited
Not applicable

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

If yes, choose all methods of obtaining patient/caregiver information
Standard Technical Expert Panel (TEP) inclusive of patient/caregiver representatives;Working groups;One-on-one interviews

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
As the U.S. struggles to optimally define and improve healthcare value, engaging patients and caregivers is becoming increasingly important. Early on the measure development process, NKF engaged approximately 40 patient members of NKF's Kidney Advocacy Committee (KAC). In addition, the NKF convened a technical expert panel (TEP) to develop the Kidney Health Evaluation measure comprised of a multidisciplinary group of experts including 4 people living with CKD. As part of the TEP participation, these patients received facilitated training using the National Health Council's Increasing Patient-Community Capacity to Engage on Quality of Health Care, comprised of six modules to address why quality is important in the current health care environment and how patients and patient organizations can become strong advocates for quality.

The Kidney Health Evaluation draft quality measure public comment feedback conducted from 4/01/19 to 4/30/19 included responses from 4 people living with kidney disease and 1 caregiver of a kidney transplant recipient. The TEP and public comments from patients found the Kidney Health Evaluation measure for two simple tests, blood eGFR and urine uACR, more conceptually attractive than the current Medical Attention for Nephropathy measure that NKF and National Committee for Quality Assurance (NCQA) seek to replace.

Total Number of Patients and/or Caregivers Consulted
50

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
1:5

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
50

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

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If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Standard TEP

Total Number of Clinicians/Providers Consulted
100

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
100

Burden for Provider: Was a provider workflow analysis conducted?
No

If yes, how many sites were evaluated in the provider workflow analysis?
N/A

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
2

Measure Testing Details

Reliability Testing Interpretation of Results
Not applicable

Type of Reliability Testing
Data Element Reliability

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Reliability Testing: Type of Testing Analysis
Complete

Reliability Testing Sample Size
Not applicable

Reliability Testing Statistical Result
Other: The reliability testing is complete. The parallel forms testing fulfills both the reliability and validity testing requirements. NCQA notes that new measures such as ours do not have robust reliability testing initially. The plan-level version of Kidney Health Evaluation is already being reported by plans. These data will be able to supplement the reliability testing data submitted (see "State of Development").

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
Data Element Validity

Validity Testing: Type of Validity Testing Analysis
Gold Standard Comparison

Validity Testing Sample Size
170

Validity Testing Statistical Result
Testing of the denominator indicated an overall agreement rate of 94%. Cohen's kappa agreement testing indicated an overall agreement rate of 78.71%, with a confidence interval between (66.14%, 91.27%); Kappa agreement for site 1 is 58.69%, with a confidence interval between (33.43%, 83.94%); Kappa agreement for site 2 is 92.65%, with a confidence interval between (82.62%, 100%).

Testing for the exclusions indicated an overall agreement rate of 70%.

Cohen's kappa agreement testing indicated an overall agreement rate of 15.87%, with a confidence interval between (0.28%, 31.47%); Kappa agreement for site 1 is 45.21%, with a confidence interval between (22.63%, 67.80%); Kappa agreement for site 2 is 6.70%, with a confidence interval between (-6.82%, 20.23%). Testing for the numerator indicated an overall agreement rate of 68%.

Cohen's kappa agreement testing indicated an overall agreement rate of 1.33%, with a confidence interval between (-4.01%, 6.67%); Kappa agreement for site 1 is 3.84%, with a confidence interval between (-8.58%, 16.25%); Kappa agreement for site 2 is 0%, confidence interval for site 2 is not calculable as site 2's EHR system indicates a numerator of exactly zero.

Validity Testing Interpretation of Results
Validity testing was conducted using data element level testing through parallel forms. Two ambulatory test sites were selected with different electronic health record systems (EHRs). Testing is used to

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determine if data elements found through electronic data pulls can be confirmed by manual abstraction of the same data elements. The sample size for this analysis was 85 patients randomly selected at each site, 170 patients total. There are 18 physicians at site 1 and 1 physician at site 2. Testing was conducted at ambulatory sites and data elements that are present in inpatient data records for the denominator were excluded from this analysis (e.g. “Inpatient Encounter” and “Outpatient Consultation” which is conducted in an inpatient setting). In addition to providing the overall agreement rate for the denominator, exclusions, and numerator, we also calculated the Cohen’s kappa agreement, which provides an understanding of the share of cases where the manual and automated methods agreed after excluding agreement that would be expected by chance. Overall agreement is both testing sites pooled.

Testing of the denominator indicated an overall agreement rate of 94%. Agreement is very high as expected.

Cohen’s kappa agreement testing indicated an overall agreement rate of 78.71%, with a confidence interval between (66.14%, 91.27%); Kappa agreement for site 1 is 58.69%, with a confidence interval between (33.43%, 83.94%); Kappa agreement for site 2 is 92.65%, with a confidence interval between (82.62%, 100%).

Testing for the exclusions indicated an overall agreement rate of 70%.

Cohen’s kappa agreement testing indicated an overall agreement rate of 15.87%, with a confidence interval between (0.28%, 31.47%); Kappa agreement for site 1 is 45.21%, with a confidence interval between (22.63%, 67.80%); Kappa agreement for site 2 is 6.70%, with a confidence interval between (-6.82%, 20.23%).

Exclusions include indicators often reported in inpatient settings such as palliative and/or hospice care. In many healthcare systems including ambulatory only, these elements are available for electronic reporting and agreement is expected to be higher. Agreement is high as expected.

Testing for the numerator indicated an overall agreement rate of 68%.

Cohen’s kappa agreement testing indicated an overall agreement rate of 1.33%, with a confidence interval between (-4.01%, 6.67%); Kappa agreement for site 1 is 3.84%, with a confidence interval between (-8.58%, 16.25%); Kappa agreement for site 2 is 0%, confidence interval for site 2 is not calculable as site 2’s EHR system indicates a numerator of exactly zero.

There are several additional factors that are impacting the numerator agreement. First, between the two numerator elements, eGFR and UACR, it was more difficult to identify a UACR than EGFR presence regardless of method (manual or automated), and even more difficult to detect UACR with EHR/automated system than with manual extracts. Overall kappa agreement for EGFR is 23.02% with confidence interval between (10.83%, 35.21%), while overall kappa agreement for UACR is 2.79% with confidence interval between (-2.18%, 7.75%). The numerator for this measure requests presence of both EGFR and UACR, as a result, the agreement tends to be low.

Second, the sites included in this study are part of a system that only provides ambulatory care and have more limitations in accessing laboratory data in discrete fields than is typically seen in other healthcare

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systems. Much of the testing is completed through smaller laboratories and results are often scanned into the EHR or the availability of data in discrete fields as received from the laboratory data is limited. This does not highlight an issue with the data flow from the EHR to the measure, but in the data transfer from the laboratory to the EHR where the level of granularity of the data is less specific and thereby more challenging to capture. However, we have confidence that the data in most large healthcare systems will be available in discrete fields and systems that have these barriers can develop appropriate data workflows and implement appropriate mapping and labelling of laboratory tests as specified in this measure. Many systems upon implementation of existing eCQMs have demonstrated the ability to make the necessary changes to enable electronic reporting.

Finally, there is an aspirational aspect to this new measure in that the UACR test necessary for the numerator requires the use of a quantitative albumin test, which is recommended by clinical guidelines as part of the gold standard for screening and monitoring for kidney disease. Many providers and practices currently use a semi-quantitative albumin test that does not meet the requirements of this new measure. This was the case with Site 2 in our study, which explains the zero-numerator performance. With the implementation of this new measure, we intend to improve the use of the guideline-recommended set of tests and thus, improve the screening and monitoring of kidney disease in patients with diabetes.

Measure performance – Type of Score
Proportion

Measure Performance Score Interpretation
Higher score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have
This is a new measure therefore there is no mean performance rate. According to Medicare and private insurance claims data, kidney evaluation using estimated glomerular filtration rate (eGFR) and urine albumin creatinine ratio (uACR) in patients with diabetes to determine risk of CKD remains suboptimal at 41.8% within Medicare data and 49% within private insurer data (Saran et al., 2019).

Benchmark, if applicable
This is a new measure therefore there is no benchmark/historical comparison.

Measure Contact Information

Measure Steward
National Kidney Foundation

Measure Steward Contact Information
Miriam Godwin

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Washington, DC 20008

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miriam.godwin@kidney.org

202-412-5526

Long-Term Measure Steward
N/A

Long-Term Measure Steward Contact Information
N/A

Primary Submitter Contact Information
Miriam Godwin

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Washington, DC 20008

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Secondary Submitter Contact Information
Daniel Roman

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Section 2: Preliminary Analysis – MUC2021-090 Kidney Health Evaluation

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

Justification and Notes: This electronic clinical quality measure (eCQM) focuses on nephrology and the critical condition of diabetes, both identified as gaps within the MIPS program and considered priority areas for future measures. This kidney health evaluation measure would replace and improve upon the existing Healthcare Effectiveness Data and Information Set (HEDIS) medical attention for nephropathy measure. This measure requires utilizing the estimated glomerular filtration rate (eGFR) and urine albumin creatinine ratio (uACR) tests to assess a patient's kidney health.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes

Justification and Notes: This is a process measure focused on improving rates of guideline-accordant kidney health evaluations in patients with diabetes to identify and potentially treat or delay progression of chronic kidney disease (CKD) in this high-risk population. This measure aligns with the Health People 2020 CKD-4.2 objective to increase the proportion of persons with type 1 or type 2 diabetes and chronic kidney disease who receive medical evaluation with serum creatinine, microalbuminuria, A1c, lipids, and eye examinations (Healthy People, 2020). Patients with CKD are readmitted to the hospital more

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frequently than those without diagnosed CKD and overall have a lower quality of life.

Does the measure address a quality challenge?
Yes/No: Yes

Justification and Notes: Diabetes is the leading cause of chronic kidney disease (CKD) in the United States, with 36.9% of adults with CKD also diagnosed with diabetes between 2015 and 2018 (United States Renal Data System (USRDS), 2020). An estimated 37 million U.S adults have CKD and are at risk for kidney failure, in addition to cardiovascular events and death. Early-stage CKD is often asymptomatic, making laboratory testing imperative for at-risk patients. Diagnosis uses two widely available, inexpensive tests: 1) serum creatinine with estimated glomerular filtration rate (eGFR), a test of kidney function, and 2) urine albumin-to-creatinine ratio (uACR) (Alfego et al., 2021).

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?
Yes/No: Yes

Justification and Notes: This measure would replace the existing HEDIS: Medical Attention for Nephropathy measure currently in use. In addition to high prevalence, the cost burden of CKD is substantial. Total 2016 Medicare expenditures for kidney disease were >$114 billion, totaling $79 billion for all CKD stages and $35 billion for ESKD, including dialysis and kidney transplants. Early detection measures would reduce cost burden (Alfego et al., 2021).

Can the measure be feasibly reported?
Yes/No: Yes

Justification and Notes: The measure has been developed as an electronic clinical quality measure (eCQM) and is aligned with the national standards described in CMS' Blueprint for the CMS Measures Management System. The main data source for the measure are electronic health records (EHRs), which are readily available to CMS through reporting in the Quality Payment Program. The measure also underwent alpha testing via completion of the NQF Feasibility Scorecard and is feasible to implement, as described in the State of Development Details section of the submission form (NQF Feasability Card).

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?
Yes/No: Yes

Justification and Notes: This measure is the physician-level equivalent of the measure, Kidney Health Evaluation for Patients with Diabetes that was adopted by the HEDIS and is already being measured by health plans. It is being tested at an ambulatory/office-based care setting. This measure has not been submitted for endorsement by NQF.

If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure been identified?
Yes/No: No

Justification and Notes: The measure is fully developed but not currently in use. No unintended consequences have been identified. The measure developer did exclude patients with a diagnosis of End Stage Renal Disease (ESRD), chronic kidney disease – stage 5 (CKD), and patients who have an order for

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or are receiving hospice/palliative care to avoid any unintended issues associated with the measure.

PAC/LTC Core Concept?
N/A

Impact Act Domain
N/A

Hospice High Priority Areas
N/A

MAP Rural Health Advisory Group Input:
Relative priority/utility:
- The goal of the measure is important.

Data collection issues:
- The rural workgroup expressed concern on whether rural providers would be able to report the measure, due to difficulties obtaining the data and lack of lab capacity in rural settings to complete the testing.

Calculation issues:
- None identified

Unintended consequences:
- None identified

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 3.5
1 – 0 votes
2 – 2 votes
3 – 5 votes
4 – 9 votes
5 – 1 vote

MAP Health Equity Advisory Group Input:
Relative priority/utility:
- This measure was noted to be an important clinical topic.

Data collection issues:
- Robust discussion occurred regarding a new CKD-EPI eGFR equation that does not include race (use of race-less eGFR estimation equation). The Advisory Group strongly supported the use of the race-less eGFR estimation equation.

Calculation issues:
- None identified

Unintended consequences:
- None identified.

Votes: Range is 1 – 5, where higher number has greater potential for positive impact on health equity.
Average: 4.2
1 – 0 votes

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2 – 0 votes
3 – 2 votes
4 – 15 votes
5 – 8 votes

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking, pending NQF endorsement.

Summary: What is the potential value to the program measure set?

This measure focuses on nephrology and the critical condition of diabetes, both identified as gaps within the MIPS program and considered priority areas for future measures. This measure will also replace and improve upon the existing Healthcare Effectiveness Data and Information Set (HEDIS) medical attention for nephropathy measure.

Summary: What is the potential impact of this measure on quality of care for patients?

The measure will encourage the at least annual evaluation of estimated glomerular filtration rate (eGFR)and urinary albumin-to-creatinine ratio (uACR) in patients with diabetes to prevent or delay chronic kidney disease. Early detection can reduce associated health risk of the co-morbidity of diabetes and CKD.

Section 3: Public Comments

American Academy of Family Physicians

This measure would replace and improve upon the existing Healthcare Effectiveness Data and Information Set (HEDIS) medical attention for nephropathy measure. This measure has also been recommended to the CQMC to replace the previous medical attention for nephropathy measure in the PCMH/ACO set. The AAFP supports this measure pending NQF endorsement.

National Kidney Foundation

December 9, 2021

Measures Application Partnership (MAP) Coordinating Committee

National Quality Forum

1099 14th Street NW

Suite 500

Washington DC 20005

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To the Co-Chairs of the MAP Coordinating Committee,

The National Kidney Foundation (NKF) is writing to express our strenuous support for the MAP's endorsement of the measure, Kidney Health Evaluation. Kidney Health Evaluation is a process measure, designed in partnership with the National Committee for Quality Assurance (NCQA), of annual estimated glomerular filtration rate (GFR) and urine albumin creatinine ratio (uACR) for adults with diabetes. Diabetes is the leading cause of chronic kidney disease (CKD). Performance of both lab tests are guideline concordant with the National Kidney Foundation (NKF) and the American Diabetes Association. Performance of both tests is also low, with rates that vary across Medicare (41.8%) and private insurers (49.0%).

The clinician-level measure was designed for the Merit-Based Incentive Payment System (MIPS); the plan-level measure for the Healthcare Effectiveness Data and Information Set (HEDIS). The HEDIS measure was in first-year reporting in MY2020. The plan- and physician- level measures either have or will replace the measure Diabetes: Medical Attention for Nephropathy (Quality ID #119 NQF 0062), a composite measure that is widely acknowledged provide an unclear picture of diabetes-related renal care processes. In the case of the HEDIS measure set, Diabetes: Medical Attention for Nephropathy (Quality ID: #119) was retired as of MY2020 and 2021.

Over the next two weeks, NKF staff and leadership will attend MAP Workgroups to discuss the measure's relevance to clinicians, rural clinicians, and health equity. Kidney Health Evaluation was designed with input from the American Association of Family Physicians (AAFP). Thus, we believe the family physicians will be able to report on the measure with no additional burden, particularly since Kidney Health Evaluation, if adopted, would replace an existing MIPS measure. While rural clinicians face unique challenges in the provision of care, we believe rural clinicians can also report on Kidney Health Evaluation. Samples for serum creatinine and urine albumin-creatinine can be obtained in the physician's office and mailed to a laboratory. Finally, Kidney Health Evaluation is highly relevant to health equity. Kidney disease is one of the starkest examples of health disparities. Structurally disadvantaged populations are more likely to progress to kidney failure and progress more rapidly. While the prevalence of CKD is similar among racial and ethnic groups, CKD risk is higher for Black/African American people at progressively higher CKD stages. Black/African American people disproportionally bear the burden of end-stage kidney disease (ESKD) representing 13% of the population but 35% of those with kidney failure. Importantly, for the purposes of Kidney Health Evaluation, Black/African American people with diabetes have between a 200 and 300% greater likelihood of having protein in their urine, highlighting the importance of eGFR and uACR testing in this population. Albuminuria testing is actually higher in Black/African American, Hispanic, and Asian populations compared to White populations. It is essential that these gains are not lost.

NKF appreciates NQF's careful consideration of the Measures Under Consideration, including Kidney Health Evaluation. We would welcome the opportunity to describe the measure in more detail and answer any questions or concerns raised by the Workgroups and the Coordinating Committee. Please contact Miriam Godwin, Health Policy Director, at miriam.godwin@kidney.org to discuss further.

Sincerely,

Kevin Longino

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CEO and transplant patient

Paul Palevsky, MD

President

Afkarian, M., Zelnick, L. R., Hall, Y. N., Heagerty, P. J., Tuttle, K., Weiss, N. S., & de Boer, I. H. (2016). Clinical Manifestations of Kidney Disease Among US Adults With Diabetes, 1988-2014. JAMA, 316(6), 602–610. https://doi.org/10.1001/jama.2016.10924

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American Medical Association

The American Medical Association (AMA) is concerned with the overall Cohen's kappa agreement rates of none to slight for the numerator and exclusions and additional testing demonstrating improved validity of the underlying data is required. As a result, we do not believe that this measure is ready for use in an accountability program such as MIPS and recommend that the highest level of MAP recommendation be "Do Not Support with Potential for Mitigation."

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American Society of Nephrology

MUC2021-090 Kidney Health Evaluation MIPS

The American Society of Nephrology supports this measure to screen for chronic kidney disease (CKD) using estimated glomerular filtration rate (eGFR) and urine albumin-to-creatinine ratio (UACR). Current guidelines from the American Diabetes Association recommend annual screening for kidney disease with eGFR and UACR for patients with diabetes. However, only about half of patients with diabetes receive this guideline-recommended care. This measure aims to bridge this performance gap. Kidney health evaluation testing using eGFR and UACR is essential to identify CKD in diabetes at stages where the new break-through therapies, as well as conventional treatments such as ACE inhibitors and ARBs, have the greatest chance to reduce progression to kidney failure, cardiovascular complications, and death. We support this measure to increase the early detection and intervention of kidney disease, which is in line with the Advancing American Kidney Health executive order.

College of American Pathologists

The College of American Pathologists (CAP) supports this measure as consistent with best practice in laboratory medicine. These tests are critical to assessing kidney function, and diagnosing and monitoring kidney disease. The CAP supports standardization of kidney health evaluation via these tests. However, the CAP is in full agreement with the MAP Health Equity Advisory Group that the CKD-EPI 2021 eGFR creatinine equation for calculating eGFRcr in adults should be used in this measure. Importantly, unlike previous iterations of the equation, the 2021 version does not include a race coefficient in computation. As race is a subjective social construct, recent guidance from the National Kidney Foundation and the American Society of Nephrology recommends the race-free eGFR creatinine equation. The CAP strongly recommends that future iterations of this quality measure explicitly require use of the race-free equation.

American College of Physicians

We believe that it is important to monitor kidney health for diabetic patients. Though there isn't complete agreement on the benefits of testing for patients on ACE/ARB, we still believe that monitoring of kidney health is very important to confirm correct dosages of medications and evaluation of the progression of CKD.

American Heart Association

We strongly support NCQA's plan to retire the current Medical Attention for Nephropathy component of the Comprehensive Diabetes Care composite measure and the introduction of this new guideline supported stand-alone measure. Despite the prevalence of CKD in patients with diabetes and overwhelming evidence of its impact on patient outcomes, quality of life and healthcare costs, a significant gap in care still exists in screening for and monitoring kidney disease, as your own testing of the new measure demonstrated.

The new measure is better aligned with current ADA standards of practice recommendations and should provide more actionable feedback to providers to help them deliver better care to their patients with diabetes. We support making this a stand-alone measure, which should help to focus efforts on this critical aspect of care. We also believe that it will help promote awareness among providers and consumers of the importance of regular and ongoing kidney health evaluations to allow early

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identification and to monitor the progression and treatment of diabetic kidney disease. However, although we understand that there may be challenges in capturing the required information from claims data, we suggest that NCQA explore ways to identify duration of diabetes. The most recent guidelines do recommend annual urinary albumin-to-creatinine ratio and eGFR assessment for all patients 18-75 with Type 2 diabetes, but for patients with Type 1 diabetes, annual assessment is recommended only for those with diabetes of at least 5 years duration. The measure as currently specified could lead to years of unnecessary testing.

