TO: Consensus Standards Approval Committee (CSAC)

FR: Elisa Munthali, Tara Murphy, Yetunde Ogungbemi, Robyn Nishimi

RE: Health and Well-Being 2015-2017

DA: January 4, 2017

CSAC ACTION REQUIRED: The CSAC will review recommendations from the Health and Well-Being 2015-2017 project at its January 10, 2017 meeting and vote whether to uphold the recommendations from the Committee.

This memo includes a summary of the project, recommended measures, and themes identified from and responses to the public and member comments.

NQF member voting on these recommended measures will close on January 5, 2017. An addendum with the NQF member voting results will be sent to the CSAC following the close of the voting period.

Accompanying this memo are the following documents:

1. **Health and Well-Being Draft Report.** The draft report has been updated to reflect the changes made following Standing Committee discussion of public and member comments. The complete draft report and supplemental materials are available on the project page.
2. **Comment Table.** Staff has identified themes within the comments received. This table lists 170 comments received during the post-meeting comment period and the NQF/Standing Committee responses.

BACKGROUND

Social, environmental, and behavioral factors can have significant negative impact on health outcomes and economic stability. These factors and other upstream determinants contribute to 60 percent of deaths in the United States; yet only 3 percent of national health expenditure is spent on prevention, while 97 percent is spent on healthcare services. Developing strategies to strengthen the measurement and analysis of health and well-being, given its multi-dimensional focus, can be best accomplished using a collaborative approach that includes public health, healthcare delivery systems, and other key sectors whose policies, practices, and procedures influence health. Using the right measures can determine how successful initiatives are in reducing mortality and excess morbidity and help focus future work to improve population health in appropriate areas.

DRAFT REPORT

The Health and Well-Being 2015-2017 Draft Report presents the results of the evaluation of 23 measures considered under the Consensus Development Process (CDP). On September 12-13, 2016, during a 2-day in-person meeting, the Health and Well-Being Standing Committee evaluated 23 measures: 12 newly-submitted measures and 11 measures undergoing maintenance review against NQF's standard evaluation criteria. During the September meeting, ten measures were recommended for endorsement, three measures were approved for Trial Use, one measure was recommended for inactive endorsement with reserve status, and three

were not recommended for endorsement. The Committee did not reach consensus on the six remaining measures until after the public comment period.

During the December 6, 2016 post-comment call, the Committee voted on the six measures for which consensus was not reached during the in-person meeting. During the call, two measures were not recommended for endorsement (#3087 and #3088). Three measures were recommended for endorsement (#00038, #0680 and #3086). The Committee also recommended measure #3089 for endorsement, however, the measure did not meet the validity criterion.

- The Committee did not reach consensus on the Composite Quality Construct and Rationale for measure #0038. The Committee stressed the importance of assessing individual components, but expressed reservations about the all-10 composite. After the in-person meeting, the developer agreed to remove the all-10 composite and the measure was then recommended for continued endorsement.

- The Committee did not reach consensus on the reliability of measure #0680, noting testing concerns on the reliability of the influenza measure items from the Long-Term Care Hospital (LTCH) Care Data Set or the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI). The developer provided additional testing data for the additional care settings. The Committee re-voted and agreed this measure meets the criteria for NQF endorsement.

- For measure #3086, the Committee did not reach consensus on Reliability and Validity. For reliability testing, the developer cited state law and quality control for its data and did not provide any empirical testing at the score or data element levels, as is required by NQF. Committee members also recommended that the developer identify the "gold standard" – data audit of viral load captured in the CDC surveillance system against state records. The developer submitted data that addressed these concerns. The Committee re-voted and recommended this measure for endorsement.

- The Committee did not reach consensus on Evidence for measures #3087 and #3088. For #3087, the Committee raised concern about the burden of screening each hospitalization (patients 18 and older) within 24 hours, regardless of patient risk or condition, as well as whether the screening to treatment link was substantiated by evidence. For #3088, Committee members debated whether the number of studies in the observation and randomized trials mentioned in the 2011 American Society for Parenteral and Enteral Nutrition guidelines (Grade E) were sufficient and able to discern the risk of bias. Committee members echoed the same concerns during the post-comment call and decided not to recommend either measure (#3087 and #3088) for endorsement.

- For measure #3089, the Committee did not achieve consensus on Validity during the in-person meeting, expressing concerns about the omission of exclusions, as well as variability of treatment protocols. The developer provided additional information to address these concerns. The Committee re-voted and the measure did not receive the necessary >60% of votes to pass validity. During the post-comment call, the number of

Committee members voting fluctuated. Since NQF staff intended to collect the additional votes (which may have changed the results for validity), the Committee elected to continue voting on Overall Suitability and the measure was recommended for NQF endorsement.

- Additionally, the developer submitted a reconsideration request for measure #3090. Ultimately, the Committee voted against reconsideration and the measure remained as not recommended for endorsement. Therefore, fourteen measures were recommended for endorsement, three were recommended with approval for trial use, one measure was recommended for inactive endorsement with reserve status and five were not recommended.

The measures were evaluated against the 2015 version of the measure evaluation criteria.

	Maintenance	New	Total
Measures under consideration	11	12	23
Measures recommended for endorsement	10	4	14
Measure recommended for inactive endorsement with reserve status	1	--	1
Measures approved for trial use	--	3	3
Measures not recommended for endorsement	--	5	5
Measures withdrawn from consideration	17	1	18
Reasons for not recommending	Importance- 0 Scientific Acceptability- 0 Overall- 0 Competing Measure- 0	Importance- 3 Scientific Acceptability- 2 Overall- 5 Competing Measure- 0	

CSAC ACTION REQUIRED

Pursuant to the CDP, the CSAC is asked to consider approval of 18 candidate consensus measures, including three measures recommended for approval for trial use and one measure recommended for inactive endorsement with reserve status.

Health and Well-Being Measures Recommended for Endorsement:

- 0032: Cervical Cancer Screening (CCS)
  - Overall Suitability for Endorsement: Y-13; N-0
- 0038: Childhood Immunization Status (CIS)

- Overall Suitability: Y-14; N-0

- 0039: Flu Vaccinations for Adults Ages 18 and Older
  - Overall Suitability for Endorsement: Y-12; N-1
- 0041: Preventive Care and Screening: Influenza Immunization
  - Overall Suitability for Endorsement: Y-14; N-0
- 0226: Influenza Immunization in the ESRD Population (Facility Level)
  - Overall Suitability for Endorsement: Y-13; N-1
- 0279: Bacterial Pneumonia Admission Rate (PQI 11)[1]
  - Overall Suitability for Endorsement: Y-12; N-2
- 0431: Influenza Vaccination Coverage Among Healthcare Personnel
  - Overall Suitability for Endorsement: Y-14; N-0
- 0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short stay)
  - Overall Suitability for Endorsement: Y-14; N-0
- 0681: Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (long stay)
  - Overall Suitability for Endorsement: Y-13; N-1
- 2828: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
  - Overall Suitability for Endorsement: Y-14; N-1
- 3039: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
  - Overall Suitability for Endorsement: Y-15; N-1
- 3070: Preventive Care and Screening: Influenza Immunization
  - Overall Suitability for Endorsement: Y-14; N-0
- 3086: Population Level HIV Viral Load Suppression
  - Overall Suitability: Y-13; N-0
- 3089: Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment (*eMeasure*)[2]

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[1] Please note: Upon recommendation from the Pulmonary and Critical Care Standing Committee, the developer has agreed to change the name to better reflect the measure focus to "Community-Acquired Pneumonia Admission Rate (PQI 11)."

[2] On the post-comment call, the number of Committee members who participated was n=14, but participation varied during the call and, for a few votes, quorum (n=12) was not maintained. Under these circumstances, the decision was made that Committee members who were not present for all votes would be provided a summary of the discussion and be asked to vote on those items for which they had not been present—thus ensuring that for each voting item n=14. It was emphasized that none of the vote tallies on the call were final. Although quorum was present for the vote on Validity for #3089 (n=12), the outcome was such that the additional votes to achieve n=14 might have meant passing the criterion. Accordingly, Committee members also voted on Overall Suitability for Endorsement during the call. Ultimately, #3089 failed Validity because it did not reach the >60% threshold. However, because the Committee had voted on Overall Suitability for Endorsement and because that vote was (Y-10; N-4), the measure was advanced as recommended for purposes of NQF member voting and additional discussion by the Consensus Standards Approval Committee.

- Validity: M-8; L-6; I-0 (57.1%)
- Overall Suitability: Y-10; N-4

Health and Well-Being Measures Recommended with Approval for Trial Use:

- 3059: One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk
  - Overall Recommendation for eMeasure Approval for Trial Use: Y-11; N-2
- 3060: Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users
  - Overall Recommendation for eMeasure Approval for Trial Use: Y-11; N-2
- 3061: Appropriate Screening Follow-up for Patients Identified with Hepatitis C Virus (HCV) Infection
  - Overall Recommendation for eMeasure Approval for Trial Use: Y-11; N-2

Health and Well-Being Measure Recommended for Inactive Endorsement with Reserve Status:

- 1659: Influenza Immunization
  - Overall Recommendation for Inactive Endorsement with Reserve Status: Y-14; N-0

Health and Well-Being Measures Not Recommended:
(See Appendix A for the Committee's votes and rationale):

- 3067: Human Immunodeficiency Virus (HIV) Infection Screening
- 3071: Follow-up Referral after Positive Developmental Screen
- 3087: Completion of a Malnutrition Screening within 24 hours of Admission*(eMeasure)*
- 3088: Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 hours of a Malnutrition Screening *(eMeasure)*
- 3090: Appropriate Documentation of a Malnutrition Diagnosis

COMMENTS AND THEIR DISPOSITION

NQF received 170 comments[3] from 27 organizations (including 11 member organizations) and individuals pertaining to the general 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 Health and Well-Being project page under the Public and Member Comment section.

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

[3] Many of these comments were multi-part, owing to character limit constraints in the NQF online system.

or topic areas with the most significant and recurring issues.

Theme 1 - Support for endorsement of measures where consensus was not reached
The 90 comments categorized under this area were submitted by 27 organizations/individuals to provide additional information about or general support for measures where consensus was not reached during the in-person meeting. In addition to the information related to #0680, we categorized the comments for consensus not reached (CNR) measures into three groups: HIV viral load suppression (#3086)[4]; childhood immunization status (#0038); and three nutrition-related measures (#3087, #3088, #3089).

Measure-Specific Comments
#0038: Childhood Immunization Status (CIS) (National Committee for Quality Assurance)
The developer submitted a comment requesting that language in the report related to disparities data for this measure (and its other measures) be revised to indicate that NCQA will "consider" pursuing working with health plans or reviewing national data in order to provide disparities information in the next measure update. NQF staff confirmed, via notes and the meeting transcript, the accuracy of the language in the report that the developer *agreed* to pursue this information. Additionally, the developer proposed edits related to clarifying the source of statements related to its cervical cancer screening measure (#0032).

Committee Response: The measure will retain the language to reflect an agreement by the developer to pursue performance data that is stratified by socioeconomic variables during a future update. Based on the discussion, clarifying edits related to #0032, which address the Committee's concerns, will be incorporated into the technical report.

#3087: Completion of a Malnutrition Screening within 24 hours of Admission (Academy of Nutrition & Dietetics/Avalere)
#3088: Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 hours of a Malnutrition Screening (Academy of Nutrition & Dietetics/Avalere)
#3089: Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment (Academy of Nutrition & Dietetics/Avalere)

Forty comments were received from 23 organizations/individuals and the developer for #3087, 39 comments from 23 organizations/individuals and the developer for #3088, and 30 comments from 18 organizations/individuals and the developer for #3089. The comments were largely repetitive and supplied the same, or nearly so, list of references. Many of the references were part of the original submission and addressed findings that malnourished patients have increased lengths of stays, increased mortality, and other adverse health outcomes, but were not specific to the measure foci (screening, completion of assessment, care plan).

[4] Because the commenter/developer (CDC) experienced difficulty with the on-line portal that could not be resolved by the deadline, the developer forwarded comments as Word and PDF files. We are working with CDC to ensure the comments are ultimately populated in the NQF database, but at this time we refer the Committee to Attachment 2 for this material, and not the Excel comment table.

- In commenting on the measure, the developer noted that it submitted a series of four measures that, in part, build on each other. Specifically, with respect to screening, the developer posited that #3087 triggers all subsequent care, noting the numerator for this measure becomes the denominator for #3088. The developer expressed concern that the lack of the initial universal screening (#3087) measure may lead to uneven implementation (i.e., ad hoc identification of the denominator) of the other measures.
- No additional information was provided through the comments that screening is linked to treatment/outcomes.
- A few commenters noted that malnutrition screening within 24 hours of admission had been a standard of The Joint Commission (TJC) for many years. One commenter noted that TJC recently removed the standard, citing that it "addresses routine part[s] of operations or clinical care processes." The commenter noted, however, there are no quality measures in place to reliably evaluate such performance. A comment by TJC "welcomes" performance measures to assess the degree that screening occurs.
- As noted, most of the references provided in the comments overlapped with those in the submission or did not directly address the measure focus/specifications to improvement. NQF staff did examine further two 2016 articles commenters cited. Based on the publication date, these appeared to be available during the submission timeframe, but we did not identify them in a "search" of the original submission:
    - An April 2016 article from Kruizenga noted that Dutch hospitals are required to screen for undernutrition on the first day of admission. One of two standardized instruments were used; study size was 564,063 patients from 2007-2014. Patients who had an undernourished screening score had a higher LOS than did patients who did not (median 6.8 compared with 4.0 d; $P < 0.001$). One out of 7 patients was scored as undernourished. For geriatrics, oncology, gastroenterology, and internal medicine, this ratio was even greater (1 out of 3–4). Hospital stay was 1.4 d longer among undernourished patients than among those who were well nourished. The study confirms other literature that reports that patients who are malnourished have longer LOS, but in this case specifically identified the patients through the use of a standardized screening tool[5].
    - The other 2016 article (Allard) merely points to other similar articles that malnutrition at admission "is prevalent and associated with prolonged LOS." Patients first underwent "the main nutrition evaluation was subjective global assessment (SGA). Body mass index (BMI) and handgrip strength (HGS) were also performed to assess other aspects of nutrition." 1,500 pts enrolled in study,

[5] Kruizenga H, Van keeken S, Weijs P, et al. Undernutrition screening survey in 564,063 patients: patients with a positive undernutrition screening score stay in hospital 1.4 d longer. Am J Clin Nutr. 2016;103(4):1026-32.

45% found to be malnourished and LOS was found to be increased in that population. Screening of all patients per se is not addressed[6].

- Regarding the Committee's concern about the burden of screening each hospitalization, a recommendation to endorse #3087 is argued by commenters that the burden is "low." A standardized 2-item questionnaire is cited as evidence of low burden; as noted during the in-person meetng, the measure does not require a standard instrument.
- Several commenters cited an AHRQ statistical brief released after the Committee meeting (September 20, 2016), which characterized hospital stays involving malnutrition, but which does not address whether the specific aspects of the measure specifications per se link to improved quality (i.e., screening, nutritional assessment, follow-up plan of care and documentation).[7]
- For #3088 (completion of a nutrition assessment once identified as at-risk), commenters again largely cited literature previously included or that do not directly link the completion to outcome. The Allard (2016) article also is cited as "new" evidence. Again, the focus of the Allard article appears to be confirmatory evidence that malnutrition at admission is associated with increased LOS, not that completing a nutrition assessment reduced LOS.[6]
- Finally, for #3089 (documentation of a care plan for patients found to be malnourished based on a complete nutrition assessment), for which the Committee did not achieve consensus on validity, the commenters and developer again recommended the Committee advance the measure. No comments appeared to address the Committee's concerns about the omission of exclusions. Regarding concerns about variability, one of the organizations (measure steward) noted that its committees are working to ensure that terms from the Academy's Nutrition Care Processes (NCP) are mapped to clinical terminologies such as SNOMED-CT® and LOINC®. The comment noted, "upon malnutrition screening and appropriate assessment of at-risk patients, the nutrition intervention is developed using the NCP. Use of appropriate malnutrition language and terminologies (via the mapping of eNCPT to clinical and/or reimbursement terminologies), the intervention can be included in the electronic Care Plan. Selection of appropriate terminology possible for a problem-etiology-signs/symptoms documentation allows for structured coded data which is consistent with other areas of an EHR."

Committee Response #3087: Though we appreciate the support the nutrition measures received during the public and member commenting period, we see no salient information in the comments provided. We remain concerned about the lack of evidence linking screening every patient to improved outcomes and also are concerned with the burden it would cause to screen every hospitalized patient, regardless of patient risk or condition, within 24 hours. We also are concerned about the lack of exclusions—including, for example, hospice patients or patients discharged against

[6] Allard JP, Keller H, Jeejeebhoy KN, et al. Malnutrition at Hospital Admission-Contributors and Effect on Length of Stay: A Prospective Cohort Study From the Canadian Malnutrition Task Force. JPEN J Parenter Enteral Nutr. 2016;40(4):487-97.

[7] Weiss AJ, et al. Characteristics of Hospital Stays Involving Malnutrition, 2013. HCUP Statistical Brief #r 210. September 2016. Agency for Healthcare Research and Quality, Rockville, MD.

medical advice.
We understand and agree that malnourished patients have increased lengths of stays, increased mortality, and other adverse health outcomes, but the references the developer provided and those identified in the comment period are not specific to the measure's focus.
For the measure to be evaluated differently, evidence is needed that documents the impact on longer-term health because of screening, as well as the impact on utilization cost.
Developer Response #3087: Exclusion criteria includes patients who have a length of stay of shorter than 24 hours. The measure focuses on malnutrition screening, which is the first step in the process of addressing malnutrition.
Committee Response #3088: The guidelines cited by the developer are based on three individual trials, and among those three trials were inconsistencies in the very limited evidence. Though the developer noted it provided several studies looking at the impact of quality improvement programs focused on nutrition and malnutrition, we note that the quantity, quality, and consistency of the evidence to address the measure construct is important. There was clear support from many commenters, but the comments were largely repetitive, and the additional information did not provide new evidence directly addressing the measure's focus to directly link the completion of a malnutrition assessment to improved outcomes.
Committee Response #3089: Though there was support for the measure from commenters, as with the other nutrition measures, we are concerned that the denominator excludes patients admitted to hospice care, who refused referrals, were discharged against medical advice, or had complications—although a few of us did feel the exclusions might be less of an issue with this measure. Some of us also feel the September 2016 AHRQ brief documenting the problem of malnutrition in hospitalized patients also address some concerns for this measure. On the other hand, we noted that a 2008 paper used by the developer to document a performance gap found that patients who received intervention (getting feedings or vitamins) did not have improved clinical outcomes. We are also concerned about the capacity of EHRs to extract the many plan of care data components and skepticism, though we understand the developer is working to get more information in standardized formats. We emphasize that we recognize that nutritional status is an important area to be addressed by quality measurement.

- **Action Taken**: After review of the comments for #3087 and #3088, the Committee voted and ultimately decided not to recommend for endorsement. For #3089, the Committee re-voted and the measure did not receive the necessary >60% of votes to pass validity. During the post-comment call, the number of Committee members voting fluctuated. Since NQF staff intended to collect the additional votes (which may have changed the results for validity), the Committee elected to continue voting on Overall Suitability and the measure was recommended for NQF endorsement.

Theme 2 – Disagreement with Committee recommendation
Six comments were received from two organizations/individuals on the following four measures:

- The Committee recommended Influenza vaccination measures #0039 (NCQA), #0041 (PCPI Foundation), and #3070 (PCPI Foundation eMeasure version of 0041), but the American Academy of Family Physicians opposes these measures because they have not been included in the Core Measures Set for ACO/PCMH/Primary Care; concern also is expressed about the numerator specifications. The American Academy of Pediatrics does not explicitly oppose #0041 and #3070, but expressed concern that the specifications do not align with its recommendations for influenza vaccinations for patients 6 months to 8 years.
- As with the other nutrition-related measures, several commenters disagreed with the Committee's decision not to recommend #3090 (documentation of malnutrition diagnosis). The Committee failed the measure on Evidence. No new evidence is offered that links documentation of the diagnosis to improved outcomes, but the developer asks the Committee to consider granting an Exception to the Evidence—i.e., does the Committee agree that it is OK (or beneficial) to hold providers accountable for performance in the absence of empirical evidence of benefits to patients?

Committee Response #3090: NQF appreciates your comment. The developer requested the Committee to reconsider this measure for endorsement during the post comment call on December 6th. After discussion and deliberation, the Committee recommended not to reconsider this measure for endorsement.

Theme 3 – Support for Committee recommendation

Ten comments from six organizations were submitted in support of the Committee's recommendations to endorse the following five measures: *#0226: Influenza Immunization in the ESRD Population; #0032: Cervical Cancer Screening (CCS); #3059: One-Time Screening for Hepatitis C Virus; #3060: Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users (Trial Use)*; *#3061: Appropriate Screening Follow-Up for Patients Identified with Hepatitis C Virus (HCV) Infection*; *#0431: Influenza Vaccination Coverage Among Healthcare Personnel; #0681: Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (long stay); #2828: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan.* Some measures received support from more than one organization/individual

NQF Response: NQF appreciates your comment.

Theme 4 – General comments on the report/project

Four comments from four organizations were submitted in general support of the report and project.

NQF Response: NQF appreciates your comment.

Theme 5 –Comments directed to the developer

Nine comments from three organizations/individuals disagreed with the developer's specifications or recommended that the developer consider revisions in future iterations. The seven measures for which developer response was specifically sought are*: #0039: Flu Vaccinations for Adults Ages 18 and Older (National Committee for Quality Assurance); #0041: Preventive Care and Screening Influenza Immunization (PCPI); #0279: Bacterial Pneumonia*

Admission Rate (Agency for Healthcare Research and Quality); #0431: Influenza Vaccination Coverage Among Healthcare (Centers for Disease Control and Prevention); #2828: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Quality Insights Pennsylvania); #3059: One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk (PCPI); #3070: Preventive Care Screening: Influenza Immunization (PCPI).

The Committee did not discuss the developer responses in detail, but concurred with the comments related to lack of harmonization with NQF's standardized influenza vaccination specifications and the multiple influenza vaccination measures (n=8) instead of a universal, setting-independent measure for which the Committee had advocated during the last maintenance cycle. The Committee expressed significant concern that progress had not been made in this regard and asked the report to reflect this, as well as for NQF staff to work with the developers toward this goal. The Committee also discussed whether issues such as lack of use in the CMS Core Set should be a factor at this time, but agreed to focus on the issues raised at the in-person meeting (reliability and validity) for this maintenance cycle. The Committee agreed that, during the next maintenance cycle, a lack of harmonization and proliferation of measures should be factored into its discussions on whether to continue any single measure's endorsement.

REMOVAL OF ENDORSEMENT

Twenty-one measures previously endorsed by NQF have not been re-submitted for maintenance of endorsement or have been withdrawn during the endorsement evaluation process. One measure was withdrawn prior to the Committee's evaluation.

Measure	Reason for withdrawal
0024 Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents (WCC)	Maintenance endorsement deferred; USPTF Guidelines being updated.
0029 Physical Activity in Older Adults (PAO)	Developer did not resubmit this measure for maintenance review, therefore NQF has removed endorsement.
0034 Colorectal Cancer Screening (CCS)	Maintenance endorsement deferred; USPTF Guidelines being updated.
0043: Pneumococcal Vaccination Status for Older Adults (PNU)	Developer did not resubmit this measure for maintenance review, therefore NQF has removed endorsement.
0522 Influenza Immunization Received for Current Flu Season (Home Health)	Developer did not resubmit this measure for maintenance review, therefore NQF has removed endorsement.
0525 Pneumococcal Polysaccharide Vaccine (PPV) Ever Received (Home Health)	Developer did not resubmit this measure for maintenance review, therefore NQF has removed endorsement.
0682 Percent of Residents or Patients Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay)	Developer submitted request to NQF with intent not to submit, therefore NQF has removed endorsement.

Measure	Reason for withdrawal
0683 Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Long-Stay)	Developer submitted request to NQF with intent not to submit, therefore NQF has removed endorsement
0717 Number of School Days Children Miss Due to Illness	Developer did not resubmit this measure for maintenance review, therefore NQF has removed endorsement.
0719 Children Who Receive Effective Care Coordination of Healthcare Services When Needed	Developer did not resubmit this measure for maintenance review, therefore NQF has removed endorsement.
0720 Children Who Live in Communities Perceived as Safe	Developer did not resubmit this measure for maintenance review, therefore NQF has removed endorsement.
0721 Children Who Attend Schools Perceived as Safe	Developer did not resubmit this measure for maintenance review, therefore NQF has removed endorsement.
0724 Measure of Medical Home for Children and Adolescents	Developer did not resubmit this measure for maintenance review, therefore NQF has removed endorsement.
1333 Children Who Receive Family-Centered Care	Developer did not resubmit this measure for maintenance review, therefore NQF has removed endorsement.
1340 Children with Special Health Care Needs (CSHCN) who Receive Services Needed for Transition to Adult Health Care	Developer did not resubmit this measure for maintenance review, therefore NQF has removed endorsement.
1346 Children Who Are Exposed To Secondhand Smoke Inside Home	Developer did not resubmit this measure for maintenance review, therefore NQF has removed endorsement.
1348 Children Age 6-17 Years who Engage in Weekly Physical Activity	Developer did not resubmit this measure for maintenance review, therefore NQF has removed endorsement.
1349 Child Overweight or Obesity Status Based on Parental Report of Body-Mass-Index (BMI)	Developer did not resubmit this measure for maintenance review, therefore NQF has removed endorsement.
1653 Pneumococcal Immunization	Measure withdrawn at request of developer.
1999 HIV Late Diagnosis	Developer did not resubmit this measure for maintenance review, therefore NQF has removed endorsement.
3062 Hypertension Screening for Children Who Are Overweight or Obese	Measure withdrawn at request of developer to conduct additional testing.

Appendix A – Measures Not Recommended for Endorsement

The table below lists the Committee's vote and rationale for the three measures not recommended for endorsement.

