NATIONAL QUALITY FORUM

Memo

October 23, 2018

To: Consensus Standards Approval Committee (CSAC)

From: Behavioral Health and Substance Use Project Team

Re: Behavioral Health and Substance Use Spring 2018 Review Cycle

CSAC Action Required

The CSAC will review recommendations from the Behavioral Health and Substance Use project at its October 23, 2018 meeting and vote on whether to uphold the recommendations from the Committee.

This memo includes a summary of the project, measure recommendations, themes identified and responses to the public and member comments and the results from the NQF member expression of support. The following documents accompany this memo:

1. **Behavioral Health and Substance Use Spring 2018 Cycle Draft Report**. The draft report has been updated to reflect the changes made following the Standing Committee's discussion of public and member comments. The complete draft report and supplemental materials are available on the project webpage.
2. **Comment Table**. Staff has identified themes within the comments received. This table lists 57 comments received during the post-meeting comment period and the NQF/Standing Committee responses.

Background

The Behavioral Health and Substance Use project aims to endorse measures of accountability for improving the delivery of behavioral health and substance use services and achieving better health outcomes for the U.S. population. The most recent review of measures for this project examines measures of suicide risk assessments; medication adherence and management; diabetes and cardiovascular screening and monitoring for individuals with schizophrenia and bipolar disorder; concurrent use of opioids and benzodiazepines; and the use of pharmacotherapy for opioid use disorder. The 23-member Behavioral Health and Substance Use Standing Committee evaluated two newly submitted measures and seven measures undergoing maintenance review against NQF's standard evaluation criteria.

Draft Report

The Behavioral Health and Substance Use Spring 2018 draft report presents the results of the evaluation of nine measures considered under the Consensus Development Process (CDP). All nine measures were recommended for endorsement.

The measures were evaluated against the 2017 version of the measure evaluation criteria.

	Maintenance	New	Total
Measures under consideration	7	2	**9**
Measures recommended for endorsement	7	2	**9**
Measures recommended for inactive endorsement with reserve status	0	0	**0**
Measures approved for trial use	0	0	**0**
Measures not recommended for endorsement or trial use	0	0	**0**
Measures withdrawn from consideration	0	0	**0**
Reasons for not recommending	**Importance – N/A** **Scientific Acceptability – N/A** **Use – N/A** **Overall – N/A** **Competing Measure – N/A**	**Importance – N/A** **Scientific Acceptability – N/A** **Use – N/A** **Overall – N/A** **Competing Measure – N/A**	

Measures Recommended for Endorsement

- 0104e Adult Major Depressive Disorder (MDD): Suicide Risk Assessment (PCPI)

Overall Suitability for Endorsement: Yes-15; No-0

- 0105 Antidepressant Medication Management (AMM) (NCQA)

Overall Suitability for Endorsement: Yes-16; No-0

- 1879 Adherence to Antipsychotic Medications for Individuals with Schizophrenia (CMS/NCQA)

Overall Suitability for Endorsement: Yes-14; No-0

- 1880 Adherence to Mood Stabilizers for Individuals with Bipolar I Disorder (CMS/NCQA)

Overall Suitability for Endorsement: Yes-13; No-0

- 1932 Diabetes Screening for People With Schizophrenia or Bipolar I Disorder Who Are Using Antipsychotic Medications (SSD) NCQA)

Overall Suitability for Endorsement: Yes-13; No-0

- 1933 Cardiovascular Monitoring for People With Cardiovascular Disease and Schizophrenia (SMC) (NCQA)

Overall Suitability for Endorsement: Yes-13; No-0

- 1934 Diabetes Monitoring for People With Diabetes and Schizophrenia (SMD) (NCQA)

Overall Suitability for Endorsement: Yes-13; No-0

- 3389 Concurrent Use of Opioids and Benzodiazepines (COB) (PQA)

Overall Suitability for Endorsement: Yes-15; No-0

- 3400 Use of Pharmacotherapy for Opioid Use Disorder (OUD) (CMS/Mathematica Policy Research)

Overall Suitability for Endorsement: Yes-13; No-1

Comments and Their Disposition

NQF received 57 comments from 17 organizations (including nine member organizations) and individuals pertaining to the draft report and to the measures under consideration.

A table of comments submitted during the comment period, with the responses to each comment and the actions taken by the Standing Committee and measure developers, is posted to the Behavioral Health and Substance Use project webpage.

Comment Themes and Committee Responses

Comments about specific measure specifications and rationale were forwarded to the developers, who were invited to respond.

The Standing Committee reviewed all of the submitted comments (general and measure specific) and developer responses. Committee members focused their discussion on measures or topic areas with the most significant and recurring issues.

Themed Comments

Theme 1 – General Comments

Five comments on the general draft report were received about the NQF endorsement process including harmonization and NQF measure evaluation criteria. NQF also received comments on NQF's measure prioritization initiative. One comment highlighted the limitations of medication adherence process measures when not combined with psychosocial supports or without an emphasis on outcomes. Another comment offered concern that measures may be used in settings that have not been tested for scientific acceptability. Other comments emphasized the importance of prioritizing outcome and patient experience measures.

NQF Response

NQF agrees that patient experience and outcome measures are a priority. We also agree that in behavioral health it is important to balance medication adherence process measures with psychosocial aspects of care. NQF has recently launched a prioritization initiative aiming to address gaps and future measurement focus areas within specific topics including behavioral health and substance use. Outcome and patient experience measures are prioritized in this new initiative.

Regarding the concerns raised that measures may be used in settings that have not been tested for scientific acceptability, NQF notes that in order to meet NQF's scientific acceptability criterion, measures must meet reliability and validity testing requirements at the level of analysis included in the submitted specifications. NQF does not endorse measures for use at other measurement levels that have not been tested.

To the extent possible, NQF assigns measures to projects based on topic area. The measures in the Behavioral Health and Substance Use portfolio address tobacco, alcohol, and substance use; depression, major depressive disorders (MDD), schizophrenia, and bipolar disorders; health screening and assessment for those with serious mental illness; attention deficit hyperactivity disorder; safe and appropriate inpatient psychiatric care; and follow-up after hospitalization. The Behavioral Health and Substance Use Standing Committee has identified several gap areas in the portfolio. Past NQF reports have highlighted these gaps. NQF acknowledges the cost of measure development, but also encourages additional measure development in the areas identified in past reports.

In regards to the suggestion to aligning, prioritizing, and indexing behavioral health and substance use measures in the NQF Quality Positioning System (QPS), NQF is committed to aligning measures and reducing measurement burden. Our endorsement criteria include considerations for importance to measure as well as related and competing measures. Measures recommended for endorsement have demonstrated significant performance gaps and/or evidence demonstrating importance to measure as well as a justification of how the measures have either been harmonized to related measures, or how they differ from established competing measures. In addition, NQF has recently launched a prioritization initiative that addresses the entire portfolio of all NQF-endorsed measures. The goal of this prioritization work is not only to prioritize meaningful measures that align with national priorities, but also to identify gaps in measurement areas.

Theme 2 – Feasibility and Data Collection

Five comments specific to feasibility/data collection were received for measures 0104e *Adult Major Depressive Disorder (MDD): Suicide Risk Assessment*, 3389 *Concurrent Use of Opioids and Benzodiazepines (COB)*, and 3400 *Use of Pharmacotherapy for Opioid Use Disorder (OUD)*. Comments highlighted how data collection may interfere with accurately calculating the measure and mentioned drug-prescribing trends, state billing guidance, and data workflow.

Measure Steward/Developer Response (PCPI)

Thank you for your comments. This measure [0104e: Adult Major Depressive Disorder (MDD): Suicide Risk Assessment] is specified and has been tested within the population with major depressive disorder. Expanding the measure beyond this population would require consultation with our TEP and additional testing to assess the feasibility, reliability and validity of the measure within a broader population. We are also aware that recent changes in healthcare delivery models (e.g., telemedicine or virtual encounters) require new considerations as they relate to performance measurement. On the next point regarding the definition of "assessment", "suicide risk assessment" is

defined in the Numerator Details section in the human readable format of this measure's technical specifications and the clinical guidance statement makes reference to key components of a complete assessment. Finally, if mapped to the measure logic, use of a standardized tool will meet criteria for this measure. However, we will consider reference to these tools for provider guidance in future updates and maintenance of this measure. We plan to bring these suggestions (expanding the denominator to include additional diagnoses, reconsideration of "healthcare visits" to include virtual encounters and reference to standardized tools) back to our TEP for consideration in future updates and maintenance of this measure. A "suicide risk assessment" is defined more explicitly in the Numerator Details section in the human readable format of this measure's technical specifications. The clinical guideline statement also makes reference to key components of a complete assessment. Clinical guidance on how to address and manage patients who screen positive for suicidal ideation are also provided in the human readable format of this measure's technical specifications. Your point about EHR availability is a good one. The PCPI has long recognized the great potential of Electronic Health Records (EHRs) and clinical data registries to advance quality measurement and quality improvement initiatives. As such, the PCPI has been an advocate for “next generation” methods that leverage clinical data for measure development, specification and testing. Access to clinical data has the potential to provide feedback to physicians and other health care providers that is timely, actionable and leads to improvement in the care delivered to patients. We hope that providers and other stakeholders continue to consider the implementation of EHR technology to advance their quality improvement efforts.

Measure Steward/Developer Response (PQA)

Measure 3389 *Concurrent Use of Opioids and Benzodiazepines (COB)* is a health-plan level performance measure that uses administrative claims as the data source. The measure rate is calculated using paid prescription claims regardless of prescriber type.