In response to your specific request for feedback regarding the appropriateness of the current age range, we believe there should be no upper age limit for this measure, especially considering the aging of the population and the importance of CKD in the older population. The exclusions you have specified should remove most patients who are less likely to benefit from early identification of CKD and initiation or intensification of treatment, so we see no reason to cap the measure at 75 years. If patients do not meet the exclusion criteria, they should be regularly screened and appropriately treated if identified as having diabetic kidney disease, regardless of age.
There is accumulating evidence for the renal and cardio protective action of Sodium-Glucose Cotransporter 2 (SGLT-2) Inhibitors and Glucagon-like Peptide 1 (GLP-1) Receptor Agonists. We would suggest that NCQA give future consideration to development of a measure addressing use of these antihyperglycemic medications in appropriate patients with diabetes and ASCVD to reduce risk of cardiovascular events, heart failure and progression of CKD, or both.
We believe this new Kidney Health Evaluation for Patients with Diabetes measure has the potential to significantly reduce the current gap in delivery of evidence-based kidney care to patients with diabetes. We recognize the challenges in developing measures that are both feasible to implement and that will provide meaningful feedback to inform improvement efforts. We look forward to future opportunities to support your efforts to improve the care of patients with diabetes.

Bayer
Bayer strongly supports the inclusion of this measure in MIPS. There is clear evidence of the feasibility, relative simplicity of report and, most importantly, significant opportunity for improvement in the testing and ultimately treatment of patients with chronic kidney disease associated with diabetes. The measure reinforces the first step in the patient care journey (identification) which today occurs too late in the disease progression for care to impact the outcome. Most patients are not identified until stage 4 or 5 when preparation for dialysis or kidney transplant is the focus.

A similar measure has been added to NCQA's HEDIS measure set for health plans and first year reporting in that setting further demonstrated the value of the measure. On average less than 50% of patients with diabetes had both of the required kidney tests performed across all product lines.

We support the inclusion of the measure immediately. In addition, we suggest NQF and NCQA explore harmonizing the measure age criteria. Although both the health plan and the clinical level measures were initially proposed and tested for those aged 18-75, NCQA determined it was appropriate to move the upper age limit to 85. There is an argument to be made in either direction and it would be ideal if both measures used the same age range. However the need to improve performance in this area is urgent. The current state of care is leading to unnecessary suffering including significant disparities in

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care for people of color. We urge NQF to endorse and CMS to use the measure regardless of the final decision on applicable ages.

American Society of Nephrology

The American Society of Nephrology supports this measure to screen for chronic kidney disease (CKD) using estimated glomerular filtration rate (eGFR) and urine albumin-to-creatinine ratio (UACR). Current guidelines from the American Diabetes Association recommend annual screening for kidney disease with eGFR and UACR for patients with diabetes. However, only about half of patients with diabetes receive this guideline-recommended care. This measure aims to bridge this performance gap. Kidney health evaluation testing using eGFR and UACR is essential to identify CKD in diabetes at stages where the new break-through therapies, as well as conventional treatments such as ACE inhibitors and ARBs, have the greatest chance to reduce progression to kidney failure, cardiovascular complications, and death. We support this measure to increase the early detection and intervention of kidney disease, which is in line with the Advancing American Kidney Health executive order.

American Medical Association

The American Medical Association (AMA) continues to be concerned with the overall Cohen's kappa agreement rates of none to slight for the numerator and exclusions and additional testing demonstrating improved validity of the underlying data is required. As a result, we do not believe that this measure is ready for use in an accountability program such as MIPS and recommend that the highest level of MAP recommendation be "Do Not Support with Potential for Mitigation."

Association of American Medical Colleges (AAMC)

The Clinician MAP Workgroup conditionally supported the Kidney Health Evaluation measure (MUC2021-090) for MIPS, pending NQF endorsement. The measure assesses percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) and Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period. The AAMC supports the recommendation. We agree that use of this measure, if endorsed as valid and reliable, supports the appropriate standard of care, and can improve early detection of renal decline before renal replacement therapy is needed.

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MUC2021-105 Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Merit-based Incentive Payment System–Quality

Workgroup
Clinician

Measure Description
Percentage of surgical pathology reports for primary colorectal, endometrial, gastroesophageal or small bowel carcinoma, biopsy or resection, that contain impression or conclusion of or recommendation for testing of mismatch repair (MMR) by immunohistochemistry (biomarkers MLH1, MSH2, MSH6, and PMS2), or microsatellite instability (MSI) by DNA-based testing status, or both

Numerator
Surgical pathology reports that contain impression or conclusion of or recommendation for testing of MMR by immunohistochemistry, MSI by DNA-based testing status, or both

Numerator Exclusions
None

Denominator
All surgical pathology reports for primary colorectal, endometrial, gastroesophageal or small bowel carcinoma, biopsy or resection

CPT: 88305, 88307, 88309

AND

ICD-10:

- C18.0: Malignant neoplasm of cecum
- C18.2: Malignant neoplasm of ascending colon
- C18.3: Malignant neoplasm of hepatic flexure
- C18.4: Malignant neoplasm of transverse colon
- C18.5: Malignant neoplasm of splenic flexure
- C18.6: Malignant neoplasm of descending colon
- C18.7: Malignant neoplasm of sigmoid colon

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- C18.8: Malignant neoplasm of overlapping sites of colon
- C18.9: Malignant neoplasm of colon, unspecified
- C19: Malignant neoplasm of rectosigmoid junction
- C20: Malignant neoplasm of rectum
- C54.1 Malignant neoplasm of endometrium
- C54.3 Malignant neoplasm of fundus uteri
- C54.8 Malignant neoplasm of overlapping sites of corpus uteri
- C54.9 Malignant neoplasm of corpus uteri, unspecified
- C55 Malignant neoplasm of uterus, unspecified
- C15.3: Malignant neoplasm of upper third of esophagus
- C15.4: Malignant neoplasm of middle third of esophagus
- C15.5: Malignant neoplasm of lower third of esophagus
- C15.8: Malignant neoplasm of overlapping sites of esophagus
- C15.9: Malignant neoplasm of esophagus, unspecified
- C16.0: Malignant neoplasm of cardia
- C16.1: Malignant neoplasm of fundus of stomach
- C16.2: Malignant neoplasm of body of stomach
- C16.3: Malignant neoplasm of pyloric antrum
- C16.4: Malignant neoplasm of pylorus
- C16.5: Malignant neoplasm of lesser curvature of stomach, unspecified
- C16.6: Malignant neoplasm of greater curvature of stomach, unspecified
- C16.8: Malignant neoplasm of overlapping sites of stomach
- C16.9: Malignant neoplasm of stomach, unspecified
- C17.0 Malignant neoplasm of duodenum
- C17.1 Malignant neoplasm of jejunum
- C17.2 Malignant neoplasm of ileum
- C17.3 Meckel's diverticulum, malignant
- C17.8 Malignant neoplasm of overlapping sites of small intestine
- C17.9 Malignant neoplasm of small intestine, unspecified
- C26.0 Malignant neoplasm of intestinal tract, part unspecified.

Denominator Exclusions

1) Patients with an existing diagnosis of Lynch Syndrome (ICD-10-CM Z15.0, Z15.04, Z15.09, Z80.0)
2) Squamous cell carcinoma of the esophagus

Denominator Exceptions

Documentation of medical reasons MMR, MSI, or both tests were not performed (e.g., patient receiving hospice or will not be treated with checkpoint inhibitor therapy, no residual carcinoma is present in the sample [tissue exhausted or status post neoadjuvant treatment], insufficient tumor for testing)

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State of development
Fully Developed

State of Development Details
Measure is fully developed, tested, and in use

What is the target population of the measure?
All Payer

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Pathology

Measure Type
Process

Is the measure a composite or component of a composite?
No

If Other, Please Specify

What data sources are used for the measure?
Administrative Data (non-claims);Claims Data;Electronic Clinical Data (non-EHR)

If applicable, specify the data source

If EHR or Chart-Abstracted data, description of parts related to these sources
Information includes demographics (Administrative Data), and CPT and ICD-10 codes, (Claims). Also necessary is information documenting that the appropriate test (immunohistochemistry for MMR proteins or DNA-based testing for MSI) was done. This is recorded in the electronic medical record. However, pathologists use Laboratory Information Systems (LIS), which are not considered EHRs (and are not eligible for CEHRT), so they would be considered Electronic Clinical Data (non-EHR).

At what level of analysis was the measure tested?
Clinician; Group

In which setting was this measure tested?
Hospital outpatient department (HOD);Other: Laboratory

What one healthcare domain applies to this measure?
Seamless Care Coordination

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
IA_CC_9: Implementation of practices/processes for developing regular individual care plans

The goal of this measure is to ascertain the appropriateness of checkpoint inhibitor therapy for a given patient based on his or her genetic makeup. Therefore this measure directly contributes to developing an individual care plan;IA_CC_9: Implementation of practices/processes for developing regular individual care plans

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The goal of this measure is to ascertain the appropriateness of checkpoint inhibitor therapy for a given patient based on his or her genetic makeup. Therefore this measure directly contributes to developing an individual care plan

CMIT ID
N/A

Alternate Measure ID
CAP 33

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?
No

If eCQM, enter Measure Authoring Tool (MAT) number
N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

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If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs
N/A

What other federal programs are currently using this measure?
N/A

Is this measure similar to and/or competing with a measure(s) already in a program?
No

Which measure(s) already in a program is your measure similar to and/or competing with?
N/A

How will this measure be distinguished from other similar and/or competing measures?
N/A

How will this measure add value to the CMS program?
N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure
Please see attached "Evidence Attachment".

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This measure has been created to work in conjunction with the new "MMR and MSI Testing in Patients Being Considered for Checkpoint Inhibitor Therapy" Guideline. Rather than waiting for the Guideline to be published then creating a measure based on recommendations, which would result in a lag of several years between the Guideline and the measure, we have developed the measure to become available at the same time as the Guideline. Due to an unforeseen delay, the Guideline was not published at the original target date of April but will be published later in the summer. We feel that the timing of the measure and the Guideline is ideal for this measure to drive quality improvement and uptake of the Guideline.

Evidence that the measure can be operationalized

Measure is in use in 2021 in the Pathologists Quality Registry. As of 1 May 2021, 17 clinicians from 6 practices were submitting data for this measure including practices whose Laboratory Information Systems send data directly to the Registry without human intervention. In 2019 a version of this measure whose denominator was only colorectal carcinoma was in use in the Registry; 11 practices totaling 56 clinicians submitted data for the colorectal-cancer-only measure to CMS. In 2020, a version of the measure whose denominator was only endometrial carcinoma was also introduced. In 2020, 12 practices totaling 123 clinicians submitted the colorectal-carcinoma-only version and 8 practices totaling 80 clinicians submitted the endometrial-carcinoma-only version. Therefore the measure has been operationalized as individual parts and as the current version in the Pathologists Quality Registry and can be directly electronically extracted from the medical record.

How is the measure expected to be reported to the program?

Clinical Quality Measure (CQM) Registry

Feasibility of Data Elements

ALL data elements are in defined fields in a combination of electronic sources

Evidence of Performance Gap

Please see attached "Performance Gap Attachment" for details

Unintended Consequences

Any measure which defines a population for genetic testing runs the risk of inadvertently disincentivizing use of the test; measures to decrease overuse of tests can lead to underuse. However, the recently-published guideline expands the population for which these tests are recommended so underuse is unlikely. Conversely, the expanded population could drive overuse of the test, leading to increased cost and inconvenience to patients. Given that the population for this measure is well-defined, we view significant overuse as unlikely. As more information becomes available regarding use of checkpoint inhibitor therapy, recommendations could change.

Outline the clinical guidelines supporting this measure

In CRC patients being considered for checkpoint blockade therapy, pathologists should use MMR IHC and/or MSI by PCR for the detection of DNA mismatch repair defects. Although MMR IHC or MSI by PCR are preferred, pathologists may use a validated MSI by NGS assay for the detection of DNA mismatch repair defects.

In gastroesophageal and small bowel cancer patients being considered for checkpoint blockade therapy,

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pathologists should use MMR IHC and/or MSI by PCR over MSI by NGS for the detection of DNA mismatch repair defects.

In endometrial cancer patients being considered for checkpoint blockade therapy, pathologists should use MMR IHC over MSI by PCR or NGS for the detection of DNA mismatch repair defects.

Were the guidelines graded?
No

If yes, who graded the guidelines?
N/A

If yes, what was the grade?
N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Unable to determine

Estimate of Annual Improvement in Measure Score
Not applicable

Type of Evidence to Support the Measure
Clinical Guidelines

Is the measure risk adjusted, stratified, or both?
None

Are social determinants of health built into the risk adjustment model?
Not Applicable

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
Not applicable

Cost Avoided Annually by Medicare/Provider
Not applicable

Source of Estimate
Not applicable

Year of Cost Literature Cited
Not applicable

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
No

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If yes, choose all methods of obtaining patient/caregiver information
N/A

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
N/A

Total Number of Patients and/or Caregivers Consulted
N/A

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
N/A

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
N/A

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Surveys;Focus groups;TEP consisting of ONLY clinicians

Total Number of Clinicians/Providers Consulted
40

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
37

Burden for Provider: Was a provider workflow analysis conducted?
Yes

If yes, how many sites were evaluated in the provider workflow analysis?
29

Did the provider workflow have to be modified to accommodate the new measure?
No

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If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
8

Measure Testing Details

Reliability Testing Interpretation of Results
A reliability equal to zero implies that all the variability in a measure is attributable to measurement error. A reliability equal to one implies that all the variability is attributable to real differences in physician performance. The reliability score for this measure is 0.96. Therefore variability is almost entirely attributable to real differences in performance. Given that real variability was seen in the performance scores and confirmed by the volunteer clinicians, this is not unexpected and speaks to the potential for improvement in the measure.

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
Signal to Noise

Reliability Testing Sample Size
51 pathologists

Reliability Testing Statistical Result
The mean reliability score was 0.96, with a standard deviation of 0.07, tenth percentile 0.91, ninetieth percentile 1.00. Assumed estimates based upon beta-binomial model distribution (using methods described by Adams in the 2009 Rand tutorial), alpha=0.2, beta=0.12. The raw performance scores had a mean of 60% with a standard deviation of 39 points, tenth percentile 0%, ninetieth percentile 100%.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
Measure Score Validity

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Validity Testing: Type of Validity Testing Analysis
Face Validity

Validity Testing Sample Size
40 clinicians including gastroenterologists and pathologists

Validity Testing Statistical Result
On a scale of 1-4 where 1 is strongly disagree and 4 is strongly agree, the average score for agreement with the statement "The MMR/MSI Testing Status quality measure as described [above] will accurately distinguish between good and poor quality of care" was 3.4

Validity Testing Interpretation of Results
Based on review of the specifications, clinicians agreed that the measure as specified reflects good quality care. A score of 3.4 is between Agree and Strongly Agree. We interpret this to mean subject matter experts in gastroenterology and pathology find that this measure will discriminate between good and poor care.

Measure performance – Type of Score
Proportion

Measure Performance Score Interpretation
Higher score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have
The current version of this measure was introduced in 2021 so a performance rate for 12 months of data is not yet available. However, in 2019 and 2020, similar measures whose denominators included only colorectal carcinoma or only endometrial carcinoma were in use. In 2019, the average performance rate for the colorectal carcinoma only measure was 64.83% with a standard deviation of 20.04 points. In 2020, the average performance rate for the colorectal carcinoma only measure was 71.05% with a standard deviation of 22.37 points. The average performance rate for the endometrial carcinoma only measure was 76.63% with a standard deviation of 15.08 points.

Given that the guideline recommendation for testing on gastroesophageal and small bowel cancers will be published in summer of 2021, we anticipate an average performance rate lower than those seen in 2020, probably more consistent with 2019 performance for the colorectal cancer only measure.

Benchmark, if applicable
N/A

Measure Contact Information

Measure Steward
College of American Pathologists

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Measure Steward Contact Information
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202-354-7142

Long-Term Measure Steward
N/A

Long-Term Measure Steward Contact Information
N/A

Primary Submitter Contact Information
N/A

Secondary Submitter Contact Information
N/A

Section 2: Preliminary Analysis – MUC2021-105 Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

Justification and Notes: The measure addresses the priority area of pathology for patients with Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma. This process measure addresses a gap in biomarker testing for specific cancer types, leading to a potential increase in personalized care.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes

Justification and Notes: 2-4% of all colorectal carcinomas can be attributed to Lynch Syndrome and detection of defective mismatch repair (MMR) or microsatellite instability (MSI) can assist with the proper detection (Rubenstein et al., 2015; Schmeler et al., 2006). Support for MMR and MSI testing for the identification of high-risk patients for Lynch Syndrome is provided by the American Society for Clinical Pathology, the College of American Pathologists, the Association for Molecular Pathology, and the American Society of Clinical Oncology (Rubenstein et al., 2015).The developer notes that guidelines to support the measure are forthcoming and NQF has confirmed they have not been published yet.

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Does the measure address a quality challenge?
Yes/No: Yes

Justification and Notes: MMR/MSI has been shown to aid in the detection of four types of cancer (Colorectal Carcinoma, Endometrial, Gastroesophageal, and Small Bowel Carcinoma), but guidelines for universal testing are lacking (currently in development with the College of American Pathologists). Most studies have examined the use of MSR/MSI testing in only one of the four cancer types. The use of MSR/MSI testing can also help to identify patients who are eligible for Checkpoint Blockade Therapy. While evaluating the genetic makeup of a patients to determine the appropriateness of checkpoint inhibitor therapy, this measure will directly contribute to the development of individual care plans.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?
Yes/No: Yes

Justification and Notes: This measure will be the first of its kind to be utilized by CMS. Biomarker testing for specific cancer types is a critical gap area to be filled in MIPS program measurement. As the number of identified biomarkers increase, so does the opportunity to provide personalized patient care and promote patient choice. Further, this measure will contribute to the efficient use of resources because it accounts for situations where MMR and MSI testing are not appropriate, safe, or possible, such as for patients receiving hospice or palliative care, or patients who are not at a high risk for Lynch syndrome.

Can the measure be feasibly reported?
Yes/No: Yes

Justification and Notes: The data sources for this measure include administrative data for demographics, claims data for CPT and ICD-10 codes, and the EHR or Laboratory Information Systems (LIS) for MMR/MSI testing documentation. The data can be feasibly reported because of their electronic nature. The reporting of this measure has not been shown to increase burden on providers or administrative staff due to its electronic nature. The MAP Clinician noted that there may be additional burden associated with the measure since the detail may not be able to capture using CPT codes. National language processing (NLP) may be required to capture all of the data for the measure and not all providers have that ability today.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?
Yes/No: Yes

Justification and Notes: This measure is appropriately specified for the clinician/group level of analysis in the hospital setting for the targeted population, which was confirmed through face validity, feasibility, and reliability testing. The results of the face validity testing indicate that 40 clinicians strongly agreed with the statement "The MMR/MSI Testing Status quality measure as described [above] will accurately distinguish between good and poor quality of care." The average score was 3.4 on a scale of 1-4 with 1 representing Strong Disagree and 4 representing Strongly Agree. The results of the feasibility testing indicate that 6 out of the 8 required data elements specified were mostly available for collection and review by pathologists. The results of the reliability testing indicate that the measure is highly reliable

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among a sample of 51 clinicians over a 12-month period. The mean reliability of the measure was 0.96, the standard deviation of the measure was 0.07, and the average performance score was 60% with a standard deviation of 39 points.

If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure been identified?
Yes/No: N/A

Justification and Notes: This measure is not currently in use. The measure developer has identified one unintended consequence regarding the expanded population for MMR/MSI testing in recent guidelines, the overuse of the testing. The results of testing overuse are increased patient cost and inconvenience. All things considered, the developers believe significant overuse is unlikely and will continue to monitor evidence as additional research is made available.

PAC/LTC Core Concept?
N/A

Impact Act Domain
N/A

Hospice High Priority Areas
N/A

MAP Rural Health Advisory Group Input:
Relative priority/utility:
This measure was suggested to be important and relevant to the rural communities, as rural patients may be less likely to receive this care/tests.
Data collection issues:
- Concern was raised regarding data availability for rural providers.

Calculation issues:
- None identified.

Unintended consequences:
- The measure may stimulate the availability of these tests in rural settings.

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 3.6
1 – 0 votes
2 – 1 vote
3 – 6 votes
4 – 6 votes
5 – 2 votes

MAP Health Equity Advisory Group Input:
Relative priority/utility:
- The Advisory Group noted that disparities exist in access to this testing.
- Access to cancer care is an issue, as was well as ongoing treatment support is an important equity concern.

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Data collection issues:

- Lack of stratification was identified as a priority for this measure

Calculation issues:

- None identified.

Unintended consequences:

- None identified.

Votes: Range is 1 – 5, where higher number has greater potential for positive impact on health equity.
Average: 2.7
1 – 1 vote
2 – 8 votes
3 – 10 votes
4 – 2 votes
5 – 1 vote

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking, pending NQF endorsement and specifically the review of the upcoming release of the guidelines.

Summary: What is the potential value to the program measure set?

The measure addresses the priority area of pathology for patients with Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma. This process measure addresses a gap in biomarker testing for specific cancer types, leading to a potential increase in personalized care.

Summary: What is the potential impact of this measure on quality of care for patients?