LEGEND: Y = Yes; N = No; H = High; M = Moderate; L = Low; I = Insufficient

Measure	Voting Results	Standing Committee Rationale
#3067: Human Immunodeficiency Virus (HIV) Infection Screening	**Evidence** H-10; M-5; L-0; I-0 **Performance Gap** H-12; M-3; L-0; I-0 **Reliability** H-0; M-5; L-5; I-5	The Committee raised concern about reliability testing of the data elements in the EHR; specifically, it questioned how patients who opt out were handled; limited geographic focus on Chicago; and verification of previous screening or test without self-reporting. Some concerns were raised about the inclusion of HIV status in the numerator and the cumulative effect on the measure's ability to discern meaningful differences in HIV infection screening for accountability purposes. While the Committee was generally supportive of the measure, several concerns were raised about the numerator and denominator. Ultimately, the measure failed the Reliability criterion.
#3071: Follow-up Referral after Positive Developmental Screen	**Evidence** H-0; M-2; L-2; I-11 **Exception to Evidence** Y-10; N-5 **Performance Gap** H-6; M-7; L-2; I-0 **Reliability** H-0; M-6; L-5; I-5 **Validity** M-2; L-5; I-7	Many of the issues that the Committee discussed related to Evidence (e.g., proximity of the process [referral for follow-up] to improved patient outcomes), were raised during the validity testing discussion. Additionally, Committee members raised significant concern with the definition of referral and the small sample size for testing.
#3087: Completion of a Malnutrition Screening within 24 hours of Admission	**Evidence** H-0; M-8; L-3; I-3	The Committee raised concern about the burden of screening each hospitalized patient within 24 hours and questioned why the measure fails to specify screening via a validated tool as supported by the evidence, as well as whether the screening to treatment link was substantiated by the evidence provided.
#3088: Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 hours of a	**Evidence** H-0; M-6; L-8; I-0	The Committee raised concerns about the evidence noting the guidelines cited were based on three trials, and among those there were inconsistencies in the evidence and even they were rather limited. NQF staff also noted that the evaluation criteria specifically call for an assessment of quality, quantity, and consistency of evidence.

Malnutrition Screening		
#3090: Appropriate Documentation of a Malnutrition Diagnosis	**Evidence** H-0; M-5; L-4; I-7 **Post-Comment Vote** **Request to Reconsider** Y-3; N-11	The Committee raised a number of issues, including: unclear definition of "malnutrition" and how it is captured; no disparities data presented; and application of the measure to a broader population (>18 years) than is recommended in the guideline (e.g., elderly). The Committee acknowledged the importance of assessing malnutrition but was concerned that there is not sufficient evidence to support the process of documenting that diagnosis is linked to improved outcomes. The measure did not pass the Evidence criterion.

Appendix B – Measure Evaluation Summary Tables

Rating Scale: H=High; **M**=Moderate; **L**=Low; **I**=Insufficient; **NA**=Not Applicable; **Y**=Yes; **N**=No

Measures Recommended

0032 Cervical Cancer Screening (CCS)
Submission | Specifications
Description: Percentage of women 21–64 years of age who were screened for cervical cancer using either of the following criteria: - Women age 21–64 who had cervical cytology performed every 3 years. - Women age 30–64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years. **Numerator Statement**: The number of women who were screened for cervical cancer. **Denominator Statement**: Women 24-64 years of age as of the end of the measurement year. **Exclusions**: Exclude: Women who had a hysterectomy with no residual cervix, cervical agenesis or acquired absence of cervix any time during their medical history through the end of the measurement year. **Adjustment/Stratification**: No risk adjustment or risk stratification. **Level of Analysis:** Health Plan, Integrated Delivery System **Setting of Care:** Ambulatory Care : Clinician Office/Clinic **Type of Measure**: Process **Data Source**: Administrative claims, Electronic Clinical Data, Paper Medical Records **Measure Steward**: National Committee for Quality Assurance
STANDING COMMITTEE MEETING [09/12/2016-09/13/2016] **1. Importance to Measure and Report: The measure meets the Importance criteria** (1a. Evidence, 1b. Performance Gap) (which may have changed the results for validity), 1a. Evidence: **Accepted Prior Evaluation;** 1b. Performance Gap: **H-1; M-11; L-1; I-0** Rationale: • This maintenance measure focuses on cervical cancer screening, which is a secondary prevention that has been shown to improve health outcomes by detecting cervical cancer in its earlier, more treatable stages. It is used in NCQA's HEDIS tool to assess performance on cervical cancer screening. • The measure is aligned with 2012 U.S. Preventive Services Task Force (USPSTF) clinical practice guidelines that recommend screening for cervical cancer in women aged 21 to 65 years with cytology (Papanicolaou smear or Pap smear) every 3 years or, for women aged 30 to 65 years who want to lengthen the screening interval, screening with a combination of cytology and HPV testing every 5 years. These guidelines are based on a comprehensive meta-analyses. • USPSTF guidelines for cervical cancer screening have been updated since 2012, however the updates do not impact the evidence base. The Committee accepted the prior evaluation of this criterion without further discussion. • In 2013, HEDIS measures covered more than 171 million people from 814 HMOs and 352 PPOs. The developer highlighted variation in cervical cancer screening within commercial and non-commercial health plans; approximately one quarter of commercial plan members and a third of Medicaid plan members are not receiving the recommended screenings. The national performance rate for commercial plans from 2012 to 2014 remained almost unchanged, 77% and 75% respectively. • One Committee member questioned whether the nearly static commercial plan performance rate signals that the measure is "topped out." The developer noted that wide variation in

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performance persists across both commercial health and Medicaid plans; in 2014 there was a 14 percentage point difference (68-82%) between commercial plans in the 10th and 90th percentile range, and a 27 percentage point difference (46-73%) among Medicaid plans.

- The developer cited literature on cervical cancer screening and disparities that reveal significant access barriers to regular cervical cancer screening for recent immigrants and women without health insurance. The data also show that Hispanic and African-American women have the highest incidence of cervical cancer, respectively.
- The developer does not collect performance data that are stratified by sociodemographic variables such as race, ethnicity, education, insurance status, income, or language preference; this was a concern that was raised by the Committee during that last maintenance review. The developer noted that individual plans are stratifying those data, but geographic and plan-level variation makes it difficult to incorporate those data into HEDIS in a standardized way. The Committee recommended that the developer work with plans that are collecting this information and include stratified performance data in the next maintenance submission. The developer agreed to include disparities data in the next maintenance submission. Ultimately, the Committee agreed that a performance gap in care remains.

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)

Specifications

<u>Rationale</u>

- Generally, the Committee believed the measure is clearly specified; however, several Committee members asked the developer for the following clarification:
    - The USPSTF guidelines recommend cervical cancer screening for average risk women, from age 21 through 65, yet the denominator states women ages 24 through 64. The developer confirmed that the measure assesses whether women 21 through 64 years received cervical cancer screening. Furthermore, the denominator is specified to start at age 24 because there's a three- year look back period (or lag period) where NCQA assesses whether a woman had cytology performed between ages 21 through 24; this assessment is done to ensure that women screened prior to 21 years of age are not captured in the measure.
- Other members questioned why high-risk women >65 years were not included in the measure. The developer confirmed that the measure is intended for health plan and Medicaid populations and not the Medicare population (>65 years). Furthermore, the specifications are aligned with USPSTF recommendation, screening from age 21 to 65. (The USPSTF recommends screening for women age >65 years who have never been screened, do not meet the criteria for adequate prior screening, or for whom the adequacy of prior screening cannot be accurately assessed or documented.) Committee members strongly urged the developer not to neglect the highest risk women, many of whom do not have access to regular cervical cancer screening or may have received abnormal screens in the past. The developer agreed to take the Committee's concern under consideration.
- One Committee member broached the issue of overutilization and unintended consequences. The developer affirmed that data on overuse of cervical cancer screening are not collected for this 21-65 age cohort, but those data are collected for a separate NCQA measure that assesses non-recommended cervical cancer screening in adolescents, ages 16 through 20.
- One Committee member suggested the developer assess the correlation between the HPV vaccine status measure and this measure, and whether receipt of the 3 HPV vaccines and subsequent refusal of a Pap smear impact performance results.

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2a. Reliability: **Accepted Prior Evaluation**; 2b. Validity: **M-13; L-0; I-0**

Rationale

- For the 2012 submission, the developer conducted beta-binomial testing to assess signal-to-noise, where the signal is the proportion of variability attributable to performance and noise is that attributable to error. The reliability score is 0.7. (A reliability score of 1 implies that all the variability is attributable to real differences in performance, and a score of 0 implies all variability is attributable to measurement error.) The score-level reliability score for commercial plans is 1.00 for commercial plans and 0.99 for Medicaid plans (2014 HEDIS data). Since reliability testing remains unchanged since the last maintenance review, the Committee accepted the prior evaluation of this criterion without further discussion.
- The developer tested the measure for face validity using a panel with expertise in women's health, oncology, family practice, health plans, state Medicaid agencies and research. The experts determined that the measure score is a valid indicator of quality.
- In addition to face validity, the developer indicated empirical validity testing-independent sample t-test-was performed since the last review, where the P-value of an independent sample t-test was compared for commercial plans in the 20th percentile against commercial plans at the 75th percentile. While this assessment was used to demonstrate meaningful differences in performance across health plans, it does not meet NQF's requirements for score-level validation; therefore, the highest eligible rating for Validity is "moderate" based on their validity testing.

3. Feasibility: H-4; 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:

- This measure is coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims), and abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry).
- The only concern the Committee raised is that "some", not all, data elements are in defined fields in electronic sources.

4. Usability and Use: H-0; M-11; L-2; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The measure is used in several public reporting and payment programs, including the Annual State of Health Care Quality; Medicaid Adult Core Set; Physician Quality Reporting System; California's Value Based Pay for Performance Program; NCQA Health Plan Rating; and CMS' EHR Incentive Program (Meaningful Use).
- Performance rates have remained fairly steady across both commercial and Medicaid plans over the past 3 years.
- Committee members noted that while the measure received support from the Measure Applications Partnership (MAP) in 2015, the MAP also raised concern about potential overuse and encouraged pairing the measure with one that assesses overuse.

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5. Related and Competing Measures • This measure is related to Measure 0579: Annual cervical cancer screening or follow-up in high-risk women. • The specifications for Measures 0579 and 0032 are not harmonized. • The developer states the numerator for both measures focuses on women who had cervical cancer screening during the year, however Measure 0579 focuses on a denominator of high-risk patients and is used in a surveillance strategy. This measure is intended to measure cervical cancer screening in the general population. • The exclusions for both measures are aligned.
Standing Committee Recommendation for Endorsement: **Y-13; N-0**
6. Public and Member Comment Comments Received: • One commenter was in support of the measure being recommended, acknowledging the burden it would have on some providers to collect the data because most screenings are done outside the physician's office.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0038 Childhood Immunization Status (CIS)
Submission | **Specifications**
Description: Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DtaP); three polio (IPV); one measles, mumps and rubella (MMR); three haemophilus influenza type B (HiB); three hepatitis B (HepB); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (HepA); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday. The measure calculates a rate for each vaccine and a combination rate. **Numerator Statement**: Children who received the recommended vaccines by their second birthday. **Denominator Statement**: Children who turn 2 years of age during the measurement year. **Exclusions**: Exclude children who had a contraindication for a specific vaccine from the denominator for all antigen rates and the combination rates. The denominator for all rates must be the same. **Adjustment/Stratification**: No risk adjustment or risk stratification. **Level of Analysis:** Health Plan, Integrated Delivery System **Setting of Care:** Ambulatory Care : Clinician Office/Clinic **Type of Measure**: Process **Data Source**: Administrative claims, Electronic Clinical Data, Paper Medical Records, Electronic Clinical Data : Registry **Measure Steward**: National Committee for Quality Assurance
STANDING COMMITTEE MEETING [09/12/2016-09/13/2016] **1. Importance to Measure and Report: The measure ~~did not reach consensus on~~ meets the Importance criteria** (1a. Evidence, 1b. Performance Gap) 1a. Evidence: **Accepted Prior Evaluation**; 1b. Performance Gap: **H-11; M-2; L-0; I-0**; 1d. Composite: **H-3; M-4; L-4; I-1** *Note: Following the meeting, the developer asked to remove the all-10 components*

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from the measure. Following the comment period, the Committee will review comments and vote on overall suitability for endorsement without the composite.

Rationale:

- Evidence for this composite, maintenance measure is based on the 2011 CDC's ACIP recommendations for individual, recommended childhood immunizations. The developer has updated the evidence to reference the 2015 ACIP recommendations; the developer states the measure remains aligned with the recommendations.
- The CDC's vaccine-specific recommendations indicate the ACIP recommendations summarize the quality, quantity, and consistency of evidence; however, there is no specific evidence for combing the 10 individual measures into 1 measure.
- Ultimately, the Committee agreed to accept the prior evaluation for the Evidence criterion.
- The developer provided rates for each of the 10 immunizations and the combined rate for all 10. For the combination rate, the developer reports:
    - Commercial: Mean = 47.57% and Minimum-Maximum Range = 0.92-77.31% (2014); 44.84% and 1.95-75.49% (2013); 34.15% and 0.52-74.06% (2012)
    - Medicaid: Mean = 36.1% and Minimum-Maximum Range = 1.7-76.1% (2014); 34.7% and 2.1-76.1% (2013); 31.4% and 1.4%-66.4% (2012)
- The developer does not collect data stratified by race, ethnicity, or language; however, the developer cites literature related to disparities and childhood immunizations:
    - Data from the National Immunization Survey showed that, while disparities in coverage were not observed for most racial/ethnic groups, disparities were seen for children of lower socioeconomic status.
    - Specifically, children living with families with incomes below the federal poverty level had lower coverage than those at or above the poverty level for Dtap, Hib, PCV, HeA, and rotavirus. The differences in rates ranged from 6.0 percentage points (HepA) to 9.5 percentage points (rotavirus).
- The Committee stressed the importance of assessing disparities in order to provide targeted solutions in at risk communities. The developer agreed to include disparities data in the next maintenance submission. Ultimately, the Committee concluded that performance gaps in care remain.
- The measure encompasses rates for 10 individual vaccines and an all-or-nothing composite rate.
- The developer conducted analyses to determine which vaccines to combine, but did not provide an explicit rationale for the composite. The developer implies that it can be inferred based on the ACIP recommendations for the individual childhood immunizations.
- Committee members stressed the importance of assessing individual components to identify meaningful performance gaps.
- The developer explained that performance rates on each vaccine and a combined rate (not only for the 10 measures included in this measure) are reported nationally to allow health plans some degree of flexibility with benchmarking and reporting for various programs.
- One Committee member asked for the number of providers that opt out of the measure. The developer explained that the measure is intended for health plans participating in HEDIS; opt outs and refusals are not specified as exclusions. Through regional reporting, the developer is able to assess geographic trends related to refusals/opt outs.
- Ultimately, the Committee failed to reach consensus on the Composite Quality Construct and Rationale.
- Following the in-person meeting, the developer withdrew the component of the specifications that pertained to the all-10 composite.
- During the post-comment call, Committee members noted that since the part of the specification in the question had been removed, the measure was no longer controversial.

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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: **Accepted Prior Evaluation**; 2b. Validity: **Accepted Prior Evaluation**; 2d. Composite: **H-3; M-7; L-3; I-0**

<u>Rationale</u>:

- The beta-binomial method was used to assess signal-to-noise, where the signal is the proportion of variability attributable to performance and noise is that attributable to error.
- A reliability score of 1 implies that all the variability is attributable to real differences in performance, and a score of 0 implies all variability is attributable to measurement error. The developer states a reliability score of 0.7 is considered "very good."
- Using the 2014 HEDIS dataset, the reliability statistics for receipt of all 10 vaccines was 0.98 for commercial plans and 0.96 for Medicaid plans.
- The reliability statistics for individual vaccine rates (again, using 2014 HEDIS data) were 0.89 to 0.98 for commercial plans and 0.89 to 0.96 for Medicaid plans.
- The previous NQF Committee concluded reliability was high, with reliability statistics of 0.84 to 0.98; these are directionally the same as the updated reliability testing. The Committee, therefore, accepted the prior Reliability evaluation without further discussion.
- For the original face validity testing, the developer used a panel of stakeholders, including representatives from women's health, oncology, family practitioners, health plans, state Medicaid agencies, and researchers.
- The face validity assessment concluded that the measure score was an indicator of quality.
- The previous NQF Committee concluded validity was moderate. The Committee, therefore, accepted the prior Validity evaluation without further discussion.
- The developer inadvertently included results of t-test empirical testing to support validity testing. The developer confirmed that these results should be considered under 2b5. Meaningful Differences
- Committee members suggested the developer conduct correlation analyses between the composite and each individual measure to increase transparency of the performance scores.
- There was considerable discussion on whether face validity on the individual measures would satisfy the 2d. criterion; however, NQF noted this testing appropriately supports the Validity criterion.
- The Committee noted that this large scale composite measure (based on health plans) could signal quality and performance issues in the broader community.

3. Feasibility: H-4; 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)

<u>Rationale</u>:

- The developer notes the following:
  - The measure is coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims);
  - The measure is abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry); and
- Some data elements are in defined fields in electronic sources.

4. Usability and Use: H-12; M-1; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

<u>Rationale</u>:

0038 Childhood Immunization Status (CIS)
• The measure is used in several public reporting and payment programs, including: ○ NCQA Health Plan Rating   ○ NCQA Annual State of Health Care Quality: ○ CMS Medicaid Child Core Set   ○ CMS Health Insurance Marketplaces - Quality Rating System   ○ CMS Physician Quality Reporting System   ○ California's Value Based Pay for Performance Program • The developer reports that during the last 5 years, performance has improved. Across commercial plans, the proportion of children documented as having received all 10 vaccines moved from less than a fourth to about half; for Medicaid, the proportion moved from 15% to a little over a third. • The 2014 rates of 47.6% for commercial plans and 36.1% for Medicaid plans show large room for improvement. • Receipt of some individual vaccines is high, while several others remain low. Across commercial plans in 2014, rates for individual vaccines ranged from an average high of 90.7% for HiB vaccine to a low of 65.1% for influenza vaccine. A similar pattern was seen in Medicaid, with average performance on some vaccines being high, but others being quite low. For Medicaid plans in 2014, receipt of individual vaccines ranged from a high of 90.0% for MMR and VZV vaccine to a low of 51.1% for influenza vaccine. • Large differences between lower and higher performing plans exists. For example, in 2014, the average rate of receipt of all vaccines was 28.4% among commercial plans in the 10th percentile and 63.2% among those in the 90th percentile. For Medicaid, the range was 23.4% to 49.6%.
5. Related and Competing Measures • 0041: Preventive Care and Screening: Influenza Immunization (PCPI) • 0475: Hepatitis B Vaccine Coverage Among All Live Newborn Infants Prior to Hospital or Birthing Facility Discharge (CDC) • 0479: Birth dose of hepatitis B vaccine and hepatitis B immune globulin for newborns of hepatitis B surface antigen (HBsAg) positive mothers (Asian Liver Center at Stanford University) • 1659: Influenza Immunization (CMS) • 0226: Influenza Immunization in the ESRD Population (KCQA)
Standing Committee Recommendation for Endorsement: **Y-14**; **N-0** • During the post comment call, the Committee voted on Overall Suitability and ultimately recommended the measure for endorsement. No vote had been previously taken on Overall Suitability.
6. Public and Member Comment Comments received: • This measure received one comment expressing general support for the measure for public health reporting purposes.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0039 Flu Vaccinations for Adults Ages 18 and Older
Submission | **Specifications**

0039 Flu Vaccinations for Adults Ages 18 and Older

Description: The percentage of adults 18 years of age and older who self-report receiving an influenza vaccine within the measurement period. This measure is collected via the CAHPS 5.0H adults survey for Medicare, Medicaid, and commercial populations. It is reported as two separate rates stratified by age: 18-64 and 65 years of age and older.

Numerator Statement: This measure is reported as two rates:

Flu Vaccination for Adults age 18-64 – Respondents to the Medicaid or commercial CAHPS survey who report having received an influenza vaccination since July of the previous year.

Flu Vaccination for Adults age 65+ - Respondents to the Medicare CAHPS survey who report having received an influenza vaccination since July of the previous year.

Denominator Statement: Flu Vaccinations for Adults Ages 18-64 – Medicaid and Commercial CAHPS respondents age 18-64

Flu Vaccination for Adults Age 65 and Older – Medicare CAHPS respondents age 65 and older.

Exclusions: N/A

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Health Plan, Integrated Delivery System

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Home Health, Hospital/Acute Care Facility, Post Acute/Long Term Care Facility : Inpatient Rehabilitation Facility, Post Acute/Long Term Care Facility : Long Term Acute Care Hospital, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility, Pharmacy, Ambulatory Care : Urgent Care

Type of Measure: Process

Data Source: Patient Reported Data/Survey

Measure Steward: National Committee for Quality Assurance

STANDING COMMITTEE MEETING [09/12/2016-09/13/2016]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

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

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

<u>Rationale</u>:

- Evidence suggests influenza vaccinations are the most effective way to prevent severe illness or death resulting from influenza and its complications (CDC 2010). This maintenance measure was updated with the 2015-2016 Advisory Committee on Immunization Practices (ACIP) recommendations for influenza vaccinations.
- The Committee discussed the seasonality of the flu and challenges of aligning the CAHPS measure development cycle with changing guidelines. The developer affirmed updating this measure during NQF's Annual Update process.
- In 2015, HEDIS measures covered 172 million commercial health plan beneficiaries. The developer provides rates for influenza vaccinations for adults ages 18-64 only:
    - Commercial: Mean = 49.2% and Minimum-Maximum Range = 38.2 -59.4% (2014); 49.2% and 38.6-59.3% (2013); 54.6% and 44.9-63.4% (2012)
    - Medicaid: Mean = 39.8% and Minimum-Maximum Range = 28.3-50.4% (2014); 39.4% and 29.5-49% (2013)
- While race and ethnicity are captured in the CAHPS survey, the developer currently does not receive those or other data stratified by sociodemographic variables like education, income, or language preference.
- The developer does note that the measure can be stratified by payer type and that the mean score for Medicaid plans is 39.8%. Additionally, the developer refers to the literature that shows that that influenza coverage was 31.5% among adults aged 19-49 years and 47.7%

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among adults aged 50-67 years. Furthermore, disparities in coverage were observed for most racial and ethnic groups: influenza coverage for whites aged 19 years and older was 47.6% compared to that for blacks was 36.5%, and for Hispanics was 33.2%.

- The Committee stressed the importance of assessing disparities in order to provide targeted solutions in at risk communities. The developer agreed to include disparities data in the next maintenance submission. Ultimately, the Committee concluded that performance gaps in care remain.

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)

- The developer noted changes to measure specifications:
  - Changed the question wording from "Have you had a flu shot since September 1, YYYY?" to "Have you had either a flu shot or flu spray in the nose since July 1, YYYY?"
  - Expanded the age range from 50-64 to 18-64, to align with ACIP guidelines.
  - Added Medicaid product line to the eligible population.
- Committee members questioned whether the measure captured persons receiving vaccinations outside the traditional clinical setting.
- Committee members noted that no information was provided on the extent of missing data, especially by subpopulations.

2a. Reliability: **Accepted Prior Evaluation**; 2b. Validity: **H-6; M-7; L-0; I-0**

<u>Rationale</u>:

- For the 2012 submission, the developer conducted empirical testing for reliability at the performance score level, and therefore the measure is eligible for a high rating. Reliability statistics of 0.89 to 0.98, depending on plan type, were noted by the developer. Reliability testing remains unchanged since the last maintenance review; therefore, the Committee accepted the prior evaluation of this criterion without further discussion.
- The developer conducted the following validity testing:
  - Face validity concluded that measure has desirable attributes of a HEDIS measure and is relevant, scientifically sound, and feasible.
  - Construct validity of the measure source compared the correlation of the Medicare Pneumococcal Vaccination Status for Older Adults with the Flu Vaccinations for Adults Ages 65 and Older measure. The results indicate that the measures and this measure were significantly positively correlated (<.0001), with a Pearson Correlation Coefficient of 0.82898.
  - Cognitive testing ensured data element validity of the survey questions. Results show that the term flu vaccination is not “sufficiently inclusive.” Respondents were best able to answer one question when the question used separate terms for each method of influenza vaccination administration. Providing additional information about the different types of influenza vaccination did not help respondents answer the questions.
- The Committee concluded that testing results demonstrate sufficient validity so that meaningful conclusions can be made about quality.

3. Feasibility: H-6; M-7; 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 CAHPS survey is conducted by third-party vendors via telephone, mail, email, or mixed protocols.