Measure Steward/Developer Response (CMS/Mathematica Policy Research)

We acknowledge the validity of this concern [for measure 3400: Use of pharmacotherapy for OUD]. Bundled payment and, more broadly, other alternative payment methodologies is a challenge that likely effects many claims-based measures, and we are not sure how common this is yet. We spoke with our technical expert panel and stakeholders from some of the states represented in the data we used to test the measure about this issue. They indicated that states are implementing ways of identifying services such as medication treatment in their alternate payment systems. The state officials we interviewed all indicated they bill outpatient treatment programs that provide methadone treatment and, with the exception of one state, are able to identify methadone use through claims. It seems likely that states who choose to implement this measure will either already have the ability to identify methadone or, like many of the stakeholders we interviewed, will implement ways of identifying the treatment. We plan as part of measure maintenance to look into how commonly states are using bundled payment for opioid use disorder, and how they identify specific services within bundles. We acknowledge that use of pharmacotherapy is dependent on many variables, and some rural areas do not have enough buprenorphine providers

and outpatient addiction treatment programs to meet their needs. As the commenter notes, this measure is intended for Medicaid beneficiaries, and is useful in that it allows states to track service needs that warrant further investigation. CMS intends for this to be a voluntary measure for Medicaid programs, for state level monitoring.

Theme 3 – Expansion of Measured Population

There were six comments addressing the expansion of measured populations. Both measure 0104e *Adult Major Depressive Disorder (MDD): Suicide Risk Assessment* and measure 0105 *Antidepressant Medication Management (AMM)* received comments proposing benefit to expanding measures beyond MDD diagnosis.

Measure Steward/Developer Response (PCPI)

This measure [0104e: Adult Major Depressive Disorder (MDD): Suicide Risk Assessment] was originally developed as part of a suite of measures to improve care for adults with major depressive disorder. As a result, this measure is specified and has been tested within the population of adults with major depressive disorder. Expanding the measure beyond this population would require consultation with our TEP and additional testing to assess the feasibility, reliability and validity of the measure within a broader population. We plan to bring this suggestion back to our TEP for consideration in future updates and maintenance of this measure. This measure [0104e Adult Major Depressive Disorder (MDD): Suicide Risk Assessment] is specified and has been tested within the population with major depressive disorder. Expanding the measure beyond this population would require consultation with our TEP and additional testing to assess the feasibility, reliability and validity of the measure within a broader population. We plan to bring this suggestion back to our TEP for consideration in future updates and maintenance of this measure.

Measure Steward/Developer Response (NCQA)

Thank you for your comment. The measure [0105: Antidepressant Medication Management (AMM)] in question specifically assesses the management of anti-depressant medication among members with major depression. Expanding the measure to include populations receiving anti-depressant medication for conditions other than major depression is outside the current scope of the measure, but is something we can explore.

Theme 4 – Unintended Consequences

NQF received five comments highlighting unintended consequences of four of the measures evaluated during this cycle: 1879, 1880, 3389, and 3400. Commenters expressed concern that these medication adherence/medication use measures may lead to unintended consequences in cases where patients are taken off of a medication due to side effects, patients have access to appropriate psychiatric care and treatment with legitimate prescriptions (specific to the opioid and benzodiazepine concurrent use measure), or patients transition to psychotherapy.

Measure Steward/Developer Response (CMS/NCQA)

Thank you for your feedback. This measure [1879: Adherence to Antipsychotic Medications for Individuals with Schizophrenia] is based on clinical guidelines and literature that demonstrate how use of antipsychotic medications in individuals with

schizophrenia can reduce symptoms and the risk of adverse events (e.g., hospitalization) (see section 1a3 “Systematic Reviews of the Evidence” in the evidence attachment). We acknowledge that for some individuals, the risks of antipsychotics outweigh the benefits. The quality measure is not designed to assess the clinical appropriateness of continuing or discontinuing a prescribed medication for individual patients, and it should not supersede shared decision making with patients about risks and benefits of antipsychotic medication use. We do not anticipate that providers or health plans will achieve 100% performance on this measure. However, the measure still provides valuable information about overall and comparative performance of providers and health plans regarding the adherence to prescribed medications.

In order to limit the possibility that individuals who are misdiagnosed with schizophrenia are included in the measure, we define the denominator as:

1) Individuals with at least two encounters with a diagnosis of schizophrenia in the outpatient setting OR at least one encounter with a diagnosis of schizophrenia in an acute inpatient setting, AND

2) At least two prescriptions for an antipsychotic medication.

Measure Steward/Developer Response (CMS/NCQA)

Thank you for your feedback. This measure [1880: Adherence to Mood Stabilizers for Individuals with Bipolar I Disorder] is based on clinical guidelines and literature that demonstrate how the use of mood stabilizer medications in individuals with bipolar I disorder can reduce symptoms and the risk of adverse events (e.g., hospitalization) (see section 1a3 “Systematic Reviews of the Evidence” in the evidence attachment). We acknowledge that for some individuals, the risks of treatment using antipsychotics and mood stabilizers outweigh the benefits. The quality measure is not designed to assess the clinical appropriateness of continuing or discontinuing a prescribed medication for individual patients, and it should not supersede shared decision making with patients about risks and benefits of antipsychotic and mood stabilizer medication use. We do not anticipate that providers or health plans will achieve 100% performance on this measure. However, the measure still provides valuable information about overall and comparative performance of providers and health plans regarding the adherence to prescribed medications.

In order to limit the possibility that individuals who are misdiagnosed with bipolar I disorder are included in the measure, we define the denominator as:

1) Individuals with at least two encounters with a diagnosis of bipolar I disorder in the outpatient setting OR at least one encounter with a diagnosis of bipolar I disorder in an acute inpatient setting, AND
2) At least two prescriptions for a mood stabilizer medication.

Measure Steward/Developer Response (PQA)

PQA appreciates the commenter's support of measure #3389. In regard to dosing thresholds, we were not able to identify dosing guidelines for benzodiazepines in terms

of thresholds for safe use with opioids. We will continue to evaluate clinical guidelines and published studies to update the measure as appropriate.

Measure Steward/Developer Response (CMS/Mathematica Policy Research)

NQF #3400 is intended to measure access to OUD pharmacotherapy, meaning it is an indicator of whether Medicaid beneficiaries initiate pharmacotherapy for OUD. While we recognize the commenter's desire to link a MAT initiation visit to receipt of MAT within a specified time, currently the research evidence does not support a specified period of time after a new diagnosis within which medications should be initiated. We do not exclude patients in remission in the denominator. When we tested the measure in 16 state Medicaid programs, we found that 6.3% of beneficiaries had a diagnosis of opioid dependence in remission, in addition to another OUD diagnosis that would include them in the denominator anyway. Only 1.8% of beneficiaries (ranging by state from 1.2% to 3.4%) had opioid dependence in remission as their sole OUD diagnosis for the year. They were included in the denominator. While this measure is not intended as an OUD maintenance treatment only measure, we tested the sensitivity of the measure to restricting the denominator to maintenance only. To do this, we examined the extent to which we included patients with withdrawal management services (detoxification) in our denominator, and how measure performance changed when we excluded patients with this service. To be conservative, we eliminated all beneficiaries with any evidence of any drug detoxification in claims (10% of the original denominator). These beneficiaries could have had detoxification only or could have had detoxification and maintenance with pharmacotherapy. We found that restricting the denominator moved performance from 57.2% for all states to 58.1%, less than a one percentage point difference. This difference varied by state from 0 to 2.4 percentage points. We view this as a relatively small difference, balanced against the challenges states would have in defining withdrawal management services across settings. Therefore, in order to preserve feasibility of the measure and capture as many beneficiaries as possible, we specified the measure to include all beneficiaries with an OUD diagnosis. In addition, although the use of pharmacotherapy among Medicaid beneficiaries overall is higher than some might expect, our testing found that it ranges widely by state, from 13.1% to 76.0%, indicating room for improvement and importance of measuring. We agree that for young adults who may be seeking non-medical programs, we would not see the extent to which they are not using Medicaid as a source of funds, and thus not evident in claims. This measure is intended for use by Medicaid programs, and is not intended to measure services provided for individuals outside of Medicaid or services other than the described medications. We agree that there's variation in the type of medication Medicaid beneficiaries are able to access for treatment. The measure is specified to report the overall use of any OUD treatment medications in addition to differentiating between the four medications. CMS intends for this measure to be voluntary for Medicaid state programs, and identifying use of different medications is intended to support states in management of OUD, not penalize them for low proportions of specific medications. We agree that this wording creates confusion. "Dispensed" is a better term than "ordered," as this is a claims-based measure. We propose to change the wording when the measure undergoes the annual update.

Member Expression of Support

Throughout the 16-week continuous public commenting period, NQF members had the opportunity to express their support ('support' or 'do not support') for each measure submitted for endorsement consideration to inform the Committee's recommendations. Four NQF members provided their expression of support regarding the Committee's endorsement recommendations. Appendix B details the expression of support.

Removal of NQF Endorsement

Two measures previously endorsed by NQF have not been re-submitted, and endorsement has been removed.

Measure	Measure Description	Reason for Removal of Endorsement
1927 Cardiovascular Health Screening for People With Schizophrenia or Bipolar Disorder Who Are Prescribed Antipsychotic Medications	The percentage of individuals 25 to 64 years of age with schizophrenia or bipolar disorder who were prescribed any antipsychotic medication and who received a cardiovascular health screening during the measurement year.	This measure was withdrawn by the developer given that it is not currently in use in the Healthcare Effectiveness Data and Information Set (HEDIS) measurement set, and therefore may not provide sufficient data to meet NQF's updated use/usability and validity standards.
1937 Follow-Up After Hospitalization for Schizophrenia (7- and 30-day)	The percentage of discharges for individuals 18 – 64 years of age who were hospitalized for treatment of schizophrenia and who had an outpatient visit, an intensive outpatient encounter or partial hospitalization with a mental health practitioner.	The developer withdrew this measure given that the developer has an existing Follow-Up After Hospitalization measure for the general population, which is already endorsed through NQF and includes this subpopulation.

Appendix A: CSAC Checklist

The table below lists the key considerations to inform the CSAC's review of the measures submitted for endorsement consideration.