2-4% of all colorectal carcinomas can be attributed to Lynch Syndrome and detection of defective mismatch repair (MMR) or microsatellite instability (MSI) can assist with the proper diagnoses (Rubenstein et al., 2015; Schmeler et al., 2006). Support for MMR and MSI testing for the identification of high-risk patients for Lynch Syndrome is provided by the American Society for Clinical Pathology, the College of American Pathologists, the Association for Molecular Pathology, and the American Society of Clinical Oncology (Rubenstein et al., 2015). A quality gap in the use of MMR/MSI for the detection of four cancer types (Colorectal Carcinoma, Endometrial, Gastroesophageal, and Small Bowel Carcinoma) and the potential utilization of Checkpoint Blockade Therapy will be addressed. This measure will be the first of its kind to be utilized by CMS and fill a gap in Biomarker testing for the MIPS program. This measure will contribute to the efficient use of resources and promote increased use of personalized patient care and patient choice.

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Section 3: Public Comments

Peter Stanich

I support this measure for several reasons, including the potential for expanded and improved treatment options and outcomes for the patients identified to have MSI high tumors as well as benefit of identifying Lynch syndrome in patients and their family members. This is already endorsed by many, many guidelines.

Lynch Syndrome Screening Network

The most common form of hereditary gastrointestinal cancer is Lynch syndrome. Lynch syndrome is estimated to affect 1 out of every 279 individuals globally and 1 out of every 25-35 individuals with colorectal or endometrial cancer. There are management guidelines for individuals with Lynch syndrome which are effective at preventing cancer or potentially diagnosing the cancers early when they are most treatable. However, it is estimated that 90% of individuals with Lynch syndrome are not aware of their diagnosis. Furthermore, studies demonstrate disparities in access to genetic counseling and testing among ethnic/racial minorities. Universal tumor screening of all newly diagnosed colorectal and endometrial cancer patients is one approach used to identify cases of Lynch syndrome. Universal tumor screening for Lynch syndrome remains underutilized. Therefore, strategies are needed to improve implementation of universal tumor screening. This is why I/we strongly support the adoption of this MIPS MUC2021-105 which would promote the use of universal tumor screening (using either microsatellite instability or mismatch repair biomarker testing) for Lynch syndrome among all colorectal, endometrial, gastroesophageal, and small bowel cancers.

University of Colorado

The most common form of hereditary gastrointestinal cancer is Lynch syndrome. Lynch syndrome is estimated to affect 1 out of every 279 individuals globally and 1 out of every 25-35 individuals with colorectal or endometrial cancer. There are management guidelines for individuals with Lynch syndrome which are effective at preventing cancer or potentially diagnosing the cancers early when they are most treatable. However, it is estimated that 90% of individuals with Lynch syndrome are not aware of their diagnosis. Furthermore, studies demonstrate disparities in access to genetic counseling and testing among ethnic/racial minorities. Universal tumor screening of all newly diagnosed colorectal and endometrial cancer patients is one approach used to identify cases of Lynch syndrome. Universal tumor screening for Lynch syndrome remains underutilized. Therefore, strategies are needed to improve implementation of universal tumor screening. This is why I strongly support the adoption of this MIPS MUC2021-105 which would promote the use of universal tumor screening (using either microsatellite instability or mismatch repair biomarker testing) for Lynch syndrome among all colorectal, endometrial, gastroesophageal, and small bowel cancers.

Fight Colorectal Cancer

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Promega, University of Wisconsin-Madison

The most common form of hereditary gastrointestinal cancer is Lynch syndrome. Lynch syndrome is estimated to affect 1 out of every 279 individuals globally and 1 out of every 25-35 individuals with colorectal or endometrial cancer. There are management guidelines for individuals with Lynch syndrome which are effective at preventing cancer or potentially diagnosing the cancers early when they are most treatable. However, it is estimated that 90% of individuals with Lynch syndrome are not aware of their diagnosis. Furthermore, studies demonstrate disparities in access to genetic counseling and testing among ethnic/racial minorities. Universal tumor screening of all newly diagnosed colorectal and endometrial cancer patients is one approach used to identify cases of Lynch syndrome. Universal tumor screening for Lynch syndrome remains underutilized. Therefore, strategies are needed to improve implementation of universal tumor screening. This is why I strongly support the adoption of this MIPS MUC2021-105 which would promote the use of universal tumor screening (using either microsatellite instability or mismatch repair biomarker testing) for Lynch syndrome among all colorectal, endometrial, gastroesophageal, and small bowel cancers.

Great Lakes Pathology/ACL Labs Wisconsin

Screening for Mismatch Repair deficiency is an essential part of modern oncology practice. First, it helps identify Lynch syndrome, the most common inherited form of GI cancers. Second, when detected it allows patients to benefit for newer forms of chemotherapy. I strongly support the adoption of MIPS MUC2021-105.

Dynacare

The most common form of hereditary gastrointestinal cancer is Lynch syndrome. Lynch syndrome is estimated to affect 1 out of every 279 individuals globally and 1 out of every 25-35 individuals with colorectal or endometrial cancer. There are management guidelines for individuals with Lynch syndrome which are effective at preventing cancer or potentially diagnosing the cancers early when they are most treatable. However, it is estimated that 90% of individuals with Lynch syndrome are not aware of their diagnosis. Furthermore, studies demonstrate disparities in access to genetic counseling and testing among ethnic/racial minorities. Universal tumor screening of all newly diagnosed colorectal and endometrial cancer patients is one approach used to identify cases of Lynch syndrome. Universal tumor screening for Lynch syndrome remains underutilized. Therefore, strategies are needed to improve implementation of universal tumor screening. This is why I strongly support the adoption of this MIPS MUC2021-105 which would promote the use of universal tumor screening (using either microsatellite instability or mismatch repair biomarker testing) for Lynch syndrome among all colorectal, endometrial, gastroesophageal, and small bowel cancers.

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Intermountain Healthcare

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American Society for Clinical Oncology (ASCO)

Yes, support for inclusion in the program

Lisen Axell

MUC2021-105 “Mismatch Repair (MMR)

The most common form of hereditary gastrointestinal cancer is Lynch syndrome. Lynch syndrome is estimated to affect 1 out of every 279 individuals globally and 1 out of every 25-35 individuals with colorectal or endometrial cancer. There are management guidelines for individuals with Lynch syndrome which are effective at preventing cancer or potentially diagnosing the cancers early when they are most treatable. However, it is estimated that 90% of individuals with Lynch syndrome are not aware of their diagnosis. Furthermore, studies demonstrate disparities in access to genetic counseling and testing among ethnic/racial minorities. Universal tumor screening of all newly diagnosed colorectal and endometrial cancer patients is one approach used to identify cases of Lynch syndrome. Universal tumor screening for Lynch syndrome remains underutilized. Therefore, strategies are needed to improve implementation of universal tumor screening. This is why I strongly support the adoption of this MIPS MUC2021-105 which would promote the use of universal tumor screening (using either microsatellite instability or mismatch repair biomarker testing) for Lynch syndrome among all colorectal, endometrial, gastroesophageal, and small bowel cancers

Promega Corporation

Lynch syndrome is the most common genetic predisposition for hereditary cancer, estimated to affect 1 in 279 individuals, yet approximately 95% of individuals with Lynch syndrome are undiagnosed (Gallon, et al. 2021, National Cancer Advisory Board 2016).To decrease this under diagnosis rate, many professional organizations, expert panels and researchers globally have concluded that maximum sensitivity for identifying individuals with Lynch syndrome can be achieved by universal screening for MSI and/or dMMR (Crosbie, et al. 2019, Ebi, et al. 2020, Gallon, et al. 2021, Kahn, et al. 2019, Mao, et al. 2021, National Comprehensive Cancer Network 2021, Seppala, et al. 2020, Soslow, et al. 2019, Stjepanovic, et al. 2019, Yozu, et al. 2019).

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Identifying Lynch syndrome through a universal screening approach has important clinical implications for improving patient outcomes. These outcomes include specific considerations for treatment recommendations and risk reducing measures with an informed prognosis and care process, including increased cancer surveillance, which may reduce morbidity and mortality for affected individuals and their families. Promega strongly supports the adoption of MIPS MUC2021-105 which would promote the use of universal tumor screening for Lynch syndrome using microsatellite instability (MSI) and mismatch repair (IHC) biomarker testing. This measure is essential in reducing the disparities and access to care that exists for those impacted by Lynch syndrome.

Evidence indicates that utilization of both MSI by PCR and IHC testing concurrently, referred to as co-testing, provides the greatest utility in identifying patients that should be tested for Lynch syndrome. Reports suggest that MSI or IHC testing alone may miss up to 10% of MSI-H/dMMR cases, effectively also missing individuals with Lynch syndrome (Dudley, et al. 2016, Ratti, et al. 2018, Zhu, et al. 2021). Research has noted that co-testing provides near 100% sensitivity when identifying Lynch syndrome associated tumors (Funkhouser, et al. 2012). To this end, several organizations globally have published guidelines recommending both universal screening and co-testing approaches to increase the number of individuals diagnosed with Lynch syndrome (Bai, et al. 2020, Cho, et al. 2019, Luchini, et al. 2019, Society of Gynecologic Oncology 2020). Additionally, current billing and coding guidance for genetic testing for Lynch syndrome cited by the CMS National Coverage Policy states one or both methods may be performed to detect the presence of defective mismatch repair for Lynch syndrome screening.

Despite current research and published guidelines, universal tumor screening for Lynch syndrome remains underutilized. As a hereditary disorder, Lynch syndrome is still often tested for based on clinical criteria and relying on family history. However, screening by these criteria alone is not an accurate indicator of possible Lynch syndrome and has been identified to potentially miss almost half of all Lynch syndrome cases (Latham et al., 2019). Data from the 2016 National Cancer Database showed only 41.1% of individuals with newly diagnosed advanced colorectal cancer received MSI/MMR testing, and patients who were of Black non-Hispanic race/ethnicity, uninsured or Medicaid or Medicare insured, or diagnosed at a community cancer program were significantly less likely to receive testing (Iorgulescu 2020). Implementation of the MIPS measure is an important step to decreasing the number of undiagnosed Lynch syndrome individuals who can benefit from the targeted treatment and surveillance options that are currently available and decrease morbidity and mortality in this hereditary cancer population.

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Collaborative Group of the Americas on Inherited Gastrointestinal Cancers

The most common form of hereditary gastrointestinal cancer is Lynch syndrome. Lynch syndrome is estimated to affect 1 out of every 279 individuals globally and 1 out of every 25-35 individuals with

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American Gastroenterological Association

The AGA supports the addition of measure MUC2021-105 to the MIPS program. Mismatch repair (MMR) and microsatellite instability (MSI) are key biomarkers in colorectal cancer (CRC), with crucial diagnostic, prognostic, and predictive implications. Gastroenterologists and other clinicians order testing for MMR/MSI during screening for Lynch syndrome and/or prognostic stratification for patients with CRC or with a personal history of colon and rectal cancer. Gastroenterologists and other ordering clinicians depend on pathologists' interpretations of and any recommendations for tests in order to provide quality patient care. If the status of genetic testing is not indicated in each pathology report, important tests may be missed, or unnecessary repeat testing may be performed leading to inappropriate treatment and/or increasing cost. Having a quality measure would provide a strict framework for management with the multi-specialty team managing the patient's oncology care. This is a measure that is applicable to several specialties and fits the larger paradigm of cross-cutting measure, which are particularly relevant. Measure -105 represents crucial step in the care process by promoting effective communication of critical information for the purpose of care coordination and efficient use of resources.

Measure MUC2021-105 is in use in the Pathologists Quality Registry. Data for this measure can be directly extracted from the pathology report and automatically sent to the Registry, reducing burden of data collection.

AliveAndKickn

Lynch syndrome is the most common genetic predisposition for hereditary cancer, estimated to affect 1 in 279 individuals, yet approximately 95% of individuals with Lynch syndrome are undiagnosed (Gallon, et al. 2021, National Cancer Advisory Board 2016).To decrease this underdiagnosis rate, many professional organizations, expert panels and researchers globally have concluded that maximum sensitivity for identifying individuals with Lynch syndrome can be achieved by universal screening for MSI and/or dMMR (Crosbie, et al. 2019, Ebi, et al. 2020, Gallon, et al. 2021, Kahn, et al. 2019, Mao, et al. 2021, National Comprehensive Cancer Network 2021, Seppala, et al. 2020, Soslow, et al. 2019, Stjepanovic, et al. 2019, Yozu, et al. 2019).

Identifying Lynch syndrome through a universal screening approach has important clinical implications

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for improving patient outcomes. These outcomes include specific considerations for treatment recommendations and risk reducing measures with an informed prognosis and care process, including increased cancer surveillance, which may reduce morbidity and mortality for affected individuals and their families. {INSERT YOUR ORGANIZATION NAME} strongly supports the adoption of MIPS MUC2021-105 which would promote the use of universal tumor screening for Lynch syndrome using microsatellite instability (MSI) and mismatch repair (IHC) biomarker testing. This measure is essential in reducing the disparities and access to care that exists for those impacted by Lynch syndrome.

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Despite current research and published guidelines, universal tumor screening for Lynch syndrome remains underutilized. As a hereditary disorder, Lynch syndrome is still often tested for based on clinical criteria and relying on family history. However, screening by these criteria alone is not an accurate indicator of possible Lynch syndrome and has been identified to potentially miss almost half of all Lynch syndrome cases (Latham et al., 2019). Data from the 2016 National Cancer Database showed only 41.1% of individuals with newly diagnosed advanced colorectal cancer received MSI/MMR testing, and patients who were of Black non-Hispanic race/ethnicity, uninsured or Medicaid or Medicare insured, or diagnosed at a community cancer program were significantly less likely to receive testing (Iorgulescu 2020). Implementation of the MIPS measure is an important step to decreasing the number of undiagnosed Lynch syndrome individuals who can benefit from the targeted treatment and surveillance options that are currently available and decrease morbidity and mortality in this hereditary cancer population.

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Memorial Sloan Kettering Cancer Center

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National Society of Genetic Counselors

December 9, 2021

To Whom It May Concern:

The National Society of Genetic Counselors (NSGC) supports the College of American Pathologists' quality measure that the National Quality Forum Measure Applications Partnership is considering for the Centers for Medicare & Medicaid Services (CMS) Merit-based Incentive Payment System (MIPS) program: "Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma."

NSGC advocates for the professional interests of genetic counselors by offering clinical guidelines, education, and other professional resources to over 4,000 members. Given the prevalence and effectiveness of screening, treatment, and preventative recommendations for hereditary cancer syndromes, including Lynch Syndrome, access to high-quality genetic services to assess a patient's risk

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and inform treatment decisions is critical.

A quality measure that specifically addresses the inclusion of, or recommendation for, testing mismatch-repair defects via immunohistochemistry or microsatellite instability in surgical pathology reports for primary colorectal, endometrial, gastroesophageal, or small bowel carcinoma, biopsy or resection samples would help institutions track process improvements that would directly inform patient care. The timely identification of a mismatch-repair defect indicative of Lynch Syndrome enables referral to genetic counselors and helps identify at-risk family members for proactive cancer risk management.

Adoption of this proposed quality measure would also harmonize with an Improvement Activity (IA) that the NSGC submitted to CMS for consideration in the MIPS program: "Improve Access to Genetic Counseling and Testing." This IA would drive appropriate engagement with genetic counselors and improve patient health outcomes by integrating genetic counselors in clinical care teams and establishing protocols to increase access to genetic services in appropriate clinical scenarios. The organizations and individuals below endorsed this IA:

- Association of Community Cancer Centers
- Beating Alzheimer's by Embracing Science President and CEO, Jamie Tyrone, RN
- Parkinson's Foundation
- Cancer Support Community
- David Godzina, MA, MBA, Director, Quality Measure & Improvement, American Gastroenterological Association
- David Leiman, MD, Asst. Prof. of Medicine, Duke Clinical Research Institute, Duke Cancer Institute; AGA Quality Committee
- Facing Our Risk of Cancer Empowered
- FH Foundation
- Foundation for Women's Cancer
- Heart Rhythm Society
- Society for Gynecologic Oncology

Given CMS' intent to complement IAs and MIPS quality measures, incorporating this measure into MIPS would align with the possible adoption of NSGC's proposed IA, especially as CMS considers future oncology or pathology MIPS Value Pathways.

Thank you for this opportunity to provide input on this proposed quality measure.

Sincerely,

Meghan E. Carey

NSGC Executive Director

Sarah Hunt

The most common form of hereditary gastrointestinal cancer is Lynch syndrome. Lynch syndrome is estimated to affect 1 out of every 279 individuals globally and 1 out of every 25-35 individuals with colorectal or endometrial cancer. There are management guidelines for individuals with Lynch syndrome

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which are effective at preventing cancer or potentially diagnosing the cancers early when they are most treatable. However, it is estimated that 90% of individuals with Lynch syndrome are not aware of their diagnosis. Furthermore, studies demonstrate disparities in access to genetic counseling and testing among ethnic/racial minorities. Universal tumor screening of all newly diagnosed colorectal and endometrial cancer patients is one approach used to identify cases of Lynch syndrome. Universal tumor screening for Lynch syndrome remains underutilized. Therefore, strategies are needed to improve implementation of universal tumor screening. This is why I strongly support the adoption of this MIPS MUC2021-105 which would promote the use of universal tumor screening (using either microsatellite instability or mismatch repair biomarker testing) for Lynch syndrome among all colorectal, endometrial, gastroesophageal, and small bowel cancers.

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MUC2021-125 Psoriasis – Improvement in Patient-Reported Itch Severity

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Merit-based Incentive Payment System–Quality

Workgroup
Clinician

Measure Description
The percentage of patients, aged 18 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 2 or more points at a follow up visit.

Numerator
Patients who achieve an assessment score that is reduced by 2 or more points (minimal clinically important difference) from the initial (index) assessment score.

Numerator Exclusions
N/A

Denominator
All patients aged 18 years and older, with a diagnosis of psoriasis with an initial (index visit) NRS, VRS, or ItchyQuant assessment score of greater than or equal to 4 who are returning for a follow-up visit.

Denominator Exclusions
N/A

Denominator Exceptions
N/A

State of development
Fully Developed

State of Development Details
Beta testing was conducted on the fully developed specification. Testing included critical data element validity, performance score reliability, feasibility testing and workflow burden assessment.

What is the target population of the measure?
All Payer

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Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Dermatology;Internal medicine;Primary care

Measure Type
Patient-Reported Outcome

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Administrative Data (non-claims);Electronic Health Record;Paper Medical Records;Standardized Patient Assessments;Patient Reported Data and Surveys;Registries;Hybrid

If applicable, specify the data source
N/A

If EHR or Chart-Abstracted data, description of parts related to these sources
N/A

At what level of analysis was the measure tested?
Clinician

In which setting was this measure tested?
Ambulatory/office-based care

What one healthcare domain applies to this measure?
Chronic Conditions

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
There are two improvement activities that are linked to these measures; both IA_AHE_3 and IA_PSPA_8 promote the use of PRO tools and the use of patient safety tools, respectively, which when reported together can align scope and reduce reporting burden. ;There are two improvement activities that are linked to these measures; both IA_AHE_3 and IA_PSPA_8 promote the use of PRO tools and the use of patient safety tools, respectively, which when reported together can align scope and reduce reporting burden. ;There are two improvement activities that are linked to these measures; both IA_AHE_3 and IA_PSPA_8 promote the use of PRO tools and the use of patient safety tools, respectively, which when reported together can align scope and reduce reporting burden. ;There are two improvement activities that are linked to these measures; both IA_AHE_3 and IA_PSPA_8 promote the use of PRO tools and the use of patient safety tools, respectively, which when reported together can align scope and reduce reporting burden.

CMIT ID
N/A

Alternate Measure ID
N/A

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What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
https://assets.ctfassets.net/1ny4yoiyrqia/4SgGWFRvD3b6KVaXWukByU/a09f36c589dd25cf1e43ed0660fa5ff8/AAD_9_Psoriasis_PRO_Improvement_Itch_Severity_2021.pdf

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?
No

If eCQM, enter Measure Authoring Tool (MAT) number
N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

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Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
Measure currently used in a CMS program being submitted as-is for a new or different program

Range of years this measure has been used by CMS Programs
MIPS reporting as a QCDR measure (2020 – current)

What other federal programs are currently using this measure?
Merit-based Incentive Payment System–Cost

Is this measure similar to and/or competing with a measure(s) already in a program?
No

Which measure(s) already in a program is your measure similar to and/or competing with?
N/A

How will this measure be distinguished from other similar and/or competing measures?
N/A

How will this measure add value to the CMS program?
N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure
Psoriasis is a chronic inflammatory disease in which pruritus is a frequent symptom. Approximately 7.4 million people in the United States have psoriasis. Direct costs of the disease are estimated between $51.7 and $63.2 billion, with the total economic burden estimated to be between $112 and $135 billion.

Chronic inflammatory skin diseases, such as psoriasis, are pruritic and tremendously burdensome; with more than 70% of psoriasis patients suffering from itch. Itch has profound effects on patients, especially in geriatric populations, where there is increased incidence of pruritus. For those over 65 years old, itch is the most common skin complaint. The number of patients with pruritus is expected to increase as the elderly population grows – becoming 25% of the US population by 2025.