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• One Committee member encouraged the developer to harmonize the multiple modes of data collection (telephone, mail, email, or mixed protocols). • The developer states that there is concern that moving to an internet-based survey administration will bias results, as older more frail adults may be less likely to complete the survey. • The Committee raised concern that "some", not all, data elements are in defined fields in electronic sources.
4. Usability and Use: H-6; M-7; L-0; I-0 *(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)* Rationale: • The measure is used in several public reporting and payment programs, including NCQA Health Plan Ranking; NCQA Annual State of Health Care Quality; NCQA Quality Compass; NCQA Accreditation and Disease Management Accreditation; CMS Medicaid Adult Core Set; and CMS Medicare Advantage Star Rating. • Performance rates for the older adult population have remained steady over the past 3 years, which the developer notes is not unusual for survey-based measures. • In 2013, MAP reviewed this measure and recommended that it be expanded to include all adults. MAP strongly encouraged NCQA to submit the new specifications to NQF during the annual update process. MAP also recommended that CMS use the most current, expanded version of the measure in the Medicaid Adult Core Set.
5. Related and Competing Measures • 0041: Preventive Care and Screening: Influenza Immunization • 0226: Influenza Immunization in the ESRD Population (Facility Level) • 0227: Influenza Immunization • 0431: Influenza Vaccination Coverage Among Healthcare Personnel • 0522: Influenza Immunization Received for Current Flu Season (Home Health) • 0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short stay) • 0681: Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (long stay) • 1659: Influenza Immunization • The developer notes that this measure is not completely harmonized with other related measures as it is the only measure collected through patient survey. • Committee members debated the impact of health plans versus providers on measure results. • The 2012 NQF Committee suggested a universal measure that incorporates all of the various populations included in the influenza immunization measures.
Standing Committee Recommendation for Endorsement: **Y-12; N-1**

0039 Flu Vaccinations for Adults Ages 18 and Older
6. Public and Member Comment Comments received: • One commenter opposed the use of influenza measures for their lack of inclusion in the Core Measures Set for Primary Care Medical Homes and Accountable Care Organizations. The commenter stated that the measure is a poor indicator of quality because most providers are not the persons in their facilities who administer the vaccination. Developer response: • This measure is specified and tested at the health plan and integrated system level of accountability. Flu shots are provided in a variety of acceptable settings (physician office, pharmacy, retail pop-up clinics, public health, and work-sites) which necessitates a survey-based approach to measurement. The intent of this measure is to assess whether members are getting vaccinated seasonally regardless of the site of vaccination. We expect health plans to ensure all adults 18 years and older receive a flu vaccine. We recognize some patients should not receive the flu vaccine due to medical reasons; however, we anticipate this to be evenly distributed across plans. We also do not expect vaccine shortages to have a significant impact on health plan rates for flu vaccination.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0041 Preventive Care and Screening: Influenza Immunization
Submission | **Specifications**
Description: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization **Numerator Statement**: Patients who received an influenza immunization OR who reported previous receipt of an influenza immunization **Denominator Statement**: All patients aged 6 months and older seen for a visit between October 1 and March 31 **Exclusions**: Documentation of medical reason(s) for not receiving influenza immunization (eg, patient allergy, other medical reasons) Documentation of patient reason(s) for not receiving influenza immunization (eg, patient declined, other patient reasons) Documentation of system reason(s) for not receiving influenza immunization (eg, vaccine not available, other system reasons) **Adjustment/Stratification**: No risk adjustment or risk stratification. **Level of Analysis:** Clinician : Group/Practice, Clinician : Individual **Setting of Care:** Ambulatory Care : Clinician Office/Clinic, Dialysis Facility, Home Health, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility, Other **Type of Measure**: Process **Data Source**: Electronic Clinical Data, Electronic Clinical Data : Registry **Measure Steward**: PCPI Foundation
STANDING COMMITTEE MEETING [09/12/2016-09/13/2016] **1. Importance to Measure and Report: The measure meets the Importance criteria**

0041 Preventive Care and Screening: Influenza Immunization

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

1a. Evidence: **H-2; M-11; L-0; I-0**; 1b. Performance Gap: **H-11; M-3; L-0; I-0**

Rationale:

- Annual influenza vaccination is the most effective method for preventing influenza virus infection and its complications. Influenza viruses cause disease among persons in all age groups. This maintenance measure is based on the Centers for Disease Control and Prevention (CDC) guidelines and recommendations of the Advisory Committee on Immunization Practices (ACIP). ACIP revised its influenza recommendations in 2010 to include a recommendation that annual vaccination be administered to all persons aged ≥6 months. This recommendation is current and has not changed as of 2016.
- Committee members questioned whether the measure has broad application beyond primary care settings. The Developer affirmed that the measure can be used broadly across sub-specialties and care settings. However, performance rates are not broken down by setting (e.g. clinician vs. facility).
- The Committee opted to vote on the Evidence criterion because there were some clarifying questions.
- Several Committee members noted the benefit of asking about the flu vaccine each year because of the seasonality of the virus and increased opportunity to track patient reasons for opting out.
- Committee members noted wide variation in performance across regions and states. For example, performance rates in Florida and South Dakota were 39% and 59%, respectively.
- Adults aged 18 years and older had lower rates of vaccination (43.6%) than children 6 months - 17 years (59.3%).
- Among people >=6 months, vaccination rates for non-Hispanic whites (48.5%) and Asians (51.0%) were higher than that of non-Hispanic blacks (43.8%), Hispanics (44.3%), and people of other or multiple races (44.3%).
- Ultimately, the Committee agreed that performance gaps in care remain.

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

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

- This measure does not align with the standard specifications for influenza vaccination. Specially,
  - Numerator: Does not include offer/decline
  - Denominator: All ages > 6months – does not differentiate high risk conditions in patients aged 19-49 years
  - Exclusions: Medical, patient and system reasons are not aligned
  - Timing: Patients seen October 1- March 31 is aligned with the standard specifications, however the measure does not acknowledge earlier availability of the vaccination

2a. Reliability: **H-6; M-8; L-0; I-0**; 2b. Validity: **M-13; L-1; I-0**

Rationale:

- One Committee member questioned the relevance of using ESRD reliability testing data for this clinician-level care setting. The developer explained that original testing submitted in 2012 included ESRD data for inter-rater reliability testing. The updated, submitted data include signal-to-noise ratio analysis conducted using registry data from the Physician Quality Reporting System (PQRS) program for January-December 2014.
- The total number of physicians reporting on this measure in 2014 via the registry is 12,184. Of those, 10,986 physicians had all the required data elements and met the minimum number of

0041 Preventive Care and Screening: Influenza Immunization
quality reporting events (10) for a total of 2,417,193 quality events. There were 2,342,385 patients included in this reliability testing and analysis. • The developer reports this measure has 0.80 reliability when evaluated at the minimum level of quality reporting events and 0.99 reliability when evaluated at the average number of quality events. • The Committee agreed that the testing results indicate that reliability at the minimum level of quality reporting events and average number of quality events is strong. • Face validity was assessed by a nine-member expert panel from the PCPI Measurement Advisory Committee that rated their agreement on whether scores from the measure as specified provided an accurate reflection of quality and can be used to distinguish good and poor quality. All but one of the panelists agreed with the statement. • The developer notes that documentation of medical reasons, patient reasons, system reasons for not receiving the vaccination are acceptable exclusions. Committee members asked for examples of system reasons, which include: "patient on waiting list"; "not entitled to benefits"; "not done –system reason"; and "vaccine not available". The developer further explained that "system reasons" are included as exclusions to not unfairly penalize providers for circumstances beyond their control.
3. Feasibility: H-10; M-4; 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: • Data are generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score). • Data are coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims). • All data elements are in defined fields in a combination of electronic sources.
4. Usability and Use: H-11; M-3; L-0; I-0 *(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)* Rationale: • The measure is currently used in Physician Quality Reporting System (PQRS). • The developer reports there have been no identified unintended consequences during testing or since implementation. • In 2013, the MAP Clinician recommended the measure be retained in PQRS and included in Physician Compare and Value-Based Payment Modifier Program. MAP stated that, while the measure was a process measure, it promotes alignment between public and private programs and addresses disparities.
5. Related and Competing Measures • 0039: Flu Vaccinations for Adults Ages 18 and Older • 0226: Influenza Immunization in the ESRD Population (Facility Level) • 0431: Influenza Vaccination Coverage Among Healthcare Personnel • 0522: Influenza Immunization Received for Current Flu Season (Home Health) • 0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short stay) • 0681: Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (long stay) • 1659: Influenza Immunization

0041 Preventive Care and Screening: Influenza Immunization

- With regards to harmonization the developer states that related measures have differing target populations from Measure #0041.

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

6. Public and Member Comment

Comment received:

- One commenter opposed the use of influenza measures for their lack of inclusion in the Core Measures Set for Primary Care Medical Homes and Accountable Care Organizations. The commenter stated that the measure is a poor indicator of quality because most providers are not the persons in their facilities who administer the vaccination.

Developer response:

- This measure is based on the CDC's Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2016–17 Influenza Season. Routine annual influenza vaccination is recommended for all persons aged ≥6 months who do not have contraindications.

Influenza may lead to serious complications and vaccination is the most effective protection against influenza virus infection. However, data indicate that less than half of all eligible individuals receive an influenza vaccination.

This measure promotes annual influenza vaccination for all persons aged ≥ 6 months. The measure assesses whether a patient received the flu vaccine or reports previous receipt of the flu vaccine at any other location or via another provider. The measure does not account for patient counseling to receive the vaccine elsewhere because this does not ensure that the patient receives the vaccination thereby reducing the risk of adverse flu-related outcomes as is the intent of this measure.

Comment received:

- One commenter was concerned about the intended misuse of the measure in value-based payment programs instead of how the developer specified within the submission. This commenter recommended influenza vaccinations be given as soon as locally available to all children and suggested that they would support the development of a seasonal influenza immunization measure specific to pediatric populations, in order to capture the needs of the population.

Developer response:

- This measure is based on the CDC's Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2016–17 Influenza Season. Routine annual influenza vaccination is recommended for all persons aged ≥6 months who do not have contraindications.

The expert work group constructed this measure based primarily on the CDC's recommendation in addition to data on peak month flu activity. While seasonal influenza may be active year-round, the CDC states that peak flu activity is between October and March (http://www.cdc.gov/flu/about/season/flu-season.htm). Additionally, the flu season covered is aligned with other NQF endorsed flu vaccine measure and in alignment with NQF's National Voluntary Consensus Standards for Influenza and Pneumococcal Immunizations. Furthermore, the PCPI aims to develop broad measures in response to current national interest in the parsimonious use of measures to reduce the resource burden on health care providers without compromising the quality of patient care.

Finally, regarding the AAP's concern about the availability of the influenza vaccine, the expert work group raised this issue and opted to include a measure exception when the vaccine is not available so as not to inappropriately penalize a clinician for an issue not within his/her control.

0041 Preventive Care and Screening: Influenza Immunization
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0226 Influenza Immunization in the ESRD Population (Facility Level)
Submission | **Specifications**
Description: Percentage of end stage renal disease (ESRD) patients aged 6 months and older receiving hemodialysis or peritoneal dialysis during the time from October 1 (or when the influenza vaccine became available) to March 31 who either received, were offered and declined, or were determined to have a medical contraindication to the influenza vaccine. **Numerator Statement**: Number of patients from the denominator who: 1. received an influenza vaccination,* documented by the provider or reported receipt from another provider by the patient (computed and reported separately); OR 2. were assessed and offered an influenza vaccination but declined (computed and reported separately); OR 3. were assessed and determined to have a medical contraindication(s) of anaphylactic hypersensitivity to eggs or other component(s) of the vaccine, history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination, and/or bone marrow transplant within the past 6 months (<6 months prior to encounters between October 1 and March 31) (computed and reported separately). *Only inactivated vaccine should be used in the ESRD population. **Denominator Statement**: All ESRD patients aged 6 months and older receiving hemodialysis and/or peritoneal dialysis during the time from October 1 (or when the influenza vaccine became available) to March 31. **Exclusions**: None. **Adjustment/Stratification**: No risk adjustment or risk stratification. **Level of Analysis:** Facility **Setting of Care:** Dialysis Facility **Type of Measure**: Process **Data Source**: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Medical Records **Measure Steward**: Kidney Care Quality Alliance
STANDING COMMITTEE MEETING [09/12/2016-09/13/2016] **1. Importance to Measure and Report: The measure meets the Importance criteria** (1a. Evidence, 1b. Performance Gap) 1a. Evidence: **Accepted Prior Evaluation**; 1b. Performance Gap: **H-5; M-7; L-1; I-0** Rationale: • Influenza immunization has been shown to decrease the likelihood of hospitalization, morbidity, and mortality among ESRD patients. • The 2012 NQF Committee noted high ratings on quantity, quality, and consistency of evidence. • The developer has updated the information to reflect the 2015-2016 ACIP recommendations.

0226 Influenza Immunization in the ESRD Population (Facility Level)

- The Committee accepted the previous evaluation and updated information, which is directionally the same, without further discussion.
- The developer noted significant performance variation across providers for ESRD patients. The mean score across the 53 dialysis facilities in the prospective cohort study and 1,115 patients was 97.1%, with a range of scores from78-100%.
- These findings indicate that despite the high overall performance rate, the performance for each individual facility ranged from 78% to 100%. Additionally, due to the significant spread between both the minimum and maximum, the measure shows clinically and practically meaningful differences among measured ESRD facilities.
- The developer also noted that the US Renal Dialysis System (USRDS) 2015 Annual Data Report indicates a steady increase in influenza vaccination rates, however only 71% patients with ESRD received an influenza vaccination in the 2012-2013 flu season. This is below the Healthy People 2020 target of 90%.

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-1; M-11; L-1; I-1**; 2b. Validity: **H-0; M-13; L-1; I-0**

<u>Rationale</u>:

- One Committee member questioned why pediatric data were not collected when the specifications include ESRD patients aged 6 months and older. The developer confirmed that the measure is tested at the data element level, where data of birth is a standard field. Furthermore, the pediatric population is fairly negligible in non-pediatric facilities, with fewer than 10,000 children being treated with ESRD.
- Following the data collection period, audits of 11 of the 53 facilities in the prospective cohort study were performed and pertinent data were re-abstracted from the patients' medical records and compared to information submitted by the facility throughout the pilot to assess the measure's reliability.
- Inter-rater reliability was assessed and summarized using Cohen's Kappa with confidence intervals.
- The Kappa statistic was found to be 0.6568 with a 95% confidence interval of 0.521-0.7926. The developer noted that based on literature, this is "substantial agreement." Additionally, the percent agreement between the auditor and facility abstractors was 98.1%. Both of these values determine that the measure is reliable.
- The measure has empirical testing and demonstrates content validity through face validity that was systematically assessed by experts.
- Per the developer, the measure was deemed appropriate by expert opinion from Kidney Care Partners (KCP) and Kidney Care Quality Alliance (KCQA), expert opinion of the NQF ESRD Technical Advisory Panel Steering Committee, and broad agreement through NQF review and voting process.
- The developer also noted that external validity has been met through the original sampling schema, which is representative of the US dialysis population, so the results can be generalized with confidence.
    - 53 facilities were part of the sample and included a mix of facility types.
- The developer has not updated validity testing since the last maintenance review.

3. Feasibility: H-6; M-8; 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>:

0226 Influenza Immunization in the ESRD Population (Facility Level)

- The developer reported that this measure is coded by someone other than the person obtaining original information (e.g., DRG, ICD-9 codes on claims), and abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry).
- All data elements are in defined fields in electronic sources.
- The developer noted that CROWNWeb will reduce the burden of data collection and that KCQA is in discussion with CMS regarding CROWNWeb compatibility and the need for system updates to accommodate the measure.

4. Usability and Use: H-9; M-5; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The measure is planned for use and currently used in several public reporting and payment programs, including:
  - Quality Improvement
  - Internal Quality Improvement by KCQA member dialysis organization(s)
  - ESRD Quality Incentive Program (QIP)
- The 2012 NQF Committee noted the focus of this facility-level measure on a high-risk population with significant risk of infection complications, strong supporting evidence of benefit of immunization and alignment with the standard specifications. The Committee recommended that risk stratification and disparities assessment be included in the next update.
- In 2013, MAP noted that the measure may not address a high-leverage opportunity and recommended looking at the impact of vaccination rates across settings.

5. Related and Competing Measures

- 0039: Flu Vaccinations for Adults Ages 18 and Older
- 0041: Preventive Care and Screening: Influenza Immunization
- 0227: Influenza Immunization
- 0522: Influenza Immunization Received for Current Flu Season (Home Health)
- 0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short stay)
- 0681: Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (long stay)
- 1659: Influenza Immunization
- This measure is fully harmonized with NQF's standardized specifications for influenza vaccinations and notes that this measure is specifically for the ESRD population and should be separate for this vulnerable population.

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

6. Public and Member Comment

Comments received:

- Commenters generally supported the Committee's decision to recommend this measure for continued endorsement.

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

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0279 Bacterial Pneumonia Admission Rate (PQI 11)

Submission | Specifications

Description: Admissions with a principal diagnosis of bacterial pneumonia per 1,000 population, ages 18 years and older. Excludes sickle cell or hemoglobin-S admissions, other indications of immunocompromised state admissions, obstetric admissions, and transfers from other institutions.

Numerator Statement: Discharges, for patients ages 18 years and older, with a principal ICD-9-CM or ICD-10-CM-PCS diagnosis code for bacterial pneumonia.

[NOTE: By definition, discharges with a principal diagnosis of bacterial pneumonia are precluded from an assignment of MDC 14 by grouper software. Thus, obstetric discharges should not be considered in the PQI rate, though the AHRQ QI software does not explicitly exclude obstetric cases.]

Denominator Statement: Population ages 18 years and older in metropolitan area or county. Discharges in the numerator are assigned to the denominator based on the metropolitan area or county of the patient residence, not the metropolitan area or county of the hospital where the discharge occurred.

Exclusions: Not applicable.

Adjustment/Stratification: Statistical risk model

The predicted value for each case is computed using a hierarchical model (logistic regression with hospital random effect) and covariates for gender, age (in 5-year age groups). An option model is available that includes percent of households under the federal poverty level as well. Because we cannot individually observe the age and gender of each person in a counties population, we use the age and gender distribution of the county to estimate the number of "cases" in each age*gender group. The reference population used in the regression is the universe of discharges for states that participate in the HCUP State Inpatient Data (SID) for the year 2013 (combined), a database consisting of 40 states, and the U.S. Census data by county. The expected rate is computed as the sum of the predicted value for each case divided by the number of cases for the unit of analysis of interest (i.e., area). The risk adjusted rate is computed using indirect standardization as the observed rate divided by the expected rate, multiplied by the reference population rate.

Level of Analysis: Population: County or City

Setting of Care: Other

Type of Measure: Outcome

Data Source: Administrative claims

Measure Steward: Agency for Healthcare Research and Quality

STANDING COMMITTEE MEETING [09/12/2016-09/13/2016]

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

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

1a. Evidence: **The Evidence rating transferred from current Pulmonary and Critical Care Standing Committee**; 1b. Performance Gap: **H-5; M-9; L-0; I-0**

Rationale:

- This population-level, maintenance measure assesses hospitalization rates for pneumonia in the community. It was recently reviewed by the Pulmonary and Critical Care Standing Committee, but was referred by CSAC to the Health and Well-Being Standing Committee for further review.
- The measure assesses an outcome of care; therefore, a systematic review of the body of evidence is not required.
- The developer provided the following rationale for this outcome measure: Access to high quality care, early intervention, and appropriate pharmaceutical treatment may minimize the likelihood of milder respiratory conditions progressing to pneumonia, reducing the likelihood of hospitalizations. The intent of this Preventive Quality Indicator (PQI) is to assess adequate

0279 Bacterial Pneumonia Admission Rate (PQI 11)

healthcare resources in the community, assuming a portion of pneumonia cases or hospitalizations can be prevented.

- The developer provided updated evidence related to hospitalization for pneumonia, but the Pulmonary and Critical Care Standing Committee agreed with the developer that the underlying rationale for this outcome measure has not changed since the last NQF endorsement review.
- The Health and Well-Being Standing Committee accepted the Pulmonary and Critical Care Standing Committee's decision to accept the prior evaluation on Evidence without further discussion.
- Data provided by the developer show the average performance rate decreased from 5.20 percent in 2009 to 3.28 percent in 2013.
- The developer provided gap data that demonstrated an improvement from 2009 to 2013 (3.02 per 1,000 population to 2.23 per 1,000 population).
- The developer did not provide disparities data related to race, but noted males, patients over 65 years, patients with the lowest income, and patients living in rural areas have the highest rate.
- The developer noted significant gaps between counties; the variation in pneumonia admission rates across counties was largely correlated with income level. The Health and Well-Being Standing Committee recognized that income level is a strong indicator of access to care.
- Overall, the Health and Well-Being Committee agreed the data demonstrate variations in care.

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-7; M-7; L-0; I-0**; 2b. Validity: **M-9; L-5; I-0**

<u>Rationale</u>:

- The developer updated the measure specifications measure by: adding diagnosis codes; removing numerator exclusions (MDC14 and MDC15); and adding exclusion of patients with any diagnosis code or procedure code for Immunocompromised state.
- Signal-to-noise reliability testing at the level of the measure score was conducted using data from the Healthcare Cost and Utilization Project (HCUP) State Inpatient Databases (SID). The developer reported a signal-to-noise ratio of 0.97.
- Validity testing was conducted with a systematic assessment of face validity by 4 clinical expert panels involving 73 panelists from 2008-2009. The developer reported the panels indicated the measure was useful.
- Like the Pulmonary and Critical Care Standing Committee, the Health and Well-Being acknowledged complex factors influence the measure.
- The measure is risk adjusted for gender and age only. Committee members debated the appropriateness of risk adjustment for socioeconomic factors like income, which was one of the most significant drivers of pneumonia admissions between counties. The Committee generally believed that risk-adjustment would mask disparities across subpopulations and suggested stratification might be more appropriate. Some Committee members noted that stratification could help highlight differences across states and related policy drivers.
- Some Committee members raised concern about the lack of risk adjustment for disease severity.

3. Feasibility: H-11; M-2; 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>:

0279 Bacterial Pneumonia Admission Rate (PQI 11)

- The Committee agreed the measure is feasible. All data elements are in defined fields in electronic claims. The measure is based on readily available administrative billing and claims data. The AHRQ QI software is publicly available and users have more than 10 years of experience using it.

4. Usability and Use: H-3; M-8; L-3; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- This measure is currently publicly reported and used in accountability programs.
- The developer reports bacterial pneumonia/community-acquired pneumonia hospital admissions have decreased by 87,000 fewer hospitalizations from 2011-2013.
- Similar to the Pulmonary and Critical Care Standing Committee, this Committee's members expressed significant concern about the unintended consequence of off-label use of the measure, meaning, the use of the measure in CMS federal programs at a practice level despite being specified for population-level evaluation. The Committee emphasized such implementation is not appropriate because testing and endorsement review occur at the specified level. At the same time, Committee members acknowledged the value of population-level measures such as this type.
- The Committee recommended NQF identify a portfolio of population-level measures and link those to appropriate drivers and intended uses.
- Generally, the Health and Well-Being Standing Committed believed that the measure assesses the health system more broadly and not only healthcare.

5. Related and Competing Measures

- No related or competing measures identified.

Standing Committee Recommendation for Endorsement: Y-12; N-2

6. Public and Member Comment

Comments received:

- One commenter opposed the continued endorsement of this measure due to its lack of adjustment for socioeconomic factors and the unintended consequences to organizations that serve rural and low income populations, noting the measure not being a good indication of physician/community wellness. Additionally, the measure is not included in the Core Measure Set for Accountable Care Organizations/Primary Care Medical Homes.

Developer response:

- AHRQ would like to clarify that this measure is intended to measure area-level access to care and community wellness, rather than the quality of physicians, hospitals or other provider groups. As such, higher rates in communities may reflect poorer health in the community, higher chronic disease burden and lower access to care. We observe disparities in populations with lower socioeconomic status, which simply highlights the need in such communities to improve the health of the population and the resources available to promote health in a community. When used as intended and tested, PQI 11 highlights communities in need rather than penalizing the physicians and hospitals in those areas. Possible mechanisms of community influence on hospitalization rates for pneumonia were discussed in the Health and Well Being Committee meeting and do span beyond the actions of any one physician. These mechanisms influence not only the vulnerability of patients in a population to develop pneumonia (e.g. Low access to vaccination) but also the resulting clinical severity of that pneumonia.
  AHRQ would like to clarify two additional aspects of PQI 11. The commenter does discuss presentation to the ED, but PQI 11 will capture these encounters only if the patient is then

0279 Bacterial Pneumonia Admission Rate (PQI 11)
hospitalized. Second, the AHRQ PQI software includes two risk models. The default uses only age and gender of the population, while an optional model adds poverty to the model. As was noted in the NQF Committee on socioeconomic adjustment of quality measures, there are valid reasons to both adjust and not adjust for socioeconomic status. As such, AHRQ provides two models to meet various user needs.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0431 Influenza Vaccination Coverage Among Healthcare Personnel
Submission | **Specifications**
Description: Percentage of healthcare personnel (HCP) who receive the influenza vaccination. **Numerator Statement**: HCP in the denominator population who during the time from October 1 (or when the vaccine became available) through March 31 of the following year: (a) received an influenza vaccination administered at the healthcare facility, or reported in writing (paper or electronic) or provided documentation that influenza vaccination was received elsewhere; or (b) were determined to have a medical contraindication/condition of severe allergic reaction to eggs or to other component(s) of the vaccine, or history of Guillain-Barré Syndrome within 6 weeks after a previous influenza vaccination; or (c) declined influenza vaccination; or (d) persons with unknown vaccination status or who do not otherwise meet any of the definitions of the above-mentioned numerator categories. Numerators are to be calculated separately for each of the above groups. **Denominator Statement**: Number of HCP who are working in the healthcare facility for at least 1 working day between October 1 and March 31 of the following year, regardless of clinical responsibility or patient contact. Denominators are to be calculated separately for: (a) Employees: all persons who receive a direct paycheck from the reporting facility (i.e., on the facility's payroll). (b) Licensed independent practitioners: include physicians (MD, DO), advanced practice nurses, and physician assistants only who are affiliated with the reporting facility who do not receive a direct paycheck from the reporting facility. (c) Adult students/trainees and volunteers: include all students/trainees and volunteers aged 18 or over who do not receive a direct paycheck from the reporting facility. **Exclusions**: None. **Adjustment/Stratification**: No risk adjustment or risk stratification **Level of Analysis:** Facility **Setting of Care:** Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinician Office/Clinic, Dialysis Facility, Hospital/Acute Care Facility, Behavioral Health/Psychiatric : Inpatient, Post Acute/Long Term Care Facility : Inpatient Rehabilitation Facility, Post Acute/Long Term Care Facility : Long Term Acute Care Hospital, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility **Type of Measure**: Process **Data Source**: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Management Data, Paper Medical Records, Patient Reported Data/Survey

0431 Influenza Vaccination Coverage Among Healthcare Personnel

Measure Steward: Centers for Disease Control and Prevention

STANDING COMMITTEE MEETING [09/12/2016-09/13/2016]

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

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

1a. Evidence: **H-5; M-9; L-0; I-0**; 1b. Performance Gap: **H-3; M-11; L-0; I-0**

Rationale:

- Increased influenza vaccination coverage among Healthcare personnel (HCP) is expected to result in reduced morbidity and mortality related to influenza virus infection among patients. This maintenance measure is based on 2010 Centers for Disease Control and Prevention guidelines: Prevention and control of influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), which state: "All HCP and persons in training for health-care professions should be vaccinated annually against influenza. Persons working in health-care settings who should be vaccinated include physicians, nurses, and other workers in both hospital and outpatient-care settings, medical emergency-response workers (e.g., paramedics and emergency medical technicians), employees of nursing home and long-term-care facilities who have contact with patients or residents, and students in these professions who will have contact with patients."
- The developer presented results of four randomized trials that are not conclusive because the primary outcome of mortality used in these studies was nonspecific and was not laboratory-confirmed influenza. However, the developer notes remarkable consistency of the findings on reduced mortality among long-term care residents across these four studies provide evidence of the beneficial effect of vaccinating healthcare personnel.
- Pursuant to NQF's standard specifications for influenza vaccinations, Committee members recommended the developer clearly indicate that scores for persons in the numerator (e.g., number of persons specified in the denominator who received the influenza vaccine, or were assessed and offered but declined the vaccination, or were assessed and determined to have a medical contraindication(s) as specified) be computed and reported separately.
- The developer noted continuing significant performance gaps across types of facilities, personnel and geographic regions. Committee members suggested the developer stratify personnel type by clinical duty and/or patient contact. The developer noted that this analysis is not specified within ACIP recommendations; furthermore, the denominator requires that all measured personnel be physically present in the facility while performing a work duty. Theoretically, personnel that meet this criterion would have the opportunity to come into contact with patients or be in a patient's room.
- The data showed an upward trend for acute care hospitals, but still with remaining opportunity for improvement. The mean performance across different types facilities ranged from 76 to 88 percent and the standard deviation ranged from 15 to 23 percent.
- The developer states that since the measure examines summary vaccination data at the facility level, data on individual differences in vaccination by race, ethnicity, gender, age, or other sociodemographic variables are not available.