Key Consideration	Yes/No	Notes
Were there any process concerns raised during the CDP project? If so, briefly explain.	Yes	During the Committee's deliberations on measure 1880 Adherence to Mood Stabilizers for Individuals with Bipolar I Disorder, the Committee did not reach consensus on validity—a must-pass criterion. NQF's Measure Evaluation Criteria and Guidance was updated in August 2017 to require empirical validity testing at the time of maintenance review, or if not possible, a justification in lieu of testing. The measure developer provided a detailed justification for not providing empirical validity testing that included a timeline for completing the testing and a plan with methodological details. The Committee did not reach consensus when voting to accept the measure developer's justification. The Committee co-chairs were concerned that measures 1880: *Adherence to Mood Stabilizers for Individuals with Bipolar I Disorder* and 1879: *Adherence to Antipsychotic Medications for Individuals with Schizophrenia* were not framed clearly during the evaluation meeting on June 15 causing confusion for the Committee on the requirements for evaluating maintenance measures with a justification. Therefore, the Committee discussed validity for this measure and re-voted on the existing face validity analysis and the developer's justification for not submitting empirical testing during the June 27 post-meeting call. The Committee agreed to accept the previous face validity results from 2014, and accepted the developer's justification and plan to submit empirical validity testing before the next maintenance review.
Did the Standing Committee receive requests for reconsideration? If so, briefly explain.	No	

Key Consideration	Yes/No	Notes
Did the Standing Committee overturn any of the Scientific Methods Panel's ratings of Scientific Acceptability? If so, state the measure and why the measure was overturned.	No	
If a recommended measure is a related and/or competing measure, was a rationale provided for the Standing Committee's recommendation? If not, briefly explain.	Yes	During the post-comment web meeting, the recommended measures that have related measures were discussed and the Committee agreed that each developer harmonized their measures to the extent possible. Additional information on the related measures that were discussed can be found in Appendix C.
Were any measurement gap areas addressed? If so, identify the areas.	No	
Are there additional concerns that require CSAC discussion? If so, briefly explain.	No	

Appendix B: NQF Member Expression of Support Results

Four NQF members provided their expression of support. NQF members provided their expression of support for all nine measures under consideration. Results for each measure are provided below.

0104e Adult Major Depressive Disorder (MDD): Suicide Risk Assessment (PCPI Foundation)

Member Council	Support	Do Not Support	Total
QMRI	1	0	1

0105 Antidepressant Medication Management (AMM) (NCQA)

Member Council	Support	Do Not Support	Total
QMRI	1	0	1

1879 Adherence to Antipsychotic Medications for Individuals with Schizophrenia (CMS/NCQA)

Member Council	Support	Do Not Support	Total
QMRI	1	0	1

1880 Adherence to Mood Stabilizers for Individuals with Bipolar I Disorder (CMS/NCQA)

Member Council	Support	Do Not Support	Total
QMRI	1	0	1

1932 Diabetes Screening for People With Schizophrenia or Bipolar Disorder Who Are Using Antipsychotic Medications (SSD) (NCQA)

Member Council	Support	Do Not Support	Total
QMRI	1	0	1

1933 Cardiovascular Monitoring for People With Cardiovascular Disease and Schizophrenia (SMC) (NCQA)

Member Council	Support	Do Not Support	Total
QMRI	1	0	1

1934 Diabetes Monitoring for People With Diabetes and Schizophrenia (SMD) (NCQA)

Member Council	Support	Do Not Support	Total
QMRI	1	0	1

3389 Concurrent Use of Opioids and Benzodiazepines (COB) (PQA)

Member Council	Support	Do Not Support	Total
Health Professional	1	0	1
QMRI	0	1	1

3400 Use of Pharmacotherapy for Opioid Use Disorder (OUD) (CMS/Mathematica Policy Research)

Member Council	Support	Do Not Support	Total
Health Professional	0	1	1
QMRI	1	0	1

Appendix C: Details of Measure Evaluation

Rating Scale: H=High; **M**=Moderate; **L**=Low; **I**=Insufficient; **NA**=Not Applicable

Measures Recommended

0104e Adult Major Depressive Disorder (MDD): Suicide Risk Assessment

Submission | Specifications

Description: Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.

Numerator Statement: Patients with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.

Denominator Statement: All patients aged 18 years and older with a diagnosis of major depressive disorder (MDD).

Exclusions: None

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Clinician : Group/Practice, Clinician : Individual

Setting of Care: Emergency Department and Services, Other, Outpatient Services

Type of Measure: Process

Data Source: Electronic Health Records

Measure Steward: PCPI

STANDING COMMITTEE MEETING 6/19/2018

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-6**; **M-9**; **L-0**; **I-0**

Rationale:

- The measure developer provided updates to the previous evidence submitted for the 2014 review, including a 2015 reaffirmation of the American Psychiatric Association (APA) guideline for the treatment of patients with major depressive disorder.
- The Standing Committee agreed that the evidence base for the measure has not changed and consented to the prior 2014 vote on evidence.
- The measure developer provided performance data from the 2015 CMS Physician Quality Reporting System (PQRS) for which the average performance rate was 71.3%.
- The measure developer was not able to provide updated disparities data as the reporting programs have not yet made these data available. The developer, however, was able to identify studies that examine disparities in suicide assessment rates among people with MDD including a 2017 Centers for Disease Control and Prevention report on suicide.

- The Committee agreed that based on the performance data provided by the developer, a gap in care continues to exist. One Committee member requested the developer include racial and ethnic disparities data for the next maintenance review.

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2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity

2a. Reliability: **H-4; M-11; L-0; I-0** 2b. Validity: **H-2; M-13; L-0; I-0**

<u>Rationale</u>:

- The measure developer used a beta-binomial model to assess the signal to noise ratio. The overall average reliability is 0.94.
- The Standing Committee encouraged the developer to increase the frequency of assessment to include assessments beyond initial diagnosis and recurrent episodes.
- The Committee expressed concern regarding the reliability of the measure due to the lack of a designated standardized tool to assess suicide risk in the measure specifications. The Committee also indicated that telehealth should be included in the specifications.
- The measure developer provided rationale for not including a specific tool in the specifications and noted that four standard questions based on the guidelines are included in the specifications and implementers of the measure can map the risk assessment to a SNOMED code.
- The Committee agreed that the four standardized questions included in the measure specifications were acceptable.
- The measure developer provided updated empirical validity testing that included a correlation analysis with the Depression Utilization of the PHQ-9 Tool measure. A positive correlation was found between the measures with a coefficient of 0.39 and p-value of 0.45.
- The Committee agreed that there was a moderate, but positive correlation.

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3. Feasibility: H-2; M-12; L-1; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The Standing Committee agreed the measure is feasible for implementation. Data element feasibility scorecard was calculated across three EHR vendors (Epic, NextGen, and Point Click Care), and all data elements are in a structured format across the EHRs with the exception of “ED visit”, which was not defined in two EHRs. In addition, identifying patients to meet the numerator may be challenging as suicide risk assessment is consistently documented in free text notes requiring manual review.

4. Use and Usability

4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)

4a. Use: **Pass-15; No Pass-0** 4b. Usability: **H-1; M-14; L-0; I-0**

Rationale:

- The measure is publically reported and used in accountability programs: CMS' Merit-based Incentive Payment System (MIPS) and prior to 2016, Physician Quality Reporting System (PQRS).
- The Committee had no other concerns, and agreed that the measure meets the use and usability criterion.

5. Related and Competing Measures

- There are no competing measures. The developer provided one related measure:
    - NQF# 1365: Child and Adolescent Major Depressive Disorder (MDD) Suicide Risk Assessment
- Both measures, #1365 and #0104, were developed by PCPI and harmonized to the extent possible.

6. Standing Committee Recommendation for Endorsement: **Y-15; N-0**

7. Public and Member Comment

- Six comments were received on this measure during the post-evaluation commenting period. Two comments were in support of the Committee's decision to recommend the measure and three additional commenters encouraged the developer to expand the measure to require suicide risk assessment for all patients with any mental health or substance use condition rather than only focusing on those with major depressive disorder. Another commenter raised concerns with the feasibility of the measure noting that clinicians who are administering a suicide risk assessment are not always working in an environment where an EHR is available (non-hospital based clinicians) so data collection could present a challenge.
    - Developer response: Thank you for your comment. This measure is specified and has been tested within the population with major depressive disorder. Expanding the measure beyond this population would require consultation with our TEP and additional testing to assess the feasibility, reliability and validity of the measure within a broader population. We plan to bring this suggestion back to our TEP for consideration in future updates and maintenance of this measure.

      Your point about EHR availability is a good one. The PCPI has long recognized the great potential of Electronic Health Records (EHRs) and clinical data registries to advance quality measurement and quality improvement initiatives. As such, the PCPI has been an advocate for "next generation" methods that leverage clinical data for measure development, specification and testing.

Access to clinical data has the potential to provide feedback to physicians and other health care providers that is timely, actionable and leads to improvement in the care delivered to patients. We hope that providers and other stakeholders continue to consider the implementation of EHR technology to advance their quality improvement efforts.

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8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; **N-X**

9. Appeals

0105 Antidepressant Medication Management (AMM)

Submission | Specifications

Description: The percentage of members 18 years of age and older who were treated antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported.

a) Effective Acute Phase Treatment. The percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks).

b) Effective Continuation Phase Treatment. The percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).

Numerator Statement: Adults 18 years of age and older who were newly treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment.

Denominator Statement: Patients 18 years of age and older with a diagnosis of major depression and were newly treated with antidepressant medication.

Exclusions: Exclude patients who use hospice services or elect to use a hospice benefit any time during the measurement year, regardless of when the services began.

Exclude patients who did not have a diagnosis of major depression in an inpatient, outpatient, ED, telehealth, intensive outpatient or partial hospitalization setting during the 121-day period from 60 days prior to the IPSD, through the IPSD and the 60 days after the IPSD.