Pruritus is a frequent and onerous symptom of psoriasis and, on its own, has significant effects on

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patients' quality of life. In a study, investigators quantified pruritic burden in a cross-sectional analysis investigating chronic pruritus and pain. They demonstrated that the quality of life impact was due to the severity of the symptom, rather than whether the symptom was pain or pruritus. Moreover, they elucidated a mean health utility score of 0.87 from chronic pruritus (CP) patients, meaning that on average, a patient would give up 13% of their life expectancy to live without pruritus.

An additional study showed the effects of CP on a population-based level. Researchers found that the point prevalence of pruritus was 13.5%. When looking at 12-months the prevalence rose to 16.4% and rose again to 22% when looking at lifetime prevalence. When studied again in 2013, the lifetime prevalence rose to 25.5%.

Moreover, data from the National Ambulatory Medical Care Survey (1999-2009) found that a total of 77 million patient visits for itch were made during the 11-year time period. This was an average of 7 million visits per year, which represented approximately 1% of all outpatient visits. Also, further analysis showed that although the majority of visits (58.6%) were for new instances of itch, almost a third (32%) were for chronic pruritus.

Pruritus is a subjective and multifaceted symptom that manifests in patients in various ways that affect quality-of-life by contributing to the development of depression, global distress, and sleep impairment. Additionally, studies of CP have shown patients to have a 17% higher mortality risk as well as being strongly associated with poorer general health.

This measure aims to improve pruritus in patients who carry a large burden with this disease; by assessing itch and aiming to make the symptom more manageable. Furthermore, the use of itch will be a measure of overall disease improvement/response.

Evidence that the measure can be operationalized

This measure has been in used in the American Academy of Dermatology's (AAD) Qualified Clinical Data Registry (QCDR) DataDerm since 2020.

How is the measure expected to be reported to the program?

Clinical Quality Measure (CQM) Registry

Feasibility of Data Elements

ALL data elements are in defined fields in a combination of electronic sources;Patient/family-reported information: electronic;Patient/family-reported information: paper

Evidence of Performance Gap

Aggregate performance score for the measure was 43.3%, indicating a gap in care and opportunities for improvement.

Additionally, the workflow burden and usability results indicated a lack of consistent itch screening with a validated tool prior to testing the measure, suggesting that there is a gap in care associated with itch assessment that would be addressed with the implementation of the measure.

Unintended Consequences

N/A

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Outline the clinical guidelines supporting this measure
Evidence-based guideline: Joint AAD - NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures.

Recommendation: Pruritus is a significant symptom of psoriasis. An itch severity assessment is recommended to appropriately assess the degree of pruritus when present.

This measure enhances compliance of the guideline by routinely assessing pruritus in psoriasis patients. For patients with moderate and severe pruritus symptoms, the measure looks to reduce pruritus burden by a minimal clinically important difference (2 or more points).

Were the guidelines graded?
Yes

If yes, who graded the guidelines?
Joint American Academy of Dermatology - National Psoriasis Foundation

If yes, what was the grade?
B

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Unable to determine

Estimate of Annual Improvement in Measure Score
Not applicable

Type of Evidence to Support the Measure
Clinical Guidelines;Systematic Review

Is the measure risk adjusted, stratified, or both?
None

Are social determinants of health built into the risk adjustment model?
Not Applicable

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
Not applicable

Cost Avoided Annually by Medicare/Provider
Not applicable

Source of Estimate
Not applicable

Year of Cost Literature Cited
Not applicable

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Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

If yes, choose all methods of obtaining patient/caregiver information
Standard Technical Expert Panel (TEP) inclusive of patient/caregiver representatives

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
Patients were involved throughout the development of the measure specification on all workgroup development calls from conceptualization to finalization.

Total Number of Patients and/or Caregivers Consulted
3

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
1:3

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
3

Burden for Patient: Does the measure require survey data from the patient?
Yes

If yes, what is the estimated time to complete the survey?
1

If yes, what is the frequency of requests for survey data per year?
2

If yes, are the survey data to be collected during or outside of a visit?
During visit

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Standard TEP

Total Number of Clinicians/Providers Consulted
11

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
17

Burden for Provider: Was a provider workflow analysis conducted?
Yes

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If yes, how many sites were evaluated in the provider workflow analysis?
3

Did the provider workflow have to be modified to accommodate the new measure?
Yes

If yes, how would you describe the degree of effort?
2

Does the measure require manual abstraction?
Yes

If yes, what is the estimated time per record to abstract data?
0

How many data elements will be collected for the measure?
3

Measure Testing Details

Reliability Testing Interpretation of Results
Reliability results for the measure implies a statistically significant difference between pairs of physicians with scores greater than 0.9.

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
Signal to Noise

Reliability Testing Sample Size
In total 1,271 records from 901 unique patient encounters were submitted through a secure data platform for analysis.

Reliability Testing Statistical Result
Reliability scores range from 0.0 to 1.0. A reliability score of 1.0 implies that variability demonstrates a real difference in performance from one physician to another. Values with a score greater than 0.7 indicate significant difference between a group of physicians.

The reliability performance score was .93.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

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Type of Validity Testing
N/A

Data Element Validity
N/A

Validity Testing: Type of Validity Testing Analysis
Other: Crude agreement, prevalence-adjusted kappa (PAK), Cohen´s kappa values and corresponding confidence intervals were also calculated for each critical data element.

Validity Testing Sample Size
A randomly selected sample of 79 records from the participating sites.

Validity Testing Statistical Result
Cohen's kappa coefficient (1), a statistic that measures inter-rater agreement for qualitative items, was used to determine reliability. Cohen´s kappa represents chance-corrected proportional agreement. Landis and Koch (2) proposed the following parameters as standards for strength of agreement for the kappa coefficient: 0=Poor, 0.01-0.20=Slight, 0.21-0.40=Fair, 0.41-0.60=Moderate, 0.61-0.80=Substantial and 0.81-1.0=Almost perfect (high). These categories are informal.

Date of birth and encounter date, which are required elements for performance score calculation, were also not subjected to validity testing and are presumed to be valid.

Data Element: Dx Psoriasis

Kappa: 1.00

Kappa 95% CI: n/a

Prevalence Adjusted Kappa: 1.00

Prevalence Adjusted Kappa 95% CI: n/a

Overall Agreement: 100.0%

Data Element: Assessment Tool

Kappa: 0.56

Kappa 95% CI: 0.39 – 0.74

Prevalence Adjusted Kappa: 0.72

Prevalence Adjusted Kappa 95% CI: 0.60 – 0.84

Overall Agreement: 81.0%

Data Element: PRO Score

Kappa: 1.00

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Kappa 95% CI: n/a

Prevalence Adjusted Kappa: 1.00

Prevalence Adjusted Kappa 95% CI: n/a

Overall Agreement: 100.0%

1. Cohen J. A coefficient of agreement for nominal scales. Educational and psychological measurement. 1960;20(1):37-46.

2. Landis JR, Koch GG. The measurement of observer agreement for categorical data. biometrics. 1977:159-174.

Validity Testing Interpretation of Results
Agreement statistics (kappa and prevalence adjusted kappa) indicate at least "Substantial" agreement abstractors' findings of documentation in the medical record and the data submitted by the practice site for all critical data elements needed to calculate performance for the quality measures tested.

Measure performance – Type of Score
Proportion

Measure Performance Score Interpretation
Higher score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have
Mean Performance Rate: 43.3%

Std Dev: n/a

Benchmark, if applicable
N/A

Measure Contact Information

Measure Steward
American Academy of Dermatology

Measure Steward Contact Information
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Long-Term Measure Steward
N/A

Long-Term Measure Steward Contact Information
N/A

Primary Submitter Contact Information
N/A

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Section 2: Preliminary Analysis – MUC2021-125 Psoriasis – Improvement in Patient-Reported Itch Severity

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

Justification and Notes: CMS has indicated their top priority for measure selection in the MIPS program is patient-reported outcome measures; as such, this measure fits that objective. If included in the program, the measure would be only the second outcome measure in the Dermatology Measure Set. The other measure is a clinical outcome measure of psoriasis disease activity level; although similar, this Measure Under Consideration distinguishes itself as a patient-reported outcome.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes

Justification and Notes: Chronic pruritis, the symptom assessed in this patient reported outcome, has a "quality of life impact comparable to that of chronic pain", a considerable burden of disease (Klini et al, 2011). Left unresolved, it can lead to "develop of symptoms of depression, global distress, and impairment of sleep" (Zachariae et al, 2008). A TEP convened by the developer included 3 patients, all three of whom indicated the measure result would help them make decisions about their care. However, the guideline on which this measure is based was only given a "B", indicating a "recommendation based on inconsistent or limited-quality patient-oriented evidence". Note that the guideline indicates that the minimal clinically important difference is of 3 to 4 points using the scales identified in the measure; however, the measure gives credit to improvements of 2 or more points.

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Does the measure address a quality challenge?
Yes/No: Yes

Justification and Notes: Psoriasis itself is common, affecting approximately 2% of the population (Menter et al, 2008), and a systematic review estimated the annual cost of the disease at $112 billion in the United States (Brezinski et al, 2015). In addition, there are over 4.5 million ambulatory health care visits for chronic pruritis in the United States every year (Shive et al, 2013). A TEP convened by the developer found that 11 of 11 providers consulted agreed that the measure was actionable to improve quality of care. In the measure's current implementation as a MIPS QCDR measure, the average performance rate is 43.3%, indicating a substantial gap in care.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?
Yes/No: Yes

Justification and Notes: There is one other measure (MIPS 410) related to psoriasis care in the MIPS Dermatology measure set, and it is conceptually similar: it is an outcome measure assessing physician or patient-reported disease activity levels for psoriasis. However, this Measure Under Consideration is specific to the pruritus symptom and is based on patient report only. Thus, both measures complement one-another in an assessment of the patient's overall health and well-being.

Can the measure be feasibly reported?
Yes/No: Yes

Justification and Notes: The measure is in current use as part of the American Academy of Dermatology QCDR. The Academy conducted a burden analysis, noting that although the clinical workflow would have to be modified to calculate the measure, as the numerator must be manually abstracted (comparing two scores on the severity assessment tools), the time to abstract per record was minimal. All data elements used to calculator the denominator is available through electronic coding, such as CPT or ICD-10.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?
Yes/No: Yes

Justification and Notes: The measure is specified for use in outpatient dermatology clinical practices, at the individual clinician level; this is consistent with MIPS program objectives, and consistent with the parameters for the reliability and validity testing that was conducted.

If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure been identified?
Yes/No: No

Justification and Notes: The measure is in current use in the MIPS QCDR, and no negative unintended issues or implementation challenges have been identified. The MAP Clinician workgroup acknowledged the challenges of responding to PROs for certain populations and the input from the Equity workgroup. MAP encouraged CMS to examine language and cultural issues in the consideration of this PRO.

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PAC/LTC Core Concept?
N/A

Impact Act Domain
N/A

Hospice High Priority Areas
N/A

MAP Rural Health Advisory Group Input:
Relative priority/utility:
The measure was noted to be relevant to rural providers, however there were concerns about the prevalence of psoriasis in rural communities.
Data collection issues:
- None identified

Calculation issues:
- There were concerns expressed regarding the low population and case minimums for individual providers. Also, concerns were noted for how low population sizes for individual providers in rural community would translate to the statistical methods used by the developer.

Unintended consequences:
- None identified.

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 4.1
1 – 0 votes
2 – 0 votes
3 – 1 vote
4 – 11 votes
5 – 3 votes

MAP Health Equity Advisory Group Input:
Relative priority/utility:
- The Health Equity Advisory Group noted that Psoriasis is an important clinical topic.

Data collection issues:
- Since this is a self-reported measure, data collection may be a problem for disadvantaged populations due to language and cultural barriers, as well as access issues.
- This measure does require two assessments, and the response rates may drop among disadvantaged population resulting in selection bias in the measure performance.

Calculation issues:
- The Advisory Group recommended this measure be stratified to assess performance based on population subgroups.

Unintended consequences:
- Disparity in diagnoses was identified as a potential issue.
- Response bias was identified as a potential issue.

Votes: Range is 1 – 5, where higher number has greater potential for positive impact on health equity.
Average: 2.7
1 – 0 votes

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2 – 11 votes
3 – 7 votes
4 – 4 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking, pending NQF endorsement.

Summary: What is the potential value to the program measure set?

This Measure Under Consideration is a patient-reported outcome for a psoriasis symptom, complementing an existing measure in the set of psoriasis disease activity. This measure would be just the second outcome measure in the MIPS Dermatology set (and just the 12th measure overall), and as a patient-reported outcome, is consistent with CMS' Meaningful Measures Initiative.

Summary: What is the potential impact of this measure on quality of care for patients?

Psoriasis is a common condition, with some 7.5 million affected nationwide, leading to millions of clinical visits every year. Chronic pruritis, the symptom assessed in this patient reported outcome, has a significant impact on quality of life and is associated with depression and global distress, among other effects. Patients and providers on a technical expert panel agreed that the quality construct measured was actionable, and the measure result could be used to evaluate quality of care. The measure is supported by a clinical guideline, although the evidence supporting the guideline is somewhat weaker and the minimum clinical impact in the measure is lower than that recommended by the guideline.

In the measure's current implementation in a MIPS QCDR, the average performance rate is 43.3%, indicating a substantial gap in care. Incorporating this measure into MIPS would encourage adherence to the guideline, leading to better symptom control and improved quality of life for the millions affected by chronic pruritis.

Section 3: Public Comments

Johnson & Johnson

Johnson & Johnson agrees with the recommendation of the MAP Workgroup to conditionally support this measure pending NQF endorsement. This measure aligns with the goal to advance meaningful, patient-centered measures that assess change in patient's quality of life over time, based on their ability to access treatment. Itch is among the bothersome symptoms for psoriasis patients, but this measure should be coupled with other measures of symptom resolution. Moreover, Johnson & Johnson recommends a more comprehensive and inclusive approach the PROs that satisfy the numerator to include any validated itch assessment tool or psoriasis questionnaire that includes itch assessment.

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OCHIN, Inc.

Support this recommendation. This is a reasonable measure. Measures that look for improvement can be problematic in determining which score is the baseline score. It can also be difficult to reliably capture patient reported outcomes.

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Part C & D Star Rating [Medicare]

MUC2021-053 Concurrent Use of Opioids and Benzodiazepines (COB)

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program

Part C & D Star Rating [Medicare]

Workgroup

Clinician

Measure Description

The percentage of Medicare Part D beneficiaries, 18 years or older with concurrent use of prescription opioids and benzodiazepines during the measurement period.

Numerator

Number of member-years of beneficiaries in the denominator with at least 2 prescription claims of a benzodiazepine with unique dates of service (DOS) and concurrent use of opioids and benzodiazepines during the measurement period.

To determine concurrent use, a beneficiary's number of overlapping days' supply must be determined first for the measurement period.

1. Use the prescriptions' DOS and days' supply to count the number of days the beneficiary was covered by both an opioid and a benzodiazepine prescription.
2. The days covered by both opioid and benzodiazepine claims will be considered days of overlapping supply. Concurrent use if defined as an overlapping supply of 30 or more cumulative days of opioids and benzodiazepines.

Note:

If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescriptions with the longest days' supply.

If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once towards the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

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Numerator Exclusions
None

Denominator
Number of member-years of enrolled beneficiaries, 18 years or older, with at least 2 fills of a prescription opioid with unique DOS and at least 15 total days' supply of opioids during the measurement period.

Note:

If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescriptions with the longest days' supply.

If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Denominator Exclusions
Cancer diagnosis, sickle cell disease diagnosis, or enrolled in hospice at any time during the measurement year are excluded.

Denominator Exceptions
N/A

State of development
Fully Developed

State of Development Details
Reliability and validity testing completed. Also, conducted Adams beta-binomial methodology on the 2018 Part D Patient Safety Reports to demonstrate reliability. Please see the results of the reliability and validity testing in the sections discussing reliability and validity.

What is the target population of the measure?
Medicare Part D members within Medicare Advantage Prescription Drug Plans (MA-PDs) and Part D Prescription Drug Plans (PDPs).

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Critical care medicine (intensivists);Emergency medicine;Family practice ;General practice;Geriatric medicine;Internal medicine;Interventional pain management;Pain management;Primary care

Measure Type
Process

Is the measure a composite or component of a composite?
No

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If Other, Please Specify
N/A

What data sources are used for the measure?
Administrative Data (non-claims);Claims Data;Other: Common Medicare Environment (CME), Medicare Enrollment Database (EDB), Risk Adjustment Processing Systems (RAPS), Common Working File (CWF), Encounter Data Systems (EDS), Pharmacy Quality Alliance (PQA) Medication Value Set

If applicable, specify the data source
N/A

If EHR or Chart-Abstracted data, description of parts related to these sources
N/A

At what level of analysis was the measure tested?
Health Plan

In which setting was this measure tested?
Other: Medicare Part D health plans such as Medicare Advantage Prescription Drug Plans (MAPDs) and Prescription Drug Plans (PDPs)

What one healthcare domain applies to this measure?
Chronic Conditions

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
N/A

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Endorsed

NQF ID Number
NQF #3389

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
No

If not exactly as endorsed, specify the locations of the differences
Denominator

If not exactly as endorsed, describe the nature of the differences
PQA uses continuous enrollment. However, Medicare Part D uses member-years to account for partial enrollment.

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If endorsed: Year of most recent CDP endorsement
2018

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
2021

Submitter Comments
N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?
No

If eCQM, enter Measure Authoring Tool (MAT) number
N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
Measure currently used in a CMS program being submitted as-is for a new or different program

Range of years this measure has been used by CMS Programs
Medicaid Adult Core Set and Medicaid 1115 Substance Use Disorder Waiver programs 2018. Medicare Part D Patient Safety reporting 2018. Part C & D Display Page 2019-2020.

What other federal programs are currently using this measure?
Medicaid Adult Core Set and Medicaid 1115 Substance Use Disorder Waiver programs and Part C & D

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Display Page (Medicare) and previously Part D Patient Safety Reporting (Medicare)

Is this measure similar to and/or competing with a measure(s) already in a program?
Yes

Which measure(s) already in a program is your measure similar to and/or competing with?
Medicaid's CMIT 5887 Concurrent Use of Opioids and Benzodiazepines (COB)

How will this measure be distinguished from other similar and/or competing measures?
One of the key differences that will distinguish the similar measures is the population measured. The COB measure submitted for the Part C and D Star Ratings measures Medicare PDP and MA-PD health plans while the Medicaid's COB measures Medicaid health plans.

How will this measure add value to the CMS program?
The COB measure adds value to the CMS program because it is expected to assist health plans with identifying beneficiaries who are experiencing concurrent use of opioids and benzodiazepines. There is significant risk of respiratory depression and fatal overdose with opioids and benzodiazepines when concurrently taken. The COB measure can help health plans encourage providers to prescribe opioids and benzodiazepines appropriately and avoid use unless clinical necessary in the Medicare Part D population.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure
See attachment

Evidence that the measure can be operationalized
Primary data source used for this measure is the Medicare Part D prescription drug event (PDE) data claims used for identifying prescription drug fills. The PDE is readily available to CMS. In addition, CMS provides each Part D sponsor monthly reports of this COB measure for monitoring. CMS solicited comments in the 2019 Call Letter and received positive support for the COB measure as being included in the display page for 2021 (2019 data) and 2022 (2020 data) with consideration for moving the COB measure to the Part C & D Star Ratings program pending rulemaking.

How is the measure expected to be reported to the program?
Other: Health plans receive a rate for the measure. We do not provide claims data to health plans.

Feasibility of Data Elements
ALL data elements are in defined fields in administrative claims;ALL data elements are in defined fields in a combination of electronic sources

Evidence of Performance Gap
The COB measure is anticipated to help health plans to identify individuals who are experiencing

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concurrent use of opioids and benzodiazepines and may be at risk of respiratory depression and fatal overdose. This measure can also facilitate health plans to encourage providers to prescribe opioids and benzodiazepines appropriately and avoid concurrent use except when clinically necessary. Reduced concurrent prescription of opioid and benzodiazepines should result in better patient outcomes.

We tested this measure and announced the results in the 2019 Call Letter. After adjusting for member-years and including contracts greater than 30 member-years in the denominator, there were a total of 680 Part D contracts (MA-PD, PDP, and employer direct contracts) that met the eligibility requirements for the Concurrent Use of Opioids and Benzodiazepine measure. The rate associated with the top 5% of PDP contracts was 42.9% while MA-PD contracts had a higher rate of 51.4%. Thus, there is a need to implement this measure to help health plans encourage providers to prescribe opioids and benzodiazepines appropriately and avoid concurrent use.

Unintended Consequences

Patients receiving pain management in hospice care, and those with cancer or sickle cell disease, may have unique therapeutic goals, ethical considerations, opportunities for medical supervision, and factors to consider when balancing the risks and benefits of opioid therapy. Another concern is the potential misapplication of current chronic pain management guidelines to patients outside of their intended scope. Thus, these patients are excluded from these measures whenever data are available. The exclusions of hospice and cancer are consistent with the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain, which does not apply to active cancer treatment, palliative care, and end-of life treatment because of the unique therapeutic goals, ethical considerations, opportunities for medical supervision, and balance of risks and benefits with opioid therapy in such care.