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-1; M-13; L-0; I-0**; 2b. Validity: **H-3; M-11; L-0; I-0**

Rationale:

- The developer attests that there are no significant changes to the measure specifications since the last maintenance review.

0431 Influenza Vaccination Coverage Among Healthcare Personnel

- Inter-rater reliability was assessed via 93 randomly-selected facilities in California, New Mexico, New York City and Pennsylvania to determine agreement with how facility personnel categorized the numerator and denominator.
- Sixty records were selected for the sample population across 3 personnel types: 20 employees; 20 credentialed non-employees; 20 other non-employees.
- Inter-rater agreement was 88% in the first facility (kappa: 0.82), 94% in the second facility (kappa: 0.89), and 80% in the third facility (kappa: 0.66). The developer explained that the percent numerator disagreement was due to facilities reporting verbal "declined vaccination" rather than unknown status.
- In addition to inter-rater reliability, the developer conducted case studies with a series of vignettes in order to classify HCP in the appropriate numerator or denominator group. While most numerator and denominator elements were correctly identified by the majority of respondent, persistent deferrals or verbal declinations for non-medical reasons were difficult to resolve.
- Committee members noted lack of geographic variation in the testing sample population. Absent from the sample was representation from the Midwest and South.
- One Committee member noted that at least 2 of the 4 states recruited for measure testing (New York and California) require HCP be vaccinated or wear a mask; these existing mandates may skew performance results.
- Convergent validity was assessed using a one-way ANOVA, where the developer examined the association between the number of evidence-based strategies used by a healthcare institution to promote influenza vaccination and the institution's reported vaccination rate among each denominator group of HCP. The developer expected that vaccination rates would be positively correlated with an increasing number of strategies that have been found previously to be associated with higher influenza vaccination coverage among HCP.
- The association between employee vaccination rates and number of strategies used was borderline significant at p=0.05; between credentialed non-employee vaccination rates and number of strategies it was significant at p=0.02; and between other non-employee vaccination rates and number of strategies used was significant at p=0.01.
- Face validity was assessed in 2011 using a modified Delphi technique via a panel of 9 experts. The panel reached consensus on the definition of the various HCP type groups.

3. Feasibility: H-2; M-12; 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:

- Data are generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score).
- The data are coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims).
- Some data elements are in defined fields in a combination of electronic sources. The developer stated that all data could not be captured because the measure is for healthcare personnel as opposed to patients.
- Committee members inquired about the burden of data collection for facilities since, as the developer noted, HCPs may not be part of electronic medical record system within facilities.
- The developer was unable to quantify the data collection burden but acknowledges challenges for facilities without appropriate electronic records systems.

4. Usability and Use: H-11; M-3; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

0431 Influenza Vaccination Coverage Among Healthcare Personnel

Rationale:

- The measure is currently used in several programs, including:
  - CMS Hospital Inpatient Quality Reporting (IQR) Program
  - CMS Hospital Outpatient Quality Reporting (OQR) Program
  - CMS Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP)
  - CMS Long Term Care Hospital Quality Reporting (LTCHQR) Program
  - CMS Ambulatory Surgical Center Quality Reporting (ASCQR) Program
  - CMS End Stage Renal Disease (ESRD) Quality Improvement Program (QIP)
  - CMS Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program
  - HRSA Medicare Beneficiary Quality Improvement Program (MBQIP)
  - National Healthcare Safety Network Public Health/Disease Surveillance
  - Joint Commission Regulatory and Accreditation Programs
- In 2013 the MAP did not support including the measure in Value Based Payment (VBP) because more experience with the measure is needed. At that time the MAP asserted that the measure was not ready for a pay-for-performance program. The measure was finalized for OQR and IRF QRP.

5. Related and Competing Measures

- The measure is aligned with the NQF standard specifications for influenza vaccinations. However, as with the standard specifications, the 3 numerator populations be computed and reported separately.

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

6. Public and Member Comment

Comments received:

- Both commenters support the Committee's recommendation for continued endorsement. One commenter expressed concerns about the intended use of the measure not being as developer specified in the submission, but for use in value-based payment programs.

Developer response:

- NQF 0431 is based on the National Voluntary Consensus Standards for Influenza and Pneumococcal Immunizations published by the National Quality Forum in 2008. In this report, NQF notes that the issue of denominator exclusions for delays in influenza vaccine availability was discussed by its Steering Committee of experts. Ultimately, the Steering Committee did not include an exclusion for delays in influenza vaccine supply in the standard measure specifications because (a) there was no systematic and consistent way to implement this exclusion and (b) influenza vaccine supply issues have become less frequent. The Committee further noted that in the event of a declared shortage of influenza vaccine, all healthcare providers purchasing the vaccine in question would be affected and a measure with no exclusions could be useful in assessing any differential impact of the delay or shortage on different providers.

The window for influenza vaccination (numerator) as measured by NQF 0431 begins as soon as vaccine for the current influenza season becomes available at the reporting facility and extends through March 31 of the following year. In the event of small or brief delays in vaccine availability, the length of this time window should permit reporting facilities adequate time to vaccinate and report data on vaccination even if the process begins later than usual. In the event of a more substantial or lengthier supply interruption, it is likely that many or most reporting facilities would be affected and that influenza vaccine supply concerns would be taken into account by measurement programs and organizations when scoring the measure for that season.

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

8. Board of Directors Vote: Y-X; N-X

0431 Influenza Vaccination Coverage Among Healthcare Personnel
9. Appeals

0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short stay)
Submission | **Specifications**

Description: The measure reports the percentage of short-stay residents or patients who are assessed and appropriately given the seasonal influenza vaccine during the most recently-completed influenza season. The influenza vaccination season (IVS) is defined as beginning on October 1, or when the vaccine first becomes available*, and ends on March 31 of the following year. This measure is based on the NQF´s National Voluntary Standards for Influenza and Pneumococcal Immunizations.

The measure is the aggregate of three separately calculated submeasures to reflect the process by which a resident or patient is assessed and appropriately given the influenza vaccination during the current or most recent influenza season.

The three submeasures are as follows:

- residents or patients who received the influenza vaccine during the most recently completed influenza season, either in the facility/hospital or outside the facility/hospital (NQF #0680a);
- residents or patients who were offered and declined the seasonal influenza vaccine (NQF #0680b);
- residents or patients who were ineligible to receive the seasonal influenza vaccine due to contraindication(s) (e.g., anaphylactic hypersensitivity to eggs or other components of the vaccine, see http://www.cdc.gov/flu/professionals/vaccination/vax-summary.htm) (NQF #0680c).

*Note: While the IVS officially begins when the vaccine becomes available, which may be before October 1, the denominator time window for the quality measure and references to the IVS for the denominator specification is from October 1 to March 31 of the following year. The numerator time window and references to the IVS in the numerator specifications may include patients and residents who are assessed and offered the vaccine before October 1. This is based on how the influenza items were coded by the facility.

The denominator consists of patients or short-stay residents 180 days of age or older on the target date of assessment who were in the facility/hospital for at least one day during the most recently-completed influenza vaccination season (IVS). The measure is based on data from the Minimum Data Set (MDS) assessments of nursing home residents, Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) assessments for Inpatient Rehabilitation Facility (IRF) patients, and the Long-Term Care Hospital (LTCH) Continuity Assessment Record & Evaluation (CARE) Data Set Version assessments of LTCH patients.

Data are collected in each of these three settings using standardized items across the three assessment instruments. For the nursing homes, the measure is limited to short-stay residents, identified as residents who have had 100 or fewer days of nursing home care. For the LTCHs, this measure will include all patients, irrespective of a patient's length of stay. For IRFs, this measure includes all Medicare Part A and Part C patients, irrespective of a patient's length of stay.

Numerator Statement: The numerator for the overall measure (NQF #0680) is the number of residents or patients in the denominator sample who, during the numerator time window, meet any one of the following criteria: (1) those who received the seasonal influenza vaccine during the most recently-completed influenza season, either in the facility/hospital or outside the facility/hospital (NQF #0681a); (2) those who were offered and declined the seasonal influenza vaccine (NQF #0681b); or (3) those who were ineligible due to contraindication(s) (NQF #0681c). The numerator time window coincides

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with the most recently-completed seasonal IVS which begins on October 1 and ends on March 31 of the following year.

Each of the three submeasures numerators described above will be computed and reportedly separately, alongside the overall numerator calculated as the aggregate of the three submeasure numerators.

Denominator Statement: The denominator consists of patients or short-stay residents 180 days of age and older on the target date of the assessment who were in the facility/hospital for at least one day during the denominator time window. The denominator time window is defined as the most recently-completed IVS, from October 1 to March 31 of the following year. For IRF and LTCH, the QM is based on completed patient stays (have discharge assessments). An IRF or LTCH patient with multiple stays during the denominator time window (IVS) will be included more than once in the QM. If a nursing home resident has more than one episode during the denominator time window only the more recent episode is included in this QM.

Exclusions: Residents or patients whose age is 179 days of less of age on target date of the selected influenza vaccination assessment are excluded. LTCH patients whose expired assessments are completed before April 1, 2016 are excluded. After April 1, 2016 expired patients are no longer excluded from the QM, because the influenza items were added to the LCDS expired assessments. Nursing homes with denominator counts of less than 20 residents and IRFs and LTCHs with less than 20 stays in the sample are excluded from public reporting due to small sample size.

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Facility

Setting of Care: Post Acute/Long Term Care Facility: Inpatient Rehabilitation Facility, Post Acute/Long Term Care Facility: Long Term Acute Care Hospital, Post Acute/Long Term Care Facility: Nursing Home/Skilled Nursing Facility

Type of Measure: Process

Data Source: Electronic Clinical Data

Measure Steward: Centers for Medicare & Medicaid Services

0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short stay)

STANDING COMMITTEE MEETING [09/12/2016-09/13/2016]

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

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

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

Rationale:

- Since the 2012 maintenance review, the measure underwent an ad hoc review by 3 technical experts to evaluate expanding the measure beyond the nursing home setting to include inpatient rehabilitation facilities (IRF) and long-term care hospitals (LTCH).
- The developer presented the most recent guideline recommendations from the CDC Advisory Committee on Immunization Practices (ACIP). The recommendations were recently published in the CDC's *Morbidity and Mortality Weekly Report* (MMWR) in August 2015.
- The developer provided a systematic review and Quantity, Quality, and Consistency of a meta-analysis of influenza vaccination in institutionalized older adults. The meta-analysis included 4 prospective cohort studies, 1 prospective study of outbreak studies, 5 retrospective case-control for outbreak studies, and 1 retrospective case-control study from 1986 to 2013.
- The Committee recommended the developer add measure scores that will be computed and reported, separately, to minimize confusion and align with NQF's standard specifications for influenza vaccination measures.
- The Committee accepted the prior evaluation on the Evidence criterion without discussion.
- The developer provided the performance rates from CMS on short-stay nursing home residents for influenza vaccination season (IVS) 2013-2014 and 2014-2015, and calculated Spear rank coefficients between facility-level scores on the measure and 6 socioeconomic variables of the facilities counties.
- For the 2014-2015 IVS, the percent of facilities with a perfect score, where all residents and patients were assessed and vaccinated, were low for nursing homes and LTCHs, and for IRFs were around 13 percent. The between facilities' differences in scores were found to have a small to medium and significant effect on QM scores across the setting.
- The developer found that 10% of IRFs had more than 34% of their patients decline the vaccine, and 10% of nursing homes had more than 42% of their short stay residents decline the vaccine.
- Disparities in nursing home residents' vaccination status were observed more than 10 years ago, and there is continued evidence of disparities in whether post-acute residents and patients are assessed and receive the vaccine.
- Males, whites, and older individuals were more likely to receive the vaccine, and women, blacks, Hispanics, and younger individuals were more likely to decline the vaccine across all of the settings.
- The developer also noted disparities between urban and rural facilities.

2. Scientific Acceptability of Measure Properties: The measure ~~did not reach consensus on~~ meets the Scientific Acceptability criteria

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

2a. Reliability: ~~H-1; M-6; L-5; I-2~~ **H-7; M-7; L-0; I-0**; 2b. Validity: ~~H-1; M-6; L-4; I-3~~ **H-9; M-5, L-0; I-0**

Rationale:

- Since the last maintenance review, the developer expanded the population to include IRFs and LTCHs. Electronic clinical data was collected from the following setting-specific data source/collection instruments:
  - NHs: Nursing Home Minimum Data Set 3.0
  - IRFs: Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI)

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  - LTCHs: LTCH Continuity Assessment Record & Evaluation (Care) Data Set
- The developer provided inter-rater reliability results using MDS, where influenza related items were assessed on 94 patients from April 1 to December 31, 2006. The results demonstrated a 13.1% discrepancy rate between the nursing facility assessment and the nurse reviewer.
- Testing was not conducted on the reliability of the influenza measure items from the LTCH Care Data Set or the IRF-PAI. The developer stated that it is reasonable to apply the reliability testing from the MDS to the LTCH CARE Data Set and the IRF-PAI. The developer also noted the populations are not identical and some differences in reliability may exist.
- For all 3 settings, the developer conducted a confidence interval analysis to examine the proportion of facilities with measure scores that are significantly different from the national facility-level mean. The confidence interval analysis for IRFs found that 66.0% of facilities had significantly different measure scores from the mean. The confidence interval analysis for LTCHs found that that 88.0% of facilities had significantly different measure scores from the mean. The confidence interval analysis for NHs found that that 68.0% of facilities had significantly different measure scores from the mean.
- For performance score testing, the developer refers to the missing data analysis for performance measure score testing, which NQF does not consider an appropriate statistical method for this purpose.
- NQF staff asked for further clarification on the methods and measure results used to assess reliability, given the developer indicated it was inferring item-level reliability for IRFs and LTCHs from MDS (nursing homes) and that it had indicated that the populations are not identical so some differences in reliability may exist.
- Ultimately, the Committee failed to reach consensus on the Reliability criterion.
- The developer did not present data-element validity testing of the influenza-related items in IRF-PAI or the LTCH CARE Data Set v2.0 and stated that previous validity results of the nursing home MDS items are applicable to the IRF-PAI and LTCH CARE Data Set v2.0 items. NQF guidance states that validity testing of data elements typically analyzes agreement with another authoritative source of the same information.
- The developer cited public comments as confirmation of face validity.
- Committee members raised concern about the face validity assessment and asked the developer for more specificity.
- NQF staff noted that face validity of the measure score, as an indicator of quality, may be adequate if accomplished through a systematic and transparent process by identified experts and explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality.
- The developer noted that the expert panel that assessed face validity was asked about the importance, value of the measure; the impact on processes of care; whether the measure will result in the staff assessing and vaccinating patients or residents; and the unintended consequences and potential burden. The panel also determined that the measure appropriately distinguishes good quality of care from poor care; all but 1 of the expert panel members voted to maintain this measure.
- Overall, the testing data were difficult for NQF staff and several Committee members to interpret. The developer agreed to work with NQF staff following the in-person meeting to clarify any remaining concerns and misinterpretations of the data.
- Ultimately, the Committee failed to reach consensus on the Validity criterion.
- Following the in-person meeting, NQF worked with the developer to bring forward the additional data for the additional levels of analysis. The developer submitted a detailed explanation of testing methods, and new score-level reliability testing results for the additional care settings, including analyses of variance and confidence interval.

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- On the call, the lead discussants from the in-person meeting, as well as other Committee members believed the new data sufficiently addressed their concerns.
- The Committee re-voted and passed this measure on Scientific Acceptability.

3. Feasibility: H-13; 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)

Rationale:

- All defined elements are in defined fields in a combination of electronic sources; the data are collected from influenza items included in the MDS 3.0 for nursing homes, the IRF-PAI assessment instrument for IRFs, and the LCDS assessment admission and discharge instruments for LTCHs.

4. Usability and Use: H-12; M-2; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- This measure is used in the following public reporting programs:
  - NH: Nursing Home Quality Reporting Program - Nursing Home Compare website.
  - IRF and LTCH: Inpatient Rehabilitation Facility Quality Reporting Program and LTCH Quality Reporting Program (to begin 2017).
- This measure is used in the following payment program:
  - IRF and LTCH: Inpatient Rehabilitation Facility Quality Reporting Program and LTCH Quality Reporting Program.
- This measure is used for the following quality Improvement with benchmarking (external benchmarking to multiple organizations) purposes:
  - NH: *Healthy People 2020* Goal: Immunization and Infectious Diseases. This measure is included in the Quality Measure Composite Score used in the National Nursing Home Quality Care Collaborative (NNHQCC) led by CMS and the Quality Innovation Network-Quality Improvement Organizations (QIN-QIOs).
- This measure is used for several quality improvement initiatives (Internal to the specific organization):
  - NH: Certification and Survey Provider Enhanced Reports (CASPER) /Centers for Medicare and Medicaid Services.
  - IRF and LTCH: Inpatient Rehabilitation Facility CASPER Provider Reports and LTCH CASPER Provider Reports are planned.
- The developer noted that the mean performance rates for NHs decreased from 81.6% from the 2013-2014 IVS to 80.6% during the 2014-2015 IVS.
- Data collection for IRFs and LTCHs started in 2014, therefore performance trends are not available.
- The developer stated that no published evidence of unintended consequences to the populations was identified, other than the low rate of adverse reaction to the vaccine and potential for being vaccinated more than once. Discomfort from the injection was described by some experts as a potential unintended consequence that may limit activity for a few days. Some experts reported that some short-stay residents and patients did not like being repeatedly offered the vaccine across settings and providers, or being asked about and offered the vaccine when they were experiencing serious health problems. However, the benefits of the influenza vaccine were felt to greatly outweigh these unintended consequences.

0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short stay)

5. Related and Competing Measures

- 0039: Flu Vaccinations for Adults Ages 18 and Older
- 0226: Influenza Immunization Status for ESRD Population (Facility Level)
- 0681: Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (long stay)
- 1659: Influenza Immunization
- The developer stated that the measure for nursing homes was expanded to both additional post-acute care settings (LTCHs and IRFs) and is harmonized with the NQF Voluntary Consensus Standards for Influenza and Pneumococcal Immunizations.
- Measure #0039 is based on the CAHPS Health Plan Survey and targets a different and non-institutionalized population.
- Measure #1659 targets a different population in multiple settings and does not include those assessed but not given the vaccine. #1659 has a different target population with a broader numerator (multiple other vaccines).

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

6. Public and Member Comment

No comments were received on this measure during public and member comment.

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

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0681 Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (long stay)

Submission | Specifications

Description: This measure reports the percentage of long-stay residents, 180 days of age and older, who were in a nursing facility for at least one day during the most recently completed influenza vaccination season (IVS), and who were assessed and appropriately given the seasonal influenza vaccine. The IVS is defined as beginning on October 1 and ends on March 31 of the following year. The measure is the aggregate of three separately calculated submeasures to reflect the process by which a resident is assessed and appropriately given the influenza vaccination during the current or most recent influenza season.

The three submeasures are as follows:

- resident received the influenza vaccine during the current or most recent influenza season, either in the facility or outside the facility (NQF #0681a);
- resident was offered and declined the seasonal influenza vaccine (NQF #0681b); and
- resident was ineligible to receive the seasonal influenza vaccine due to contraindication(s) (e.g., anaphylactic hypersensitivity to eggs or other components of the vaccine, see http://www.cdc.gov/flu/professionals/vaccination/vax-summary.htm) (NQF #0681c).

The denominator consists of long-stay residents 180 days of age or older on the target date of assessment who were in the facility for at least one day during the most recently-completed influenza vaccination season (IVS). This measure is based on data from the Minimum Data Set (MDS 3.0) OBRA, PPS, and/or discharge assessments during the selected influenza season. Long-stay residents are identified as those who have had 101 or more cumulative days of nursing facility care.

0681 Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (long stay)

A separate measure (NQF #0680, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short stay)) is to be used for residents who have had 100 or fewer cumulative days of nursing facility care.

Numerator Statement: The numerator is the number of long-stay residents with a target assessment (OBRA admission, quarterly, annual or significant change/correction assessments; PPS 5-,14-, 30-, 60-, 90-day, or readmission/return assessments; or discharge assessment with or without return anticipated) who were in the denominator sample, AND who meet any of the following criteria for the selected influenza season: (1) they received the influenza vaccine during the most recent influenza season, either in the facility or outside the facility (NQF #0681a), (2) they were offered and declined the influenza vaccine (NQF #0681b), or (3) they were ineligible due to medical contraindication(s) (NQF #0681c) . The influenza season is defined as July 1 of the current year to June 30 of the following year. The IVS begins on October 1 and ends on March 31 of the following year.

Each of the three submeasure numerators described above will be computed and reported separately, alongside the overall numerator calculated as the aggregate of the three submeasure numerators.

Denominator Statement: The denominator is the total number of long-stay residents 180 days of age or older on the target date of the assessment who were in the nursing facility who were in a nursing facility for at least one day during the most recently completed IVS that have an OBRA, PPS, or discharge assessment and who did not meet the exclusion criteria.

Exclusions: Residents whose age is 179 days or less on target date of selected influenza vaccination assessment are excluded.

If the facility sample includes fewer than 30 residents after all other resident-level exclusions are applied, then the facility is excluded from public reporting.

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Facility

Setting of Care: Post Acute/Long Term Care Facility: Nursing Home/Skilled Nursing Facility

Type of Measure: Process

Data Source: Electronic Clinical Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING [09/12/2016-09/13/2016]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

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

1a. Evidence: **Accepted Prior Evaluation**; 1b. Performance Gap: **H-1; M-13; L-0; I-0**

<u>Rationale</u>:

- Since the 2012 maintenance review, the measure underwent an ad hoc review by 3 technical experts to evaluate expanding the measure beyond the nursing home setting to include inpatient rehabilitation facilities (IRF) and long-term care hospitals (LTCH).
- The developer presented the most recent guideline recommendations from the CDC Advisory Committee on Immunization Practices (ACIP). The recommendations were recently published in the CDC's *Morbidity and Mortality Weekly Report* (MMWR) in August 2015.
- The developer provided a systematic review and Quantity, Quality, and Consistency of a meta-analysis of influenza vaccination in institutionalized older adults. The meta-analysis included 4 prospective cohort studies, 1 prospective study of outbreak studies, 5 retrospective case-control for outbreak studies, and 1 retrospective case-control study from 1986 to 2013.
- The Committee recommended the developer add “measure scores will be computed and reported separately” to minimize confusion and align with NQF’s standard specifications for influenza vaccination measures.

0681 Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (long stay)

- The Committee accepted the prior evaluation on the Evidence criterion without discussion.
- The developer provided the performance rates from CMS for long-stay nursing home residents for influenza vaccination season (IVS) 2011-2012, 2012-2013, 2013-2014, and calculated Spear rank coefficients between facility-level scores on the measure and 6 socioeconomic variables of the facilities counties.
- For the 2014-2015 IVS, the percent of facilities with a perfect score, where all residents and patients were assessed and vaccinated, was 20% for nursing homes.
- Disparities in nursing home residents' vaccination status were observed over 10 years ago, and there is continued evidence of disparities in whether post-acute residents and patients are assessed and receive the vaccine.
- Males, whites, and older individuals were more likely to receive the vaccine, and women, blacks, Hispanics, and younger individuals were more likely to decline the vaccine across all of the settings.
- The developer also noted disparities between urban and rural facilities.

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-1; M-9; L-2; I-2**; 2b. Validity: **H-1; M-13; L-0; I-0**

<u>Rationale</u>:

- For this maintenance measure, the developer provided inter-rater reliability results using MDS, where influenza related items were assessed on 94 patients from April 1 to December 31, 2006. The results demonstrated a 13.1% discrepancy rate between the nursing facility assessment and the nurse reviewer.
- For measure score reliability testing, the developer conducted a confidence interval analysis to examine the proportion of facilities (stratified by facility size) with measure scores that are significantly different from the national facility-level mean using 2014-2015 IVS MDS 3.0 data. The confidence interval analysis for IRFs found that 61.3% of facilities had significantly different measure scores from the mean. 48.1% of facilities had significantly higher measure scores than the national mean and 13.1% of facilities had significantly lower measure scores than the mean.
- Data-element validity testing was conducted using “gold-standard” nurses trained in the MDS 3.0 instrument from August 2006 to February 2007 and included 19 Veterans Affairs (VA) nursing homes with 754 residents and 71 community nursing facilities with 3,822 residents. The gold-standard nurse trained a facility nurse in the MDS 3.0 instrument. Two MDS items were calculated and then compared, “Influenza vaccine given” and “Reason influenza vaccine not given”. For the “influenza vaccine given” item, the kappa statistics for the gold-standard nurse to gold-standard nurse agreement was 0.989 (n=349), and the kappa for gold-standard nurse to facility nurse agreement was 0.941 (n=900). For the item “reason the vaccine was not given”, the kappa statistic for the gold-standard nurse to gold-standard nurse agreement was 0.976, and the kappa for gold-standard nurse to facility nurse agreement was 0.820.
- Empirical validity testing of the measure score was conducted by assessing the correlation of the performance measure score on this measure and NQF 0680: Percent of Residents or Patients or Patients Assessed and Appropriately Given the Seasonal Influenza Vaccine (short-stay) for the 2014-2015 IVS. It is expected that the quality of care provided by a facility to residents with a nursing home stay of 101 days or more (long-stay), would be of similar quality as the care provided to residents with a nursing home stay of 100 days or less (short-stay) and long-stay residents receiving the pneumococcal vaccine, therefore the respective performance measure scores should be similar. The developer reported an r value of 0.65

0681 Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (long stay)
(p<0.001) between this measure and the short-stay influenza vaccination measure which means that 65.0% of the total variation in performance on this measure can be explained by variation in performance on the measure for residents with short-stays.
3. Feasibility: H-12; 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: • All defined elements are in defined fields in a combination of electronic sources; the data are collected from influenza items included in the MDS 3.0 for nursing homes, the IRF-PAI assessment instrument for IRFs, and the LCDS assessment admission and discharge instruments for LTCHs.
4. Usability and Use: H-11; M-3; L-0; I-0 *(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)* Rationale: • The measure is in use in the Nursing Home Quality Reporting Program - Nursing Home Compare website. • The developer noted that the mean quality measure increased from the 2011-2012 IVS (92.6%) to the 2012-2013 IVS (93.6%), and it decreased through the 2014-2015 IVS (93.2%). However, the magnitude of these changes is small, and the developer posited that the decrease in the performance scores may be due to confounding factors rather than performance on the measure. • The developer stated that no published evidence of unintended consequences to the populations have been identified, other than the low rate of adverse reaction to the vaccine and potential for being vaccinated more than once. Discomfort from the injection was described by some experts as a potential unintended consequence that may limit activity for a few days. Some experts reported that some short-stay residents and patients did not like being repeatedly offered the vaccine across settings and providers, or being asked about and offered the vaccine when they were experiencing serious health problems. However, the benefits of the influenza vaccine were felt to greatly outweigh these unintended consequences.
5. Related and Competing Measures • 0680: Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (short stay) • 0226: Influenza Immunization in the ESRD Population (Facility Level) • 0039: Flu Vaccinations for Adults Ages 18 and Older • 1659: Influenza Immunization • The developer stated that #0680 applies to short-stay nursing home residents as well as additional post-acute settings (LTCHs and IRFs), and is based on different data sources for each setting. The developer noted that #0680 and #0681 are harmonized with the NQF Voluntary Consensus Standards for Influenza Immunizations and each other to the extent possible. • Measure 0039 is based on the CAHPS Health Plan Survey and targets a different and non-institutionalized population.