Exclude patients who filled a prescription for an antidepressant 105 days prior to the IPSD.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Health Plan

Setting of Care: Outpatient Services

Type of Measure: Process

Data Source: Claims

Measure Steward: National Committee for Quality Assurance

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1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-4; M-11; L-0; I-0**

Rationale:

- The measure developer provided updates to the evidence submitted previously for the 2014 review, including guidelines and systematic reviews to support the diagnosis and treatment of patients with major depressive disorder with antidepressant medications. In addition, the measure developer provided an updated logic model linking the continuation of antidepressant medications to less episodes of major depression and lower morbidity.
- The Standing Committee agreed that the evidence base for the measure has not changed and consented to the previous vote on evidence.
- The Committee noted the low overall change in performance of the measure, but agreed that there was still evidence of variation in care indicating a performance gap.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-9; M-7; L-0; I-0**; 2b. Validity: **H-4; M-12; L-0; I-0**

Rationale:

- The measure developer provided updated measure score reliability testing using 2016 Healthcare Effectiveness Data and Information Set (HEDIS) data that included Medicare, Medicaid, and commercial health plans.
- A beta-binomial model was used to calculate the signal to noise ratio for the two reported rates of the measure (acute phase treatment and continuation phase treatment) across all three plan types: Commercial, acute phase and continuation phase were both 0.97; Medicare, acute phase and continuation phase were both 0.97; and Medicaid, acute phase and continuation phase were both 0.99.
- The measure developer provided updated empirical testing for construct validity by exploring whether the Antidepressant Medication Management measure correlated with the Statin Therapy for Patients with Diabetes measure in Medicare, Commercial, and Medicaid plans. The Pearson correlation coefficient was used and the results indicate a positive correlation across all three plans:
    - Medicaid: correlation coefficient for acute phase is 0.50 and continuation phase is 0.49;
    - Commercial: correlation coefficient for the acute phase is 0.69 and continuation phase is 0.69; and
    - Medicare: correlation coefficient for the acute phase is 0.56 and continuation phase is 0.60.
- The Standing Committee had no concerns with the updated reliability and validity testing.

3. Feasibility: H-10; M-6; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Standing Committee agreed the measure is feasible for implementation. The measure is specified for claims and electronic health records. All data elements are in defined fields and available in a combination of electronic sources.

4. Use and Usability

4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)

4a. Use: **Pass-16; No Pass-0** *4b. Usability:* **H-3; M-13; L-0; I-0**

Rationale:

- The measure is publically reported and used in accountability programs, including: Medicaid Adult Core Set; Merit Based Incentive Payment System (MIPS) Quality Payment Program (QPP); Health Insurance Exchange Quality Rating System (QRS); State of Health Care Annual Report; Health Plan Rating/Report Cards; Health Plan Accreditation; and Quality Compass.
- The Standing Committee questioned the overall 1% increase in performance, but agreed that without implementation data (e.g. how stable is the denominator population, how the measure is being implemented, or how the measure is incentivized) it was difficult to determine what a reasonable increase in performance should be.

5. Related and Competing Measures

- This measure is related to NQF #1880 – Adherence to Mood Stabilizers for People with Bipolar I Disorder. Measures #1880 and #0105 both assess medication adherence for specific populations. The developer notes measure #1880 differs from #0105 in two ways: 1) it focuses on a population with bipolar disorder, rather than major depressive disorder, and 2) it tracks medication adherence using a "proportion of days covered" method, rather than a calculation of number of days of a dispensed prescription. The developer has not submitted a plan to harmonize the two measures. The developer's rationale was acceptable to the Committee and no additional action was taken.

6. Standing Committee Recommendation for Endorsement: **Y-16; N-0**

7. Public and Member Comment

- Four comments were received on this measure during the post-evaluation commenting period. Two comments were in support of the Committee's decision to recommend the measure and one commenter encouraged the developer to expand the measure's

population to consist of anyone prescribed antidepressants as guided by current evidence.

- Developer response: The measure in question specifically assesses the management of anti-depressant medication among members with major depression. Expanding the measure to include populations receiving anti-depressant medication for conditions other than major depression is outside the current scope of the measure, but is something we can explore.

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8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; **N-X**

9. Appeals

1879 Adherence to Antipsychotic Medications for Individuals with Schizophrenia

Submission | Specifications

Description: Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescription drug claims for antipsychotic medications and had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).

Numerator Statement: Individuals with schizophrenia or schizoaffective disorder who had at least two prescription drug claims for antipsychotic medications and have a PDC of at least 0.8 for antipsychotic medications.

Denominator Statement: Individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder and at least two prescription drug claims for antipsychotic medications during the measurement period (12 consecutive months).

Exclusions: Individuals with any diagnosis of dementia during the measurement period.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Clinician : Group/Practice, Health Plan, Population : Regional and State

Setting of Care: Outpatient Services

Type of Measure: Process

Data Source: Claims

Measure Steward: Centers for Medicare and Medicaid Services

STANDING COMMITTEE MEETING 6/15/2018

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Previous Evidence Evaluation Accepted** 1b. Performance Gap: **H-0; M-16; L-0; I-0**

Rationale:

- The measure developer provided updates to evidence including two clinical practice guidelines.
- The measure developer provided updated performance data from 2015, Physician Compare, reflecting a continued opportunity for improvement.
- Updated disparities data were also submitted by the measure developer demonstrating low rates of adherence among individuals with schizophrenia who are prescribed antipsychotic medications.
- The Standing Committee agreed that the overall evidence for the measure had not changed since the prior review and consented to hold the previous vote.
- The Committee was satisfied with the updated performance data but noted that this is a disparities sensitive measure and they would like to see additional analysis in a future submission.

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2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity

2a. Reliability: **H-2; M-12; L-1; I-0** 2b. Validity: **M-15; L-0; I-0**

Rationale:

- The measure developer provided updated reliability testing at the health plan level that included inter-rater agreement of measure scores randomly selected from Medicare Part D plans. The results indicate moderate to high reliability.
- Previous state and physician level reliability testing, for the measure's last endorsement evaluation, included beta-binomial model to assess signal to noise ratio demonstrating reliable scores.
- The measure developer provided a justification for not submitting empirical validity testing with an analysis plan and timeline for updated testing submission.

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3. Feasibility: H-6; M-9; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Standing Committee had no concerns in regards to feasibility, but noted that it is typical for schizophrenics to fill prescriptions and not take medications.

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4. Use and Usability

4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)

4a. Use: **Pass-14; No Pass-0** *4b. Usability:* **H-3; M-12; L-0; I-0**

Rationale:

- The measure is currently in use in CMS' Quality Payment Program, New York State DSRIP Program, and a SAMHSA demonstration program.
- The measure went through a re-evaluation process through NCQA's measure advisory panel for which medications were added or removed based on FDA approvals.
- No unintended consequences were identified during testing or have been brought to the developer's attention since implementation.

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5. Related and Competing Measures

- There are no competing measures.
- This measure is related to multiple adherence measures including:
    - NQF #0541 Proportion of Days Covered: 3 Rates by Therapeutic Category;
    - NQF# 1880: Adherence to Mood Stabilizers for Individuals with Bipolar I Disorder.
- The measure developer states that the measure specifications are harmonized with the related measures where possible using the same calculation for adherence across.

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6. Standing Committee Recommendation for Endorsement: **Y-14**; **N-0**

7. Public and Member Comment

- Six comments were received on this measure during the post-evaluation commenting period. Three comments were in support of the Committee's decision to recommend the measure and several commenters suggested additional medication and diagnosis exclusions. Another commenter expressed concern about data collection for the measure due to the nature of separating pharmaceutical claims data from regular claims by many health plans.
    - Developer response: We appreciate and agree with the comment. The measure currently includes long-acting (depot) injectable antipsychotic medications in the adherence calculation. The days' supply is imputed for depot injectable antipsychotic medications billed under Medicare Part D and Part B, and include the below (see S.7 of the submission):
        - fluphenazine decanoate
        - haloperidol decanoate
        - aripiprazole
        - aripiprazole lauroxil
        - olanzapine pamoate
        - paliperidone palmitate
        - risperidone microspheres

      We appreciate your comments about the challenges of data collection for this measure. At this time, we believe claims data is the most appropriate data source for this measure. We will encourage measure implementers, such as CMS or NCQA, to work closely with health plans that are submitting data to minimize data collection burdens.

      Although some members with dementia who have schizophrenia or schizoaffective disorder may be appropriately managed on an antipsychotic

medication, we exclude these members from the measure because of the public health advisory and black box warning issued by the Food and Drug Administration (FDA). In April 2005, the FDA issued a Public Health Advisory warning of increased risk of mortality associated with the use of atypical antipsychotics in elderly patients with dementia. This warning was based on the findings of a meta-analysis of 17 short-term, randomized, placebo-controlled trials and showed that the risk of death in drug-treated patients was 1.6 to 1.7 times the risk of death in placebo-treated patients (Schneider et al., 2005). In 2008, the FDA advisory and black box warning was extended to all antipsychotic medications when further studies (Liperoti et al., 2009; Schneeweiss et al., 2007; Setoguchi et al., 2008) showed that conventional antipsychotics were associated with a similar increased risk of death when administered to elderly patients with a diagnosis of dementia. (See section 2b2 in the testing attachment). Excluding individuals with dementia from the measure denominator does not preclude physicians from prescribing antipsychotic medications to these individuals. Physicians may still decide with patients through shared decision making whether the benefits of treatment with antipsychotic medications outweigh the risks.

References:

Liperoti, R., Onder, G., Landi, F., Lapane, K. L., Mor, V., Bernabei, R., & Gambassi, G. (2009). All-cause mortality associated with atypical and conventional antipsychotics among nursing home residents with dementia: A retrospective cohort study. Journal of Clinical Psychiatry, 70(10),1340-1347.

Schneeweiss, S., Setoguchi, S., Brookhart, A., Dormuth, C., & Wang, P. S. (2007). Risk of death associated with the use of conventional versus atypical antipsychotic drugs among elderly patients. CMAJ, 176, 627–632. [PubMed: 17325327]

Schneider, L. S., Dagerman, K. S., & Insel, P. (2005). Risk of death with atypical antipsychotic drug treatment for dementia: Meta-analysis of randomized placebo-controlled trials. Journal of the American Medical Association, 294, 1934–1943. [PubMed: 16234500]

Setoguchi, S., Wang, P. S., Brookhart, M., Canning, C. F., Kaci, L., & Schneeweiss, S. (2008). Potential causes of higher mortality in elderly users of conventional and atypical antipsychotic medications. JAGS, 56, 1644–1650.