Notably, the Centers for Disease Control have also recommended unique opioid prescribing considerations for patients with sickle cell disease [Available at https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2019-CDC-Opioid-Guideline-Clarification-Letter-to-ASCO-ASH-NCCN.pdf]. Due to these considerations, and their unique therapeutic goals, ethical considerations, opportunities for medical supervision, and balance of risks and benefits, individuals with a diagnosis of sickle cell disease are excluded from this measure.

The PQA Concurrent Use of Opioids and Benzodiazepines measure evaluates a process that correlates with increased risk of opioid overdose. Efforts to prevent opioid overdose deaths should include a multi-faceted approach, including strategies that focus on monitoring and reducing opioid prescribing that has an unfavorable balance of benefit and harm for most patient populations.

This measure is not intended for clinical-decision-making. This measure is intended for retrospective evaluation of populations of patients and should not be used to guide clinical decisions for individual patients. For clinical guidance on opioid prescribing, see the Center for Disease Control and Prevention CDC Guideline for Prescribing Opioids for Chronic Pain and Guideline Resources.

Outline the clinical guidelines supporting this measure

According to the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, clinicians should avoid concurrent prescribing of opioids and benzodiazepines whenever possible.(1) This is a Category A recommendation (applies to all persons; most patients should receive the recommended course of action) and is based on Type 3 evidence

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(observational studies or randomized clinical trials with notable limitations). In August 2016, the US Food and Drug Administration added concurrent use of opioids and benzodiazepines as a black box warning to prescription opioids (analgesic and cough medicine) and benzodiazepines.(2)

1) Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016. MMWR Recomm Rep. 2016; 65:1-49. PMID: 26987082.
2) US Food and Drug Administration. FDA Drug Safety Communication: FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning [Internet]. 2016 [2016 Nov 9]. Available from: http://www.fda.gov/Drugs/DrugSafety/ucm518473.htm.

Were the guidelines graded?
Yes

If yes, who graded the guidelines?
Centers for Disease and Control (CDC) developed the guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) method. Method has been adapted by the CDC Advisory Committee on Immunization Practices (ACIP).

If yes, what was the grade?
Evidence informing the recommendations is based on observational studies or randomized clinical trials with notable limitations, as well as clinical experience and observations, characterized as low in quality under GRADE methodology.

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Per the 2018 Patient Safety data, the total Medicare denominator for the COB measure was 5,734,736 member-years.

Estimate of Annual Improvement in Measure Score
Data from 2018 and 2019 in the Medicare Part D Patient Safety Reports demonstrate a downward trend across both the MAPD and PDP lines of business:

MAPD Mean 2018: 19.44%

MAPD Mean 2019: 17.39%

Trend: -2.05

PDP Mean 2018: 19.36%

PDP Mean 2019: 17.44%

Trend: -1.92%

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Type of Evidence to Support the Measure
Clinical Guidelines

Is the measure risk adjusted, stratified, or both?
None

Are social determinants of health built into the risk adjustment model?
No

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
Unable to determine. A formal economic analysis of the cost savings has not been conducted. However, the literature demonstrates that savings associated with improved performance on these measures is likely to be substantial.

According to a CDC publication using the National Vital Statistics System from 2017, the total cost of fatal overdose in 2017 was $549.691 billion with spending measured in 2017 dollars. The costs can be segmented into value of lost productivity at $68.694 billion, health care costs at $260 million, and value of statistical life lost at $480.737 billion.

Additionally, on a per-overdose basis for opioid-related events, a study using hospital intensive care unit admission data from 162 hospitals between 2009 to 2015 an average cost of $92,408 (2015 dollars) in 2015. Using a large, commercially insured population a study explored direct costs associated with concomitant users of opioids and benzodiazepines from 2012-2013.The study found that the incremental total costs among patients with concomitant use were $3,111 in 2013 dollars. Additionally, concomitant users were associated with higher odds of hospitalization or emergency department use.

Cost Avoided Annually by Medicare/Provider
Per literature (in 2017 dollars), among health care costs associated with opioid use disorder and nonfatal overdose, Medicare incurred $3.170 billion. Therefore, per literature, the costs that could be avoided by Medicare could be approximately $3 billion.

Source of Estimate
Estimates were from literature and considered the estimated costs of opioid use disorder and fatal overdose in the United States.

Sources are from following:

Florence C, Luo F, Rice K. The economic burden of opioid use disorder and fatal opioid overdose in the United States, 2017. Drug Alcohol Depend. 2021 Jan 1;218:108350. doi: 10.1016/j.drugalcdep.2020.108350. Epub 2020 Oct 27. PMID: 33121867.

Stevens JP, Wall MJ, Novack L, Marshall J, Hsu DJ, Howell MD. The Critical Care Crisis of Opioid Overdoses in the United States. Ann Am Thorac Soc. 2017 Dec;14(12):1803-1809. doi: 10.1513/AnnalsATS.201701-022OC. PMID: 28800256.

Chang HY, Kharrazi H, Bodycombe D, Weiner JP, Alexander GC. Healthcare costs and utilization

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associated with high-risk prescription opioid use: a retrospective cohort study. BMC medicine. 2018 Dec;16(1):1-1.

Year of Cost Literature Cited
2017

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

If yes, choose all methods of obtaining patient/caregiver information
Other: PQA systematically gathered patient input during the development of the COB measure through PQA's Patient and Caregiver Advisory Panel (PCAP). The PCAP was a small group of individuals, selected by PQA staff through a nomination process, to provide patient and caregiver input into the measure development process and thereby reflect the patient's voice in PQA measures. The PCAP is charged with reflecting the patient voice in PQA processes through the involvement of patients, caregivers, and patient advocacy organizations. Additionally, through the PCAP, the patient and caregiver input that is provided is integrated where appropriate into the measure development process for medication-related measures. The recommendations provided by the PCAP are addressed with the Measure Development Teams and Task Forces to refine measures based on patient characteristics/preferences. The information gathered from the PCAP assist in identifying high priorities for potential new patient-focused measure development work.

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
Met twice with patients and caregivers.

Once during development of specifications in June 2016.

Once following specification and testing phase in August 2016.

Total Number of Patients and/or Caregivers Consulted
10

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
The 2016 PCAP consisted of a 1:1 ratio between patient/caregiver/advocates and healthcare professionals. The PCAP did not conduct formal voting on the measure concepts. However, the PCAP provided meaningful feedback and affirmed the importance of measure concepts to patients and caregivers.

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
10

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Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Other: Measure development teams (MDT), Quality Metrics Expert Panel (QMEP), and Measure Validity Panel (MVP)

Total Number of Clinicians/Providers Consulted
129

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
129

Burden for Provider: Was a provider workflow analysis conducted?
No

If yes, how many sites were evaluated in the provider workflow analysis?
N/A

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
11

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Measure Testing Details

Reliability Testing Interpretation of Results
Based on the reliability score of 0.91 for PDPs and 0.87 for MAPDs, the measure is considered reliable as used in the Medicare Part D Patient Safety reports since the minimum threshold for reliability is 0.7.

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
Signal to Noise

Reliability Testing Sample Size
PDP: n=63 and MAPD: n=676

Reliability Testing Statistical Result
MAPD:

- Mean: .87
- Standard Deviation: .17
- Min: .33
- Max: 1.00

PDP

- Mean: .91
- Standard Deviation: .15
- Min: .36
- Max: 1.00

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
Yes

If yes, specify the number of cases and the percentage of providers
Minimum denominator of 30 was used for all measures. Percentages meeting the minimum sample are: PDP: 92% and MAPD: 90%

Type of Validity Testing
Measure Score Validity

Validity Testing: Type of Validity Testing Analysis
Face Validity;Other: Criterion Validity

Validity Testing Sample Size
COB (face validity): MDT: 27 participants, 27 voting; QMEP: 22 participants, 16 voting; MVP: 6 participants, 6 voting. COB (empirical validity): PDP n=50 contracts and MAPD n=380 contracts.

Validity Testing Statistical Result
COB (face validity):

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- MDT: 93% support
- QMEP: 94% support
- MVP: 100% support

COB (empirical validity)

Within the Medicare 5% sample, the Spearman's correlation coefficient was .45 within PDPs (moderate) [p<.0001] and .21 for MAPDs (weak) [p=.001].

Validity Testing Interpretation of Results

For face validity, findings demonstrate that the measure has face validity.

The empirical validity of the measure score was assessed using a criterion validity approach, a methodology that evaluates the extent to which performance on a quality measure is associated with conceptually and clinically related outcomes. Specifically, our assessment evaluated the correlation between plan-level performance on the COB measure as specified, and plan-level rates of a composite of inpatient stays and emergency department utilization due to opioid- and benzodiazepine-related adverse events (OBRAEs). This analysis is based on the expected convergent relationship between measure rates and OBRAEs; the better a given plan performs on the COB measure (i.e. lower rate), the lower plan-level rates of OBRAEs are hypothesized to be.

The correlations produced in the criterion validity analyses suggest a statistically significant and moderate-strength relationship between the measure rate and incidence of opioid- and benzodiazepine-related adverse events. Correlations were stronger for PDPs than MAPDs.

Analyses to correlate measure rates to outcomes, particularly outcomes involving inpatient stays and ED utilization, will always encounter noise. There are numerous factors that may contribute to patients experiencing (or not experiencing) these events, and quality measures such as COB are only able to capture one potential contributor: namely, receiving concurrent days' supply for opioids and benzodiazepines.

Given the numerous factors that can contribute to these outcomes, very high correlations would be unexpected. However, the correlations found in this analysis do demonstrate a consistent, statistically significant relationship in the expected direction, with greater strength for PDPs and lesser strength for MAPDs, between the COB measure and OBRAEs.

Measure performance – Type of Score

Other: Percentage

Measure Performance Score Interpretation

Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have

This measure is only intended to be calculated and submitted using administrative claims data.

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MAPD

Mean 17.20%

SD 5.68%

PDP

Mean 17.43%

SD 3.98%

Benchmark, if applicable
Not applicable

Measure Contact Information

Measure Steward
Pharmacy Quality Alliance

Measure Steward Contact Information
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Long-Term Measure Steward
N/A

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N/A

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Section 2: Preliminary Analysis – MUC2021-053 Concurrent Use of Opioids and Benzodiazepines (COB)

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

Justification and Notes: This measure promotes a high priority for Part C & D, specifically effective prevention, and treatment of chronic disease through measurement of Concurrent Use of Opioids and Benzodiazepines. This measure was initially endorsed in 2018 and endorsement was upheld in the Spring 2021 cycle. Measure addresses class A recommendation for clinicians to avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible (Centers for Disease Control and Prevention, 2016). Measure developers provided updated measure evidence: four additional cohort studies, one case cohort study, and a technical brief from the Agency for Healthcare Research and Quality (AHRQ) during NQF June 2021 Measure Evaluation Web Meeting.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes

Justification and Notes: This is a process measure correlating high-risk prescribing practice with a negative health outcome in target beneficiaries. Opioid therapy with a concurrent use of benzodiazepines can increases a patient's additive respiratory depression along with the risk of overdose and all-cause mortality (Rosenquist et al., 2021). Measure is supported by clinical guidelines supported by Type 3 evidence, observational studies, or randomized clinical trials with notable limitations (Centers for Disease Control and Prevention, 2016). NQF Standing Committee supported the measure evidence as submitted.

Does the measure address a quality challenge?
Yes/No: Yes

Justification and Notes: This measure addresses the risk of opioid-related adverse events in patients concurrently prescribed opioids and benzothiazines. The Joint Commission reported that 11% of opioid-related adverse drug events were attributed to excessive dosage and medication interactions. The most commonly associated medication interactions leading to side effects were benzodiazepines and cardiac medications (Savelloni et al., 2017).

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Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?

Yes/No: Yes

Justification and Notes: This measure is in the Medicaid Adult Core Set and Medicaid 1115 Substance Use Disorder Waiver programs and the Part C & D Display Page (Medicare) and previously Part D Patient Safety Reporting (Medicare) setting. There are several related measures, however, the NQF Standing Committee did not note any as competing measures (National Quality Forum, 2021).

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure is currently publicly reported and will in the future be used in an accountability program. This process measure uses medical claims, prescription claims, and enrollment data for reporting.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: Yes

Justification and Notes: The measure is specified and tested at the outpatient care setting, health plan level of analysis. The measure was initially endorsed by NQF in October 2018 and renewed in the CDP Spring 2021 Cycle by the Patient Safety Standing Committee. The Standing Committee considered the evidence that was submitted by the developer in support of this process measure and voted to pass on evidence. The Standing Committee reviewed the reliability testing for this measure and voted to pass the measure with a moderate rating for validity. The Standing Committee did not have any concerns with feasibility and voted to pass the measure on feasibility.

If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure been identified?

Yes/No: No

Justification and Notes: The measure developer did not report any unexpected findings. Patients with cancer, sickle cell, or residing in a hospice care facility may have unique therapeutic goals, ethical considerations, opportunities for medical supervision, and factors to consider when balancing the risks and benefits of opioid therapy, therefore the measure developer has excluded these populations from the measure to avoid any unintended consequences. During endorsement review in the CDP Spring 2021 Cycle, NQF received public comments from Humana, Kaiser Permanente, and Magellan Health but no unintended issues were raised (National Quality Forum, 2021).

The MAP Clinician workgroup raised questions regarding potential negative unintended consequences from the implementation of this measure. MAP noted denominator concerns raised in the public comments. Efforts to reduce overall opioid use in the population may reduce the denominator population, which may inadvertently make performance on the measure look worse. Taken another way, overprescribing of opioids may lead to a larger denominator which makes performance on this measure look better. Further, MAP noted that the measure is not risk adjusted, particularly for social determinants. The developer noted that goal of the measured denominator is an at-risk population. The

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measure is not intended for clinical decision-making for individual patients and there will be some baseline concurrent use of these medications, but the variation demonstrates room for improvement. The developer also noted that the measure is intended to be used with monitoring of prescribing behaviors and other performance measures in the program.

PAC/LTC Core Concept?

N/A

Impact Act Domain

N/A

Hospice High Priority Areas

N/A

MAP Rural Health Advisory Group Input:

Relative priority/utility:

This measure was identified as a high need in the rural communities.

Data collection issues:

- There were no concerns for data collection, as this measure was considered to have a low burden for data collection.

Calculation issues:

- None identified.

Unintended consequences:

- Possible unintended consequences identified for patient populations that are excluded.
- Concerns raised about populations that may need high doses.
- Concerns regarding the tapering of the drugs when de-prescribing.

Votes: Range is 1 – 5, where higher is more relevant to rural.

Average: 4.4

1 – 0 votes

2 – 0 votes

3 – 1 vote

4 – 6 votes

5 – 7 votes

MAP Health Equity Advisory Group Input:

Relative priority/utility:

- This is an important measure in terms of use of opioids and benzodiazepines as it relates to minorities and underserved populations.

Data collection issues:

- None identified.

Calculation issues:

- Lack of stratification was identified as a priority for this measure
- No other issues identified.

Unintended consequences:

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- None identified.

Votes: Range is 1 – 5, where higher number has greater potential for positive impact on health equity.
Average: 3.2
1 – 0 votes
2 – 2 votes
3 – 14 votes
4 – 4 votes
5 – 1 vote

Recommendation

Preliminary Analysis Recommendation:

Support for Rulemaking

Summary: What is the potential value to the program measure set?

This NQF endorsed measure addresses the prevention and treatment of chronic disease, high-priority area of concern for CMS. The measure has been updated since its initial endorsement in 2018 and has no competing measure that addresses both the same measure focus and same target population. The MAP Clinician workgroup strongly encouraged CMS to monitor for potential negative unintended consequences due to the denominator definition.

Summary: What is the potential impact of this measure on quality of care for patients?

Patients concurrently using opioids and benzodiazepines are at a higher risk for opioid-related adverse events, for example respiratory depression. This is due to inadequate monitoring, lack of knowledge, regarding differing potencies of opioids, and improper prescribing (Savelloni et al., 2017).

This measure focuses on monitoring and reducing opioid prescribing with negative outcomes in most patient populations, except for patients with cancer, sickle cell, and those in hospice.

Section 3: Public Comments

NYP Columbia

Yes, support for inclusion in the program

Blue Cross Blue Shield of Massachusetts

BCBSMA opposes any high-stakes use of MUC2021-053 (Concurrent Use of Opioids and Benzodiazepines (COB)) due to serious flaws in the measure specification that undermine its validity. Similar to MUC2021-056 (Polypharmacy: Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH)) and MUC2021-066 (Polypharmacy: Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS)), the denominator for MUC2021-053 is restricted to patients who fill high-risk drugs (at least 2 fills of opioids, 15 days supply) that are overused and that should be prescribed less

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frequently overall. If a provider or health plan or any other measured entity conducts a successful program to reduce the unnecessary use of these high-risk denominator drugs, this would be a good thing for public health. But as currently specified, MUC2021-053 will penalize the measured entity in this scenario by shrinking the measure denominator, thus raising the measure score. When truly better care produces a higher score on a lower-is-better/higher-is-worse measure like MUC2021-053, this is a fundamental threat to measure validity. In other words, the directionality of better care (is "better" represented by a higher or lower score?) on this measure, as currently specified, is unknown. Therefore, this measure is unsuitable for high-stakes applications such as payment and public reporting. We advise the measure developer to use a different measure denominator that does not hinge on prescribing high-risk drugs. For example, using the count of members attributed to a measured entity, regardless of drug use, as the denominator would avoid this validity threat entirely.

American Academy of Family Physicians

The AAFP supports harmonization across measure sets and this measure is in the Medicaid Adult Core Set. In addition, a wide measure gap exists, and the burden of measurement is low. The obvious shortfall is patients with no insurance would not be included, but this may be the best available measure without adding burden.

Federation of American Hospitals

The Federation of American Hospitals (FAH) recognizes the need to address inappropriate opioid use given the ongoing concerns around this important public health issue, but we have concerns with the potential unintended consequences of this measure. Specifically, discontinuation of these medications can be complex and require medical oversight. Since the measure includes patients who are already receiving these concurrent medications, requiring that these drugs be discontinued has the potential to compromise patient safety and lead to patient harm. This measure could result in providers not offering suitable pain solutions, which is contrary to the goal of a positive patient care experience if these treatments are needed. In addition, we do not believe that focusing on prescription rates in the absence of understanding the root cause of the pain and pain management strategies will solve this public health concern; rather, examining pain and standardizing pain assessments and alternative therapies would assist all of us in understanding the true problem rather than removing a downstream intervention. It would also be applicable to a broader set of patients and pain medications rather than the limited focus on opioids and benzodiazepines.

The FAH believes that these concerns must be addressed prior to implementation of this measure in Part C & D Star Ratings. As a result, the FAH requests that the highest level of MAP recommendation be "Do Not Support with Potential for Mitigation."

American Medical Association

The American Medical Association (AMA) continues to have concerns that this measure lacks the precision needed to ensure that only those patients for whom concurrent prescribing of two or more opioids or an opioid and benzodiazepine are included in the denominator. The patient population could likely include patients for whom concurrent prescribing of these medications may be appropriate, particularly those with chronic pain.

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In addition, and more importantly, the Measures Application Partnership (MAP) must consider the potential for unintended consequences and complete robust evaluations to minimize these risks. In fact, we believe that the narrow and reactionary response to the drug overdose epidemic has exacerbated the stigma around opioid use and made it more difficult for patients with pain or opioid use disorder to receive treatment. Research continues to demonstrate that individuals may or may not have access to pain management therapies based on their race/ethnicity and measures that may further exacerbate this problem should be avoided (Goshal, 2020). In addition to stigmatization of those with substance use disorder, patients with other complex pain management conditions (such as sickle cell disease) are often viewed as opioid-seeking when presenting in the emergency department. Therefore, we urge the MAP to consider whether this and other measures that are focused on areas such as opioid dose and duration continue to be appropriate.

As a result, the AMA believes that there is a significant risk for performance to be inaccurately represented. More importantly, there is a substantial risk that patients for whom these medications may be warranted will not receive appropriate therapies, leading to potential adverse outcomes, including depression, loss of function and other negative unintended consequences.

The AMA believes that quality measurement needs to focus on how well patients' pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain. If pain can be well controlled and function improved without the need of these concurrent medications, then that is an indication of good patient care, but the measure must precisely define the patients for which it is appropriate and be tested to ensure that negative unintended consequences are not experienced by patients. We do not believe that this measure as specified is an appropriate goal as it may leave patients without access to needed therapies.

The AMA supports addressing the opioid crisis through quality measurement in addition to other avenues but strongly believes that any measure used in a quality program must also demonstrate that it does not compromise patient care. As a result, the AMA requests that the highest level of MAP recommendation be "Do Not Support."