0681 Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (long stay)
• Measure 1659 targets a different population in multiple settings and does not include those assessed but not given the vaccine; #1659 has a different target population with a broader numerator (multiple other vaccines).
Standing Committee Recommendation for Endorsement: **Y-13; N-1**
6. Public and Member Comment No comments were received on this measure during public and member comment.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

2828 Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
Submission | **Specifications**
Description: Percentage of patients aged 18 years and older with a documented BMI during the encounter or during the previous six months AND when the BMI is outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the encounter Normal Parameters: Age 65 years and older BMI >= 23 and < 30 Age 18 – 64 years BMI >= 18.5 and < 25 **Numerator Statement**: Patients with a documented BMI during the encounter or during the previous six months, AND when the BMI is outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the current encounter. **Denominator Statement**: There are two (2) Initial Patient Populations for this measure: Initial Patient Population 1: All patients 18 through 64 years on the date of the encounter with at least one eligible encounter during the measurement period. Initial Patient Population 2: All patients 65 years of age and older on the date of the encounter with at least one eligible encounter during the measurement period. **Exclusions**: Initial Patient Population 1: Patients who are pregnant or encounters where the patient is receiving palliative care, refuses measurement of height and/or weight, the patient is in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status, or there is any other reason documented in the medical record by the provider explaining why BMI measurement was not appropriate. Initial Patient Population 2: Encounters where the patient is receiving palliative care, refuses measurement of height and/or weight, the patient is in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status, or there is any other reason documented in the medical record by the provider explaining why BMI measurement was not appropriate. **Adjustment/Stratification**: No risk adjustment or risk stratification. **Level of Analysis:** Clinician: Group/Practice, Clinician: Individual **Setting of Care:** Ambulatory Care: Clinician Office/Clinic **Type of Measure**: Process **Data Source**: Electronic Clinical Data: Electronic Health Record **Measure Steward**: Centers for Medicare & Medicaid Services
STANDING COMMITTEE MEETING [09/12/2016-09/13/2016] **1. Importance to Measure and Report: The measure meets the Importance criteria**

2828 Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan

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

1a. Evidence: **H-2; M-10; L-3; I-1**; 1b. Performance Gap: **H-7; M-7; L-1; I-0**

Rationale:

- This new measure is the eMeasure version of measure 3039 (formerly Measure 0421). The information provided for Evidence and Performance Gap is identical to that submitted for 3039. The ratings for Evidence and Performance Gap from Measure 3039 were automatically assigned to this eMeasure without further discussion.
- This measure addresses the importance of BMI measurement and follow-up when the measurement is outside normal parameters.
- More than one-third (34.9%) of adults in the United States are obese. Obesity among adults younger than 65 years has been shown to reduce life expectancy and increase medical costs.
- Only 50 percent of obese adults in 2010 received advice to exercise or perform physical activity.
- Weight loss has been shown to decrease blood pressure, reduce triglycerides and decrease blood glucose levels and hemoglobin A1c, all of which may slow the progression of type 2 diabetes and cardiovascular disease.
- The developer cited clinical practice guideline recommendations for BMI and follow-up from the American College of Cardiology (ACC)/American Heart Association (AHA)/The Obesity Society (TOS) and National Heart, Lung and Blood Institute (NHLBI).
- The measure is intended for all eligible providers, including social workers, psychologists, physical therapists, occupational therapists.
- The developer stated that the measure specifications for a follow-up plan are not prescriptive; the plan does not need to include testing or measurement, like height.
- Some Committee members were skeptical that the measure would be able to influence behavior without a robust follow-up plan, while others believed it is a good first step in assessing performance of BMI and follow-up.
- One Committee member questioned whether the evidence was aligned with current USPSTF guidelines that specifically recommend screening for all adults, but the follow-up plan focuses on the obese population, not overweight.
- Cited literature shows a performance gap among clinicians recommending exercise and physical activity for obese adults.
- While average provider-level performance rates by year are improving, the data suggest there are opportunities for improvement: In 2011, 2.7% of eligible professionals reported BMI rates and follow-up when measurement was outside normal parameters and in 2014, 19.2% of eligible professionals did the same.
- Committee members noted studies that caution against measuring obesity indiscriminately because of physiological differences between racial and ethnic groups that have influence on how obesity is identified. The developer did not find statistical difference in BMI rates between racial and ethnic groups.

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-1; M-13; L-1; I-0**; 2b. Validity: First Vote: **M-7; L-8; I-0;** Second Vote: **M-10; L-5; I-0**

Rationale:

- Health Quality Measures Format (HQMF) specifications for this eMeasure were provided with the submission.
- The submitted eMeasure specifications use existing value sets when possible and new value sets that have been vetted through the Value Set Authority Center (VSAC). Each of the value

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sets has been published and is publicly accessible. However, after a review of the value sets through the VSAC, the Quality Improvement Program (QIP) included the metadata but did not fill out the general purpose statements or include the inclusion/exclusions of the value sets. The new feasibility assessment will require that the measure developer fill out all of this information to constitute a high-quality value set. It is strongly recommended that QIP go back and complete all of this information for the value sets it has published.

- Reliability testing was conducted on the performance score using data collected from 3 primary care practices. One practice provided data from 10/3/2015 – 12/31/2015; 1 provided data from 1/1/2014 – 12/31/2014; and 1 provided data from 3/28/2015 – 3/26/2016. Combined, the data from these 3 sites reflect 357 eligible professionals (EPs), each with an average of 190 patients. The 3 practices provided 2 types of data from their EHRs: an extract containing patient-level data for all eligible patients, and a manual abstraction of a simple random sample of 104 or 105 patient records from each practice.
- A signal-to-noise analysis using the beta-binomial model was conducted.
- Data element validity was assessed by comparing the results of the EHR extract and manual abstraction for the sample of patients. Clinical reviewers abstracted 314 patient records (104 or 105 from each of 3 sites) from 66 providers to assess validity of data extracted from the EHR.
- Agreement on the numerator criteria to meet performance is substantial (90.16%, kappa 0.80), as is its inverse on failing performance (89.84%, 0.80).
- Agreement on exclusion from the denominator also is substantial (99.05%), although the limited number of exclusions in the abstracted data set resulted in a lower chance-adjusted kappa statistic (0.40).
- The developer acknowledged implementation barriers, including variability in how BMI outside normal parameters is captured in electronic health record (EHR) systems; some capture these data in structured fields and others in unstructured fields.
- One Committee member raised concern that in most the EHR systems, information about whether a patient is in palliative care is in unconstructed fields and is difficult to capture.

3. Feasibility: H-6; M-6; L-3; 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:

- All data elements are generated by and used by healthcare personnel during the provision of care and are in defined fields in EHRs
- A feasibility assessment is provided with this eMeasure submission.

4. Usability and Use: H-4; M-9; L-2; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The claims based version of this measure (#3039) is currently reported in Physician Quality Reporting System (PQRS). According to the 2014 PQRS Reporting Experience, in 2014, Measure #3039 was 1 of the top 5 reported measures within PQRS; 105,261 EPs (19.2% of all eligible entities) reported the measure.
- Measure #3039 is also reported in the Medicare and Medicaid EHR Incentive Programs (commonly referred to, collectively, as the Meaningful Use program). At this time, no publicly available data are available on the frequency with which this measure is reported as part of the Meaningful Use Program.

5. Related and Competing Measures

2828 Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
• #3039: Preventive Care and Screening: Body Mass Index Screening and Follow-up Plan • #0024: Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents (WCC) • #1349: Child Overweight or Obesity Status Based on Parental Report of Body-Mass-Index (BMI) • #2601: Body Mass Index Screening and Follow-Up for People with Serious Mental Illness
Standing Committee Recommendation for Endorsement: **Y-14; N-1**
6. Public and Member Comment No comments were received on this measure during public and member comment.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

3039 Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
Submission | Specifications
Description: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous six months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the encounter Normal Parameters: Age 65 years and older BMI >= 23 and < 30 kg/m2 Age 18–64 years BMI >= 18.5 and < 25 kg/m2 **Numerator Statement**: Patients with a documented BMI during the encounter or during the previous six months, AND when the BMI is outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the current encounter. **Denominator Statement**: All patients aged 18 years and older **Exclusions**: Not Eligible for BMI Calculation or Follow-Up Plan – A patient is not eligible if one or more of the following reasons are documented: Patient is receiving palliative care Patient is pregnant Patient refuses BMI measurement (refuses height and/or weight) Any other reason documented in the medical record by the provider why BMI calculation or follow-up plan was not appropriate Patient is in an urgent or emergent medical situation where time is of the essence, and to delay treatment would jeopardize the patient's health status **Adjustment/Stratification**: No risk adjustment or risk stratification. **Level of Analysis:** Clinician: Group/Practice, Clinician: Individual **Setting of Care:** Ambulatory Care: Clinician Office/Clinic **Type of Measure**: Process **Data Source**: Administrative claims, Electronic Clinical Data: Registry **Measure Steward**: Centers for Medicare & Medicaid Services
STANDING COMMITTEE MEETING [09/12/2016-09/13/2016] **1. Importance to Measure and Report: The measure meets the Importance criteria** (1a. Evidence, 1b. Performance Gap)

3039 Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan

1a. Evidence: **H-2; M-10; L-3; I-1**; 1b. Performance Gap: **H-8; M-8; L-0; I-0**

Rationale:

- This maintenance measure (formerly Measure 0421) is the claims-based version of eMeasure 2828. The information provided for Evidence and Performance Gap is identical to that submitted for 2828. The ratings for Evidence and Performance Gap were automatically assigned to Measure 2828 without further discussion.
- This measure addresses the importance of body mass index (BMI) measurement and follow-up when the measurement is outside normal parameters.
- More than one-third (34.9%) of adults in the United States are obese. Obesity among adults younger than 65 has been shown to reduce life expectancy and increase medical costs.
- Only 50 percent of obese adults in 2010 received advice to exercise or perform physical activity.
- Weight loss has been shown to decrease blood pressure, reduce triglycerides, and decrease blood glucose levels and hemoglobin A1c, all of which may slow the progression of type 2 diabetes and cardiovascular disease.
- The developer cites clinical practice guideline recommendations for BMI and follow-up from the American College of Cardiology (ACC)/American Heart Association (AHA)/The Obesity Society (TOS) and National Heart, Lung and Blood Institute (NHLBI).
- The measure is intended for all eligible providers, including social workers, psychologists, physical therapists, occupational therapists.
- The developer stated that the measure specifications for a follow-up plan are not prescriptive; the plan does not need to include testing or measurement, like height.
- Some Committee members were skeptical that the measure would be able to influence behavior without a robust follow-up plan, while others believed it is a good first step in assessing performance of BMI and follow-up.
- One Committee member questioned whether the evidence was aligned with current USPSTF guidelines, which specifically recommend screening for all adults, but the follow-up plan focuses on the obese population, not overweight.
- Cited literature shows a performance gap among clinicians recommending exercise and physical activity for obese adults.
- While average provider-level performance rates by year are improving, the data suggest there are opportunities for improvement: In 2011, 2.7% of eligible professionals reported BMI rates and follow-up when measurement was outside normal parameters and in 2014, 19.2% of eligible professionals did the same.
- Committee members noted studies that caution against measuring obesity indiscriminately because of physiological differences between racial and ethnic groups that have influence on how obesity is identified. The developer did not find statistical differences in BMI rates between racial and ethnic groups.

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-10; M-6; L-0; I-0**; 2b. Validity: **M-12; L-4; I-0**

Rationale:

- Reliability testing was conducted on the performance score using Medicare Part B claims and PQRS registry data at the individual clinician level.
- The claims data used for testing included encounters between 1/1/2014 and 12/31/2014 reported by 67,715 providers, with an average of 170 patients in the denominator per provider.

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• The registry data included encounters between 1/1/2014 and 12/31/2014 reported by 19,087 providers through PQRS, with an average of 211 cases in the denominator per provider. • A signal-to-noise analysis using the beta-binomial model was conducted. The average reliability scores are 0.97 for both claims and registry reported data. • Face validity was conducted by a group of 9 clinicians eligible to report the measure. • 6 of the 9 experts polled agree or strongly agree that the measure provides an accurate reflection of quality.
3. Feasibility: H-4; M-11; 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)* Rationale: • The developer stated that all data elements are in defined fields in a combination of electronic sources. The developer also stated that given past experience with this measure's use in current CMS quality reporting programs, providers find the measure feasible to report. • The developer acknowledged implementation barriers, including variability in how the BMI outside normal parameters is captured across electronic health record (EHR) vendors; some capture these data in structured fields and others in unstructured fields.
4. Usability and Use: H-7; M-8; L-1; I-0 *(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)* Rationale: • This measure is currently reported in Physician Quality Reporting System (PQRS). According to the 2014 PQRS Reporting Experience, in 2014, this measure was 1 of the top 5 reported measures within PQRS; 105,261 EPs (19.2% of all eligible entities) reported the measure.
5. Related and Competing Measures • #0024: Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents (WCC) • #1349: Child Overweight or Obesity Status Based on Parental Report of Body-Mass-Index (BMI) • #2601: Body Mass Index Screening and Follow-Up for People with Serious Mental Illness
Standing Committee Recommendation for Endorsement: **Y-15; N-1** Rationale • The Committee recommended that by the next maintenance review, the developer re-specify requirements for the follow-up plan to include intervention strategies like motivational interviewing or gym referrals, for example, which have a strong link to improved patient outcomes. • The Committee also recommended that the developer better align the evidence with the USPSTF's current guidelines related to the appropriate referral population (obese vs. overweight).
6. Public and Member Comment No comments were received on this measure during public and member comment.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

3086 Population Level HIV Viral Load Suppression

Submission | Specifications

Description: Percentage of persons > 13 years of age with diagnosed HIV infection who are virally suppressed in the measurement year.

Numerator Statement: Number of HIV-diagnosed persons, aged =13 years and alive at the end of the measurement year, whose most recent viral load test showed that HIV viral load was suppressed

Denominator Statement: Number of persons >= 13 years with HIV infection diagnosed by previous year and alive at year end.

Exclusions: Definition excludes persons with HIV diagnosed during the measurement year and persons no longer alive at the end of measurement year.

Adjustment/Stratification: No risk adjustment or risk stratification.

For current measure application at sub-national level, data are stratified by jurisdiction of residence (for 2012, 27 states and the District of Columbia).

National data are typically also stratified and presented by sex/gender, transmission risk category, age, and race/ethnicity (specific variables and code sets in case form supplied in appendix--results available in tables 5a/5b of appended report, cdc-hiv-surveillancereport_vol20_no2). States with complete viral load (VL) reporting can also conduct such stratification locally, but these data are not required for current public reporting activities.

Level of Analysis: Population: State

Setting of Care: Other

Type of Measure: Intermediate Clinical Outcome

Data Source: Other

Measure Steward: Centers for Disease Control and Prevention

STANDING COMMITTEE MEETING [09/12/2016-09/13/2016]

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

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

1a. Evidence: **H-5; M-10; L-0; I-0**; 1b. Performance Gap: **H-10; M-5; L-0; I-0**

Rationale:

- This new measure is intended to assess state performance in achieving viral load suppression among people living with HIV.
- The developer notes that viral load suppression is a good barometer of whether individual needs of people living with HIV are met and a good indicator of transmission, and therefore, addresses an important public health issue from the individual patient perspective.
- The developer indicated the measure is supported by clinical practice guideline recommendations from the Panel on Antiretroviral Guidelines for Adults and Adolescents and the World Health Organization (WHO), with systematic review and grading of evidence.
- Committee members asked why the lower age limit (13 years) was not aligned with the guidelines (15 years). The developer explained that the measure is based on CDC's surveillance systems, which assess pediatric HIV/ADIS separately from adult HIV/AIDS.
- One Committee member questioned the necessity of this performance measure to collect state-level surveillance and who is being measured.
- Committee members also acknowledged that this performance measure could also be used by state Medicaid programs and CMMI's state innovation models (SIM) to drive improvement in this area of measurement.
- The developer explained that states are already collecting these data to drive improvement in viral load suppression rates for people living with HIV.
- The developer noted that 33 states and the District of Columbia (DC) are measuring and reporting viral load suppression among people living with HIV to their state surveillance

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program. (At the time of measure submission, the developer indicated that 27 states were measuring and reporting viral load suppression rates.) For the remaining states, there is growing momentum to enact laws that mandate reporting or ensure quality assurance and standardization, and consistency, where these data are already collected and calculated.

- Of persons aged >13 years with diagnosed HIV infection by year-end 2011 and alive at year-end 2012 in the measured states and DC, 265,644 had a suppressed viral load. These 265,644 persons represented 50.1% of the total number of persons aged >13 years with HIV infection diagnosed by year-end 2011 and alive at year-end 2012.
- From the data provided, the range of percentages of patients with a suppressed viral load, was 29.4% in Arkansas to 64.1% in Washington state.
- One Committee member raised concern about the lag time of CDC surveillance reporting (typically 2-3 years) and suggested interim reporting.

2. Scientific Acceptability of Measure Properties: The measure ~~did not reach consensus on~~ meets the Scientific Acceptability criteria

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

2a. Reliability: ~~H-0; M-7; L-5; I-3~~ **M-11; L-3; I-0; I-3**; 2b. Validity: ~~H-0; M-9; L-3; I-3~~ **H-1; M-13; L-0; I-0**

Rationale:

- This is a new intermediate outcome measure that is specified at the state level of analysis.
- For reliability testing, the developer cited state law and quality control for its data and did not provide any empirical testing at the data element level.
- The developer questioned whether NQF's evaluation criteria can be appropriately applied to surveillance measures. NQF staff confirmed past and continued endorsement of similar surveillance measures, including measures developed by the CDC. Furthermore, during the technical assistance phase of the project, NQF recommended the developer assess state audit data and related inputs, where available, to determine reliability and validity.
- To meet NQF's requirements for testing, 1 Committee member suggested the developer identify the "gold standard" – data audit of viral load captured in the CDC surveillance system against state records. The developer feared this may increase state data collection burden.
- To further inform NQF's evaluation of public health surveillance measures, 1 Committee member recommended NQF review the CDC's surveillance measure evaluation guidance that focuses more on public health rather than clinical standards.
- Ultimately, the Committee failed to reach consensus on the Reliability and Validity criterions.
- Prior to the post-comment call, the developer presented data from an article (Dixon, 2013)[1] that addressed the data element-level validity (may be used for reliability under the NQF algorithm) of states' data (electronic lab data then transmitted to CDC) as compared to the gold standard of the patient's medical record. CDC also presented data from three published articles and unpublished data to address potential validity issues of data from multiple sources (recall that, depending on the system, some states have e-lab reporting or manual entry or a mix); duplicate counting; and construct validity examining surveillance data as compared to measures derived from the medical record (Subharwal, 2014) or a medical record abstraction project CDC supports in Georgia.[2]
- During the post-comment call, one Committee member raised questions about the benefit of a state-level quality measure, especially given that the CDC can collect the data without the measure and the measure will not be used for accountability. Another Committee member felt it would aid in standardization of care across states, particularly in states where there are less resources in the Department of Health.

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- One Committee member noted the measure provided a population health perspective, not about individual clinical management, so that states, cities, and other bodies submitting the information can improve their process of care more broadly—which may include providing better access to care for patients, identifying patients and bringing them into the care system, and ensuring good management at the population level as well as the clinical level. NQF staff advised that NQF is seeking broader quality measurement that spans into the population realm.
- Finally, a Committee member expressed concern over possible misuse of the measure—while it is being endorsed at the population measure, there are several examples of these types of NQF-endorsed measures now being used at facility and clinician leaves. NQF noted the endorsement is intended to be specific to the level submitted by the developer, but recognized that "off label" use if of concern and does not dispute the high stakes. Staff stated it will continue to emphasize the endorsed level of analysis for this measure.
- The developer spoke in support of the measure, agreeing with the argument that the measure will give states support at the individual and state level more broadly as well as get patients into care.
- Ultimately, the measure passed on the Reliability and Validity criteria.

3. Feasibility: H-5; M-8; L-2; 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 developer presented calculations based on case and laboratory reports entered in the HIV Surveillance System. Laboratory data reports contain viral load test results ordered by providers as part of care. The required data elements are generally available in electronic health records or other electronic sources.
- The data have been collected and reported at the state level via the National HIV Surveillance System. For 2012, the developer indicated 33 states provide complete data, and it expected the number of states completing these data to rise to more than 40 within the next year or two.
- The developer explained that the absence of viral load suppression rates on state progress reports has incentivized several states to push for legislation that mandates reporting and to build infrastructure to support it.

4. Usability and Use: H-4; M-10; L-1; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- This measure is currently used for CDC state progress reports, Public Health/Disease Surveillance and to monitor progress towards the National HIV/AIDS Strategy.
- In 2014, the MAP supported this measure for the Medicare and Medicaid EHR Incentive Program for Eligible Professionals since it addresses a measure type not adequately represented in the program measure set. MAP did not support this measure for the Physician Compare and VBPM Programs since it prefers outcome measures for these programs.
- In 2015, MAP did not encourage this measure for further consideration for MSSP. MAP recommended that this be part of a composite measure for specific conditions for MSSP.
- NQF notes that the measure is specified at the population level, however, the MAP recommendations are for levels of analyses not intended by the developer.

5. Related and Competing Measures

3086 Population Level HIV Viral Load Suppression

- 2082: HIV viral load suppression (HRSA): Percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.
- The level of analysis for the HRSA measure is clinician. Furthermore, it does not specify age of over 13 years; and it indicates the measure target population is all patients with HIV diagnosis, regardless of age.

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

6. Public and Member Comment

Comments received:

- This measure received three identical comments from one organization in general support of the measure. The comment cites the potential for enhanced standardization of care across states, health care programs and insurance plans, reducing disparities in clinical outcomes. Additionally, the comment mentions the potential for improved public health and surveillance as a result of the measures endorsement.

Committee response:

- The Committee agreed the new information provided in the comment on testing addressed its concerns. These concerns specifically focused on the benefit of a state-level quality measure, especially given that the CDC can collect standardized data across states which will aid in surveillance and patient access to care. Additionally, the Committee expressed concern over possible misuse of the measure—while the measure is being endorsed at the population level, there are several examples of these types of NQF-endorsed measures now being used at facility and clinician levels.

NQF Response:

- NQF notes that endorsement is intended to be specific to the level stated by the developer at the time of submission, but recognize that "off label" use is of concern and does not dispute the high stakes. Staff will continue to emphasize the endorsed level of analysis for this measure.

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

8. Board of Directors Vote: Y-X; N-X

9. Appeals

3070 Preventive Care and Screening: Influenza Immunization

Submission | **Specifications**

Description: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization

Numerator Statement: Patients who received an influenza immunization OR who reported previous receipt of an influenza immunization

Denominator Statement: All patients aged 6 months and older seen for a visit between October 1 and March 31

Exclusions: Documentation of medical reason(s) for not receiving influenza immunization (eg, patient allergy, other medical reasons)

Documentation of patient reason(s) for not receiving influenza immunization (eg, patient declined, other patient reasons)

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Documentation of system reason(s) for not receiving influenza immunization (eg, vaccine not available, other system reasons)

Adjustment/Stratification: No risk adjustment or risk stratification.

Consistent with CMS' Measures Management System Blueprint and recent national recommendations put forth by the IOM and NQF to standardize the collection of race and ethnicity data, we encourage the results of this measure to be stratified by race, ethnicity, administrative sex, and payer and have included these variables as recommended data elements to be collected.

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

Setting of Care: Ambulatory Care: Clinician Office/Clinic, Dialysis Facility, Home Health, Post Acute/Long Term Care Facility: Nursing Home/Skilled Nursing Facility, Other

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record

Measure Steward: PCPI Foundation

STANDING COMMITTEE MEETING [09/12/2016-09/13/2016]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

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

1a. Evidence: Accepted vote from Measure 0041 **H-2; M-11; L-0; I-0**; 1b. Performance Gap: **H-10; M-4; L-0; I-0**

<u>Rationale</u>:

- This is the eMeasure version of the claims-based Measure #0041, Preventive Care and Screening: Influenza Immunization. Therefore, the vote and discussion from Measure #0041 applies to this new measure:
  - Annual influenza vaccination is the most effective method for preventing influenza virus infection and its complications. Influenza viruses cause disease among persons in all age groups. This maintenance measure is based on the Centers for Disease Control and Prevention (CDC) guidelines and recommendations of the Advisory Committee on Immunization Practices (ACIP). ACIP revised its influenza recommendations in 2010 to include a recommendation that annual vaccination be administered to all persons aged <u>≥</u>6 months. This recommendation is current and has not changed as of 2016.
  - Committee members questioned whether the measure has broad application beyond primary care settings. The developer affirmed that the measure can be used broadly across sub-specialties and care settings. However, performance rates are not broken down by setting (e.g. clinician vs. facility).
  - Several Committee members noted the benefit of asking about the flu vaccine each year because of the seasonality of the virus and increased opportunity to track patient reasons for opting out.
- Committee members noted wide variation in performance across regions and states. For example, performance rates in Florida and South Dakota were 39% and 59%, respectively.
- Adults aged 18 years and older had lower rates of vaccination (43.6%) than children 6 months - 17 years (59.3%).
- Among people >=6 months, vaccination rates for non-Hispanic whites (48.5%) and Asians (51.0%) were higher than that of non-Hispanic blacks (43.8%), Hispanics (44.3%), and people of other or multiple races (44.3%).
- Ultimately, the Committee agreed that performance gaps in care remain.