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8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

9. Appeals

1880 Adherence to Mood Stabilizers for Individuals with Bipolar I Disorder

Submission | Specifications

Description: Percentage of individuals at least 18 years of age as of the beginning of the measurement period with bipolar I disorder who had at least two prescription drug claims for mood stabilizer medications and had a Proportion of Days Covered (PDC) of at least 0.8 for mood stabilizer medications during the measurement period (12 consecutive months).

Numerator Statement: Individuals with bipolar I disorder who had at least two prescription drug claims for mood stabilizer medications and have a PDC of at least 0.8 for mood stabilizer medications.

Denominator Statement: Individuals at least 18 years of age as of the beginning of the measurement period with bipolar I disorder and at least two prescription drug claims for mood stabilizer medications during the measurement period (12 consecutive months).

Exclusions: Not Applicable

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Clinician : Group/Practice, Health Plan, Integrated Delivery System, Population : Regional and State

Setting of Care: Outpatient Services

Type of Measure: Process

Data Source: Claims

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 6/15/2018

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Previous Evidence Evaluation Accepted** 1b. Performance Gap: **H-3; M-11; L-0; I-0**

Rationale:

- The measure developer provided updates to the evidence submitted previously for the 2014 review, including two clinical practice guidelines. Additionally, the developer provided an updated logic model outlining how the process of identifying patients with Bipolar I Disorder who are not adherent to mood stabilizer medication treatment is related to improved symptom control for those patients identified and a reduction in hospitalization.
- The Standing Committee agreed that the evidence base for the measure has not changed and consented to the previous vote on evidence.
- The measure developer provided updated performance data. The previous submission included 2007 and 2008 Medicare claims data indicating performance gaps and a wide variation in adherence to mood stabilizer medications across health plans, states and provider groups.
- The measure developer provided an updated literature review on disparities reporting higher adherence rates among White persons with Bipolar I Disorder than among African- American and Hispanic persons with Bipolar I Disorder.

- The Committee agreed that based on the performance and disparities data provided by the developer, a gap in care continues to exist.

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2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity

2a. Reliability: **H-3; M-11; L-0; I-0** 2b. Validity: **M-7; L-4; I-3 Validity re-vote on June 27, 2018: M-13; L-0; I-0**

<u>Rationale</u>:

- The measure developer provided updated reliability testing at the health plan level. Reliability was assessed using Cohen's Kappa. The measure scores for five randomly selected Medicare Part D plans from two states were compared, and inter-rater agreement was calculated. Results obtained by two independent programmers were 1.00, which is greater than the Kappa threshold of 0.9.
- Previously submitted reliability testing included signal-to-noise ratio to assess variability across multiple measurement units including states, prescription drug plans, Accountable Care Organizations, and physician groups.
- The Standing Committee agreed the measure was reliable. One Committee member recommended the developer broaden the measure criteria by broadening the proxy for adherence, which is currently specified as two prescriptions.
- The measure developer provided a justification that included a plan with a timeline and methodological details to support previous face validity in lieu of updated empirical validity testing.
- During the initial evaluation webinar, the Committee did not reach consensus on the validity vote.
- After the initial evaluation webinar, NQF refined its guidance for Committee members on how to consider and vote on validity when only face validity and justification are submitted for a maintenance measure in lieu of empirical validity. The Committee re-voted and agreed to accept the existing face validity analysis and the measure developer's justification for not having empirical testing.

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3. Feasibility: H-0; M-7; L-7; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The Standing Committee agreed the measure is feasible for implementation. The measure is specified for electronic claims. All data elements are in defined fields and readily available and accessible.

4. Use and Usability

4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)

4a. Use: **Pass-14; No Pass-0** *4b. Usability:* **H-1; M-13; L-0; I-0**

Rationale:

- The measure is publically reported and used in accountability programs, including: New York State Delivery System Reform Incentive Payment (DSRIP) Program, Value Based Payment (VBP) Quality Measure Set for the Health and Recovery Plan (HARP) subpopulation and Substance Abuse and Mental Health Services Administration (SAMHSA) Section 223 Demonstration Program.
- The Committee agreed that the measure meets the use and usability criterion.

5. Related and Competing Measures

- There are no competing measures.
- The developer notes the following related measures:
    - NQF# 0541 : Proportion of Days Covered (PDC): 3 Rates by Therapeutic Category
    - NQF# 1879 : Adherence to Antipsychotic Medications for Individuals with Schizophrenia
    - NQF# 1932: Diabetes Screening for People With Schizophrenia or Bipolar Disorder Who Are Using
    - Antipsychotic Medications (SSD)
    - N/A: Adherence to Antipsychotic Medications for Individuals with Schizophrenia (NCQA measure)
- The measure developer indicates measure #1880 has been harmonized to the extent possible with measures #1879, #0542, #0543, #0545, #0541, #1879, #1927, and #1932.

6. Standing Committee Recommendation for Endorsement: **Y-13**; **N-0**

Rationale

- During the post-evaluation meeting on June 27, 2018, the Standing Committee voted on overall suitability and recommended the measure for endorsement

7. Public and Member Comment

- Six comments were received on this measure during the post-evaluation commenting period. Three comments were in support of the Committee's decision to recommend the measure and one comment was specific to unintended consequence of medication adherence. Two additional comments were received specific to the measure specifications list of mood stabilizer drugs.
    - Developer response: We appreciate and agree with the comment. The measure currently includes long-acting (depot) injectable antipsychotic medications FDA-approved for the treatment of bipolar disorder in the adherence calculation.

The days' supply is imputed for these medications billed under Medicare Part D and Part B, and include the below (see S.7 of the submission):

- aripiprazole
- risperidone microspheres

This measure includes all FDA-approved treatments for bipolar disorder (anticonvulsants, atypical antipsychotics, phenothiazine/related antipsychotics, other antipsychotics, lithium salts, and long-acting injectable antipsychotic medications). Based on feedback from our expert panel, the measure developer decided to not include any medications used off-label to treat bipolar I disorder. This decision is consistent with our approach for measure #1879. Experts who advised on this measure agreed that while individuals with bipolar I disorder are sometimes treated with medications which are not FDA-approved for that condition, it is not appropriate to include those medications in a quality measure. We also want to note that individuals treated with off-label medications would not be included in the denominator of this measure, and thus, taking this approach, a provider's or health plan's performance on the measure would not be penalized. In order to qualify for the denominator, the patient must be dispensed two prescriptions for one of the medications included in the measure.

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8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

9. Appeals

1932 Diabetes Screening for People With Schizophrenia or Bipolar Disorder Who Are Using Antipsychotic Medications (SSD)

Submission | Specifications

Description: The percentage of patients 18 – 64 years of age with schizophrenia or bipolar disorder, who were dispensed an antipsychotic medication and had a diabetes screening test during the measurement year.

Numerator Statement: Among patients 18-64 years old with schizophrenia or bipolar disorder, those who were dispensed an antipsychotic medication and had a diabetes screening testing during the measurement year.

Denominator Statement: Patients ages 18 to 64 years of age as of the end of the measurement year (e.g., December 31) with a schizophrenia or bipolar disorder diagnosis and who were prescribed an antipsychotic medication.

Exclusions: Exclude members who use hospice services or elect to use a hospice benefit any time during the measurement year, regardless of when the services began.

Exclude patients with diabetes during the measurement year or the year prior to the measurement year.

Exclude patients who had no antipsychotic medications dispensed during the measurement year.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Health Plan, Integrated Delivery System, Population : Regional and State

Setting of Care: Other, Outpatient Services

Type of Measure: Process

Data Source: Claims

Measure Steward: National Committee for Quality Assurance

STANDING COMMITTEE MEETING 6/19/2018

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-3; M-10; L-0; I-0**

Rationale:

- In the previous submission, the measure developer provided evidence in the form of guidelines and recommendations from the American Diabetes Association that suggested that individuals with schizophrenia and bipolar disorder are at higher risk for diabetes than the general population and that use of certain antipsychotic medications increases this risk.
- For this submission, the measure developer provided updated guidelines from the American Diabetes Association and the American Psychiatric Association, which show that patients with schizophrenia or bipolar disorder are at an increased risk for diabetes, and antipsychotic medications are an expected treatment that increases the risk of metabolic diseases. Therefore, screening for diabetes will allow for proper diagnosis and treatment.
- The Standing Committee agreed these updates were directionally the same as the evidence presented in the last review, hence there was no need to repeat the discussion and revote on evidence.
- The measure developer summarized the performance data at the health plan level using Healthcare Effectiveness Data and Information Set (HEDIS) health plan performance rates from 2015-2017 which demonstrates a continued performance gap with the 90th percentile performing at 87.4% and the 10th percentile performing at 74%. The Committee agreed that while there is little improvement, an important gap remains.
- The measure developer did not provide disparities data since HEDIS data are stratified by type of insurance. While not specified in this measure, this measure can also be stratified by demographic variables in order to assess other health care disparities.

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2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-5; M-8; L-0; I-0** 2b. Validity: **H-3; M-10; L-0; I-0**

Rationale:

- The measure developer used a beta-binominal model to assess the signal-to-noise ratio that showed high reliability. The Standing Committee agreed that the data elements are clearly defined and unlikely to be prone to unreliability.
- To assess the validity of the measure, the measure developer conducted construct validity testing using the Pearson correlation coefficient to examine the association between using this measure and measure 1934, which both focus on patients with schizophrenia and whether they received care for diabetes. The developer found that there is a statistically significant (0.25) and positive relationship between the two measures. The Committee questioned whether the statistically significant results are because the providers are simply doing a large amount of screening but cautioned that it does not mean they are providing higher quality of care. Ideally, one would want to see if the measure was associated with better outcomes (e.g., lower hyperglycemic events among the population).

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3. Feasibility: H-8; M-5; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Standing Committee agreed that this measure is feasible given that all data elements are in defined fields in electronic claims, no fees are associated with the use of this measure, and that no manual abstraction is required.

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4. Use and Usability

4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)

4a. Use: **Pass-13; No Pass-0** 4b. Usability: **H-5; M-8; L-0; I-0**

Rationale:

- This measure is currently used in several programs including the Medicaid Adult Core Set and various NCQA programs.
- The Standing Committee agreed that although there has been little improvement in the past six years (3 percent), the measure continues to move in the right direction.
- The Committee noted that the small amount of improvement for this measure, specifically for the Medicaid population, may require special attention and incentives.
- The Committee agreed that there are no known harms associated with this measure and that the benefits are considerable given the risks of diabetes for this population.

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5. Related and Competing Measures

- There are no competing measures.
- The measure developer notes the following related measures:

1933: Cardiovascular Monitoring for People with Cardiovascular Disease and Schizophrenia (SMC)

1934: Diabetes Monitoring for People with Diabetes and Schizophrenia (SMD)

- The measure developer noted that the specifications are harmonized to the extent possible.

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6. Standing Committee Recommendation for Endorsement: **Y-13**; **N-0**

7. Public and Member Comment

- Four comments were received on this measure during the post-evaluation commenting period, all of which were in support of the Committee's decision to recommend the measure.

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8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

9. Appeals

1933 Cardiovascular Monitoring for People With Cardiovascular Disease and Schizophrenia (SMC)

Submission | Specifications

Description: The percentage of patients 18 – 64 years of age with schizophrenia and cardiovascular disease, who had an LDL-C test during the measurement year.

Numerator Statement: An LDL-C test performed during the measurement year.

Denominator Statement: Patients 18-64 years of age as of the end of the measurement year (e.g., December 31) with a diagnosis of schizophrenia and cardiovascular disease.

Exclusions: Exclude patients who use hospice services or elect to use a hospice benefit any time during the measurement year, regardless of when the services began.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Health Plan, Integrated Delivery System, Population : Regional and State

Setting of Care: Outpatient Services

Type of Measure: Process

Data Source: Claims

Measure Steward: National Committee for Quality Assurance

STANDING COMMITTEE MEETING 6/19/2018

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-1; M-12; L-0; I-0**

Rationale:

- In the previous submission, the measure developer provided evidence in the form of studies that demonstrated that individuals with schizophrenia have a higher prevalence of cardiovascular disease than the general population.
- For this submission, the measure developer provided updated guidelines from the American Psychiatric Association that show that appropriate monitoring of individuals with schizophrenia and cardiovascular disease may lead to proper treatment and management.
- The Standing Committee agreed these updates were directionally the same as the evidence presented in the last review and therefore there was no need to repeat the discussion and revote on evidence.
- The measure developer summarized the performance data at the health plan level using Healthcare Effectiveness Data and Information Set (HEDIS) health plan performance rates from 2015-2017 which demonstrates a continued performance gap. The Committee agreed that while there is little improvement, an important gap remains.
- The measure developer did not provide disparities data since HEDIS data are stratified by type of insurance. While not specified in this measure, this measure can also be stratified by demographic variables in order to assess other health care disparities.

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2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity

2a. Reliability: **H-3; M-10; L-0; I-0** 2b. Validity: **H-4; M-9; L-0; I-0**

Rationale:

- The measure developer used a beta-binominal model to assess the signal-to-noise ratio, which showed high reliability. The Committee agreed that there is no reason that this measure cannot be consistently implemented.
- Given that cardiovascular disease is often not diagnosed in patients with schizophrenia, the Committee questioned why the denominator requires a prior diagnosis of cardiovascular disease rather than giving all patients with schizophrenia an LDL-C test annually. The measure developer responded that this is based on the evidence guidelines; the developer has a separate cardiovascular screening measure, in addition to this measure, that strictly looks at individuals who already have a diagnosis of cardiovascular disease.
- To assess the validity of the measure, the measure developer conducted construct validity testing using the Pearson correlation coefficient to examine the association between using this measure and measure 1934, which both focus on patients with schizophrenia and whether their chronic condition (diabetes or cardiovascular disease) is being monitored. They found that there is a statistically significant (0.66) and positive relationship between the two measures.

3. Feasibility: H-11; M-2; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Standing Committee agreed that given that all data elements are in defined fields in electronic claims and no fees are associated with use, that this measure is feasible.

4. Use and Usability

4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)

4a. Use: **Pass-13; No Pass-0** 4b. Usability: **H-5; M-8; L-0; I-0**

Rationale:

- This measure is currently used in several programs including the Physician Value-Based Payment Modifier and various NCQA programs.
- The Standing Committee agreed that the performance results are critical to improving outcomes for individuals with schizophrenia and addressing early mortality in this population and that the benefits of this measure far outweigh any possible unintended consequences.

5. Related and Competing Measures

- There are no competing measures.
- The measure developer notes the following related measures:

  1932: Diabetes Screening for People With Schizophrenia or Bipolar Disorder Who Are Using Antipsychotic Medications (SSD)

  1934: Diabetes Monitoring for People with Diabetes and Schizophrenia (SMD)
- The measure developer noted that the specifications are harmonized to the extent possible.

6. Standing Committee Recommendation for Endorsement: **Y-13**; **N-0**

7. Public and Member Comment

- Four comments were received on this measure during the post-evaluation commenting period. Three comments were in support of the Committee's decision to recommend the measure. Another comment questioned whether the measure should be diagnostically specific, while one comment cautioned the use of the measure in regards to cardiovascular monitoring outside of the acute care setting suggesting this type of monitoring may be beyond practice scope.
  - Developer response: For this measure, members who have a diagnosis of schizophrenia or schizoaffective disorder and cardiovascular disease are

identified using claims data that signifies the member received care in a variety of allowable care settings (e.g., outpatient, emergency department, acute inpatient, telehealth). Among members identified as having a diagnosis of schizophrenia and cardiovascular disease, the measure assesses the percentage who had an LDL-C test during the measurement year, which can be identified using administrative claims data or automated laboratory data. Guidelines and evidence do not specify the type of provider that can order and review the laboratory tests required for monitoring in these measures.

The two measures in question are meant to assess appropriate monitoring of individuals with schizophrenia and either cardiovascular disease or diabetes. Guidelines for the treatment of patients with schizophrenia recommend that laboratory tests to evaluate health status, including glucose and cholesterol, be performed. Evidence suggests that the prevalence of diabetes and cardiovascular disease among patients with schizophrenia is higher than among the general population. Additionally, there is a known relationship between the use of antipsychotic medications and increased cardiac and metabolic effects. Guidelines and evidence do not specify the type of provider that can order and review the laboratory tests required for monitoring in these measures.

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8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

9. Appeals

1934 Diabetes Monitoring for People With Diabetes and Schizophrenia (SMD)

Submission | Specifications

Description: The percentage of patients 18 – 64 years of age with schizophrenia and diabetes who had both an LDL-C test and an HbA1c test during the measurement year.

Numerator Statement: One or more HbA1c tests and one or more LDL-C tests performed during the measurement year.

Denominator Statement: Patients age 18-64 years of age as of the end of the measurement year (e.g. December 31) with a schizophrenia and diabetes diagnosis.

Exclusions: Exclude patients who use hospice services or elect to use a hospice benefit any time during the measurement year, regardless of when the services began.

Exclude patients who do not have a diagnosis of diabetes (Diabetes Value Set), in any setting, during the measurement year or year prior to the measurement year and who had a diagnosis of gestational diabetes or steroid-induced diabetes (Diabetes Exclusions Value Set), in any setting, during the measurement year or the year prior to the measurement year.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Health Plan, Integrated Delivery System, Population : Regional and State

Setting of Care: Outpatient Services

Type of Measure: Process

Data Source: Claims

Measure Steward: National Committee for Quality Assurance

STANDING COMMITTEE MEETING 6/19/2018

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-9; M-4; L-0; I-0**

Rationale:

- In the previous submission, the measure developer provided evidence in the form of studies that demonstrated that there is a higher prevalence of diabetes and non-treatment rates for individuals with schizophrenia and that monitoring may lead to proper management for diabetes in this population and may reduce morbidity and mortality.
- For this submission, the measure developer provided updated guidelines from the American Psychiatric Association and the American Diabetes Association that furthers the known link between metabolic side effects and antipsychotics used to treat schizophrenia.
- The Standing Committee agreed these updates were directionally the same as the evidence presented in the last review and so there was no need to repeat the discussion and revote on evidence.
- The measure developer summarized the performance data at the health plan level using Healthcare Effectiveness Data and Information Set (HEDIS) health plan performance

rates from 2015-2017 which demonstrates a continued performance gap. The Committee agreed that while there is little improvement, an important gap remains.
- The measure developer did not provide disparities data since HEDIS data are stratified by type of insurance. While not specified in this measure, this measure can also be stratified by demographic variables in order to assess other health care disparities.

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2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity

2a. Reliability: **H-5; M-8; L-0; I-0** 2b. Validity: **H-2; M-11; L-0; I-0**

<u>Rationale</u>:

- The measure developer used a beta-binominal model to assess the signal-to-noise ratio that showed high reliability. The Committee agreed that the data elements are clearly defined and unlikely to be prone to unreliability.
- To assess the validity of the measure, the developer conducted construct validity testing using the Pearson correlation coefficient to examine the association between using this measure and measure #1932, which both focus on patients with schizophrenia and whether they received care for diabetes. The developer found that there is a statistically significant (0.66) and positive relationship between the two measures.

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3. Feasibility: H-12; M-1; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The Standing Committee agreed that given that all data elements are in defined fields in electronic claims and no fees are associated with use, that this measure is feasible.

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4. Use and Usability

4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)

4a. Use: **Pass-13; No Pass-0** 4b. Usability: **H-8; M-5; L-0; I-0**

<u>Rationale</u>:

- This measure is currently used in several programs including the Physician Value-Based Payment Modifier and various NCQA programs.
- The Standing Committee agreed that collecting data on diabetes management in this population is critical public health priority and is essential to improving the health of people with schizophrenia and addressing early mortality. Any unintended consequences are far outweighed by the potential public health benefit.