America's Health Insurance Plans

On behalf of AHIP, thank you for the opportunity to comment on this measure. We appreciate CMS's efforts to ensure safe prescribing of these medications and protect patients from harm occurring from interactions between medications. However, we are concerned that implementing this measure in the Star Ratings at this time could have negative consequences for patients. We believe it may be premature to move this measure from the Display Page without a full assessment of its current specifications and exclusions. We are concerned that moving this measure from the Display Page to the Star Ratings without adequate exclusions could result in beneficiaries having limited safe and efficacious therapeutic alternatives for treatments like pain management. We urge the MAP and CMS to leave this measure on the Display Page to allow health plans, CMS, and the measure developer an opportunity to understand how this measure currently performs, potential negative consequences of its implementation, and if there is a need for refinement of the specifications to ensure that patients are not denied necessary treatments. Leaving the measure on the Display Page would still allow health plans to understand and improve performance and consumers to assess health plan results. We believe this would allow stakeholders the information they need while protecting patients from access challenges. Until the measure undergoes further evaluation, we ask the MAP to give this measure a

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recommendation of “Do Not Support” for the Star Ratings program.

National Society of Genetic Counselors

The National Society of Genetic Counselors (NSGC) supports the College of American Pathologists’ quality measure that the National Quality Forum Measure Applications Partnership is considering for the Centers for Medicare & Medicaid Services (CMS) Merit-based Incentive Payment System (MIPS) program: “Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma.”

NSGC advocates for the professional interests of genetic counselors by offering clinical guidelines, education, and other professional resources to over 4,000 members. Given the prevalence and effectiveness of screening, treatment, and preventative recommendations for hereditary cancer syndromes, including Lynch Syndrome, access to high-quality genetic services to assess a patient’s risk and inform treatment decisions is critical.

A quality measure that specifically addresses the inclusion of, or recommendation for, testing mismatch-repair defects via immunohistochemistry or microsatellite instability in surgical pathology reports for primary colorectal, endometrial, gastroesophageal or small bowel carcinoma, biopsy or resection samples would help institutions track process improvements that would directly inform patient care. The timely identification of a mismatch-repair defect indicative of Lynch Syndrome enables referral to genetic counselors and helps identify at-risk family members for proactive cancer risk management.

Adoption of this proposed quality measure would also harmonize with an Improvement Activity (IA) that the NSGC submitted to CMS for consideration in the MIPS program: “Improve Access to Genetic Counseling and Testing.” This IA would drive appropriate engagement with genetic counselors and improve patient health outcomes by integrating genetic counselors in clinical care teams and establishing protocols to increase access to genetic services in appropriate clinical scenarios.

The organizations and individuals below endorsed this IA:

- Association of Community Cancer Centers
- Beating Alzheimer’s by Embracing Science President and CEO, Jamie Tyrone, RN
- Parkinson’s Foundation
- Cancer Support Community
- David Godzina, MA, MBA, Director, Quality Measure & Improvement, American Gastroenterological Association
- David Leiman, MD, Asst. Prof. of Medicine, Duke Clinical Research Institute, Duke Cancer Institute; AGA Quality Committee
- Facing Our Risk of Cancer Empowered
- FH Foundation
- Foundation for Women’s Cancer
- Heart Rhythm Society
- Society for Gynecologic Oncology

Given CMS’ intent to complement IAs and MIPS quality measures, incorporating this measure into MIPS would align with the possible adoption of NSGC’s proposed IA, especially as CMS considers future

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oncology or pathology MIPS Value Pathways.

Thank you for this opportunity to provide input on this proposed quality measure.

Cerner
With changes in regulatory requirements and a shift towards a value-based paradigm, it is now more important than ever to have complete data. As data becomes more complex, we have the ability to extract multifaceted insights and provide actionable analytics to organizations striving to satisfy the triple aim at the core of healthcare reform - promoting better health, providing better care, and reducing cost.

To excel in population health management, you need to understand how patient characteristics and contextual factors, external to the care delivery process, impact your patients. We help you to better understand how these characteristics affect segments of your patient population, optimize care delivery, understand variation in outcomes related to SBDH burden, excel in value-based care and achieve health equity.

Health Hats
The Social Determinants of Health criteria don't include internet access. A major miss.

Johnson & Johnson
Johnson & Johnson supports the recommendation of the Workgroup.

American Medical Association
The American Medical Association (AMA) continues to have concerns with this measure and we refer the Coordinating Committee to our comments submitted during the first public comment for additional information. In summary, we believe that:

- This measure lacks the precision needed to ensure that only those patients for whom concurrent prescribing of two or more opioids or an opioid and benzodiazepine are included in the denominator.

- There is significant potential for unintended consequences and complete robust evaluations must be completed to minimize these risks. In fact, we believe that the narrow and reactionary response to the drug overdose epidemic has exacerbated the stigma around opioid use and made it more difficult for patients with pain or opioid use disorder to receive treatment.

- There is a significant risk for performance to be inaccurately represented as a result of these issues.

- More importantly, there is a substantial risk that patients for whom these medications may be warranted will not receive appropriate therapies, leading to potential adverse outcomes, including depression, loss of function and other negative unintended consequences.

The AMA supports addressing the opioid crisis through quality measurement in addition to other avenues but strongly believes that any measure used in a quality program must also demonstrate that it does not compromise patient care. As a result, the AMA requests that the highest level of MAP recommendation be “Do Not Support.”

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Karen L. Smith, MD PA
Yes, support for inclusion in the program.

America's Health Insurance Plans
On behalf of AHIP, thank you for the opportunity to comment on this measure. We appreciate CMS's efforts to ensure safe prescribing of these medications and protect patients from harm occurring from interactions between medications and appreciate MAP's concerns about the risks of inappropriate prescribing. However, as noted in our comments to the Clinician Workgroup, we are concerned that implementing this measure in the Star Ratings at this time could have negative consequences for patients. We believe it may be premature to move this measure from the Display Page without a full assessment of its current specifications and exclusions. We are concerned that moving this measure from the Display Page to the Star Ratings without adequate denominator exclusions could result in beneficiaries having limited safe and efficacious therapeutic alternatives for pain management. This measure assesses patients who are currently opioids and benzodiazepines at the same time; however, an abrupt discontinuation of these medications could jeopardize patient safety. Moreover, this measure could lead to providers not offering suitable pain solutions.

We urge the Coordinating Committee to re-evaluate the MAP recommendation on this measure due to the risk of causing access challenges for patients who need these medications. The Coordinating Committee should instead give this measure a MAP recommendation of Do Not Support or Do Not Support with Potential for Mitigation. MAP should recommend that CMS to leave this measure on the Display Page to allow health plans, CMS, and the measure developer an opportunity to understand how this measure currently performs, potential negative consequences of its implementation, and if there is a need for refinement of the specifications to ensure that patients are not denied necessary treatments. Leaving the measure on the Display Page would still allow health plans to understand and improve performance and consumers to assess health plan results. We believe this would allow stakeholders the information they need while protecting patients from access challenges.

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MUC2021-056 Polypharmacy: Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH)

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Part C & D Star Rating [Medicare]

Workgroup
Clinician

Measure Description
The percentage of Medicare Part D beneficiaries 65 years of age or older with concurrent use of two or more unique anticholinergic (ACH) medications during the measurement period.

Numerator
Number of member-years of beneficiaries in the denominator with concurrent use of 2 or more anticholinergic medications during the measurement period. Each medication must have at least 2 fills with unique dates of service (DOS) during the measurement period.

Concurrent Use: To determine concurrent use, a beneficiary's number of overlapping days' supply is determined for each measurement period.

Use the prescriptions' DOS and days' supply to count the number of days the beneficiary was covered by ACH medications.

If multiple prescription claims for the same ACH medication (active ingredient) are dispensed on the same day, calculate the number of days covered by the target medication using the claim with the longest days' supply.

If multiple prescription claims for the same ACH medication (active ingredient) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. These is no adjustment for early fills or overlapping days' supply.

The days covered by two or more unique ACH medications during the measurement period are considered days of overlapping supply. Concurrent use is defined as 30 or more cumulative overlapping days' supply of at least 2 unique ACH medications.

Numerator Exclusions
None

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Denominator
Number of member-years of enrolled beneficiaries, 65 years or older, with at least 2 fills with unique dates of service (DOS) of the same medication in the targeted drug class(es) during the measurement period.

Denominator Exclusions
Beneficiaries enrolled in hospice at any time during the measurement period are excluded from the denominator.

Denominator Exceptions
N/A

State of development
Fully Developed

State of Development Details
Currently the measure is fully developed and implemented within Medicare Part D. This measure is included as one of the Medicare Part D display page measures that is publicly displayed on the CMS's Part C & D Performance Data website.

What is the target population of the measure?
Medicare Part D members within Prescription Drug Plans and Medicare Advantage Prescription Drug Plans

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Emergency medicine;Family practice ;Geriatric medicine;Internal medicine;Primary care

Measure Type
Process

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Administrative Data (non-claims);Claims Data;Other: Pharmacy Quality Alliance (PQA) National Drug Codes (NDC) Medication Value Sets, Common Medicare Environment (CME), Medicare Enrollment Database (EDB), Common Working File (CWF), and Encounter Data Systems (EDS)

If applicable, specify the data source
N/A

If EHR or Chart-Abstracted data, description of parts related to these sources
N/A

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At what level of analysis was the measure tested?
Health Plan

In which setting was this measure tested?
Other: Medicare Part D health plans (Medicare Advantage Prescription Drug Plans (MAPDs) and Prescription Drug Plans (PDPs))

What one healthcare domain applies to this measure?
Chronic Conditions

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
N/A

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Never Submitted

NQF ID Number

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?
No

If eCQM, enter Measure Authoring Tool (MAT) number
N/A

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If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
Measure currently used in a CMS program being submitted as-is for a new or different program

Range of years this measure has been used by CMS Programs
Medicare Part D Patient Safety reporting 2018. Part C & D Display Page 2019-2020.

What other federal programs are currently using this measure?
Part C & D Display Page and previously Part D Patient Safety Reporting

Is this measure similar to and/or competing with a measure(s) already in a program?
No

Which measure(s) already in a program is your measure similar to and/or competing with?
N/A

How will this measure be distinguished from other similar and/or competing measures?
N/A

How will this measure add value to the CMS program?
N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

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Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure

A systematic review of the literature, evaluating 27 studies from 1966 to 2008, determined that a high burden of anticholinergic use consistently shows a negative association with cognitive performance in older adults.(1) Several more recent studies have shown an association between concurrent use of anticholinergic medications and an increased risk of dementia and cognitive impairment. In 2015, Gray et al conducted a cohort study of 3434 individuals over age 65 who were followed up with every two years to examine the relationship between anticholinergics and cognitive decline.(2) Hazard ratios for dementia associated with cumulative anticholinergic use were 0.92 (95% CI, 0.74-1.16) for total standardized daily doses (TSDDs) of 1 to 90; 1.19 (95% CI, 0.94-1.51) for TSDDs of 91 to 365; 1.23 (95% CI, 0.94-1.62) for TSDDs of 366 to 1095; and 1.54 (95% CI, 1.21-1.96) for TSDDs greater than 1095; findings were similar for Alzheimer's, suggesting a strong relationship between cumulative anticholinergic use and cognitive decline.

In 2013, Cai et al conducted a retrospective cohort study of 3,690 individuals over age 65 to examine the association between cognitive impairment and anticholinergic exposure within the prior year.(3) In comparison to older adults with no anticholinergic exposure and after adjusting for age, race, gender, and underlying comorbidity, the odds ratio (OR) for having a diagnosis of mild chronic impairment was 2.73 (95% CI; 1.27-5.87) among older adults who were exposed to at least three possible anticholinergic for at least 90 days.

Clinical research from Risacher et al published by JAMA in 2016 found that among older adults, use of anticholinergics was associated with increased brain atrophy and dysfunction and cognitive decline based on performance on several cognitive scores at initiation of anticholinergic use and follow-up (mean follow-up 32 months).(4) In 2017, Campbell et al conducted an observational cohort study of 350 adults 65 and older to examine the effects of anticholinergic use on transition to mild cognitive impairment.(5) Compared with stable cognition, increasing use of strong anticholinergics calculated by total standard daily dose increased the odds of transition from normal cognition to MCI (OR 1.15; 95% CI 1.01–1.31).

In addition to cognitive decline, anticholinergic use in older adults is also associated with increased hospitalizations, with a study by Kalisch et. al., finding that older persons taking two or more anticholinergic medications had a significantly greater risk of hospitalization for confusion or dementia (adjusted incident rate ratio [IRR] 2.58; 95% CI 1.91-3.48); risk was further increased by taking three or more anticholinergics (IRR 3.87; 95% CI 1.83-8.21).(6) Evidence also suggests anticholinergics may increase risk for falls, with a 2016 case control study (n case [falls] = 263; n control [no falls] =165) finding a significant association between anticholinergic burden and fall risk (OR, 1.8; 95% CI; 1.1–3.0).(7)

References

1.Campbell N, Boustani M, Limbil T, et al. The cognitive impact of anticholinergics: a clinical review. Clin Interv Aging. 2009; 4:225-33. PMID: 19554093.

2.Gray SL, Anderson ML, Dublin S, et al. Cumulative use of strong anticholinergics and incident

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dementia: a prospective cohort study. JAMA Intern Med. 2015; 175(3):401-7. PMID: 25621434.

3.Cai X, Campbell N, Khan B, et al. Long-term anticholinergic use and the aging brain. Alzheimers Dement. 2013; 9(4):377-85. PMID: 23183138.

4.Risacher SL, McDonald BC, Tallman EF, et al. Association Between Anticholinergic Medication Use and Cognition, Brain Metabolism, and Brain Atrophy in Cognitively Normal Older Adults. JAMA Neurol. 2016;73(6):721–732. PMID: 27088965

5.Campbell NL, Lane KA, Gao S, Boustani MA, Unverzagt F. Anticholinergics Influence Transition from Normal Cognition to Mild Cognitive Impairment in Older Adults in Primary Care. Pharmacotherapy. 2018 May;38(5):511-519. doi: 10.1002/phar.2106. Epub 2018 Apr 25. PMID: 29600808;

6.Kalisch Ellett LM, Pratt NL, Ramsay EN, et al. Multiple anticholinergic medication use and risk of hospital admission for confusion or dementia. J Am Geriatr Soc. 2014; 62(10):1916-22. PMID: 25284144.

7.Zia A, Kamaruzzaman S, Myint PK, Tan MP. Anticholinergic burden is associated with recurrent and injurious falls in older individuals. Maturitas. 2016 Feb;84:32-7. doi: 10.1016/j.maturitas.2015.10.009. Epub 2015 Oct 23. PMID: 26531071

Evidence that the measure can be operationalized

Data source is available to CMS. The primary data source used for this measure is Medicare Part D prescription drug event (PDE) data. PDE is readily available to CMS. In addition, CMS provides each Part D sponsor monthly reports of this Poly-ACH measure for monitoring. CMS solicited comments in the 2019 Call Letter and received positive support for the measure as being included in the display page for 2021 (2019 data) and 2022 (2020 data) with consideration for moving the Poly-ACH measure to the Part C & D Star Ratings program pending rulemaking.

How is the measure expected to be reported to the program?

Other: Health plans receive a rate for the measure. We do not provide claims data to health plans.

Feasibility of Data Elements

ALL data elements are in defined fields in administrative claims;ALL data elements are in defined fields in a combination of electronic sources

Evidence of Performance Gap

The measure is anticipated to help health plans with identifying individuals who are experiencing polypharmacy with multiple anticholinergics and may be at risk of cognitive decline. This measure can also facilitate health plans to encourage providers to prescribe anticholinergic medications appropriately and avoid polypharmacy except when clinically necessary. Reduced concurrent prescription of 2 or more anticholinergic medications should result in better patient outcomes and quality of life.

As referenced in the 2019 Call Letter, PQA noted in their Measure Manual, medication combinations in the Poly-ACH measure are associated with serious adverse effects reported in older adults. It is accepted that a high burden of anticholinergic use is consistently associated with cognitive impairment and increased risk of dementia in older adults. Our measure testing demonstrated that rate distributions were variable in use across both MA-PDs and PDPs suggesting that there is an opportunity for

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improvement to reduce the use of multiple concurrent use of ACH medications within Part D enrolled in older adults.

Unintended Consequences

Individuals receiving hospice care are excluded from the POLY-ACH measure, as the AGS Beers Criteria are not in-scope for patients receiving hospice care. Patients receiving hospice care may have unique therapeutic goals, and treatment with anticholinergics may have a balance of benefits and risks that differ from the general population. For these reasons and to avoid unintended consequences, individuals receiving hospice care are excluded from the POLY-ACH measure.

This measure was designed for monitoring and improving quality of care across populations of patients. Medication combinations in this measure are those for which serious adverse effects have been reported among older adults. Therefore, co-prescription of the selected combinations has an unfavorable balance of benefits and harms for many, if not most, older adults. Although the combinations should be avoided in older adults, there are older adults for whom concurrent use of multiple anticholinergic medications may be appropriate. Thus, the combinations are a potential serious safety concern (i.e., potentially inappropriate) and merit special scrutiny, but are not universally unsafe or inappropriate in all older adults.

Outline the clinical guidelines supporting this measure

The American Geriatrics Society 2019 Updated Beers Criteria provides a strong recommendation based on moderate evidence to avoid concurrent use of two or more anticholinergic medications in older adults because of an increased risk of cognitive decline.(1) Numerous scales are available to rank medication anticholinergic activity. The AGS panel used a composite of several scales to compile a list of medications with strong anticholinergic properties.(2-5)

References:

1. American Geriatrics Society 2019 Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019 Apr;67(4):674-694. PMID: 30693946.
2. Durán CE, Azermai M, Vander Stichele RH. Systematic review of anticholinergic risk scales in older adults. Eur J Clin Pharmacol. 2013; 69(7):1485-96. PMID: 23529548.
3. Campbell N, Boustani M, Limbil T, et al. The cognitive impact of anticholinergics: a clinical review. Clin Interv Aging. 2009; 4:225-33. PMID: 19554093.
4. Rudolph JL, Salow MJ, Angelini MC, et al. The anticholinergic risk scale and anticholinergic adverse effects in older persons. Arch Intern Med. 2008; 168(5):508-13. PMID: 18332297.
5. Carnahan RM, Lund BC, Perry PJ, Pollock BG, Culp KR. The Anticholinergic Drug Scale as a measure of drug-related anticholinergic burden: associations with serum anticholinergic activity. J Clin Pharmacol. 2006; 46(12):1481-6. PMID: 17101747.

Were the guidelines graded?

Yes

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If yes, who graded the guidelines?
Grading of Recommendations Assessment, Development and Evaluation (GRADE) guidelines for clinical practice guideline development and consistent with the recommendations from the National Academy of Medicine. American College of Physicians' Guideline Grading System which is based on the GRADE scheme.

If yes, what was the grade?
Recommendations were graded and grade ranges from high, moderate to low. Per the American Geriatrics Society Updated Beers Criteria from 2019 provides a strong recommendation with a moderate evidence to avoid concurrent use of two or more anticholinergic medications in older adults.

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Per the 2019 Patient Safety data, the total Medicare denominator for the POLY-ACH measure was 3,680,077 member-years.

Estimate of Annual Improvement in Measure Score
Data from 2018 and 2019 in the Medicare Part D Patient Safety Reports demonstrate a relatively similar but slight upward trend across both the MAPD and PDP lines of business.

Average MAPD rates 2018: 7.32%

Average MAPD rates 2019: 7.52%

Trend: +0.2%

Average PDP rates 2018: 8.53%

Average PDP rates 2019: 8.54%

Trend: +0.01%

Type of Evidence to Support the Measure
Clinical Guidelines;Systematic Review

Is the measure risk adjusted, stratified, or both?
None

Are social determinants of health built into the risk adjustment model?
No

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
Unable to determine. PQA has not conducted a formal economic analysis of the cost savings with the Poly-ACH measure. However, literature demonstrates that the savings associated with improved performance on the Poly-ACH measure is likely to be substantial. Additionally, literature examining the economic impacts of cognitive decline are limited. Yet, because cognitive decline is associated with increased risk for falls, there is some literature regarding the economic impact information related to falls. Per the CDC, about $50 billion is spent each year on medical costs related to non-fatal fall injuries

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and $754 million is spent related to fatal falls. So potentially, could avoid $50 billion on non-fatal fall injuries and $754 million on fatal falls.

Cost Avoided Annually by Medicare/Provider

Unable to determine. However, per the CDC, about $50 billion is spent each year on medical costs related to non-fatal fall injuries and $754 million is spent related to fatal falls. Of these, about $29 billion is paid by Medicare. So approximately, $29 billion/year could be avoided by Medicare. An additional study estimated (using costs inflated to 2015 dollars) that an average cost of $25,487 per fatal fall and $29,562 per non-fatal fall (hospitalization), $4,763 per non-fatal fall (emergency department), and $5,625 per non-fatal fall (outpatient visit).

Source of Estimate

Estimate is from a study by the Centers for Disease Control and Prevention, National Vital Statistics System, the Web-based Injury Statistics Query and Reporting System, the Medicare Current Beneficiaries Survey, the Medical Expenditure Panel Survey, and the Medicare fee-for-service Standard Analytical File.

Centers for Disease Control and Prevention. Cost of Older Adult Falls. Nd. Available from https://www.cdc.gov/homeandrecreationalsafety/falls/data/fallcost.html.

Florence CS, Bergen G, Atherly A, Burns E, Stevens J, Drake C. Medical Costs of Fatal and Nonfatal Falls in Older Adults. J Am Geriatr Soc. 2018 Apr;66(4):693-698. doi: 10.1111/jgs.15304. Epub 2018 Mar 7. PMID: 29512120.