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

3070 Preventive Care and Screening: Influenza Immunization

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

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

Rationale:

- This measure does not align with the standard specifications for influenza vaccination. Specially,
  - Numerator: Does not include offer/decline
  - Denominator: All ages > 6months - does not differentiate high risk conditions in patients aged 19-49 years
  - Exclusions: Medical, patient and system reasons are not aligned
  - Timing: Patients seen October 1- March 31 is aligned with the standard specifications, however the measure does not acknowledge earlier availability of the vaccination
- The submitted eMeasure specifications follow the industry accepted format for eMeasure (HL7 Health Quality Measures Format (HQMF).
- All components in the measure logic of the submitted eMeasure are represented using the HQMF 2.0 and the elements map to the most recent version of the QDM.
- The submitted eMeasure specifications use existing value sets when possible and new value sets that have been vetted through the Value Set Authority Center (VSAC). The developer also used standard code sets from both ICD-10-CM and SNOMED-CT.
- The submission includes test results from a simulated data set demonstrating the measure logic can be interpreted precisely and unambiguously. Testing was conducted in 3 facilities; the developer was able to check compliance from a large PQRS data set that came from multiple EHR vendors. The developer also used BONNIE on a simulated test cohort of 52 patients to ensure the logic calculated correctly.
- The beta-binomial method was used to assess signal-to-noise, where the signal is the proportion of variability attributable to performance and noise is that attributable to error. Signal to noise ratio analysis was conducted using registry data from the PQRS program for the time period January 2014 through December 2014.
- The total number of physicians reporting on this measure, via the registry option, in 2014, is 12,184. Of those, 10,986 physicians had all the required data elements and met the minimum number of quality reporting events (10) for a total of 2,417,193 quality events. There were 2,342,385 patients included in this reliability testing and analysis. These were the patients that were associated with physicians who had 10 or more patients eligible for this measure and remained after exceptions were removed.
- The developer reports this measure has 0.80 reliability when evaluated at the minimum level of quality reporting events and 0.99 reliability when evaluated at the average number of quality events.
- The developer states that the results indicate that reliability at the minimum level of quality reporting events is high and reliability at the average number of quality events is very high.
- The developer reports the measure logic performs as expected in the BONNIE system.

3. Feasibility: H-2; M-10; 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)

Rationale:

- The submission contains a feasibility assessment that addresses data element feasibility and follow-up; the measure developer indicates that the measure logic is feasible based on EHR vendors' assessments. Given that the measure has been used in Meaningful Use 2 (MU2) and in PQRS successfully, there are few issues with feasibility. Although exceptions and

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exemptions are not in a structured form, it is not difficult to retrieve these from the notes section because electronic immunization reporting has been implemented for some time.
- BONNIE testing was also conducted for the eMeasure using 2 academic medical centers and an EHR vendor on 35 elements.
- The Committee raised concern that the feasibility testing was conducted in only 2 academic medical facilities. The developer noted difficulties recruiting sites to participating in feasibility testing, because they do not incentivize potential participants.
- One Committee member questioned why this measure was not considered for the Trial Approval Program because it has not been tested extensively. NQF confirmed that eMeasures are eligible for the Program, if they do not have sufficient testing and have not been implemented. This measure has been implemented and is part of Meaningful Use 2; however, while the claims-based counterpart, Measure #0041, was previously-reviewed by NQF, this measure was never reviewed by NQF.
- The developer is continuing to recruit and identify test sites, and test, and will make every effort to test this eMeasure in another EHR system and setting by the next Annual Update.

4. Usability and Use: H-3; M-11; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:
- This measure is currently part of Meaningful Use Stage 2 (EHR Incentive Program).
- The claims based version of this measure (0041) is currently used in Physician Quality Reporting System (PQRS).
- The developer did not provide information on the performance of this measure in Meaningful Use.
- The developer only provided information on the performance of 0041 in PQRS. The average performance rates on Preventive Care and Screening: Influenza Immunization over the last several years are as follows: 2011: 50.4%; 2012: 43.9%; 2013: 46.8%; 2014: 46.3%. These rates reflect a gradual, yet slow improvement.

5. Related and Competing Measures
- 0039: Flu Vaccinations for Adults Ages 18 and Older
- 0226: Influenza Immunization in the ESRD Population (Facility Level)
- 0431: Influenza Vaccination Coverage Among Healthcare Personnel
- 0522: Influenza Immunization Received for Current Flu Season (Home Health)
- 0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short stay)
- 0681: Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (long stay)
- 1659: Influenza Immunization

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

6. Public and Member Comment

Comments received:
- One commenter opposed the use of influenza measures for their lack of inclusion in the Core Measures Set for Primary Care Medical Homes and Accountable Care Organizations. The commenter stated that the measure is a poor indicator of quality because most providers are not the persons in their facilities who administer the vaccination.
- One commenter was concerned about the intended misuse of the measure in value-based payment programs instead of how the developer specified within the submission. This

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commenter recommended influenza vaccinations be given as soon as locally available to all children and suggested that they would support the development of a seasonal influenza immunization measure specific to pediatric populations, in order to capture the needs of the population.

Developer response:

- This measure is based on the CDC's Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2016–17 Influenza Season. Routine annual influenza vaccination is recommended for all persons aged ≥6 months who do not have contraindications.

The expert work group constructed this measure based primarily on the CDC's recommendation in addition to data on peak month flu activity. While seasonal influenza may be active year-round, the CDC states that peak flu activity is between October and March (http://www.cdc.gov/flu/about/season/flu-season.htm). Additionally, the flu season covered is aligned with other NQF endorsed flu vaccine measure and in alignment with NQF's National Voluntary Consensus Standards for Influenza and Pneumococcal Immunizations. Furthermore, the PCPI aims to develop broad measures in response to current national interest in the parsimonious use of measures to reduce the resource burden on health care providers without compromising the quality of patient care.

Finally, regarding the AAP's concern about the availability of the influenza vaccine, the expert work group raised this issue and opted to include a measure exception when the vaccine is not available so as not to inappropriately penalize a clinician for an issue not within his/her control.

Influenza may lead to serious complications and vaccination is the most effective protection against influenza virus infection. However, data indicate that less than half of all eligible individuals receive an influenza vaccination.

This measure promotes annual influenza vaccination for all persons aged ≥ 6 months. The measure assesses whether a patient received the flu vaccine or reports previous receipt of the flu vaccine at any other location or via another provider. The measure does not account for patient counseling to receive the vaccine elsewhere because this does not ensure that the patient receives the vaccination thereby reducing the risk of adverse flu-related outcomes as is the intent of this measure.

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

8. Board of Directors Vote: Y-X; N-X

9. Appeals

3089 Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment

Submission | **Specifications**

Description: A nutrition care plan for those patients who are found to be malnourished based on a completed nutrition assessment with findings of malnutrition

Numerator Statement: Patients with a nutrition care plan documented in the patient's medical record.

Care plan components include, but are not limited to: Completed assessment results; data and time stamp; treatment goals; prioritization based on treatment severity; prescribed treatment/intervention; identification of members of the Care Team, timeline for patient follow-up

Denominator Statement: Patients from the initial population with completed nutrition assessment documented in their medical record with findings of malnutrition.

Exclusions: Patients with a length of stay of <24 hours and patients who left against medical advice should be excluded from the measure denominator due to their very short inpatient stay.

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Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data: Electronic Health Record

Measure Steward: Avalere Health/Academy of Nutrition & Dietetics

STANDING COMMITTEE MEETING [09/12/2016-09/13/2016]

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

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

1a. Evidence: **H-1; M-14; L-0; I-1**; 1b. Performance Gap: **H-1; M-11; L-1; I-2**

Rationale:

- This new, process eMeasure is supported by 2011 American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) guidelines that recommend nutrition support intervention for patients identified by screening and assessment as at risk for malnutrition or malnourishment. This evidence received a Grade C.
- The developer presented findings from a 2009 Cochrane Review, which included several trials supporting the supplement or nutrition support intervention; however, the findings did not show differences in outcomes.
- Three additional studies are reported published since the guidelines that relate nutrition plans to outcomes.
- The only performance data provided by the developer is from the Netherlands, where researchers assessed 395 patients to determine if they were provided appropriate malnutrition care after being identified as at-risk for malnutrition via nutrition screening. With regard to appropriate nutritional intervention for malnourished patients, when a dietitian was consulted during a malnourished patient's case, 80.6% of patients were provided additional feeding and/or vitamin supplements compared to 13.2% and 27.9% respectively by medical doctors.
- An evidence synthesis prepared for the Agency for Healthcare Research and Quality (AHRQ) found that older African American patients as well as older Hispanic women were at a higher risk of malnutrition compared to Caucasian patients.
- One Committee member asked why the developer did not cite more up-to-date data to support the evidence. The developer noted that recent evidence has not been systematically reviewed.

2. Scientific Acceptability of Measure Properties: The measure ~~did not reach consensus on~~ meets the Scientific Acceptability criteria

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

2a. Reliability: **M-10; L-5; I-0**; 2b. Validity: **M-8; L-6; I-0**

Rationale:

- All components in the measure logic of the submitted eMeasure are represented using the Health Quality Measures Format (HQMF) and Quality Data Model (QDM).
- The submitted eMeasure specifications use existing value sets, which are used within the measure, published within the Value Set Authority Center (VSAC), and are available for public use; however, Avalere has yet to complete purpose statements for each of their value sets.
- The measure was tested in 2 sites using 3 electronic health record (EHR)-systems, indicating that the measure logic works correctly and is calculating an appropriate metric for this measure.

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- The submission contains a feasibility assessment that addresses data element feasibility and follow-up. The data availability, standardization and impact on workflow all have scores nearing the 3.0 range, with future availability of elements well-described in the measure submissions form.
- The developer assessed reliability at data element level using inter-rater reliability between chart abstractors in 2 sites for 2 data elements. 200 charts were assessed at both sites.
- One Committee member noted that the Kappa statistics at both sites were lower most likely because of the small sample size. For example, for the data element "nutrition care plan documented" the percent agreement at site 1 and 2 was 83% and 94%, respectively, with Kappa scores of 0.58 and 0.85.
- Validity testing was assessed in 2 hospitals with different EHR systems (EPIC and CERNER) in 2016.
- Data elements from manual chart abstraction were compared with data elements in the EHR. The percent agreement was 98%, with a Kappa score of 0.96, and (0.93-0.97) within the 95% confidence interval.
- The developer states that the overall summary of the results from validity testing of the specific data elements to be incorporated into this measure denominator demonstrated near perfect chance-adjusted agreement rates for the electronically extracted data element (Nutrition Assessment) once the excluded cases were removed from the calculation. However, a poorer validity result with the chart abstracted data element representing the numerator criteria (nutrition care plan documented) was evident. Although the specificity for the nutrition care plan data element was strong, the sensitivity suffered due to disagreement between the chart abstractors.
- One Committee member asked if hospice patients are excluded from the measure. The developer confirmed that hospice, discharge against medical advice, and length of stay under 24 hours are all excluded from the measure.
- During the public commenting period, several commenters cited an AHRQ statistical brief that was released after the Committee's in-person meeting in September 2016. The brief characterizes hospital stays involving malnutrition. On the post-comment call, a few Committee members mentioned that their concerns had been addressed by the AHRQ brief.
- It also was noted that the exclusions were less of an issue on this measure than on #3087 and #3088. One Committee member, however, expressed continued concern over the exclusions not including patients on hospice, who refused referral or had complications.
- It was also noted that the 2008 paper that was used to cite a performance gap found that patients who received intervention (getting feedings or vitamins) did not result in any difference and improve clinical outcomes.
- Concern was also raised about using the EHR to extract the many plan of care data components and skepticism raised about EHRs' ability to do this. Another Committee member noted, however, that the developer was working hard on the ability to get more information from SNOMED and LOINC and those efforts were moving forward.
- The Committee re-voted on Validity, but the measure did not pass. However, given that quorum was lost prior to voting on this measure and the outcome during the post-comment call was such that the additional votes might have meant passing the criterion, the Committee members also voted on Overall Suitability for Endorsement (Y-10; N-4). Accordingly, the measure was recommended for endorsement.

3. Feasibility: H-5; M-9; L-2; 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)

3089 Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment

Rationale:

- This measure is specified for use in EHRs.
- A feasibility assessment is included in the submission rating.
- Feasibility was tested in 2 different EHR systems, within 2 hospital EHR systems.

4. Usability and Use: H-2; M-11; L-2; I-1

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The developer reports that the Academy of Nutrition & Dietetics and Avalere Health are working with leading hospitals and health systems to implement a Malnutrition Quality Improvement Demonstration and Learning Collaborative focused on reducing clinical practice variability in malnutrition care through the implementation of a standardized toolkit. This would include the collection of data on malnutrition care provided in the inpatient setting for use in internal quality improvement. The initiative involves 6 medium- large hospitals and health systems across the country representing 6 different states and thousands of patients.
- This new measure is planned for submission to the Centers for Medicare & Medicaid Services Measures Under Consideration pathway for the Inpatient Quality Reporting Program. The measure steward is also working with The Joint Commission (TJC) for consideration as 1 of the TJC's accreditation measures.

5. Related and Competing Measures

- 3087: Completion of a Malnutrition Screening within 24 hours of Admission
- 3088: Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 hours of a Malnutrition Screening
- 3090: Appropriate Documentation of a Malnutrition Diagnosis
- The developer is the steward for all 4 measures and states that they are harmonized.

Standing Committee Recommendation for Endorsement: **Y-10**; **N-4**

- The Committee re-voted on Overall Suitability for Endorsement, given that quorum was lost prior to voting on this measure and the outcome during the post-comment call was such that the additional votes might have meant passing the criterion. The Committee voted to recommend the measure for endorsement.

6. Public and Member Comment

Comments received:

- Measure #3089 received 30 comments from 18 organizations/individuals.
- Commenters and the developer recommend the Committee advance the measure. None of the comments received address the Committee's concerns about the omission of exclusions.
- Regarding concerns about variability, one of the organizations (measure steward) (Hoggle, Academy of Nutrition & Dietetics on behalf of Informatics & Interoperability Committees) noted that its committees are working to ensure that terms from the Academy's Nutrition Care Processes (NCP) are mapped to clinical terminologies such as SNOMED-CT® and LOINC®. The comment notes, "upon malnutrition screening and appropriate assessment of at-risk patients, the nutrition intervention is developed using the NCP. Use of appropriate malnutrition language and terminologies (via the mapping of eNCPT to clinical and/or reimbursement terminologies), the intervention can be included in the electronic Care Plan. Selection of appropriate terminology possible for a problem-etiology-signs/symptoms

3089 Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment
documentation allows for structured coded data which is consistent with other areas of an EHR." Committee Response: • Though there was support for the measure from commenters, as with the other nutrition measures, we are concerned that the denominator excludes patients admitted to hospice care, who refused referrals, were discharged against medical advice, or had complications—although a few of us did feel the exclusions might be less of an issue with this measure. Some of us also feel the September 2016 AHRQ brief documenting the problem of malnutrition in hospitalized patients also address some concerns for this measure. On the other hand, we noted that a 2008 paper used by the developer to document a performance gap found that patients who received intervention (getting feedings or vitamins) did not have improved clinical outcomes. We are also concerned about the capacity of EHRs to extract the many plan of care data components and skepticism, though we understand the developer is working to get more information in standardized formats. We emphasize that we recognize that nutritional status is an important area to be addressed by quality measurement.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-10; N-4
8. Board of Directors Vote: Y-X; N-X
9. Appeals

Measure Recommended for Inactive Endorsement with Reserve Status

1659 Influenza Immunization
Submission | Specifications
Description: Inpatients age 6 months and older discharged during October, November, December, January, February or March who are screened for influenza vaccine status and vaccinated prior to discharge if indicated. **Numerator Statement**: Inpatient discharges who were screened for influenza vaccine status and were vaccinated prior to discharge if indicated. **Denominator Statement**: Acute care hospitalized inpatients age 6 months and older discharged during the months of October, November, December, January, February or March. **Exclusions**: The following patients are excluded from the denominator: • Patients less than 6 months of age • Patients who expire prior to hospital discharge • Patients with an organ transplant during the current hospitalization (Appendix_A.Table 12.10 Organ Transplant codes.xls) • Patients for whom vaccination was indicated, but supply had not been received by the hospital due to problems with vaccine production or distribution • Patients who have a Length of Stay greater than 120 days • Patients who are transferred or discharged to another acute care hospital • Patients who leave Against Medical Advice (AMA) **Adjustment/Stratification**: No risk adjustment or risk stratification. **Level of Analysis:** Facility **Setting of Care:** Hospital/Acute Care Facility **Type of Measure**: Process **Data Source**: Administrative claims, Electronic Clinical Data: Electronic Health Record, Paper Medical Records

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Measure Steward: Centers for Medicare and Medicaid Services

STANDING COMMITTEE MEETING [09/12/2016-09/13/2016]

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

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

1a. Evidence: **Accepted Prior Evaluation**; 1b. Performance Gap: **H-0; M-7; L-7; I-0;** Second Vote: **H-0; M-5; L-9; I-0**

Rationale:

- This maintenance measure is based on recommendations from the Advisory Committee on Immunization Practices (ACIP).
- The 2012 NQF Committee voted high for Quantity, Quality, and Consistency ratings of evidence, which included a Cochrane review of 51 studies.
- The developer updated this submission to reflect 2015-2016 ACIP recommendations; the developer states the measure remains aligned with the recommendations.
- The Committee accepted the prior evaluation on Evidence without further discussion.
- The Committee noted marginal gaps in overall performance, where for the 2014-2015 flu season, 10% of hospital cases were not vaccinated.
- The developer explained that the sample population was a little more than 1.5 million cases; out of those, about 92,000 were not screened and/or vaccinated. If extrapolated to the larger population of patients discharged from hospitals during that time, a little more than a million patients were not screened and/or vaccinated.
- The developer noted slight disparities in care between racial and ethnic groups; specifically, Hispanic patients have lower vaccination rates than non-Hispanics (91% vs 95%). However, American Indian or Alaska Native (83.97%) are less likely than those identified as White (94.76%) to be screened and vaccinated.
- The Committee acknowledged the importance of this hospital-based measure, but did not believe the narrowing performance gaps were clinically significant.
- The Committee opted to proceed with the Inactive with Reserve Status pathway, and recommended that clinical practice and behavior be periodically monitored.

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-7; M-2; L-4; I-1**; 2b. Validity: **M-11; L-3; I-0**

Rationale:

- Performance score reliability was calculated to distinguish differences between the performances of different facilities. The testing calculated signal-to-noise ratio for each facility meeting the minimum case count.
- Reliability was estimated using the beta-binomial model. The developer noted that reliability scores vary from 0.0 to 1.0. A score of zero implies that all variation is attributed to measurement error (noise or the individual accountable entity variance) whereas a reliability of 1.0 implies that all variation is caused by a real difference in performance (across accountable entities).
- Results were provided from Hospital Compare during the October 1, 2014-March 31, 2015 data collection period. Reliability scores range from 0.33 to 1.00, with an average reliability score of 0.97. The developer stated that this indicates that the measure is able to identify differences in performance between individual facilities.
- Embedded in ICD-9 was a specific code for influenza vaccination. Committee members raised concern about the two, general immunization codes for hospital settings that are embedded in ICD-10 and the subsequent impact on reliability and validity of the measure. Influenza

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vaccination can be gleaned from CPT codes, however, these codes are not used in hospital admissions. • Empirical validity testing was assessed at the data element level via the CDAC validation method. Abstractors pulled the same data elements from each chart that the hospital abstracted when originally submitting data. Results were compared and cases and data elements where there were mismatches were identified. • For the 2014-2015 influenza season, a total of 5,285 cases were used for validation. The 2 data elements abstracted were IMM-2, Discharge Disposition and Influenza Vaccination Status. • For the discharge disposition data element, 5,284 records were validated, showing 131 abstraction mismatches, representing a 97.52% agreement. • For the influenza immunization status data element, 4,875 records were validated, showing 475 abstraction mismatches, representing 90.26% agreement. • The developer stated that the results show a high degree of agreement before hospital abstraction and CDAC validation abstraction for both data elements.
3. Feasibility: H-2; M-8; L-4; 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: • This measure is currently chart-abstracted, however, the developer noted plans to re-specify it as and eMeasure. • Some data elements are in defined fields in electronic sources. • The developer noted that this measure is coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims), and abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry). • The Committee discussed the potential burden of manual chart abstraction in the absence of an ICD-10 code that indicates screened and/or vaccinated. • The developer noted hospitals are collecting these data via screening forms upon admission, which has minimized the data collection burden.
4. Usability and Use: H-9; M-5; L-0; I-0 *(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)* Rationale: • This measure is used in several public reporting and payment programs, including: ○ Hospital Compare   ○ Annual Payment Update   ○ The Joint Commission Accreditation   ○ QualityNet Benchmarks of Care • Several Committee members had difficulty assessing this measure for usability and use in light of the relatively few opportunities for improvement.
5. Related and Competing Measures • 0038: Childhood Immunization Status (CIS) • 0039: Flu Vaccinations for Adults Ages 18 and Older • 0041: Preventive Care and Screening: Influenza Immunization • 0226: Influenza Immunization in the ESRD Population (Facility Level) • 0431: Influenza Vaccination Coverage Among Healthcare Personnel • 0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (short stay)

1659 Influenza Immunization
• 0681: Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (long stay)
Standing Committee Recommendation for Inactive Endorsement with Reserve Status: Y-14; N-0
6. Public and Member Comment No comments were received on this measure during public and member commenting.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

Measures Approved for Trial Use

3059 One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk

Submission | **Specifications**

Description: Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945–1965 who received one- time screening for hepatitis C virus (HCV) infection

Numerator Statement: Patients who received one-time screening for HCV infection

Denominator Statement: All patients aged 18 years and older who were seen twice for any visit or who had at least one preventive visit within the 12 month reporting period with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945–1965

Exclusions: Denominator Exclusions:

Patients with a diagnosis of chronic hepatitis C

Denominator Exceptions:

Documentation of medical reason(s) for not receiving one-time screening for HCV infection (eg, decompensated cirrhosis indicating advanced disease [ie, ascites, esophageal variceal bleeding, hepatic encephalopathy], hepatocellular carcinoma, waitlist for organ transplant, limited life expectancy, other medical reasons)

Documentation of patient reason(s) for not receiving one-time screening for HCV infection (eg, patient declined, other patient reasons)

Adjustment/Stratification: No risk adjustment or risk stratification.

Consistent with CMS' Measures Management System Blueprint and recent national recommendations put forth by the IOM and NQF to standardize the collection of race and ethnicity data, we encourage the results of this measure to be stratified by race, ethnicity, administrative sex, and payer and have included these variables as recommended data elements to be collected.

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

Setting of Care: Ambulatory Care: Clinician Office/Clinic, Home Health, Post Acute/Long Term Care Facility: Nursing Home/Skilled Nursing Facility, Other

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record

Measure Steward: PCPI Foundation

STANDING COMMITTEE MEETING [09/12/2016-09/13/2016]

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

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

1a. Evidence: **H-4; M-8; L-1; I-0**; 1b. Performance Gap: **H-3, M-7, L-3, I-0**

Rationale:

- This newly-submitted measure is eligible for Approval for Trial Use.
- The developer presented guidelines from 2 societies (American Association for the Study of Liver Diseases [AASLD] and Infectious Disease Society of American [IDSA]) that recommend "persons should be screened for risk factors for HCV infection, and one-time testing should be performed for all persons with behaviors, exposures, and conditions associated with an increased risk of HCV infection" and high risk individuals and persons born between 1945 and 1965 without prior ascertainment of risk."
- The Quality, Quantity, and Consistency for all guidelines and USPSTF guidelines were provided with the submission.

3059 One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk

- Committee members questioned the developer about the availability of recent data on screening performance gaps.
- Since this is a new measure without performance data from use of the measure, the developer cited data from Indian Health Services that includes 1.9 million members and 566 Federally recognized tribes. Through a wide network of facilities, screening in this cohort was assessed, including one-time cohort screening for those at risk. From 2012 to 2015 the baseline rate increased from 7.9 percent to 32.5 percent. The study also showed gender and regional variation in screening; more women received screening than men and regions varied from 31.2% to 41.2%.

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)

2. Specifications: **H-4; M-8; L-1; I-0**

<u>Rationale</u>:

- The submitted eMeasure specifications follow the industry accepted format for eMeasure (HL7 Health Quality Measures Format (HQMF)).
- All components in the measure logic of the submitted eMeasure are represented using the HQMF and QDM.
- The submitted eMeasure specifications use existing value sets, which are used within the measure, published within the Value Set Authority Center (VSAC), and are available for public use.
- The measure submission included test results from a simulated data set demonstrating the measure logic can be interpreted precisely and unambiguously. The testing included data from 3 separate EHRs, totally approximately 27,000 patients and demonstrated that the logic works correctly and that the appropriate metric is calculated.
- The submission contained a feasibility assessment that addresses data element feasibility and follow-up with the developer indicated that the measure logic is feasible based on assessment by EHR vendors. The feasibility scorecard was included with an evaluation of each data element across each EHR system, showing that data was available, standardized, and did not interrupt workflow.
- This eMeasure has not been tested. With this submission the developer is applying for the Trial Use program. The Trial Use program is available to encourage use of eMeasures so that sufficient data can be collected to adequately test measures, as required by NQF endorsement.
- BONNIE testing was performed to assess the measure algorithm. Results indicated an accurate calculation from the algorithm.
- The developer indicated the testing that will be performed when sufficient data are collected from use of the measure.
- The developer plans to assess face validity when sufficient data are available to evaluate.

3. Feasibility: H-1; M-10; L-2; 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>:

- One Committee member questioned whether people who have a history of one-time test will be captured in the measure.
- Committee members extensively discussed the high cost of HCV treatment strategies (e.g., medication), which Medicaid and facilities serving low-income, vulnerable populations like public health centers, cannot afford. Furthermore, HCV patients who continue to engage in

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high-risk behavior, increase the likelihood of re-infection, so screening and subsequent treatment are usually not one-time only.

- The developer noted that even under the most restrictive Medicaid reimbursement criteria, HCV infected people would qualify for treatment.
- The developer mentioned that HHS is examining how to reduce treatment expenses and shared results from CDC's societal cost effective modeling that indicate that HCV treatment cost are decreasing; in 2014, drugs cost per curative cost range from $86,000 to $94,000. Within 2 years, the price has fallen to $46,000.
- One Committee member raised the issue of broad implementation across different types of entities like health plans, HMOs, public health clinics and hospitals.
- The developer mentioned that CDC is tracking testing using millions of records from 2 large commercial laboratories and noted a 60% increase in testing since the screening recommendations were put forth in 2012.
- The Committee noted that increases in testing for HCV were noted across Medicaid populations, however, access to treatment, because of budgetary constraints for Medicaid programs remains a disincentive to test.
- Finally, it was noted that the CDC, state health department, and Federally-Qualified Health Centers (FQHCs) are working together to improve access to HCV testing, follow-up and treatment.