5. Related and Competing Measures

- There are no competing measures.
- The measure developer notes the following related measures:

  1932: Diabetes Screening for People with Schizophrenia or Bipolar Disorder Who Are Using Antipsychotic Mediations (SSD)

  1933: Cardiovascular Monitoring for People with Cardiovascular Disease and Schizophrenia (SMC)
- The measure developer noted that the specifications are harmonized to the extent possible.

6. Standing Committee Recommendation for Endorsement: **Y-13**; **N-0**

7. Public and Member Comment

- Four comments were received on this measure during the post-evaluation commenting period. Three comments were in support of the Committee's decision to recommend the measure and one comment involved limiting the measures scope to individuals with uncomplicated diabetes. Another comment questioned whether the measure should be diagnostically specific while one comment cautioned the use of the measure in regards to diabetes monitoring outside of the acute care setting or beyond the practice scope.
  - Developer response: For this measure, we do not differentiate between complicated and uncomplicated diabetes, as we did not find evidence in the literature or guidelines to support limiting the measure in this way. Evidence suggests that the prevalence of diabetes among patients with schizophrenia is higher than among the general population. Additionally, there is a known relationship between the use of antipsychotic medications and increased risk of metabolic syndrome and diabetes. People with Schizophrenia and are also less likely to receive care for diabetes than the general population. This measure aims to shed light on disparities in care and assess the proper management of diabetes among a high-risk subset of the general population.

    The two measures in question [1934: Diabetes Monitoring for People With Diabetes and Schizophrenia (SMD); 1933: Cardiovascular Monitoring for People with Cardiovascular Disease and Schizophrenia] are meant to assess appropriate monitoring of individuals with schizophrenia and either cardiovascular disease or diabetes. Guidelines for the treatment of patients with schizophrenia recommend that laboratory tests to evaluate health status, including glucose and cholesterol, be performed. Evidence suggests that the prevalence of diabetes and cardiovascular disease among patients with schizophrenia is higher than among the general population. Additionally, there is a known relationship between the use of antipsychotic medications and increased cardiac and metabolic effects. Guidelines and evidence do not specify the type of provider that can order and review the laboratory tests required for monitoring in these measures.

8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

9. Appeals

3389 Concurrent Use of Opioids and Benzodiazepines (COB)

Submission | Specifications

Description: The percentage of individuals 18 years and older with concurrent use of prescription opioids and benzodiazepines during the measurement year.

A lower rate indicates better performance.

Numerator Statement: The number of individuals from the denominator with concurrent use of opioids and benzodiazepines for 30 or more cumulative days during the measurement year.

Denominator Statement: The denominator includes individuals 18 years and older with 2 or more prescription claims for opioids with unique dates of service, for which the sum of the days' supply is 15 or more days. Individuals with cancer or in hospice are excluded.

Exclusions: Individuals with cancer or in hospice at any point during the measurement year are excluded from the denominator.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Health Plan

Setting of Care: Other

Type of Measure: Process

Data Source: Claims

Measure Steward: PQA, Inc.

STANDING COMMITTEE MEETING 6/14/2018

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-8; M-7; L-0; I-0**; 1b. Performance Gap: **H-6; M-9; L-0; I-0**

Rationale:

- The measure developer submitted strong evidence for the measure including a CDC guideline, three studies, and a FDA black box warning.
- The performance gap was demonstrated with measure testing results based on 2015 Medicare Part D data indicating a significant performance gap for which 24% of patients had concurrent prescribing.
- Disparities rates were measured via beneficiary level Low-Income Subsidy (LIS) variable for which the measure rate was 29.9% while the rate of the non-LIS population was lower at 19.9%.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity

2a. Reliability: **H-2; M-13; L-0; I-0** 2b. Validity: **H-14; M-1; L-0; I-0**

Rationale:

- Testing was conducted on Medicare and Medicaid data. A beta-binomial model was used to calculate plan-specific reliability scores. The mean reliability score for Medicare is .77 and the mean reliability score for Medicaid is .94.
- The measure developer provided systematic assessment of face validity for the measure score. The measure was reviewed by several PQA expert panels as well as the entire PQA membership. Ninety-three percent of the Quality Metrics Expert Panel recommended the measure for endorsement and of the 93 PQA member organizations who cast a vote, eighty-nine percent voted in favor of the measure.
- The Standing Committee noted one concern in regards to threats to validity, related to missing data as a result of individuals paying cash for opioids and benzodiazepines resulting in missing claims.

3. Feasibility: H-10; M-5; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- Pilot sites testing the measure indicated that the measure was feasible and results were reported efficiently, accurately, and without difficulty.
- The required data (prescription and medical claims) are readily available in electronic format.
- Measure developer (PQA) retains the rights to measure and can rescind or alter the measure at any time.
- The Standing Committee had no concerns in regards to feasibility.

4. Use and Usability

4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)

4a. Use: **Pass-15; No Pass-0** 4b. Usability: **H-9; M-6; L-0; I-0**

Rationale:

- The measure was added to the 2018 CMS Medicaid Adult Core Measure set.
- The measure developer anticipates adoption of the measure over time to meet the 25 state threshold for public reporting.

5. Related and Competing Measures

- This measure is related to:
  - NQF #2940 : Use of Opioids at High Dosage in Persons Without Cancer
  - NQF #2950 : Use of Opioids from Multiple Providers in Persons Without Cancer
  - NQF #2951 : Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer
  - Use of Opioids at High Dosage (NCQA)
  - Use of Opioids from Multiple Providers (NCQA)
- The PQA opioid measures (NQF # 2940, 2950, and 2951) use the same target population (denominator), and each have different areas of focus (numerator) related to opioid prescribing. The NCQA opioid measures were developed as an adaptation to existing PQA measures; the NCQA opioid measure denominators are similar to the PQA opioid measures, but have a different area of focus than the concurrent use of opioids and benzodiazepines measure.

6. Standing Committee Recommendation for Endorsement: **Y-15**; **N-0**

7. Public and Member Comment

- Nine comments were received on this measure specific to feasibility and data collection, unintended consequences, and general support. There was one comment that expressed concern about the measure as specified as well as its relation to another newly endorsed measure NQF #3316 *Safe Use of Opioids – Concurrent Prescribing*.
  - Developer response: Thank you for the opportunity to respond to these additional comments received regarding the PQA measure #3389 Concurrent Use of Opioids and Benzodiazepines that retrospectively evaluates the performance of health plans using administrative claims data. To clarify, the measure denominator includes individuals 18 years and older with 2 or more prescription claims for opioids with unique dates of service, for which the sum of the days' supply is 15 or more days. The numerator is the number of individuals from the denominator with concurrent use of opioids and benzodiazepines for 30 or more cumulative days during the measurement year. Individuals with cancer or in hospice at any point during the measurement year are excluded from the denominator.

    The measure rationale and exclusions are based on the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, that provides a category A recommendation (applies to all persons; most patients should receive the recommended course of action) that prescribers should avoid concurrent prescriptions of opioids and benzodiazepines.1 The CDC guideline states that although there are circumstances when it might be appropriate to prescribe opioids to a patient

receiving benzodiazepines (e.g., severe acute pain in a patient taking long-term, stable low-dose benzodiazepine therapy), clinicians should avoid concurrent prescribing whenever possible. Additional rationale for the measure is the 2016 US Food and Drug Administration Boxed Warnings added to prescription drug labeling for prescription opioid pain and prescription opioid cough medications, and benzodiazepines, based on studies finding that combined use of opioids and benzodiazepines has resulted in serious side effects, including death.2 Since the publication of the CDC prescribing guideline, several retrospective observational studies have been published that add to the growing body of evidence to support the lack of broad therapeutic benefit combined with the increased risk for overdose associated with co-prescribing of these medications.3-5

Measure exclusions were carefully considered and vetted through PQA's transparent, multi-stakeholder, consensus-based development process. According to the CDC guideline and subject matter expert feedback during the measure development process, few medication situations warrant concurrent use of opioids and benzodiazepines. The measure excludes patients with cancer and those in hospice due to the unique therapeutic goals, ethical considerations, increased opportunities for medical supervision, and balance of risks and benefits with opioid therapy. Other exclusions were not recommended for the measure, though opioid products that are indicated for medication assisted treatment for opioid use disorder are not included in the measure.

The intent of measure #3389 is to address the known consequences of concurrent prescribing and the risk of adverse events, including severe respiratory depression and death. The performance results from the measure can be used to establish benchmarks and identify opportunities to decrease co-prescribing of opioid and benzodiazepines. As a retrospective population-level measure, it is not intended to serve as a guide for individual patient care decisions. Although a lower rate indicates better performance, the rate is not expected to be zero. We acknowledge that in certain situations, providers may choose to concurrently prescribe opioid and benzodiazepine medications for individual patients due to patient individualization considerations. This performance measure is not intended to preclude such situations.

To date, implementation of measure #3389 includes the Centers for Medicare & Medicaid Services (CMS) reporting within the Medicare Patient Safety reports, addition to the 2018 Medicaid Adult Core Set, and use in Medicaid 1115 Substance Use Disorder Demonstrations, and negative unintended consequences have not been identified. We will monitor for potential unintended consequences based on feedback from measure implementers to ensure that the benefits of the performance measure in facilitating progress toward achieving high-quality healthcare outweigh evidence of unintended negative consequences.

Although measure #3389 does not focus on pain, pain management is a complex topic that is central to the issue of opioid stewardship. Efforts to prevent opioid overdose deaths should comprise a balanced and multi-faceted approach, including strategies that focus on reducing opioid prescribing, limiting use of potentially dangerous drug-drug combinations, and being mindful and vigilant about pain management considerations.

We are aware of the NQF-endorsed measure, #3316e, Safe use of opioids - concurrent prescribing, which was reviewed by the Patient Safety Standing Committee during the Fall 2017 Cycle. Specifically, #3316e evaluates, patients age 18 years and older prescribed two or more opioids or an opioid and benzodiazepine concurrently at discharge from a hospital-based encounter (inpatient or emergency department [ED], including observation stays). The PQA measure #3389 is related to #3316e conceptually because they both focus on concurrent prescribing of opioids and benzodiazepines. However, the measures do not use the same target population (denominator) and the data sources (claims vs. electronic health records), levels of analysis (health plan vs. facility) and settings (ambulatory vs. emergency department, inpatient/hospital) are distinctly different. PQA did not identify any competing measures (i.e., those that addresses both the same measure focus and the same target population) that would necessitate harmonization of measure elements.

References

1. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016. MMWR Recomm Rep. 2016;65(1):1-49. doi:10.15585/mmwr.rr6501e1.

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. August 31, 2016. Available at: http://www.fda.gov/Drugs/DrugSafety/ucm518473.htm. Accessed: November 9, 2016.

3. Sun EC, Dixit A, Humphreys K, et al. Association between concurrent use of prescription opioids and benzodiazepines and overdose: retrospective analysis. BMJ. 2017;356:j760. doi: 10.1136/bmj.j760. PMID: 28292769

4. Gaither JR, Goulet JL, Becker WC, et al. The Association Between Receipt of Guideline-Concordant Long-Term Opioid Therapy and All-Cause Mortality. J Gen Intern Med 2016; 31:492

5. Dasgupta N, Funk MJ, Proescholdbell S, et al. Cohort Study of the Impact of High-Dose Opioid Analgesics on Overdose Mortality. Pain Med 2016; 17:85.

8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

9. Appeals

3400 Use of Pharmacotherapy for Opioid Use Disorder (OUD)

Submission | Specifications

Description: The percentage of Medicaid beneficiaries ages 18 to 64 with an OUD who filled a prescription for or were administered or ordered an FDA-approved medication for the disorder during the measure year. The measure will report any medications used in medication-assisted treatment of opioid dependence and addiction and four separate rates representing the following types of FDA-approved drug products: buprenorphine; oral naltrexone; long-acting, injectable naltrexone; and methadone.

Numerator Statement: Beneficiaries ages 18 to 64 with an OUD who filled a prescription for or were administered or ordered an FDA-approved medication for the disorder during the measure year.

Denominator Statement: Number of Medicaid beneficiaries with at least one encounter with a diagnosis of opioid abuse, dependence, or remission (primary or other) at any time during the measurement year.

Exclusions: None.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Population : Regional and State

Setting of Care: Emergency Department and Services, Inpatient/Hospital, Outpatient Services

Type of Measure: Process

Data Source: Claims

Measure Steward: Centers for Medicare & Medicaid Services, Centers for Medicaid & CHIP Services

STANDING COMMITTEE MEETING 6/14/2018

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-2; M-8; L-2; I-1**; 1b. Performance Gap: **H-7; M-7; L-0; I-0**

Rationale:

- The measure developer submitted a clinical practice guideline and six systematic reviews indicating pharmacotherapy for the treatment of opioid use disorder is proven effective.
- Performance gap is demonstrated with testing results based on 2014 Medicaid Analytic extract data from 16 states. Overall performance rate for pharmacotherapy use was 57.2% and the state-level scores ranged from 13.1% - 76.5% indicating wide variation.

- The Standing Committee discussed the omission of psychosocial support in the measure and agreed that it would be beneficial to include in future versions.
- The Committee questioned how the measure accounted for individuals who are in remission and not on pharmacotherapy. The developer responded that patients in remission tend to be on pharmacotherapy already and that they had excluded the remission cohort of patients in testing but there was minimal change.

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2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity

2a. Reliability: **H-5; M-9; L-0; I-0** 2b. Validity: **H-1; M-10; L-2; I-1**

<u>Rationale</u>:

- Reliability and validity testing was based on Medicaid Analytic extract (MAX) 2014 data that included inpatient, other services, long term care, and drug files. Sixteen states were included in the testing.
- Signal-to-noise reliability analysis for the measure was highly reliable in terms of ability to distinguish the measure's performance in different states.
- Convergent validity was assessed by comparing performance of the measure with two other Healthcare Effectiveness Data and Information Set (HEDIS) alcohol or drug dependence measures. The state-level performances between this measure and the two HEDIS measures have a strong positive correlation – states with high or low substance use disorder rates respectfully tend to have high or low Initiation and engagement of treatment for alcohol and drug rates.
- Face validity was assessed via a multi-stakeholder technical expert panel of 19. Nine of the ten respondents agreed or strongly agreed the performance scores can be used to distinguish good from poor quality of care.
- The measure developer shared with the Committee that two states participating in the measure testing did not have methadone billing codes, so it is possible that there was under reporting.

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3. Feasibility: H-6; M-7; L-1; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The measure is coded by someone other than the person obtaining original information. This measure requires gathering data from a variety of different data sources and may be complex for certain states to gather.
- All data elements are in defined fields in electronic claims.
- There are no fees or licensing requirements to use this measure, which is in the public domain.

4. Use and Usability

4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)

4a. Use: **Pass-14; No Pass-0** 4b. Usability: **H-1; M-12; L-1; I-0**

Rationale:

- Adoption of the measure has the potential to improve the quality of care for Medicaid beneficiaries who have an opioid use disorder.
- The Standing Committee discussed unintended consequences for this measure pertaining to the risks of pharmacotherapy such as overdose or dependence and recommended surveillance to detect such harms be paired with the measure.
- CMS is considering implementation plans for this measure. The measure is currently intended for voluntary use by states to monitor and improve the quality of care.

5. Related and Competing Measures

- No competing measures.
- The measure developer notes related measures stating that the specifications have been harmonized to the extent possible:
    - 3175: Continuity of Pharmacotherapy for Opioid Use Disorder
    - Evidence of medication-assisted treatment (MAT) among patients with opioid use disorder (OUD) or OD, Steward: OptumLabs

6. Standing Committee Recommendation for Endorsement: **Y-13**; **N-1**

7. Public and Member Comment

- Nine comments were received on this measure specific to feasibility and data collection, unintended consequences, and general support. One commenter expressed concern with how data collection may interfere with accurately calculating the measure and also cited drug-prescribing trends, state billing guidance, and data workflow as other interfering factors. Another commenter recommended that this measure assess the receipt of medication assisted therapy (MAT) within 30 days of a new OUD diagnosis (or within 30 days of the MAT initiation visit). As currently specified, this measure is a cross sectional analysis that is unsubstantiated by the evidence regarding the importance of MAT initiation. One comment was received noting that the measure is similar to an existing endorsed measure: #3175 *Continuity of Pharmacotherapy for Opioid Use.*
    - Developer response: We acknowledge the validity of this concern. Bundled payment and, more broadly, other alternative payment methodologies is a challenge that likely effects many claims-based measures, and we are not sure how common this is yet. We spoke with our technical expert panel and stakeholders from some of the states represented in the data we used to test

the measure about this issue. They indicated that states are implementing ways of identifying services such as medication treatment in their alternate payment systems. The state officials we interviewed all indicated they bill outpatient treatment programs that provide methadone treatment and, with the exception of one state, are able to identify methadone use through claims. It seems likely that states who choose to implement this measure will either already have the ability to identify methadone or, like many of the stakeholders we interviewed, will implement ways of identifying the treatment. We plan as part of measure maintenance to look into how commonly states are using bundled payment for opioid use disorder, and how they identify specific services within bundles.

NQF #3400 is intended to measure access to OUD pharmacotherapy, meaning it is an indicator of whether Medicaid beneficiaries initiate pharmacotherapy for OUD. While we recognize the commenter's desire to link a MAT initiation visit to receipt of MAT within a specified time, currently the research evidence does not support a specified period of time after a new diagnosis within which medications should be initiated. We do not exclude patients in remission in the denominator. When we tested the measure in 16 state Medicaid programs, we found that 6.3% of beneficiaries had a diagnosis of opioid dependence in remission, in addition to another OUD diagnosis that would include them in the denominator anyway. Only 1.8% of beneficiaries (ranging by state from 1.2% to 3.4%) had opioid dependence in remission as their sole OUD diagnosis for the year. They were included in the denominator. While this measure is not intended as an OUD maintenance treatment only measure, we tested the sensitivity of the measure to restricting the denominator to maintenance only. To do this, we examined the extent to which we included patients with withdrawal management services (detoxification) in our denominator, and how measure performance changed when we excluded patients with this service. To be conservative, we eliminated all beneficiaries with any evidence of any drug detoxification in claims (10% of the original denominator). These beneficiaries could have had detoxification only or could have had detoxification and maintenance with pharmacotherapy. We found that restricting the denominator moved performance from 57.2% for all states to 58.1%, less than a one percentage point difference. This difference varied by state from 0 to 2.4 percentage points. We view this as a relatively small difference, balanced against the challenges states would have in defining withdrawal management services across settings. Therefore, in order to preserve feasibility of the measure and capture as many beneficiaries as possible, we specified the measure to include all beneficiaries with an OUD diagnosis. In addition, although the use of pharmacotherapy among Medicaid beneficiaries overall is higher than some might expect, our testing found that it ranges widely by state, from 13.1% to 76.0%, indicating room for improvement and importance of measuring. We agree that for young adults who may be seeking non-medical programs, we would not see the extent to which they are not using Medicaid as

a source of funds, and thus not evident in claims. This measure is intended for use by Medicaid programs, and is not intended to measure services provided for individuals outside of Medicaid or services other than the described medications. We agree that there's variation in the type of medication Medicaid beneficiaries are able to access for treatment. The measure is specified to report the overall use of any OUD treatment medications in addition to differentiating between the four medications. CMS intends for this measure to be voluntary for Medicaid state programs, and identifying use of different medications is intended to support states in management of OUD, not penalize them for low proportions of specific medications. We agree that this wording creates confusion. "Dispensed" is a better term than "ordered," as this is a claims-based measure. We propose to change the wording when the measure undergoes the annual update.

Measures #3400: Use of pharmacotherapy for opioid use disorder (OUD) and #3175: Continuity of pharmacotherapy for opioid use have been identified as related by the developer. The Behavioral Health and Substance Use Committee will evaluate these measures during the post-comment call and provide guidance and recommendations.

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8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

9. Appeals