Burns ER, Stevens JA, Lee R. The direct costs of fatal and non-fatal falls among older adults - United States. J Safety Res. 2016 Sep;58:99-103. doi: 10.1016/j.jsr.2016.05.001. Epub 2016 May 28. PMID: 27620939.

Year of Cost Literature Cited

2015, 2011, 2012, 2007, and 1999 data.

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?

Yes

If yes, choose all methods of obtaining patient/caregiver information

Other: PQA systematically gathered patient input during the development of the Poly-ACH measure through PQA's Patient and Caregiver Advisory Panel (PCAP). The PCAP was a small group of individuals, selected by PQA staff through a nomination process, to provide patient and caregiver input into the measure development process and thereby reflect the patient's voice in PQA measures. The PCAP is charged with reflecting the patient voice in PQA processes through the involvement of patients, caregivers, and patient advocacy organizations. Additionally, through the PCAP, the patient and caregiver input that is provided is integrated where appropriate into the measure development process

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for medication-related measures. The recommendations provided by the PCAP are addressed with the Measure Development Teams and Task Forces to refine measures based on patient characteristics/preferences. The information gathered from the PCAP assist in identifying high priorities for potential new patient-focused measure development work.

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
Once during the specification phase in November 2016.

Total Number of Patients and/or Caregivers Consulted
10

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
The 2016 PCAP consisted of a 1:1 ratio between patient/caregiver/advocates and healthcare professionals. The PCAP did not conduct formal voting on the measure concepts. However, the PCAP provided meaningful feedback and affirmed the importance of measure concepts to patients and caregivers.

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
10

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Other: Measure development teams (MDT), Quality Metrics Expert Panel (QMEP), and Measure Validity Panel (MVP)

Total Number of Clinicians/Providers Consulted
127

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
127

Burden for Provider: Was a provider workflow analysis conducted?
No

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If yes, how many sites were evaluated in the provider workflow analysis?
N/A

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
13

Measure Testing Details

Reliability Testing Interpretation of Results
Based on a mean reliability score of .77 for MAPDs and .82 for PDPs, the measure is considered reliable.

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
Signal to Noise

Reliability Testing Sample Size
PDP: n=69 and MAPD: n=766

Reliability Testing Statistical Result
MAPD:

- Mean: .77
- Standard Deviation (SD): .23
- Min: .12
- Max: 1.00
- PDP:
- Mean: .82
- Standard Deviation (SD): .22
- Min: .18
- Max: 1.00

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Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
Yes

If yes, specify the number of cases and the percentage of providers
Minimum denominator of 30 was used for this measure. Percentages meeting the minimum sample are included: PDP: 84% and MAPD: 61%

Type of Validity Testing
Measure Score Validity

Validity Testing: Type of Validity Testing Analysis
Face Validity

Validity Testing Sample Size
POLY-ACH (face validity): MDT: 29 participants, 17 voting; QMEP: 23 participants, 22 voting; MVP: 10 participants, 10 voting

Validity Testing Statistical Result
POLY-ACH (face validity):

- MDT: 100%
- QMEP: 82%
- MVP: 4.2 / 5 support (Likert scale)

Validity Testing Interpretation of Results
For face validity, findings demonstrate that the measure has face validity.

Measure performance – Type of Score
Other: Score is presented as a percentage

Measure Performance Score Interpretation
Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have
MAPD

- Mean: 7.92%
- SD: 3.16%

PDP

- Mean: 7.53%
- SD: 2.13%

Benchmark, if applicable
Not Applicable.

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Measure Contact Information

Measure Steward
Pharmacy Quality Alliance

Measure Steward Contact Information
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Long-Term Measure Steward
N/A

Long-Term Measure Steward Contact Information
N/A

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Section 2: Preliminary Analysis – MUC2021-056 Polypharmacy: Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH)

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?

Yes/No: Yes

Justification and Notes: This polypharmacy use of anticholinergic medications (Poly-ACH) measure promotes effective communication and coordination of care as well as the effective treatment of chronic diseases, both high priorities for Part D measure consideration. This measure addresses anticholinergic burden, the cumulative effect of using 2 or more medications with ACH properties concurrently, and the adverse effects on older adults (Kouladjian O'Donnell et al., 2016).

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?

Yes/No: Yes

Justification and Notes: This measure is designed to promote safe prescribing practices relating to anticholinergic medications in older adults. The American Geriatrics Society 2019 Updated Beers Criteria provided a strong recommendation based on moderate-to-high evidence (depending on which specific agent) to avoid concurrent use of two or more ACH-active agents in older adults due to risk of cognitive decline (Fixen, 2019). The anticholinergic burden can lead to an increased risk for hospitalization, falls, and medical utilization along with a decreased overall quality of life (Rochon et al., 2021).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: Use of anticholinergic medications has been associated with impaired cognitive and physical function, increased risk of falls, vascular events, and hospitalization. The developer notes that anticholinergics may increase risk for falls (Odds Ratio: 1.8). Age-related pharmacokinetic and pharmacodynamic changes in older adults increases the risk of adverse drug related events, including, cognitive impairment, confusion, delirium and falls (Kouladjian O'Donnell et al., 2016). The consequences of these adverse events could lead to poor patient outcomes and a poor quality of life.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?

Yes/No: Yes

Justification and Notes: This process measure is in the Medicare Part C & D Display Page and previously in the Part D Patient Safety (2018) setting. The measure developer has reported no related and/or competing measures. However, the measure steward Pharmacy Quality Alliance (PQA) has submitted MUC 21.066 Polypharmacy: Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS) as a potential measure for 2021-2022.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure was previously reported on as part of Medicare's Part D Patient Safety reporting in 2018 and Part C & D's Display Page from 2019-2020. The measure uses data from

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administrative (non-claims), claims, PQA National Drug Codes Medication Value Sets, Common Medicare Environment, and the Medicare enrollment database for reporting. The primary data source used for this measure is Medicare Part D prescription drug event (PDE) data. In addition, CMS provides each Part D sponsor monthly reports of this Poly-ACH measure for monitoring.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: Yes

Justification and Notes: This measure is not endorsed by NQF. The process measure specified for the health plan level. The measure was tested for reliability and validity using the Signal to Noise ratio and Face Validity test, respectively. The measure was tested for reliability using a sample size composed of prescription drug plans (PDP) and Medicare Advantage prescription drug plans (MAPD) (PDP: n=69; MAPD: n=766). Reliability average scores were as follows, MAPD mean: .77, PDP mean: .82. The measure developer used a face validity analysis to show validity with a sample size of 62 participants. The sample size was comprised of measure development teams (MDT), measure validity panel members (MVP), and quality metrics expert panel members (QMEP). Validity results showed 100% support from MDT, 82% support from QMEP, and 4.2/5 support (Likert scale) from MVP participants. The developer notes that the Poly-ACH measure has reliability and face validity.

If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure been identified?

Yes/No: No

Justification and Notes: The measure is implemented within Medicare Part D and included as one of the display pages measures. Those receiving hospice care may have unique therapeutic goals, and treatment with anticholinergics may have risks that differ from the general population. The measure developer excluded patients receiving hospice care from the POLY-ACH measure to avoid any unintended consequences.

The MAP Clinician workgroup raised questions regarding potential negative unintended consequences from the implementation of this measure. MAP noted denominator concerns raised in the public comments. Efforts to reduce overall opioid use in the population may reduce the denominator population, which may inadvertently make performance on the measure look worse.

PAC/LTC Core Concept?

N/A

Impact Act Domain

N/A

Hospice High Priority Areas

N/A

MAP Rural Health Advisory Group Input:

Relative priority/utility:

- This measure was suggested to be relevant to older rural residents.
- Concerns raised regarding the included medications (e.g., prescribed vs. OTC).

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Data collection issues:
- Data collection is at the health plan level which does not present any additional burden for rural providers.

Calculation issues:
- None identified.

Unintended consequences:
- Concerns raised regarding de-prescribing appropriately.

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 4.0
1 – 0 votes
2 – 0 votes
3 – 4 votes
4 – 7 votes
5 – 4 votes

MAP Health Equity Advisory Group Input:
Relative priority/utility:
- The measure is an important polypharmacy related to patient safety.

Data collection issues:
- None identified.

Calculation issues:
- Lack of stratification was identified as a priority for this measure
- No other issues identified.

Unintended consequences:
- None identified.

Votes: Range is 1 – 5, where higher number has greater potential for positive impact on health equity.
Average: 3.2
1 – 0 votes
2 – 2 votes
3 – 14 votes
4 – 4 votes
5 – 1 vote

Recommendation

Preliminary Analysis Recommendation:
Conditional Support for Rulemaking, pending NQF endorsement.

Summary: What is the potential value to the program measure set?
Conditional support pending submission of measure for NQF endorsement.
This measure addresses polypharmacy of ACH-active medications in older adults and the effective communication and coordination of care and effective treatment of chronic diseases, a high priority for Part D measure consideration. The MAP Clinician workgroup encouraged CMS to monitor for potential negative unintended consequences due to the denominator definition raised by the commenters.

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Summary: What is the potential impact of this measure on quality of care for patients?

This measure focuses on monitoring beneficiaries 65 years of age and older at risk for cognitive decline due to anticholinergic burden. The anticholinergic burden can lead to an increased risk for hospitalization, falls, and medical utilization along with a decreased overall quality of life (Rochon et al., 2021).

Section 3: Public Comments

Blue Cross Blue Shield of Massachusetts

BCBSMA opposes any high-stakes use of MUC2021-056 (Polypharmacy: Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH)) due to serious flaws in the measure specification that undermine its validity. Similar to MUC2021-053 (Concurrent Use of Opioids and Benzodiazepines (COB)) and MUC2021-066 (Polypharmacy: Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS)), the denominator for MUC2021-056 is restricted to patients who fill high-risk drugs (at least 2 fills of anticholinergic drugs included in the measure numerator) that are overused and that should be prescribed less frequently overall. If a provider or health plan or any other measured entity conducts a successful program to reduce the unnecessary use of these high-risk denominator drugs, this would be a good thing for public health. But as currently specified, MUC2021-056 will penalize the measured entity in this scenario by shrinking the measure denominator, thus raising the measure score. When truly better care produces a higher score on a lower-is-better/higher-is-worse measure like MUC2021-056, this is a fundamental threat to measure validity. In other words, the directionality of better care (is "better" represented by a higher or lower score?) on this measure, as currently specified, is unknown. Therefore, this measure is unsuitable for high-stakes applications such as payment and public reporting. We advise the measure developer to use a different measure denominator that does not hinge on prescribing high-risk drugs. For example, using the count of members attributed to a measured entity, regardless of drug use, as the denominator would avoid this validity threat entirely.

American Medical Association

The American Medical Association (AMA) supports the consideration of measures that address patient safety including the overuse of medications, particularly in the elderly but believe that the potential unintended consequences to patient care must be continuously monitored. We urge the Centers for Medicare and Medicaid Services to evaluate whether implementation of this measure leads to payers limiting access or requiring prior authorization when the prescription of more than one medication may be clinically appropriate. In addition, we note that the minimum measure score reliability was well below what we consider to be the acceptable threshold of 0.7 and the minimum number of cases for inclusion in the measure should be increased. As a result, the AMA recommends that the highest level of MAP recommendation be "Do Not Support with Potential for Mitigation."

AHIP

On behalf of AHIP, thank you for the opportunity to comment on this measure. We appreciate CMS's efforts to ensure safe prescribing of these medications and protect patients from harm occurring from interactions between medications. However, we are concerned that implementing this measure in the

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Star Ratings at this time could have negative consequences for patients. We believe it may be premature to move this measure from the Display Page without a full assessment of its current specifications and exclusions. We are concerned that moving this measure from the Display Page to the Star Ratings without adequate exclusions could result in beneficiaries having limited safe and efficacious therapeutic alternatives for treatments like pain management. We urge the MAP and CMS to leave this measure on the Display Page to allow health plans, CMS, and the measure developer an opportunity to understand how this measure currently performs, potential negative consequences of its implementation, and if there is a need for refinement of the specifications to ensure that patients are not denied necessary treatments. Leaving the measure on the Display Page would still allow health plans to understand and improve performance and consumers to assess health plan results. We believe this would allow stakeholders the information they need while protecting patients from access challenges. Until the measure undergoes further evaluation, we ask the MAP to give this measure a recommendation of "Do Not Support" for the Star Ratings program.

Johnson & Johnson

Johnson & Johnson supports the recommendation of the Workgroup.

American Medical Association

The American Medical Association (AMA) supports the current recommendation for this measure but asks that additional detail regarding the negative unintended consequences be added to the rationale; specifically, whether implementation of this measure leads to payers limiting access or requiring prior authorization when the prescription of more than one medication may be clinically appropriate.

AHIP

On behalf of AHIP, thank you for the opportunity to comment on this measure. We appreciate CMS's efforts to ensure safe prescribing of these medications and protect patients from harm occurring from interactions between medications and appreciate MAP's concerns about the risks of inappropriate prescribing.

However, as noted in our comments to the Clinician Workgroup, we are concerned that implementing this measure in the Star Ratings at this time could have negative consequences for patients. We believe it may be premature to move this measure from the Display Page without a full assessment of its current specifications and exclusions. We are concerned that moving this measure from the Display Page to the Star Ratings without adequate denominator exclusions could result in beneficiaries having limited treatment options or being inappropriately deprescribed from a necessary medication. For example, tricyclic antidepressants are considered anticholinergic medications. Discontinuation of these medications requires a multi-week taper to avoid symptoms of withdrawal.

We urge the Coordinating Committee to re-evaluate the MAP recommendation on this measure due to the risk of causing access challenges for patients who need these medications. The Coordinating Committee should instead give this measure a MAP recommendation of Do Not Support or Do Not Support with Potential for Mitigation. MAP should recommend that CMS to leave this measure on the Display Page to allow health plans, CMS, and the measure developer an opportunity to understand how this measure currently performs, potential negative consequences of its implementation, and if there is a need for refinement of the specifications to ensure that patients are not denied necessary treatments. Leaving the measure on the Display Page would still allow health plans to understand and improve

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performance and consumers to assess health plan results. We believe this would allow stakeholders the information they need while protecting patients from access challenges.

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MUC2021-066 Polypharmacy: Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS)

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Part C & D Star Rating [Medicare]

Workgroup
Clinician

Measure Description
The percentage of Medicare Part D beneficiaries 65 years of age or older, with concurrent use of 3 or more unique central-nervous system (CNS)-active medications during the measurement period.

Numerator
Number of member-years of beneficiaries in the denominator with concurrent use of 3 or more CNS-active medications during the measurement period. Each medication must have at least 2 fills with unique DOS during the measurement period.

Concurrent Use: To determine concurrent use, a beneficiary's number of overlapping days' supply is determined for each measurement period.

Use the prescriptions' DOS and days' supply to count the number of days the beneficiary was covered by CNS-active medications.

If multiple prescription claims for the same CNS-active medication (active ingredient) are dispensed on the same day, calculate the number of days covered by the target medication using the claim with the longest days' supply.

If multiple prescription claims for the same CNS-active medication (active ingredient) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. These is no adjustment for early fills or overlapping days' supply.

The days covered by three or more unique CNS-active medications during the measurement period are considered days of overlapping supply. Concurrent use is defined as 30 or more cumulative overlapping days' supply of at least 3 unique CNS-active medications.

Numerator Exclusions
N/A

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Denominator
Number of member-years of enrolled beneficiaries, 65 years or older, with at least 2 fills with unique dates of service (DOS) of the same medication in the targeted drug class(es) (CNS-active) during the measurement period.

Denominator Exclusions
Beneficiaries enrolled in hospice at any time during the measurement period are excluded from the denominator. Additionally, beneficiaries with a seizure disorder diagnosis are excluded from the denominator.

Denominator Exceptions
N/A

State of development
Fully Developed

State of Development Details
Currently the measure is fully developed and implemented within Medicare Part D. This measure is included as one of the Medicare Part D display page measures that is publicly displayed on the CMS's Part C & D Performance Data website.

What is the target population of the measure?
Medicare Part D members within Prescription Drug Plans and Medicare Advantage Prescription Drug Plans.

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Emergency medicine;Family practice ;General practice;Geriatric medicine;Internal medicine;Neurology ;Primary care

Measure Type
Process

Is the measure a composite or component of a composite?
No

If Other, Please Specify

What data sources are used for the measure?
Administrative Data (non-claims);Claims Data;Other: Pharmacy Quality Alliance (PQA) National Drug Codes (NDC) Medication Value Sets, Common Medicare Environment (CME), Medicare Enrollment Database (EDB), Common Working File (CWF), and Encounter Data Systems (EDS)

If applicable, specify the data source
N/A

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If EHR or Chart-Abstracted data, description of parts related to these sources
N/A

At what level of analysis was the measure tested?
Health Plan

In which setting was this measure tested?
Other: Medicare Part D health plans (Medicare Advantage Prescription Drug Plans and Prescription Drug Plans)

What one healthcare domain applies to this measure?
Chronic Conditions

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
N/A

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
N/A

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Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?
No

If eCQM, enter Measure Authoring Tool (MAT) number
N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
Measure currently used in a CMS program being submitted as-is for a new or different program

Range of years this measure has been used by CMS Programs
Medicare Part D Patient Safety reporting 2018. Part C & D Display Page 2019-2020

What other federal programs are currently using this measure?
Part C & D Display Page (Medicare) and previously Part D Patient Safety Reporting (Medicare).

Is this measure similar to and/or competing with a measure(s) already in a program?
No

Which measure(s) already in a program is your measure similar to and/or competing with?
N/A

How will this measure be distinguished from other similar and/or competing measures?
N/A

How will this measure add value to the CMS program?
N/A

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If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure

A recent analysis published in JAMA in 2017 showed that CNS polypharmacy in older adults has been trending upward.(1) The frequency of three or more CNS-active medications being initiated or continued in older adults during a physician office visit more than doubled from 2004 to 2013. In particular, nearly half (46%) of CNS polypharmacy visits for older adults in 2013 were for individuals without pain, insomnia, or other mental health diagnoses. This is consistent with other findings suggesting frequent CNS use in older adults: among a sample of 18,752 nursing home residents across two states in 2013, 66.8% received at least one CNS-active drug.(2)

Multiple studies of older adults have reported that the use of CNS-active medications is linked to an increased risk of fractures, falls, and recurrent falls.(3-7) Specifically, a cohort study published in 1998 found that older adults taking one or more CNS-active medications were at a 1.5-fold increased risk (OR 1.54; 95% CI 1.07-2.22) and those taking two or more CNS-active medications were at a 2.5-fold increased risk (OR 2.37; 95% CI 1.14-4.94) of falling compared to a reference group of no CNS-active medications, suggesting that a dose-response relationship exists between CNS-active medications and falls.(3) A nested case-control study of adults 65 and over using data from 1994 to 2005 (including 17,198 cases and 85,990 controls) found that the risk ratio for concomitant use of benzodiazepines and interacting drugs, and hip fracture, ranged from 1.5 (95% CI 1.3, 1.7) to 2.1 (95% CI 1.5, 2.8).(4)

A 2009 longitudinal cohort study following 3,055 older adults annually for five years found that as many as 24.1% of CNS-users took multiple agents annually.(5) Those taking multiple CNS medications had an increased risk of recurrent falls (OR 1.95; 95% CI 1.35-2.81) compared to non-users, and patients taking higher doses of CNS-active medications had a threefold increased risk (OR 2.89; 95% CI 1.96-4.25) of recurrent falls.(6) Additionally, a nested case-control study of 5,556 nursing home residents using 2010 data found that patients taking 3 or more CNS-active standardized daily doses were more likely to have a serious fall than those who did not take any CNS medications (adjusted OR 1.83; 95% CI 1.35-2.48).(7)

References:

1. Maust DT, Gerlach LB, Gibson A, et al. Trends in Central Nervous System-Active Polypharmacy Among Older Adults Seen in Outpatient Care in the United States. JAMA Intern Med. 2017; 177(4):583-585. PMID: 28192559.
2. Bathena SP, Lippek IE, Kanner AM, Birnbaum AK. Antiseizure, Antidepressant, and Antipsychotic Medication Prescribing in Elderly Nursing Home Residents. Epilepsy Behav. 2017;69:116-20. PMID: 28242474.
3. Weiner DK, Hanlon JT, Studenski SA. Effects of central nervous system polypharmacy on falls liability in community-dwelling elderly. Gerontology. 1998; 44(4):217-21. PMID: 9657082.

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4. Zint K, Haefeli WE, Glynn RJ, et al. Impact of drug interactions, dosage, and duration of therapy on the risk of hip fracture associated with benzodiazepine use in older adults. Pharmacoepidemiol Drug Saf. 2010; 19(12):1248-55. PubMed PMID: 20931664.
5. Hanlon JT, Boudreau RM, Roumani YF, et al. Number and dosage of central nervous system medications on recurrent falls in community elders: the Health, Aging and Body Composition study. J Gerontol A Biol Sci Med Sci. 2009; 64(4):492-8. PMID: 19196642.
6. Nurminen J, Puustinen J, Piirtola M, et al. Opioids, antiepileptic and anticholinergic drugs and the risk of fractures in patients 65 years of age and older: a prospective population-based study. Age and Ageing. 2013; 42(3):318-24. PMID: 23204431.
7. Hanlon JT, Zhao X, Thorpe CT. Central Nervous System Medication Burden and Serious Falls in Older Nursing Home Residents. J Am Geriatr Soc. 2017;65(6):1183-89. PMID: 28152179.

Evidence that the measure can be operationalized

Medicare Part D Prescription Drug Event (PDE) data is readily available to CMS. In addition, CMS provides each Part D sponsor monthly reports of this Poly-CNS measure for monitoring. CMS solicited comments in the 2019 Call Letter and received positive support for the measure as being included in the display page for 2021 (2019 data) and 2022 (2020 data) with consideration for moving the Poly-CNS measure to the Part C & D Star Ratings program pending rulemaking.

How is the measure expected to be reported to the program?

Other: Health plans receive a rate for the measure. We do not provide claims data to health plans.

Feasibility of Data Elements

ALL data elements are in defined fields in administrative claims;ALL data elements are in defined fields in a combination of electronic sources

Evidence of Performance Gap

The measure is anticipated to help health plans with identifying individuals who are experiencing polypharmacy with multiple CNS-active medications and may be at risk for fractures or falls. This measure can also facilitate health plans encouragement of providers to prescribe CNS-active medications appropriately and avoid polypharmacy except when clinically necessary. Reduced concurrent prescription of 3 or more CNS active medications should result in better patient outcomes and quality of life.

Per the 2019 Call Letter, we noted that according to the American Geriatrics Society, there is moderate evidence to avoid concurrent use of three or more CNS agents in older adults due to an increased risk of falls and possible fractures. Based on our testing, we found variability across Part D contracts on the use of multiple concurrent CNS medications. CMS believes that the Poly-CNS measures represents an opportunity to identify and reduce concurrent use of multiple CNS medications and improve the health of Medicare Part D enrollees.

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Unintended Consequences

Individuals receiving hospice care are excluded from the POLY-CNS measure, as the AGS Beers Criteria are not in-scope for patients receiving hospice care. Patients receiving hospice care may have unique therapeutic goals, and treatment with anticholinergics may have a balance of benefits and risks that differ from the general population. For these reasons and to avoid unintended consequences, individuals receiving hospice care are excluded from the POLY-CNS measure.

Additionally, individuals with a seizure disorder are excluded from the POLY-CNS measure. With the addition of antiepileptics to the medication tables, subject matter experts involved in PQA's measure maintenance process raised concerns about unintended consequences with the measure penalizing providers for patients with seizure disorders that may require antiepileptics and other CNS-active medications (such as antidepressants), noting that patients with seizure disorders who are being stably treated with antiepileptics should not be incentivized to change that patient's regimen. To mitigate unintended consequences, individuals with seizure disorders are excluded from the POLY-CNS measure.

This measure was designed for monitoring and improving quality of care across populations of patients. Concurrent use of CNS-active medications in this measure are those for which serious adverse effects have been reported among older adults. Therefore, co-prescription of the selected CNS-active medications has an unfavorable balance of benefits and harms for many, if not most, older adults. Although the combinations should be avoided in older adults, there are older adults for whom concurrent use of multiple CNS-active medications may be appropriate. Thus, the combinations are a potential serious safety concern (i.e., potentially inappropriate) and merit special scrutiny, but are not universally unsafe or inappropriate in all older adults.

The measure is anticipated to help health plans with identifying individuals who are experiencing polypharmacy with multiple CNS-active medications and may be at risk for fractures or falls. This measure can also facilitate health plans encouragement of providers to prescribe CNS-active medications appropriately and avoid polypharmacy except when clinically necessary. Reduced concurrent prescription of 3 or more CNS active medications should result in better patient outcomes and quality of life.

Outline the clinical guidelines supporting this measure

The American Geriatrics Society 2019 Updated Beers Criteria provided a strong recommendation based on moderate-to-high evidence (depending on which specific agent) to avoid concurrent use of three or more CNS-active agents in older adults because of an increased risk of falls, and for some CNS-active combinations, fractures (see Appendix for Evidence Table).1 CNS-active medications are defined as: antiepileptics; antipsychotics; antidepressants (i.e. selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors, tricyclic antidepressants); benzodiazepines and nonbenzodiazepine sedative/hypnotics; and opioid analgesics.

Were the guidelines graded?

Yes

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If yes, who graded the guidelines?
Grading of Recommendations Assessment, Development and Evaluation (GRADE) guidelines for clinical practice guideline development and consistent with the recommendations from the National Academy of Medicine. American College of Physicians' Guideline Grading System which is based on the GRADE scheme.

If yes, what was the grade?
Recommendations were graded. Grade ranges from high, moderate to low. Per the American Geriatrics Society Updated Beers Criteria from 2019 provides a strong recommendation based on moderate to high evidence to avoid unless safer alternatives are not available. Avoid antiepileptics except for seizure and mood disorders.

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Per the 2019 Patient Safety data, the total Medicare denominator for the POLY-CNS measure was 11,286,186 member-years.

Estimate of Annual Improvement in Measure Score
Data from 2018 and 2019 in the Medicare Part D Patient Safety Reports demonstrate downward trend across both the MAPD and PDP lines of business.

Average MAPD rates 2018: 6.39%

Average MAPD rates 2019: 5.71%

Trend: -0.68%

Average PDP rates 2018: 7.36%

Average PDP rates 2019: 6.54%

Trend: -0.82%

Type of Evidence to Support the Measure
Clinical Guidelines; Systematic Review

Is the measure risk adjusted, stratified, or both?
None

Are social determinants of health built into the risk adjustment model?
No

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
Unable to determine. PQA has not conducted a formal economic analysis of the cost savings associated with the Poly-CNS measure. However, the literature demonstrates that savings associated with improved performance on the Poly-CNS measure is likely to be substantial. Additionally, literature examining the economic impacts of cognitive decline are limited. Yet, because cognitive decline is

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associated with increased risk for falls, there is some literature regarding the economic impact information related to falls. The literature demonstrates that savings associated with improved performance on these measures is likely to be substantial. Per the CDC, about $50 billion is spent each year on medical costs related to non-fatal fall injuries and $754 million is spent related to fatal falls. So potentially, could avoid $50 billion on non-fatal fall injuries and $754 million on fatal falls.

Cost Avoided Annually by Medicare/Provider

Unable to determine. However, per the CDC, about $50 billion is spent each year on medical costs related to non-fatal fall injuries and $754 million is spent related to fatal falls. Of these, about $29 billion is paid by Medicare. So approximately, $29 billion/year could be avoided by Medicare. An additional study estimated (using costs inflated to 2015 dollars) that an average cost of $25,487 per fatal fall and $29,562 per non-fatal fall (hospitalization), $4,763 per non-fatal fall (emergency department), and $5,625 per non-fatal fall (outpatient visit).

Source of Estimate

Estimate is from the Centers for Disease Control and Prevention, a study by the National Vital Statistics System, the Web-based Injury Statistics Query and Reporting System, the Medicare Current Beneficiaries Survey, the Medical Expenditure Panel Survey, and the Medicare fee-for-service Standard Analytical File.

Centers for Disease Control and Prevention. Cost of Older Adult Falls. Nd. Available from https://www.cdc.gov/homeandrecreationalsafety/falls/data/fallcost.html

Florence CS, Bergen G, Atherly A, Burns E, Stevens J, Drake C. Medical Costs of Fatal and Nonfatal Falls in Older Adults. J Am Geriatr Soc. 2018 Apr;66(4):693-698. doi: 10.1111/jgs.15304. Epub 2018 Mar 7. PMID: 29512120.

Burns ER, Stevens JA, Lee R. The direct costs of fatal and non-fatal falls among older adults - United States. J Safety Res. 2016 Sep;58:99-103. doi: 10.1016/j.jsr.2016.05.001. Epub 2016 May 28. PMID: 27620939.

Year of Cost Literature Cited

2015, 2011, 2012, 2007, and 1999 data.

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?

Yes

If yes, choose all methods of obtaining patient/caregiver information

Other: PQA systematically gathered patient input during the development of the Poly-CNS measure through PQA's Patient and Caregiver Advisory Panel (PCAP). The PCAP was a small group of individuals, selected by the PQA staff through a nomination process, to provide patient and caregiver input into the

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measure development process and thereby reflect the patient's voice in PQA measures. The PCAP is charged with reflecting the patient voice in PQA's processes through the involvement of patients, caregivers, and patient advocacy organizations; providing patient and caregiver input where appropriate into the measure development process for medication-related measures; providing recommendations to the Measure Development Teams (MDTs) and Task Forces to refine measures based on patient characteristics/preferences; and assisting in identifying high priorities for potential new patient-focused measure development work.

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
Once during specification phase in November 2016.

Total Number of Patients and/or Caregivers Consulted
10

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
The 2016 PCAP consisted of a 1:1 ratio between patient/caregiver/advocates and healthcare professionals. The PCAP did not conduct formal voting on the Poly-CNS measure concept. The PCAP provided meaningful feedback and affirmed the importance of measure concepts to patients and caregivers.

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
10

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Other: Measure development teams (MDT), Quality Metrics Expert Panel (QMEP), and Measure Validity Panel (MVP)

Total Number of Clinicians/Providers Consulted
121

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Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
121

Burden for Provider: Was a provider workflow analysis conducted?
No

If yes, how many sites were evaluated in the provider workflow analysis?
N/A

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
13

Measure Testing Details

Reliability Testing Interpretation of Results
Based on a mean reliability score of .88 for MAPDs, .91 for PDPs, and .88 for Medicaid plans, the measure is considered reliable.

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
Signal to Noise

Reliability Testing Sample Size
PDP: n=69; MAPD: n=766; and Medicaid: n=21

Reliability Testing Statistical Result
MAPD:

- Mean: .88
- Standard Deviation (SD): .17
- Min: .15
- Max: 1.00

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PDP:

- Mean: .91
- Standard Deviation (SD): .14
- Min: .37
- Max: 1.00

Medicaid:

- Mean: .88
- Standard Deviation (SD): .13
- Min: .56
- Max: 1.00

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?

Yes

If yes, specify the number of cases and the percentage of providers

Minimum denominator of 30 was used for the Poly-CNS measure. Percentages meeting the minimum sample are included: PDP: 84%; MAPD: 64%; and Medicaid: 71%.

Type of Validity Testing

Measure Score Validity

Validity Testing: Type of Validity Testing Analysis

Face Validity

Validity Testing Sample Size

MDT: 29 participants, 17 voting; QMEP: 23 participants, 22 voting; MVP: 10 participants, 10 voting

Validity Testing Statistical Result

- MDT: 100% support
- QMEP: 82% support
- MVP: 4.3 / 5 support (Likert scale)

Validity Testing Interpretation of Results

Findings demonstrate that the Poly-CNS measure has face validity.

Measure performance – Type of Score

Other: Score is presented as a percentage

Measure Performance Score Interpretation

Lower score is better

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Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have

MAPD

- Mean: 6.31%
- SD: 3.03%

PDP

- Mean: 5.93%
- SD: 1.56%

Benchmark, if applicable

Not applicable.

Measure Contact Information

Measure Steward

Pharmacy Quality Alliance

Measure Steward Contact Information

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508-454-4442

Long-Term Measure Steward

N/A

Long-Term Measure Steward Contact Information

N/A

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410-786-1103

Section 2: Preliminary Analysis – MUC2021-066 Polypharmacy: Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS)

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

Justification and Notes: This Poly-CNS measure promotes effective communication and coordination of care, a high priority for Part D measure consideration. The measure addresses polypharmacy, the concurrent use of multiple medications, specifically central nervous system (CNS) active medications and the increased risk for an adverse drug event in older adults (Rochon et al., 2021). There are no competing measures to note.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes

Justification and Notes: This process measure is designed to avoid polypharmacy and encourage providers to prescribe CNS-active medications appropriately. The American Geriatrics Society 2019 Updated Beers Criteria provided a strong recommendation based on moderate-to-high evidence (depending on which specific agent) to avoid concurrent use of three or more CNS-active agents in older adults because of an increased risk of falls (Fixen, 2019). The reduced concurrent prescription of 3 or more CNS active medications can result in better patient outcomes and quality of life.

Does the measure address a quality challenge?
Yes/No: Yes

Justification and Notes: This measure addresses associated risk factors of polypharmacy in older adults prescribed CNS-active medications. Among a sample of 18,752 nursing home residents across two states in 2013, 66.8% received at least one CNS-active medication (Bathena et al., 2017). Polypharmacy has been shown to be an important risk factor for falling in older adults, increasing the likelihood of adverse drug events including fractures. Approximately 73%-90% of hip fractures among the elderly result from a fall (Lai et al., 2010).

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Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?

Yes/No: Yes

Justification and Notes: This measure is in the Part C & D Display Page (Medicare) and previously Part D Patient Safety Reporting (Medicare) setting. This measure has no related and/or competing measures to note. However, the measure steward Pharmacy Quality Alliance (PQA) has submitted MUC2021-056Polypharmacy: Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH) as a potential measure for 2021-2022.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure was previously reported on as part of Medicare's Part D Patient Safety reporting in 2018 and Part C & D's Display Page from 2019-2020. The measure uses data from administrative (non-claims), claims, PQA National Drug Codes Medication Value Sets, Common Medicare Environment, and the Medicare enrollment database for reporting.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: Yes

Justification and Notes: This measure is not endorsed by NQF. The process measure specified for the health plan level. The measure was tested for reliability using a sample size composed of prescription drug plans (PDP), Medicare Advantage prescription drug plans (MAPD), and Medicaid (PDP: n=69; MAPD: n=766; and Medicaid: n=21). Reliability average scores were as follows, MAPD mean: .88, PDP mean: .91, Medicaid mean: .88. The measure developer used a face validity analysis to show validity with a sample size of 62 participants. The sample size was comprised of measure development teams (MDT), measure validity panel members (MVP), and quality metrics expert panel members (QMEP). Validity results showed 100% support from MDT, 82% support from QMEP, and 4.3/5 support (Likert scale) from MVP participants. The developer notes that the Poly-CNS measure has reliability and face validity.

If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure been identified?

Yes/No: No

Justification and Notes: The measure is currently implemented within Medicare Part D. However, the measure developer did exclude patients enrolled in hospice care and those diagnosed with a seizure disorder to avoid any unintended consequences. The measure developer raised concerns about unintended consequences with the measure penalizing providers for patients with seizure disorders that may require antiepileptics and other CNS-active medications (such as antidepressants), noting that patients with seizure disorders who are being stably treated with antiepileptics should not be incentivized to change medications. Individuals receiving hospice care are excluded from the POLY-CNS measure, as the American Geriatric Society (AGS) Beers Criteria are not in-scope for patients receiving hospice care.

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The MAP Clinician workgroup raised questions regarding potential negative unintended consequences from the implementation of this measure. The MAP noted denominator concerns raised in the public comments. Efforts to reduce overall targeted drug class(es) (CNS-active) use during the measurement period may reduce the denominator population, which may inadvertently make performance on the measure look worse.

PAC/LTC Core Concept?

N/A

Impact Act Domain

N/A

Hospice High Priority Areas

N/A

MAP Rural Health Advisory Group Input:

Relative priority/utility:

- This measure was suggested to be an important area for geriatric populations in rural communities.

Data collection issues:

- Concerns raised regarding the capture of medication use in nursing homes (e.g., short stay versus long stay patients)

Calculation issues:

- None identified.

Unintended consequences:

- None identified.

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 3.9
1 – 0 votes
2 – 2 votes
3 – 2 votes
4 – 8 votes
5 – 4 votes

MAP Health Equity Advisory Group Input:

Relative priority/utility:

- Measure is an important to address for patient safety.
- Important impact on institutionalization for people with disabilities

Data collection issues:

- None identified.

Calculation issues:

- Stratification was identified as a priority for this measure
- No other issues identified.

Unintended consequences:

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- The advisory group noted that hospice patients and seizure diagnoses excluded to reduce unintended consequences.

Votes: Range is 1 – 5, where higher number has greater potential for positive impact on health equity.
Average: 3.2
1 – 0 votes
2 – 2 votes
3 – 13 votes
4 – 7 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:
Conditional Support for Rulemaking, pending NQF endorsement.

Summary: What is the potential value to the program measure set?
Conditional support pending submission of measure for NQF endorsement.
This measure addresses polypharmacy of CNS-active medications in older adults and the effective communication and coordination of care, a high priority for Part D measure consideration. The MAP Clinician workgroup encouraged CMS to monitor for potential negative unintended consequences due to the denominator definition raised by the commenters.

Summary: What is the potential impact of this measure on quality of care for patients?
This measure focuses on identifying individuals prescribed multiple CNS-active medications and monitoring them for adverse drug events, including falls and fractures. The reduced concurrent prescription of 3 or more CNS active medications can result in better patient outcomes and quality of life.

Section 3: Public Comments

Blue Cross Blue Shield of Massachusetts
BCBSMA opposes any high-stakes use of MUC2021-066 (Polypharmacy: Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS)) due to serious flaws in the measure specification that undermine its validity. Similar to MUC2021-053 (Concurrent Use of Opioids and Benzodiazepines (COB)) and MUC2021-056 (Polypharmacy: Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH)) and MUC2021-056 (Polypharmacy: Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH)), the denominator for MUC2021-066 is restricted to patients who fill high-risk drugs (at least 2 fills of the CNS-active drugs included in the measure numerator) that are overused and that should be prescribed less frequently overall. If a provider or health plan or any other measured entity conducts a successful program to reduce the unnecessary use of these high-risk denominator drugs, this would be a good thing for public health. But as currently specified, MUC2021-

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066 will penalize the measured entity in this scenario by shrinking the measure denominator, thus raising the measure score. When truly better care produces a higher score on a lower-is-better/higher-is-worse measure like MUC2021-066, this is a fundamental threat to measure validity. In other words, the directionality of better care (is "better" represented by a higher or lower score?) on this measure, as currently specified, is unknown. Therefore, this measure is unsuitable for high-stakes applications such as payment and public reporting. We advise the measure developer to use a different measure denominator that does not hinge on prescribing high-risk drugs. For example, using the count of members attributed to a measured entity, regardless of drug use, as the denominator would avoid this validity threat entirely.

AHIP

On behalf of AHIP, thank you for the opportunity to comment on this measure. We appreciate CMS's efforts to ensure safe prescribing of these medications and protect patients from harm occurring from interactions between medications. However, we are concerned that implementing this measure in the Star Ratings at this time could have negative consequences for patients. We believe it may be premature to move this measure from the Display Page without a full assessment of its current specifications and exclusions. We are concerned that moving this measure from the Display Page to the Star Ratings without adequate exclusions could result in beneficiaries having limited safe and efficacious therapeutic alternatives for treatments like pain management. We urge the MAP and CMS to leave this measure on the Display Page to allow health plans, CMS, and the measure developer an opportunity to understand how this measure currently performs, potential negative consequences of its implementation, and if there is a need for refinement of the specifications to ensure that patients are not denied necessary treatments. Leaving the measure on the Display Page would still allow health plans to understand and improve performance and consumers to assess health plan results. We believe this would allow stakeholders the information they need while protecting patients from access challenges. Until the measure undergoes further evaluation, we ask the MAP to give this measure a recommendation of "Do Not Support" for the Star Ratings program.

Johnson & Johnson

Johnson & Johnson supports the recommendation of the Workgroup.

American Medical Association

The American Medical Association (AMA) supports the current recommendation for this measure but asks that additional detail regarding the negative unintended consequences be added to the rationale; specifically, whether implementation of this measure leads to payers limiting access or requiring prior authorization when the prescription of more than one medication may be clinically appropriate.

AHIP

On behalf of AHIP, thank you for the opportunity to comment on this measure. We appreciate CMS's efforts to ensure safe prescribing of these medications and protect patients from harm occurring from interactions between medications and appreciate MAP's concerns about the risks of inappropriate prescribing.

However, as noted in our comments to the Clinician Workgroup, we are concerned that implementing

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this measure in the Star Ratings at this time could have negative consequences for patients. We believe it may be premature to move this measure from the Display Page without a full assessment of its current specifications and exclusions. We are concerned that moving this measure from the Display Page to the Star Ratings without adequate denominator exclusions could result in beneficiaries having limited treatment options. For example, numerous therapeutic categories including antipsychotics, opioids, selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors, tricyclic antidepressants, and antiepileptics. While we agree these medications should be prescribed carefully there are select patient populations who may need these medications to address comorbid conditions. Moreover, these medications require careful discontinuation and incentivizing abrupt changes could jeopardize patient safety.

We urge the Coordinating Committee to re-evaluate the MAP recommendation on this measure due to the risk of causing access challenges for patients who need these medications. The Coordinating Committee should instead give this measure a MAP recommendation of Do Not Support or Do Not Support with Potential for Mitigation. MAP should recommend that CMS to leave this measure on the Display Page to allow health plans, CMS, and the measure developer an opportunity to understand how this measure currently performs, potential negative consequences of its implementation, and if there is a need for refinement of the specifications to ensure that patients are not denied necessary treatments. Leaving the measure on the Display Page would still allow health plans to understand and improve performance and consumers to assess health plan results. We believe this would allow stakeholders the information they need while protecting patients from access challenges.

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