4. Usability and Use: H-1; M-8; L-3; I-1

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The developer listed the planned uses as "Payment Program" and "Quality Improvement with Benchmarking (external benchmarking to multiple organizations)," but did not provide specifics.
- The measure is a part of AHIP's Core Quality Measure Collaborative. The Collaborative intends to promote alignment and harmonization of measures across payers in the public and private sectors through core measure sets. CMS intends to include the core sets in proposed rules, where appropriate. Private payers will use a phased in approach to implementation of the core measure sets and may use them for negotiations between physicians and private payers.
- MAP 2014-2015: MAP encouraged continued development of this population health screening eMeasure aligned with CDC recommendations.

5. Related and Competing Measures

- 0393: Hepatitis C: Confirmation of Hepatitis C Viremia

Standing Committee Recommendation for eMeasure Approval for Trial Use: Y-11; N-2

6. Public and Member Comment

Comments received:

- One commenter supported the recommendation of the Committee for continued endorsement of the measure.

Developer response:

- Measure 3059 is designed to promote the identification of hepatitis C to ensure early intervention and proper management of the virus through one-time screening for the birth cohort and other at risk populations. The measure, as drafted, is designed to be consistent with the recent recommendations from the CDC and USPSTF which outline various target populations for screening. As noted in the CDC recommendations, the recommendation for screening persons born during 1945-1965 does not replace previous guidelines for HCV testing that are based on known risk factors and clinical indications, but rather it defines an

3059 One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk
additional target population for one-time testing with the goal of achieving greater success in disease identification and engagement into treatment than risk-based strategies alone. HCV testing is the first step toward improving health outcomes for persons infected with HCV given that most persons with HCV do not know they are infected, do not receive needed care (e.g., education, counseling, and medical monitoring), and are not evaluated for treatment. Additionally, the measure has undergone initial feasibility testing at two different sites which supported the current measure construction and failed to identify any significant challenges in identifying or collecting the various data elements included in the measure. Additional testing will be conducted to meet additional NQF requirements and to advance the measure from approval for trial use to full endorsement.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

3060 Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users
Submission | **Specifications**
Description: Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12 month reporting period **Numerator Statement**: Patients who received screening for HCV infection within the 12 month reporting period **Denominator Statement**: All patients, regardless of age, who are seen twice for any visit or who had at least one preventive care visit within the 12 month reporting period who are active injection drug users **Exclusions**: Denominator Exclusions: Patients with a diagnosis of chronic hepatitis C Denominator Exceptions: Documentation of medical reason(s) for not receiving annual screening for HCV infection (eg, decompensated cirrhosis indicating advanced disease [ie, ascites, esophageal variceal bleeding, hepatic encephalopathy], hepatocellular carcinoma, waitlist for organ transplant, limited life expectancy, other medical reasons) Documentation of patient reason(s) for not receiving annual screening for HCV infection (eg, patient declined, other patient reasons) **Adjustment/Stratification**: No risk adjustment or risk stratification. Consistent with CMS' Measures Management System Blueprint and recent national recommendations put forth by the IOM and NQF to standardize the collection of race and ethnicity data, we encourage the results of this measure to be stratified by race, ethnicity, administrative sex, and payer and have included these variables as recommended data elements to be collected. **Level of Analysis:** Clinician : Group/Practice, Clinician : Individual **Setting of Care:** Ambulatory Care : Clinician Office/Clinic, Home Health, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility, Other **Type of Measure**: Process **Data Source**: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record **Measure Steward**: PCPI Foundation
STANDING COMMITTEE MEETING [09/12/2016-09/13/2016] **1. Importance to Measure and Report: The measure meets the Importance criteria**

3060 Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users

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

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

Rationale:

- This newly-submitted eMeasure is eligible for Approval for Trial Use.
- The developer presented guidelines from the American Association for the Study of Liver Diseases (AASLD) and Infectious Disease Society of American (IDSA) that recommend annual HCV testing for persons who inject drugs and for HIV-seropositive men who have unprotected sex with men. Periodic testing should be offered to other persons with ongoing risk factors for exposure to HCV.
- The Quality, Quantity, and Consistency for all guidelines, including a 2013 USPSTF guideline were provided with the submission.
- Committee members, however, debated whether annual screening as specified in the measure is aligned with the guidelines. The developer confirmed that it is aligned with the AASLD guideline for one-year screening and generally aligned with the USPSTF, which recommends "periodic screening" for at-risk populations, including IVD users.
- Since this is a new measure without performance data from use of the measure, the developer cited data from the literature that show that 72% of persons with a history of injection-drug use and are infected with HCV, remain unaware of their infection status.
- The developer also noted that, according to the CDC, American Indians and Alaska natives have the highest incidence of acute HCV cases. While African Americans make up 12% of the U.S. population, they account for more than 22% of chronic HCV cases. African Americans diagnosed with HCV infection often have less desirable outcomes compared to white patients. In addition, chronic liver disease, often related to HCV infection, is a leading cause of death among African Americans aged 45-64. One study found that minorities had lower treatment rates than whites, despite fewer medical and psychiatric comorbidities, higher incomes and educational levels. Asians had the lowest treatment rates and Hispanics have lower levels of treatment compared to whites, despite a higher incidence of cirrhosis.
- One Committee member suggested the developer assess both active injection drug use and non-IVD within the Indian Health Services catchment because performance gaps in screening for HCV generally may exist.

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

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

2b. Specifications: **H-0; M-10; L-3; I-0**

Rationale:

- The specifications for this eMeasure follow the industry accepted format for eMeasure (HL7 Health Quality Measures Format (HQMF)).
- All components in the measure logic of the submitted eMeasure are represented using the HQMF and QDM.
- The specifications use existing value sets when possible and new value sets that have been vetted through the Value Set Authority Center (VSAC), with the exception of a couple of value sets which were not in structured form within 1 of the EHRs.
- The submission included test results from a simulated data set demonstrating the measure logic can be interpreted precisely and unambiguously; in addition, the developer also tested in 2 sites and was able to implement with minimal difficulty.
- The feasibility analysis submitted by the measure developer meets the requirements to be considered for eMeasure Trial Approval. However, the variability in the structured/non-structured elements may signal an issue with implementation. While the developer outlined

3060 Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users

the pathway for the elements to be structured in the future, the current implementation indicates that the information may be collected differently, which may pose some difficulties in getting the information needed to obtain an appropriate metric for the measure.

- The specifications are not completely consistent with the evidence. The developer confirmed that the measure is aligned with the AASLD guideline for one-year screening and generally aligned with the USPSTF, which recommends "periodic screening" for at risk populations, including IVD users.
- This eMeasure has not been tested. With this submission, the developer is applying for the Trial Use program and not NQF endorsement. The Trial Use program is available to encourage use of eMeasures so that sufficient data can be collected to adequately test measures, as required by NQF endorsement.
- BONNIE testing of a synthetic data set of 38 patients was provided. The developer did not summarize the findings from the BONNIE testing.
- The developer described the plan to test the reliability of the measure.
- Committee members questioned the sensitivity and specificity of identifying intravenous drug use (IVDU) from medical records. When the measure returns with testing data, the Committee suggested the developer not only include IVDU data from the social history, but also information from recent emergency department visits, hospitalization, and other healthcare resource use associated with overdose, treatment, referrals etc.
- One Committee member suggested that the developer consider how to quantify and differentiate "history of IVDU" from "active IVDU" because active users often go in and out of detox.

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

- This is an untested eMeasure for consideration in the Trial Use program. It is not being considered for NQF endorsement.
- The developer provided a feasibility assessment.

4. Usability and Use: H-0; M-11; L-2; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The developer lists the planned uses as "Payment Program" and "Quality Improvement with Benchmarking (external benchmarking to multiple organizations)" but did not provide specifics.
- In 2014-2015, the MAP encouraged further development of this measure (3060) and Measures 3059 and 3061 for potential, future inclusion in the Meaningful Use and PQRS programs.
- MAP also recommended combining or pairing the screening follow-up (Measure 3061) with the one-time screening measure (Measure 3059).

5. Related and Competing Measures

- 0393: Hepatitis C: Confirmation of Hepatitis C Viremia
    - The developer noted this measure and Measure 0393 are not harmonized. According to the developer, "The quality action performed in measure 0393 is confirming the hepatitis C antibody is present following initial testing and does not include the initial testing before diagnosis as a part of the quality action performed in the measure."

3060 Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users
• 0398: Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Testing Between 4-12 Weeks after Initiation of Treatment • 0395: Paired Measure: Hepatitis C Ribonucleic Acid (RNA) Testing Before Initiating Treatment (paired with 0396) • 0396: Paired Measure: Hepatitis C Virus (HCV) Genotype Testing Prior to Treatment (paired with 0395)
Standing Committee Recommendation for eMeasure Approval for Trial Use: **Y-11; N-2**
6. Public and Member Comment Comments received: • One commenter supported the recommendation of the Committee for continued endorsement of the measure.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

3061 Appropriate Screening Follow-up for Patients Identified with Hepatitis C Virus (HCV) Infection
Submission | **Specifications**
Description: Percentage of patients aged 18 years and older with either (1) a positive HCV antibody test result and a positive HCV RNA test result 1or (2) a positive HCV antibody test result and an absent HCV RNA test result who are prescribed treatment or are referred to evaluation or treatment services **Numerator Statement**: Patients who are prescribed treatment or are referred to evaluation or treatment services **Denominator Statement**: All patients aged 18 years and older who are seen twice for any visit or who had at least one preventive visit with either (1) a positive HCV antibody test result and a positive HCV RNA test result or (2) a positive HCV antibody test result and an absent HCV RNA test result **Exclusions**: Denominator Exclusions: Patients with a negative HCV RNA result, patients with a diagnosis of chronic hepatitis C Denominator Exceptions: Documentation of medical reason(s) for not prescribing treatment or being referred to evaluation or treatment services (eg, participation in a clinical trial, decompensated cirrhosis indicating advanced disease [ie, ascites, esophageal variceal bleeding, hepatic encephalopathy], hepatocellular carcinoma, waitlist for organ transplant, limited life expectancy, other medical reasons) Documentation of patient reason(s) for not prescribing treatment or being referred to evaluation or treatment services (eg, patient declined, other patient reasons) **Adjustment/Stratification**: No risk adjustment or risk stratification. Consistent with CMS' Measures Management System Blueprint and recent national recommendations put forth by the IOM and NQF to standardize the collection of race and ethnicity data, we encourage the results of this measure to be stratified by race, ethnicity, administrative sex, and payer and have included these variables as recommended data elements to be collected. **Level of Analysis:** Clinician: Group/Practice, Clinician: Individual **Setting of Care:** Ambulatory Care: Clinician Office/Clinic, Home Health, Post Acute/Long Term Care Facility: Nursing Home/Skilled Nursing Facility, Other **Type of Measure**: Process **Data Source**: Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record

3061 Appropriate Screening Follow-up for Patients Identified with Hepatitis C Virus (HCV) Infection

Measure Steward: PCPI Foundation

STANDING COMMITTEE MEETING [09/12/2016-09/13/2016]

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

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

1a. Evidence: **H-7; M-4; L-2; I-0**; 1b. Performance Gap: **H-7; M-5; L-1; I-0**

Rationale:

- This newly-submitted eMeasure is eligible for Approval for Trial Use.
- The Quality, Quantity and Consistency for all guidelines, including a 2013 USPSTF guideline, is provided with the submission.
- CDC recommends: "Persons who test positive for both HCV antibody and HCV RNA should be informed that they have HCV infection and need further medical evaluation for liver disease, ongoing medical monitoring, and possible treatment."
- According to the American Association for the Study of Liver Diseases (AASLD) and Infectious Disease Society of American (IDSA), only an estimated 13% to 18% of HCV-infected persons in the United States received treatment by 2013
- Since this is a new measure without performance data from use of the measure, the developer provided data from the literature. One study found that only 63 to 77% of people who have tested positive for HCV antibodies—32 to 38% of all HCV-infected people in the United States—received follow-up hepatitis care, only 5-6% of all individuals. Likewise, a survey of 494 primary care clinicians practicing in low-income medically underserved communities across the United States found that 54% of clinicians refer 75% or fewer patients; less than 18% of clinicians provide antiviral treatment. Key factors influencing a physician's decision to treat patients with HCV include patient comorbidities, access to care, and treatment tolerance for patients who are infected with HCV.

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

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

2. Scientific Acceptability: **H-2; M-9; L-2; I-0**

Rationale:

- The eMeasure specifications follow the industry accepted format for eMeasure (HL7 Health Quality Measures Format (HQMF)).
- All components in the measure logic of the submitted eMeasure are represented using the HQMF and QDM and are accepted within the model.
- The submitted eMeasure specifications use existing value sets when possible and use new value sets that have been vetted through the Value Set Authority Center (VSAC), with the exception of a couple of value sets which were not in structured form within 1 of the EHRs used, but are relatively common data elements.
- The measure submission included test results from a simulated data set demonstrating the measure logic can be interpreted precisely and unambiguously; in addition, the developer also tested in 2 sites and was able to implement with minimal difficulty.
- The feasibility analysis submitted by the measure developer meets the requirements for eMeasure Trial Approval Use consideration. However, the variability in the structured/non-structured elements may signal a concern with implementation. While the developer outlined the pathway for structuring data in the future, the current submission indicated that information may be collected differently. This may make it difficult to obtain appropriate data for the measure.
- This eMeasure has not been tested. With this submission the developer is applying for the Trial Use program and not NQF endorsement. The Trial Use program encourages use of

3061 Appropriate Screening Follow-up for Patients Identified with Hepatitis C Virus (HCV) Infection
eMeasures so that sufficient data can be collected to adequately test measures, as required by NQF endorsement. • The developer provided BONNIE testing of a synthetic data set of 52 patients, but did not summarize the findings from the BONNIE testing. • The developer described how it plans to test the reliability of the measure. • The Committee noted gaps between referral and treatment, and the challenges of assessing follow-up and meaningful adequacy. When the measure is submitted for endorsement consideration, with testing data, the Committee would like to review a measurement construct, with testing results and specifications, for both referral and treatment; The Committee strongly believes that assessing referral for HCV treatment alone would fall short of meaningful, comprehensive improvement. • The developer said it conducting a cohort study in 4 sites and working with referral data within health system databases to assess linkages to HCV care and treatment. • One Committee member suggested the developer segment referral in 2 parts: First, assess whether the PCP referred the patient to a specialist; and second, assess whether the patient visited the specialist.
3. Feasibility: H-2; M-10; 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)* Rationale: • The measure specifications are consistent with the evidence. • A feasibility assessment for this eMeasure was provided.
4. Usability and Use: H-1; M-10; L-2; I-0 *(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)* Rationale: • The developer indicated that the planned use of the eMeasure is Quality Improvement with Benchmarking (external benchmarking to multiple organizations), however, the developer did not provide details.
5. Related and Competing Measures • 0398: Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Testing Between 4-12 Weeks after Initiation of Treatment • 0393: Hepatitis C: Confirmation of Hepatitis C Viremia • 0395: Paired Measure: Hepatitis C Ribonucleic Acid (RNA) Testing Before Initiating Treatment (paired with 0396) • 0396: Paired Measure: Hepatitis C Virus (HCV) Genotype Testing Prior to Treatment (paired with 0395)
Standing Committee Recommendation for eMeasure Approval for Trial Use: Y-11; N-2
6. Public and Member Comment No comments were received on this measure during public and member comment.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

Measures Not Recommended

3067 Human Immunodeficiency Virus (HIV) Infection Screening
Submission | Specifications
Description: Percentage of patients 15-65 years of age who were tested at least once for HIV. **Numerator Statement**: Patients with either documentation of an HIV test after their 15th birthday or evidence of HIV infection. **Denominator Statement**: Patients 15 to 65 years of age who had a visit in the measurement period*. *The measurement period refers to a defined, 12 month interval that begins and ends prior to the measure calculation date. **Exclusions**: None **Adjustment/Stratification**: No risk adjustment or risk stratification. The numerator should be reported according to the following 3 strata: • Stratum 1: Patients with HIV Testing Performed; • Stratum 2: Patients with prior diagnosis of HIV infection; • Stratum 3: Patients with either HIV Testing Performed or prior diagnosis of HIV infection In essence, Stratum 3 looks at the numerator population as a whole, while strata 1 and 2 look at two distinct, key sub-populations within the numerator population (i.e., those for whom testing evidence is direct and in the form of a lab order or result, and those for whom testing evidence is indirect or implicit, based on the presence of an HIV diagnosis code) The proposed stratification allows individuals seeking to use the measure results (e.g., for performance assessment and comparison or quality improvement activities) to differentiate between physicians whose performance may be driven by their having a large number of persons living with HIV (PLWH) among their patients and physicians whose performance may be driven by their HIV screening practices vis-à-vis persons who are not known, at the time of their testing, to be living with HIV. It is not unreasonable to argue that comparing performance between the two groups of providers favors the former(those treating large numbers of PLWH) and disadvantages the latter (more typically primary care providers with limited experience—or occasion—to actively oversee the care of large numbers of PLWH): the combination of still evolving EHRs and an "ever" look back period necessarily favors calculations based on more typically recurrent or recently used data elements (i.e., diagnoses, relative to results for a specific lab). Detailed data elements and code sets available in Zipped Folder titled "HIVScreening_v4_Tue Feb 24 22.20.27 CST" **Level of Analysis:** Facility, Clinician : Group/Practice **Setting of Care:** Ambulatory Care : Clinician Office/Clinic **Type of Measure**: Process **Data Source**: Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry **Measure Steward**: Centers for Disease Control and Prevention
STANDING COMMITTEE MEETING [09/12/2016-09/13/2016] **1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>** (1a. Evidence, 1b. Performance Gap) 1a. Evidence: **H-10; M-5; L-0; I-0**; 1b. Performance Gap: **H-12; M-3; L-0; I-0** <u>Rationale</u>: • This new, HIV infection screening measure is based on a 2013 US Preventive Services Task Force (USPSTF) guideline that recommends clinicians screen for HIV infection in adolescents and adults aged 15 to 65 years. The guideline also recommends that younger adolescents and older adults who are at increased risk should also be screened. Grade A: High Certainty of Net Benefit. (Moyer, 2013).

3067 Human Immunodeficiency Virus (HIV) Infection Screening

- USPSTF found no direct evidence on the effects of screening versus no screening on clinical outcomes. Since the 2013 USPSTF recommendation, however, the developer reported that 2 randomized controlled trials have demonstrated that immediate initiation of anti-retroviral therapy meaningfully affects morbidity, mortality, and forward transmission.
- The Committee asked whether the measure captures patients who are screened, diagnosed, and referred to timely, appropriate care. The developer cited surveillance data that show approximately 70% of HIV infected patients receive care within 3 months of diagnosis. However, the developer also noted the difficulty of assessing these linkages, especially referral documentation in electronic health records (EHRs). The developer also mentioned unsuccessful uptake of measures that assess retention in care.
- Committee members questioned the upper age limit of 65 years. The developer acknowledged interest within the CDC in reexamining the upper age bound, but doubted widespread uptake in the absence of aligned USPSTF guidelines.
- The Committee asked why the lower age limit is 15 years, while the CDC recommends screening to begin at age 13. The developer noted significant resistance from influential stakeholder groups when attempts were made to align the measure with CDC's lower age limit.
- The Committee also discussed the challenges of adequately assessing screening for adolescents, specially related to confidentially and unintended consequences of disclosing screening to their parents through insurance claims.
- One Committee member noted that "testing" and "screening" were used interchangeably. The CDC uses screening to refer to a generalized assessment of HIV infection, not dependent on risk. Whereas testing is used to refer to risk-based or diagnostic testing.
- Several Committee members questioned how "evidence of HIV infection" in the numerator can be substantiated without testing. The developer noted that this was included to capture patients with HIV who were tested or screened at some point. The developer is willing to remove this data element from the numerator and denominator to minimize confusion.
- The developer does not have national gap information for this new measure, however testing at 4 community health centers (CHC) found a range of 20.6-31.1%. Results for a fifth CHC with a significant high-risk pool were 65.3%.
- 2011 data from the Behavioral Risk Factor Surveillance System (BRFSS) found that for adults 18-64 years,
- 66.2% of Blacks/African Americans, 44.8% of Hispanics, 38.1% of Whites and 38.8% of other races/ethnicities reported ever being tested for HIV.

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

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

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

<u>Rationale</u>:

- This is a Health Quality Measures Format-compliant (HQMF) eMeasure.
- All components in the measure logic of the submitted eMeasure are represented using the HQMF and Quality Data Model (QDM).
- The submitted eMeasure specifications use existing value sets when possible and use new value sets that have been vetted through the Value Set Authority Center (VSAC).
- The measure submission includes test results from 5 Chicago-area community health centers (CHC) that belong to a Health Center Controlled Network and using GE Centricity Practice Solutions (3 versions among the 5 sites) and that demonstrate the measure logic can be interpreted precisely and unambiguously.

3067 Human Immunodeficiency Virus (HIV) Infection Screening

- The submission contained a feasibility assessment of the data elements. For 1 organization (5 sites), data availability, data accuracy, and workflow scored 3 for each criterion (best possible score). For the second organization, the developer stated the feasibility assessment was conducted early in the development process, so 2 elements were not included; no information on individual criterion was provided for this early phase assessment. Follow-up with the developer indicated the measure logic is feasible based on an assessment by EHR vendors.
- The developer assessed empirical reliability at the data element level and validity of the measure score.
- Data element testing used a random sample of 300 charts; 100 patients who met the measure and 200 who did not were pulled for chart review. Data element testing results were 96% sensitivity, 100% specificity, and kappa=0.97. The developer concluded results represent a highly valid and reliable representation of the numerator elements between the manual vs. automated extractions.
- Score-level testing involved examining performance at the 5 different CHCs, each of which involved multiple care sites and 3 versions of the GE Centricity platform, and also comparing these score results to other practices with established EHRs (Kaiser Permanente Mid-Atlantic States and the Department of Veterans Affairs).
- For score-level testing, the developer concluded the share of visits ever screened in its sample "compares favorably" (20.6-65.3%) to the data from Kaiser (35% screened) and VA (22.9% screened for VA facilities in Chicago area.
- The Committee raised concern about reliability testing of the data elements in the EHR; specifically, it questioned how patients who opt out were handled; limited geographic focus on Chicago; and verification of previous screening or test without self-reporting.
- The developer confirmed that opt outs are not factored into the measure because screening should be part of standard practice. With regard to geographic variation, the developer confirmed future testing in other cities and in different health systems. Finally, the developer acknowledged potential over-testing with this measure, but concluded that the value of testing outweighed the potential risk of over-testing.
- Some concerns were raised about the inclusion of HIV status in the numerator and the cumulative effect on the measure's ability to discern meaningful differences in HIV infection screening for accountability purposes.
- While the Committee was generally supportive of the measure, several concerns were raised about the numerator and denominator. Ultimately, the measure failed the Reliability criterion.

3. Feasibility: H-X; M-X; L-X; I-X

(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:

-

4. Usability and Use: H-X; M-X; L-X; I-X

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

5. Related and Competing Measures

- This measure directly competes with [NQF # and Title] [Description]. [Summarize the related/competing measure issue here, and the disposition of it]

OR

- No related or competing measures noted.

3067 Human Immunodeficiency Virus (HIV) Infection Screening
Standing Committee Recommendation for Endorsement: **Y-X**; **N-X**
6. Public and Member Comment No comments were received on this measure during public and member comment.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

3071 Follow-up Referral after Positive Developmental Screen
Submission | **Specifications**
Description: Percentage of patients aged 6 to 36 months who were referred for follow-up care within 7 calendar days of receiving a positive developmental screening result. **Numerator Statement**: Patients who received a referral for follow-up care (1) by the screening clinician within 7 calendar days of receiving a positive developmental screening result (2) **Denominator Statement**: All patients aged 6 months to 36 months who received a positive developmental screening result through the use of a validated screening tool or an indication from the family that there is a developmental concern. **Exclusions**: Patients who did not receive a developmental screen using a validated developmental screening tool or who have already received or are receiving therapy, intervention, or education that would also be applicable for developmental delay follow-up care. **Adjustment/Stratification**: No risk adjustment or risk stratification. This measure does not require stratification or risk adjustment. **Level of Analysis:** Clinician: Group/Practice, Clinician: Individual, Integrated Delivery System **Setting of Care:** Ambulatory Care: Clinician Office/Clinic **Type of Measure**: Process **Data Source**: Electronic Clinical Data: Electronic Health Record **Measure Steward**: Northwestern University
STANDING COMMITTEE MEETING [09/12/2016-09/13/2016] **1. Importance to Measure and Report: The measure meets the Importance criteria** (1a. Evidence, 1b. Performance Gap) 1a. Evidence: **H-0; M-2; L-2; I-11;** Evidence Exception: **Y-10; N-5;** 1b. Performance Gap: **H-6; M-7; L-2; I-0** Rationale: • The developer provides information in support of a 2006 recommendation of the American Academy of Pediatrics (AAP), reaffirmed in 2014. The guideline is based on consensus/expert opinion and recommends that if developmental screening results are concerning, the child should be scheduled for developmental and medical evaluations as quickly as possible, and professionals should coordinate activities and share findings. • However, the developer cited other data, including a 2016 USPSTF systematic review, which concluded insufficient or inconsistent evidence exists to recommend for or against routine use of brief, formal screening instruments in primary care to detect speech and language delay in children up to 5 years of age. • The developer also noted that 34-37% of high-risk infants and 61% of young children who fail a developmental screen are not referred for further evaluation.

3071 Follow-up Referral after Positive Developmental Screen

- The Committee noted evidence that early intervention for children with developmental delays improves the outcome, but debated whether referrals per se result in improved patient outcomes.
- To strengthen the measure, 1 Committee member suggested the developer include an assessment of whether the patient received the necessary care or treatment after referral. The developer stated it is testing another measure that tracks referral, follow-up, and whether the family actually followed up and was/is actively engaged in further evaluation or treatment.
- Committee members also questioned the appropriateness of referral versus scheduling a follow-up visit or monitoring development over time. The developer explained the time-sensitive nature of many developmental delays.
- The Committee questioned whether the 7-day referral period was substantiated in the literature: Ideally, a child with a positive developmental screen should receive a referral on the same day. The developer responded that its expert panel recognized that some practices will not be able to reach this benchmark, and therefore recommended referrals within 7 days.
- The developer noted significant disparities in the use of validated developmental screen tools. Nationwide, providers used validated tools to evaluate children approximately 80% of the time; safety net providers used validated tools about 38% of the time.
- Following lengthy discussion, the Committee agreed that referral is an important intermediary step in the sequence of developmental screen, follow-up, treatment, and re-evaluation process and voted for Evidence with Exception.
- This is a new measure, so extensive performance gap information from implementation is unavailable; the developer provided performance data from 4 Chicago primary care network test sites (range 31-100%, N=15 charts) and the private pediatrics practice in North Carolina (23%, N=12 charts).

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

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

2a. Reliability: **H-0; M-6; L-7; I-2**; 2b. Validity: **M-2; L-5; I-7**

<u>Rationale</u>:

- Reliability testing was conducted using a chart abstraction tool. Inter-rater reliability between abstractors was assessed for each element of the measure; measure performance also was calculated and compared between abstractors.
- The developer tested the measure in 2 cohorts: primary care practice networks for 4 hospitals in the Chicago Pediatric Quality and Safety Consortium; and Ashe Pediatrics, a private pediatrics practice in North Carolina. (N=117 charts, data period of 1/1/13-12/31/14)
- Overall agreement and kappa statistic for the use of a validated screening tool was 93.6%, with a kappa of 0.87.
- Agreement on the denominator criteria, patients with a positive developmental screening result, was 99.29%, with a kappa of 0.964.
- Agreement and kappa for the numerator criteria, patients who received a referral for follow-up care by the screening clinician within 7 calendar days of receiving a positive developmental screening result, was 73.0%, with a kappa of 0.38.
- The developer attributes the lower kappa for the numerator criteria to the drop-off in charts meeting the denominator (N=16). The developer further reported that kappa values in the range of 0.4 to 0.75 are considered fair to good, again positing that 0.38 falls just below this range because of sample size.

3071 Follow-up Referral after Positive Developmental Screen
• The developer conducted empirical validity testing at the data element. This methodology assesses reliability, not validity. • The developer conducted face validity through an open comment period by stakeholders; the developer reports more than 100 individuals commented. • One Committee inquired about the geographic diversity of the stakeholder group, but the developer was unable to confirm the composition of the group. • The developer reported that 65% of respondents agreed the measure is "extremely valid," (8-9 score). • The developer concluded the face validity assessment indicates performance on this measure would be useful for quality improvement. • Many of the issues that the Committee discussed related to Evidence (e.g., proximity of the process [referral for follow-up] to improved patient outcomes), were raised during the validity testing discussion. Additionally, Committee members raised significant concern with the definition of referral and small sample size for testing. • Ultimately, the measure failed the Validity criterion.
3. Feasibility: H-X; M-X; L-X; I-X *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)*
4. Usability and Use: H-X; M-X; L-X; I-X *(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)*
5. Related and Competing Measures • No related or competing measures noted.
Standing Committee Recommendation for Endorsement: **Y-X**; **N-X**
6. Public and Member Comment No comments were received on this measure during public and member comment.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

3087 Completion of a Malnutrition Screening within 24 hours of Admission
Submission | **Specifications**
Description: Completion of a malnutrition screening to determine if a patient is at-risk for malnutrition, within 24 hours of admission to the hospital **Numerator Statement**: Patients in the denominator who have a completed malnutrition screening documented in the medical record within 24 hours of admission to the hospital. For the purposes of this measure, it is recommended that a malnutrition screening be performed using a validated screening tool which may include but is not limited to one of the following validated tools: Malnutrition Screening Tool (MST) (Wu, 2012), Nutrition Risk Classification (NRC) (Kovacevich, 1997), Nutritional Risk Index (NRI) (Honda, 2016), Nutritional Risk Screening 2002 (NRS-2002) (Bauer, 2005), Short Nutrition Assessment Questionnaire (SNAQ) (Pilgrim, 2016). Bauer JM, Vogl T, Wicklein S, Trögner J, Mühlberg W, Sieber CC. Comparison of the Mini Nutritional Assessment, Subjective Global Assessment, and Nutritional Risk Screening (NRS 2002) for nutritional screening and assessment in geriatric hospital patients. Z Gerontol Geriatr. 2005;38(5):322-7.

3087 Completion of a Malnutrition Screening within 24 hours of Admission

Kovacevich DS, Boney AR, Braunschweig CL, Perez A, Stevens M. Nutrition risk classification: a reproducible and valid tool for nurses. Nutr Clin Pract. 1997;12(1):20-5.

Honda Y, Nagai T, Iwakami N, et al. Usefulness of Geriatric Nutritional Risk Index for Assessing Nutritional Status and Its Prognostic Impact in Patients Aged =65 Years With Acute Heart Failure. Am J Cardiol. 2016;

Pilgrim AL, Baylis D, Jameson KA, et al. Measuring Appetite with the Simplified Nutritional Appetite Questionnaire Identifies Hospitalised Older People at Risk of Worse Health Outcomes. J Nutr Health Aging. 2016;20(1):3-7.

Wu ML, Courtney MD, Shortridge-baggett LM, Finlayson K, Isenring EA. Validity of the malnutrition screening tool for older adults at high risk of hospital readmission. J Gerontol Nurs. 2012;38(6):38-45.

Denominator Statement: All patients age 18 years and older at time of admission who are admitted to an inpatient hospital

Exclusions: No denominator exclusions for this measure.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Electronic Health Record

Measure Steward: Avalere Health/Academy of Nutrition & Dietetics

STANDING COMMITTEE MEETING [09/12/2016-09/13/2016]

1. Importance to Measure and Report: The measure ~~did not reach consensus on~~ does not meet the Importance criteria

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

1a. Evidence: ~~H-0; M-8; L-2; I-6~~ **H-0; M-8; L-3; I-3**; 1b. Performance Gap: **H-4; M-9; L-2; I-1**

Rationale:

- For this new eMeasure, the developer presented 2011 guidelines from the American Society for Parenteral and Enteral Nutrition (ASPEN) that demonstrate that assessing nutrition risk, identified by nutrition screening is associated with longer length of hospital stay, complications, and mortality. The guidelines are based on 9 observational studies; 1 non-randomized cohort with contemporaneous controls relating nutritional assessment to adverse patient outcomes.
- The developer noted that the guideline cited in support of this measure recommends screening for nutrition risk for all hospitalized patients; the guideline was rated Grade C.
- Committee members raised concern about the burden of screening each hospitalization (patients 18 and older) within 24 hours, regardless of patient risk or condition. The developer noted that screening for malnutrition is relatively straightforward. Furthermore, screening tools are sensitive enough to identify those at risk for malnutrition.
- Additionally, Committee members were concerned that the screening, assessment, diagnosis to treatment link was not substantiated by the evidence.
- The Committee questioned why the measure does not specify screening via a validated tool as supported by the evidence. The developer acknowledged the challenges with identifying a validated screening tool currently (i.e., selecting 1 tool that would meet every hospital's needs), but stated it anticipates implementation of the measure will help advance the need for such a tool.
- The Committee failed to reach consensus on the Evidence criterion.
- The developer cited a national survey of hospital-based professionals in the United States focused on nutrition screening and assessment practices and associated gaps in knowledge of

3087 Completion of a Malnutrition Screening within 24 hours of Admission

nutrition care. Out of 1,777 unique respondents, only 36.7% reported completing nutrition screening at admission, and 50.8% reported doing so within 24 hours, and 69% reported documenting the findings in the medical record.

- The developer reposted an evidence synthesis prepared for the Agency for Healthcare Research and Quality (AHRQ) found that older African American patients as well as older Hispanic women were at a higher risk of malnutrition compared to white patients. Some Committee members noted that performance gap information was derived from only 2 hospitals and therefore was concerned about generalizability.
- During the post-comment call, Committee members echoed concerns raised during the in-person meeting about the burden of screening each hospitalization (patients 18 and older) within 24 hours, regardless of patient risk or condition, as well as whether the screening to treatment link was substantiated by evidence. It was noted that the majority of comments received were in support of measures #3087, #3088, and #3089, but a Committee member felt that despite the large number of comments, no new information was provided and the Committee's previous concerns still stand. It was noted that many of the references included in comments were part of the original submission or addressed similar findings as before—i.e., that malnourished patients have increased lengths of stays, increased mortality, and other adverse health outcomes, but the references were not specific to the measures' foci (screening, completion of assessment, care plan). One Committee member noted that many articles looked at malnutrition and length of stay, but that did not seem the most relevant endpoint to be addressing for screening and food security—it should be about longer term health and impact on utilization cost.
- Two Committee members expressed support for the measure intent and one member referred the developer to recent work to inform their progress. Concerns existed around the denominator and its need for targeting beyond simply those 18 and older.
- The developer was provided the opportunity to address the Committee. The developer stated that exclusion criteria include patients who have a length of stay shorter than 24 hours. The developer stated that measure focuses on malnutrition screening, which is the first step in the process of addressing malnutrition.

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-0; M-11; L-2; I-3**; 2b. Validity: **H-1; M-9; L-5; I-1**

<u>Rationale</u>:

- This eMeasure's specifications follow the industry accepted format for eMeasure (HL7 Health Quality Measures Format (HQMF)) and have been constructed with the appropriate elements from the QDM.
- The value sets used in the measure are published and available to the public through the VSAC, which complies with NQF criteria.
- The feasibility assessment is adequately scored, and the supporting documentation provided by the developer justifies the scores.
- The measure was tested in 2 sites using 3 EHR-systems; the developer indicated that the measure logic works correctly and is calculating an appropriate metric.
- Reliability testing was assessed using data element validity testing.
- Validity testing results found that of the 200 patient records that were included in the validation study, there was 100% agreement and a kappa statistic of 1.0 between the 2 sets of data extracted automatically and manually; this was for the data element that identifies the documentation of a completed malnutrition screening. For the data element that calculates

3087 Completion of a Malnutrition Screening within 24 hours of Admission

which malnutrition screenings were completed in less than 24 hours, the percent agreement was slightly lower, (97.5%) and the kappa statistic was 0.87.

- With regard to sensitivity, the first data element (completed nutrition screening correctly), identification was 100%; it was slightly lower for the second data element (completed malnutrition screening within 24 hours [97.24%]). Percentage of patients who did not meet the criteria for the data element was 100% for completion of a screening and also 100% for those screenings completed within 24 hours. The EHR data set had 100% positive predictive value compared with the gold standard, which indicates the ability of the specifications to identify patients in the numerator. However, the ability of the specifications to accurately identify patients who *do not* meet numerator criteria was lower at 79.2%.
- One Committee member raised concern about the degree of variability in screening practice (i.e., who conducts the screening; how screening is defined) in the absence of a standardized screening tool and process.
- Another Committee member questioned why the measure as specified and submitted to NQF does not include exclusions, when exclusions were calculated during testing. (The 3 exclusions are patients who were discharged to hospice care; patients with a length of stay <24 hours; and patients who left against medical advice (AMA)). The developer explained that it conducted feasibility testing on excluded and non-excluded populations. For reliability and validity testing, specific measure exclusion analyses were assessed of the 200 patient records at both testing sites. The number of excluded patients was 3-5%; impact on the data element or performance results was negligible. The developer will consider adding excluded patients in the future, when more hospitals have implemented the measure.

3. Feasibility: H-2; M-12; L-2; 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:

- This measure is specified for use in EHRs.
- A feasibility assessment rating the feasibility, in 3 different EHR systems at 2 sites, was included in the submission.
- The Committee raised no concerns about feasibility.

4. Usability and Use: H-0; M-11; L-5; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- This measure is currently used in the Academy of Nutrition & Dietetics and Avalere Health Malnutrition Quality Improvement Initiative. Both organizations are working with leading hospitals and health systems, as well as with other national stakeholders, in implementing a Malnutrition Quality Improvement Demonstration and Learning Collaborative focused on reducing clinical practice variability in malnutrition care through the implementation of a standardized toolkit, which includes the collection of data on malnutrition care provided in the inpatient setting; the Initiative focuses on internal quality improvement. Six medium to large hospitals and health systems across the country in 6 different states participate.
- This measure is intended for submission to the Centers for Medicare & Medicaid Services Measures Under Consideration pathway for the Inpatient Quality Reporting Program. The measure steward is also working with The Joint Commission for consideration as part of its accreditation measures. The measure steward is seeking NQF endorsement in anticipation of this submission.

3087 Completion of a Malnutrition Screening within 24 hours of Admission

- One Committee raised concern about the degree of variability in screening practice (i.e., who conducts the screening; how screening is defined) in the absence of a standardized screening tool and process.
- Another Committee member asked whether this measure was aligned with CMS' screening for food and security that is part of the Accountable Health Communities Program. The developer responded that the CMS focus and current focus of the measure is on inpatient populations, however, the developer intends to expand the measure to capture at-risk elderly populations in home and community based settings.
- Concern was raised about the potential unintended consequences of endorsing this new, yet-to-be-implemented measure, without evidence demonstrating that screening leads to quality improvement. The developer agreed to update the measure submission with plans for future use by the next maintenance review.

5. Related and Competing Measures

- 3088: Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 hours of a Malnutrition Screening
- 3089: Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment
- 3090: Appropriate Documentation of a Malnutrition Diagnosis
- The developer states that all 4 measures are harmonized.

Standing Committee Recommendation for Endorsement: **Y-4**; **N-10**

6. Public and Member Comment

Comments received:

- Forty comments (some multi-part) were received from 23 organizations/individuals and the developer for #3087. The comments were largely repetitive and listed the same references. Two additional references were included for comments on measure #3087. The first new article is from Kruizenga, which notes that Dutch hospitals are required to screen for undernutrition on the first day of admission. The study confirms other literature that reports that patients who are malnourished have longer LOS, but in this case specifically identified the patients through the use of a standardized screening tool. The second new article is from Allard and points to similar articles that malnutrition at admission "is prevalent and associated with prolonged LOS."
- In commenting on the measure, the developer notes it submitted a series of four measures that, in part, build on each other. Specifically, with respect to screening, the developer posits that #3087 triggers all subsequent care, noting the numerator for this measure becomes the denominator for #3088. The developer expresses concern that the lack of the initial universal screening (#3087) measure may lead to uneven implementation (i.e., ad hoc identification of the denominator) of the other measures.

Committee response:

- Though we appreciate the support the nutrition measures received during the member and public commenting period, we see no salient information in the new addition provided. We remain concerned about the lack of evidence linking screening every patient to improved outcomes and also are concerned with the burden it would cause to screen every hospitalized patient, regardless of patient risk or condition, within 24 hours. We also are concerned about the lack of exclusions—including, for example, hospice patients or patients discharged against medical advice. We understand and agree that malnourished patients have increased lengths of stays, increased mortality, and other adverse health outcomes, but the references the developer provided and those identified in the comment period are not specific to the measures' focus.

3087 Completion of a Malnutrition Screening within 24 hours of Admission
For the measure to be evaluated differently, evidence is needed that documents the impact on longer-term health because of screening, as well as the impact on utilization cost. Developer response: • Exclusion criteria includes patients who have a length of stay of shorter than 24 hours. The measure focuses on malnutrition screening, which is the first step in the process of addressing malnutrition.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

3088 Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 hours of a Malnutrition Screening
Submission | **Specifications**
Description: Patients age 65 years and older identified as at-risk for malnutrition based on a malnutrition screening who have a nutrition assessment documented in the medical record within 24 hours of the most recent malnutrition screening. **Numerator Statement**: Patients in the denominator who have a nutrition assessment documented in the medical record within 24 hours of the most recent malnutrition screening. Recommended nutrition assessment tools include: Subjective Global Assessment (Detsky, 1987), Patient Generated Subjective Global Assessment (Bauer, 2002), Nutrition-Focused Physical Exam (White, 2012) Detsky AS, Mclaughlin JR, Baker JP, et al. What is subjective global assessment of nutritional status?. JPEN J Parenter Enteral Nutr. 1987;11(1):8-13. Bauer J, Capra S, Ferguson M. Use of the scored Patient-Generated Subjective Global Assessment (PG-SGA) as a nutrition assessment tool in patients with cancer. Eur J Clin Nutr. 2002;56(8):779-85. White JV, Guenter P, Jensen G, et al. Consensus statement: Academy of Nutrition and Dietetics and American Society for Parenteral and Enteral Nutrition: characteristics recommended for the identification and documentation of adult malnutrition (undernutrition). JPEN J Parenter Enteral Nutr. 2012;36(3):275-83. **Denominator Statement**: Patients age 65 years and older who were identified as at-risk for malnutrition upon completing a malnutrition screening. **Exclusions**: Denominator exclusions include: • Length of Stay <24 hours **Adjustment/Stratification**: No risk adjustment or risk stratification. **Level of Analysis:** Facility **Setting of Care:** Hospital/Acute Care Facility **Type of Measure**: Process **Data Source**: Electronic Clinical Data: Electronic Health Record **Measure Steward**: Academy of Nutrition and Dietetics
STANDING COMMITTEE MEETING [09/12/2016-09/13/2016] **1. Importance to Measure and Report: The measure does not meet ~~not reach consensus~~ on the Importance criteria** (1a. Evidence, 1b. Performance Gap) 1a. Evidence: ~~H-0; M-8; L-5; I-3~~ **H-0; M-6; L-8; I-0**; 1b. Performance Gap: **H-3; M-11; L-1; I-0**

3088 Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 hours of a Malnutrition Screening

Rationale:

- For this new eMeasure, the developer presented 2011 guidelines from the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) that recommends nutrition support intervention for patients identified by screening and assessment as at risk for malnutrition or malnourished. The developer noted in the submission a Grade C rating.
- The guidelines are based on 3 small, randomized trials, 1 nonrandomized cohort with historical controls, and 1 nonrandomized cohort with contemporaneous control.
- Committee members noted a discrepancy with the evidence rating. The developer inadvertently cited another part of the guideline and intended to cite the part that suggests nutrition assessment for all patients who were identified to be a nutrition risk by nutrition screening; the rating for this part of the guideline is Grade E. The developer will update the measure submission before NQF Member and public comment.
- Some Committee members debated whether the number of studies in the observation and randomized trials mentioned above were sufficient, and able to discern the risk of bias.
- Ultimately, the Committee failed to reach consensus on the Evidence criterion.
- The developer data from the literature to demonstrate a performance gap for this screening measure. A national survey of hospital-based professionals in the United States focused on nutrition screening and assessment practices and associated gaps in knowledge of nutrition care. Out of 1,777 unique respondents, only 23.1% reported using a validated assessment tool to help identify clinical characteristics for a malnutrition diagnosis.
- On the post-comment call, a Committee member noted that the guideline cited is based on three trials, and even among those there were inconsistencies in the evidence and they were rather limited; nothing new was added by the literature cited by the new comments. It was noted the many comments received were largely repetitive and supplied many of the same references, which do not directly link the completion to outcome. The developer noted that it provided several studies looking at the impact of quality improvement programs focused on nutrition and malnutrition. A Committee member responded that it's not just the publication of articles, but also the quality of the articles—what the study evaluated and whether it is even a good study and applies to a performance measure. NQF staff also noted that the evaluation criteria specifically call for an assessment of quality, quantity, and consistency of evidence.
- Ultimately, the measure did not pass on Evidence but the outcome was such that the additional votes might have meant passing the criterion. Accordingly, the Committee members also voted on Overall Suitability for Endorsement. Ultimately, #3088 is not recommended; it did not pass on Evidence, and it failed the vote on Overall Suitability, which was Y-5; N-9.

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: **M-14; L-3; I-0**; 2b. Validity: **M-12; L-3; I-2**

Rationale:

- This eMeasure's specifications follow the industry accepted format for eMeasure (HL7 Health Quality Measures Format (HQMF)) and have been constructed with the appropriate elements from the Quality Data Model (QDM).
- The value sets used in the measure are published and available to the public through the Value Set Authority Center (VSAC), which complies with NQF criteria; however, Avalere has yet to fill out the purpose statements for each of their value sets.

3088 Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 hours of a Malnutrition Screening

- The feasibility assessment is adequately scored, and the supporting documentation justifies the scores.
- The measure was tested in 2 sites using 3 electronic health record (EHR)-systems, indicating that the measure logic works correctly and is calculating an appropriate metric for this measure.
- Reliability testing was assessed using data element validity testing.
- Validity testing results found that of the 200 patient records that were included in the validation study, there was 92% and 93% agreement, respectively, between abstractor and machine at facilities 1 and 2; and Kappa statistics were .42 and 0.75 between the 2 sets of data extracted automatically and manually. The data element nutrition assessment had a high percentage agreement and Kappa, 0.96 and .95 for facility 1 and, as well as strong sensitivity (94.97% and 92.2%) and specificity (94.62% and 92.1%) results.
- Committee members highlighted several of the same concerns raised with Measure #3087, but did not discuss them in any detail; these include, the omission of exclusions and as with screening, the variability of treatment protocols for malnutrition across hospitals.
- The Committee considered whether to suspend voting on reliability until the consensus not reached issues on Evidence were resolved; ultimately, the Committee decided to proceed with a vote.

3. Feasibility: H-1; M-15; 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)

Rationale:

- This measure is specified for use in EHRs.
- A feasibility assessment rating the feasibility in 3 different EHRs is included in the submission.
- The measure was tested in in 2 hospital EHR systems.
- The Committee raised concern about the number of hospital EHR systems used to test the measure.

4. Usability and Use: H-0; M-14; L-3; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- This measure is currently used in the Academy of Nutrition & Dietetics and Avalere Health – Malnutrition Quality Improvement Initiative. Both organizations are working with leading hospitals and health systems, as well as with other national stakeholders, in implementing a Malnutrition Quality Improvement Demonstration and Learning Collaborative focused on reducing clinical practice variability in malnutrition care through the implementation of a standardized toolkit, which includes the collection of data on malnutrition care provided in the inpatient setting for use in internal quality improvement; initiative involves 6 medium – large hospitals and health systems across the country representing 6 different states and thousands of patients.
- This measure is intended for submission to the Centers for Medicare & Medicaid Services Measures Under Consideration pathway for the Inpatient Quality Reporting Program. The measure steward is also working with the Joint Commission for consideration as part of its accreditation measures. The measure steward is seeking NQF endorsement in anticipation of this submission.

5. Related and Competing Measures

- 3087: Completion of a Malnutrition Screening within 24 hours of Admission

3088 Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 hours of a Malnutrition Screening

- 3089: Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment
- 3090: Appropriate Documentation of a Malnutrition Diagnosis
- The developer states that all 4 measures are harmonized.

Standing Committee Recommendation for Endorsement: **Y-5**; **N-9**

6. Public and Member Comment

Comments received:

- NQF received thirty-nine comments from 23 organizations for measure #3088. As with #3078, the comments were largely repetitive and many references presented were included in the original measure submission. Many of the references included in the comments were included in the original measure submission and addressed findings that malnourished patients have increased lengths of stays, increased mortality, and other adverse health outcomes but were not specific to the measure foci (screening, completion of assessment, care plan).

Committee response:

- The guidelines cited by the developer are based on three individual trials, and among those three trials were inconsistencies in the very limited evidence. Though the developer noted it provided several studies looking at the impact of quality improvement programs focused on nutrition and malnutrition, we note that the quantity, quality, and consistency of the evidence to address the measure construct is important. There was clear support from many commenters, but the comments were largely repetitive, and the additional information did not provide new evidence directly addressing the measure's focus to directly link the completion of a malnutrition assessment to improved outcomes.

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

8. Board of Directors Vote: Y-X; N-X

9. Appeals

3090 Appropriate Documentation of a Malnutrition Diagnosis

Submission | **Specifications**

Description: Appropriate documentation of a malnutrition diagnosis for those patients who are found to be malnourished based on a nutrition assessment.

Numerator Statement: Patients with a documented diagnosis of malnutrition.

Denominator Statement: Patients age 65 years and older admitted to inpatient care who have a completed nutrition assessment documented in their medical record with a finding of malnutrition.

Exclusions: Patients with a length of stay of <24 hours should be excluded from the measure denominator due to their very short inpatient stay, and the length of time typically required for the full nutrition care process (screening and assessment) to be implemented.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Electronic Health Record

3090 Appropriate Documentation of a Malnutrition Diagnosis

Measure Steward: Avalere Health/Academy of Nutrition & Dietetics

STANDING COMMITTEE MEETING [09/12/2016-09/13/2016]

1. Importance to Measure and Report: <u>The measure failed to meet the Importance criteria</u>

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

1a. Evidence: **H-0; M-5; L-4; I-7**; 1b. Performance Gap: **H-X**; **M-X**; **L-X**; **I-X**

<u>Rationale</u>:

- The developer for this new eMeasure presented data showing patients who are malnourished while hospitalized have an increased risk of complications, readmissions, and longer lengths of stays.
- The developer presented a diagram of the relationships of processes of care to patient outcomes. However, this measure -"documentation of malnutrition diagnosis in patients found to be malnourished" is not 1 of the processes indicated on the diagram.
- Furthermore, the evidence provided addresses nutrition support for patients that are malnourished.
- The Committee raised a number of issues, including: unclear definition of "malnutrition and how it is captured; no disparities data presented; and application of the measure to a broader population (>18 years) than is recommended in the guideline (e.g., elderly).
- The developer noted the disconnect between people who are being screened at risk for malnutrition and the documentation of the diagnosis of malnutrition, and even more significant disconnect in documenting a diagnosis of malnutrition. The developer added that there is evidence to indicate that a diagnosis of malnutrition can be successfully performed and when that is done, survival improves and costs are decreased in the hospitalized patient population.
- The Committee acknowledged the importance assessing malnutrition but was concerned that there is not sufficient evidence to support the process of documenting that diagnosis is linked to improved outcomes. The measure did not pass the Evidence criterion.
-

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-X**; **M-X**; **L-X**; **I-X**; 2b. Validity: **H-X**; **M-X**; **L-X**; **I-X**

<u>Rationale</u>:

-

3. Feasibility: H-X; M-X; L-X; I-X

(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>:

-

4. Usability and Use: H-X; M-X; L-X; I-X

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

<u>Rationale</u>:

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5. Related and Competing Measures

- This measure directly competes with [NQF # and Title] [Description]. [Summarize the related/competing measure issue here, and the disposition of it]

3090 Appropriate Documentation of a Malnutrition Diagnosis
OR • No related or competing measures noted.
Standing Committee Recommendation for Endorsement: **Y-X**; **N-X** Rationale • Prior to the post-comment call, the developer submitted a reconsideration request. The Committee voted not to reconsider the measure.(Y-3; N-11)
6. Public and Member Comment Comments received: • NQF received 30 comments addressed to measure 3090. These comments were in line with the large number of comments received on measure #3087, #308, and #3089. The references included in the comments are largely repetitive and offer no additional information than what is found in the measure submission.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals