NATIONAL QUALITY FORUM

Memo

September 13, 2018

To: Behavioral Health and Substance Use Standing Committee

From: NQF staff

Re: Post-comment web meeting to discuss public comments received and NQF member expression of support

Purpose of the Call

The Behavioral Health and Substance Use Standing Committee will meet via web meeting on September 20, 2018 from 2:00 pm – 4:00 pm ET. The purpose of this call is to:

- Review and discuss comments received during the post-evaluation public and member comment period;
- Provide input on proposed responses to the post-evaluation comments;
- Review and discuss NQF members' expression of support of the measures under consideration;
- Determine whether reconsideration of any measures or other courses of action are warranted; and
- Discuss related and competing measures.

Standing Committee Actions

1. Review this briefing memo the draft report.
2. Review and consider the full text of all comments received and the proposed responses to the post-evaluation comments (see comment table)
3. Review the NQF members' expressions of support of the submitted measures.
4. Be prepared to provide feedback and input on proposed post-evaluation comment responses.

Conference Call Information

Please use the following information to access the conference call line and webinar:

Public dial-in:	844-225-8373
Speaker dial-in:	866-871-4317
Web link:	http://nqf.commpartners.com/se/Rd/Mt.aspx?126759
Registration link:	http://nqf.commpartners.com/se/Rd/Rg.aspx?126759

Background

The Behavioral Health and Substance Use project aims to endorse measures of accountability for improving the delivery of behavioral health and substance use services and achieving better health outcomes for the U.S. population. The most recent review of measures for this project examines measures of suicide risk assessments; medication adherence and management; diabetes and cardiovascular screening and monitoring for

individuals with schizophrenia and bipolar disorder; concurrent use of opioids and benzodiazepines; and the use of pharmacotherapy for opioid use disorder. The 23-member Behavioral Health Standing Committee evaluated two newly submitted measures and seven measures undergoing maintenance review against NQF's standard evaluation criteria. All nine measures were recommended for endorsement:

- 0104e Adult Major Depressive Disorder (MDD): Suicide Risk Assessment (PCPI)
- 0105 Antidepressant Medication Management (AMM) (NCQA)
- 1879 Adherence to Antipsychotic Medications for Individuals with Schizophrenia (CMS/NCQA)
- 1880 Adherence to Mood Stabilizers for Individuals with Bipolar I Disorder (CMS/NCQA)
- 1932 Diabetes Screening for People With Schizophrenia or Bipolar Disorder Who Are Using Antipsychotic Medications (SSD) (NCQA)
- 1933 Cardiovascular Monitoring for People With Cardiovascular Disease and Schizophrenia (SMC) (NCQA)
- 1934 Diabetes Monitoring for People With Diabetes and Schizophrenia (SMD) (NCQA)
- 3389 Concurrent Use of Opioids and Benzodiazepines (COB) (PQA)
- 3400 Use of Pharmacotherapy for Opioid Use Disorder (OUD) (CMS/Mathematica Policy Research)

Comments Received

NQF solicits comments on measures undergoing review in various ways and at various times throughout the evaluation process. First, NQF solicits comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). Second, NQF solicits member and public comments during a 16-week comment period via an online tool on the project webpage.

Pre-evaluation Comments

NQF solicits comments prior to the evaluation of the measures via an online tool on the project webpage. For this evaluation cycle, the pre-evaluation comment period was open April 24, 2018 to June 5, 2018 for the measures under review, and no comments were received.

Post-evaluation Comments

The draft report was posted on the project webpage for public and NQF member comment on July 24, 2018 for 30 calendar days. During this commenting period, NQF received 57 comments from nine member organizations:

Member Council	# of Member Organizations Who Commented
Consumer	0
Health Plan	2
Health Professional	4
Provider Organization	1

Member Council	# of Member Organizations Who Commented
Public/Community Health Agency	1
Purchaser	0
QMRI	1
Supplier/Industry	0

All comments received during the 16-week commenting period are in the comment table (excel spreadsheet) posted to the Committee SharePoint site. This comment table contains the commenter's name, comment, associated measure, topic (if applicable), and draft responses (including measure steward/developer responses) for the Committee's consideration. Please review this table before the meeting and consider the individual comments received and the proposed responses to each.

To facilitate the discussion, NQF has categorized the majority of the post-evaluation comments into topic areas or themes. Although all comments are subject to discussion, the intent is not to discuss each individual comment on the September 20, 2018 post-comment call. Instead, we will spend the majority of the time considering the five themes discussed below, and the set of comments as a whole. Please note that the organization of the comments into major topic areas is not an attempt to limit Committee discussion. Measure stewards/developers have responded to comments where appropriate, and NQF staff have drafted proposed responses for the Committee to consider.

Comments and their Deposition

Themed Comments

Five major themes were identified in the post-evaluation comments, as follows:

1. General Comments
2. Feasibility/Data Collection
3. Expansion of Measured Population
4. Unintended Consequences
5. Measure-Specific Comments

Theme 1 – General Comments

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

Proposed NQF Response:

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

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

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

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

Theme 2 – Feasibility and Data Collection

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

Measure Steward/Developer Response

Thank you for your comments. This measure [0104e: Adult Major Depressive Disorder (MDD): Suicide Risk Assessment] is specified and has been tested within the population with major depressive disorder. Expanding the measure beyond this population would require consultation with our TEP and additional testing to assess the feasibility, reliability and validity of the measure within a broader population. We are also aware that recent changes in healthcare delivery models (e.g., telemedicine or virtual encounters) require new considerations as they relate to performance measurement. On the next point regarding the definition of "assessment", "suicide risk assessment" is defined in the Numerator Details section in the human readable format of this measure's technical specifications and the clinical guidance statement makes reference to key components of a complete assessment. Finally, if mapped to the measure logic, use of a standardized tool will meet criteria for this measure. However, we will consider reference to these tools for provider guidance in future updates and maintenance of this measure. We plan to bring these suggestions (expanding the denominator to include additional diagnoses, reconsideration of "healthcare visits" to include virtual encounters and reference to standardized tools) back to our TEP for consideration in future updates and maintenance of this measure. A "suicide risk assessment" is defined more explicitly in the Numerator Details section in the human readable format of this measure's technical specifications. The clinical guideline statement also makes reference to key components of a complete assessment. Clinical guidance on how to address and manage patients who screen positive for suicidal ideation are also provided in the human readable format of this measure's technical specifications. Your point about EHR availability is a good one. The PCPI has long recognized the great potential of Electronic Health Records (EHRs) and clinical data registries to advance quality measurement and quality improvement initiatives. As such, the PCPI has been an advocate for “next generation” methods that leverage clinical data for measure development, specification and testing. Access to clinical data has the potential to provide feedback to physicians and other health care providers that is timely, actionable and leads to improvement in the care delivered to patients. We hope that providers and other stakeholders continue to consider the implementation of EHR technology to advance their quality improvement efforts.

Measure Steward/Developer Response

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

Measure Steward/Developer Response

We acknowledge the validity of this concern [for measure 3400: Use of pharmacotherapy for OUD]. Bundled payment and, more broadly, other alternative payment methodologies is a challenge that likely effects many claims-based measures, and we are not sure how common this is yet. We spoke with our technical expert panel and stakeholders from some of the states represented in the data we used to test the measure about this issue. They indicated that states are implementing ways of identifying services such as medication treatment in their alternate payment systems.

The state officials we interviewed all indicated they bill outpatient treatment programs that provide methadone treatment and, with the exception of one state, are able to identify methadone use through claims. It seems likely that states who choose to implement this measure will either already have the ability to identify methadone or, like many of the stakeholders we interviewed, will implement ways of identifying the treatment. We plan as part of measure maintenance to look into how commonly states are using bundled payment for opioid use disorder, and how they identify specific services within bundles. We acknowledge that use of pharmacotherapy is dependent on many variables, and some rural areas do not have enough buprenorphine providers and outpatient addiction treatment programs to meet their needs. As the commenter notes, this measure is intended for Medicaid beneficiaries, and is useful in that it allows states to track service needs that warrant further investigation. CMS intends for this to be a voluntary measure for Medicaid programs, for state level monitoring.

Theme 3 – Expansion of Measured Population

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

Measure Steward/Developer Response

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

Measure Steward/Developer Response

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

Theme 4 – Unintended Consequences

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

Measure Steward/Developer Response

Thank you for your feedback. This measure [1879: Adherence to Antipsychotic Medications for Individuals with Schizophrenia] is based on clinical guidelines and literature that demonstrate how use of antipsychotic medications in individuals with schizophrenia can reduce symptoms and the risk of adverse events (e.g., hospitalization) (see section 1a3 "Systematic Reviews of the Evidence" in the evidence attachment). We acknowledge that for some individuals, the risks of antipsychotics outweigh the benefits. The quality measure is not designed to assess the clinical appropriateness of continuing or discontinuing a prescribed medication for individual patients, and it should not supersede shared decision making with patients about risks and benefits of antipsychotic medication use. We do not anticipate that providers or health plans will achieve 100% performance on this measure. However, the measure still provides valuable information about overall and comparative performance of providers and health plans regarding the adherence to prescribed medications.

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

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

2) At least two prescriptions for an antipsychotic medication.

Measure Steward/Developer Response

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

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

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

Measure Steward/Developer Response

PQA appreciates the commenter's support of measure #3389. In regard to dosing thresholds, we were not able to identify dosing guidelines for benzodiazepines in terms of thresholds for safe use with opioids. We will continue to evaluate clinical guidelines and published studies to update the measure as appropriate.

Measure Steward/Developer Response

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

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

Measure-Specific Comments

1879 Adherence to Antipsychotic Medications for Individuals with Schizophrenia

Six comments were received on this measure during the post-evaluation commenting period. Several commenters suggested additional medication and diagnosis exclusions. Another commenter expressed concern about data collection for the measure due to the nature of separating pharmaceutical claims data from regular claims by many health plans.

Measure Steward/Developer Response

Thank you for your feedback. We appreciate and agree with the comment. The measure currently includes long-acting (depot) injectable antipsychotic medications in the adherence calculation. The days' supply is imputed for depot injectable antipsychotic medications billed under Medicare Part D and Part B, and include the below (see S.7 of the submission):

- fluphenazine decanoate
- haloperidol decanoate
- aripiprazole
- aripiprazole lauroxil
- olanzapine pamoate
- paliperidone palmitate
- risperidone microspheres

Measure Steward/Developer Response

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

Although some members with dementia who have schizophrenia or schizoaffective disorder may be appropriately managed on an antipsychotic medication, we exclude these members from the measure because of the public health advisory and black box warning issued by the Food and Drug Administration (FDA). In April 2005, the FDA issued a Public Health Advisory warning of increased risk of mortality associated with the use of atypical antipsychotics in elderly patients with dementia. This warning was based on

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

References:

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

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

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

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

Proposed Committee Response

Thank you for your comments.

Action Item

Based on comments received and the information provided by the developer, would the Committee like to reconsider this measure?

1880 Adherence to Mood Stabilizers for Individuals with Bipolar I Disorder

Six comments were received during the post comment period on this measure. One comment was specific to unintended consequence of medication adherence, and the other two comments were specific to the measure specifications list of mood stabilizer drugs.

Measure Steward/Developer Response

Thank you for your feedback. We appreciate and agree with the comment. The measure currently includes long-acting (depot) injectable antipsychotic medications FDA-

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

- aripiprazole
- risperidone microspheres

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

Action Item:

Based on comments received and the information provided by the developer, would the Committee like to reconsider this measure?

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

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

Four comments specific to measure #1933 were received during the post-evaluation comment period. Three comments specific to measure #1934 were received. One comment involved limiting the measure to uncomplicated diabetes. Another comment questioned whether the measure should be diagnostically specific. The comments caution use of the measure in regards to diabetes or cardiovascular monitoring outside of acute care setting or beyond practice scope.

Measure Steward/Developer Response:

Thank you for your comment. For this measure [#1933], members who have a diagnosis of schizophrenia or schizoaffective disorder and cardiovascular disease are identified using claims data that signifies the member received care in a variety of allowable care settings (e.g., outpatient, emergency department, acute inpatient, telehealth). Among members identified as having a diagnosis of schizophrenia and cardiovascular disease, the measure assesses the percentage who had an LDL-C test during the measurement year, which can be identified using administrative claims data or automated laboratory data. Guidelines and evidence do not specify the type of provider that can order and review the laboratory tests required for monitoring in these measures.

For this measure [#1934], we do not differentiate between complicated and uncomplicated diabetes, as we did not find evidence in the literature or guidelines to support limiting the measure in this way. Evidence suggests that the prevalence of diabetes among patients with schizophrenia is higher than among the general population. Additionally, there is a known relationship between the use of antipsychotic medications and increased risk of metabolic syndrome and diabetes. People with Schizophrenia and are also less likely to receive care for diabetes than the general population. This measure aims to shed light on disparities in care and assess the proper management of diabetes among a high-risk subset of the general population.

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

Proposed Committee Response

Whether monitoring measures should target the general population or be condition specific is an important consideration that should be taken into account when evaluating a measure. In this case, the Committee discussed and agreed that a diagnostically specific measure is warranted. Collecting data on diabetes management in people with schizophrenia is a public health priority and is essential to health improvement.

Action Item

Based on comments received and the information provided by the developer, would the Committee like to reconsider this measure?

3389 Concurrent Use of Opioids and Benzodiazepines (COB)

Nine comments were received on this measure specific to feasibility and data collection, unintended consequences, and general support. There was one comment that expressed concern about the measure as specified as well as its relation to another newly endorsed measure NQF #3316 *Safe Use of Opioids – Concurrent Prescribing*.

Proposed Committee Response

Thank you for your comment. Measure #3389 *Concurrent Use of Opioids and Benzodiazepines (COB)* and #3316e *Safe Use of Opioids – Concurrent Prescribing* have been identified by the developer as related. The Behavioral Health and Substance Use Committee will evaluate these measures during the post-comment call and provide guidance and recommendations.

Measure Steward/Developer Response

Thank you for the opportunity to respond to these additional comments received regarding the PQA measure #3389 Concurrent Use of Opioids and Benzodiazepines that retrospectively evaluates the performance of health plans using administrative claims data. To clarify, the measure denominator includes individuals 18 years and older with 2 or more prescription claims for opioids with unique dates of service, for which the sum of the days' supply is 15 or more days. The numerator is the number of individuals from the denominator with concurrent use of opioids and benzodiazepines for 30 or more cumulative days during the measurement year. Individuals with cancer or in hospice at any point during the measurement year are excluded from the denominator.

The measure rationale and exclusions are based on the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, that provides a category A recommendation (applies to all persons; most patients should receive the recommended course of action) that prescribers should avoid concurrent prescriptions of opioids and benzodiazepines.1 The CDC guideline states that although there are circumstances when it might be appropriate to prescribe opioids to a patient receiving benzodiazepines (e.g., severe acute pain in a patient taking long-term, stable low-dose benzodiazepine therapy), clinicians should avoid concurrent prescribing whenever possible. Additional rationale for the measure is the 2016 US Food and Drug Administration Boxed Warnings added to prescription drug labeling for prescription opioid pain and prescription opioid cough medications, and benzodiazepines, based on studies finding that combined use of opioids and benzodiazepines has resulted in serious side effects, including death.2 Since the publication of the CDC prescribing guideline, several retrospective observational studies have been published that add to the growing body of evidence to support the lack of broad therapeutic benefit combined with the increased risk for overdose associated with co-prescribing of these medications.3-5

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

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

may choose to concurrently prescribe opioid and benzodiazepine medications for individual patients due to patient individualization considerations. This performance measure is not intended to preclude such situations.

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

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

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

References

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

2. US Food and Drug Administration. FDA Drug Safety Communication: FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning. August 31, 2016. Available at: http://www.fda.gov/Drugs/DrugSafety/ucm518473.htm. Accessed: November 9, 2016.

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

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

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

Action Item:

Committee to evaluate related and competing and to determine relation status, or "best in class" if competing.

3400 Use of Pharmacotherapy for Opioid Use Disorder (OUD)

Measure #3400 received several comments related to feasibility/data collection and unintended consequences. It also received a comment noting that the measure is similar to an existing endorsed measure: #3175 *Continuity of Pharmacotherapy for Opioid Use*.

Proposed Committee Response

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

Action Item

Committee to evaluate related and competing and to determine relation status, or "best in class" if competing.

NQF Member Expression of Support

Throughout the 16-week continuous public commenting period, NQF members had the opportunity to express their support ('support' or 'do not support') for each measure submitted for endorsement consideration to inform the Committee's recommendations. Three NQF members provided their expressions of support: See Appendix A.

Appendix A: NQF Member Expression of Support Results

Four NQF members provided their expressions of support. All nine measures under consideration received support from NQF members. Results for each measure are provided below.

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

Member Council	Support	Do Not Support	Total
Consumer	0	0	0
Health Plan	0	0	0
Health Professional	0	0	0
Provider Organization	0	0	0
Public/Community Health Agency	0	0	0
Purchaser	0	0	0
QMRI	1	0	1
Supplier/Industry	0	0	0
All Councils	**1**	**0**	**1**

0105 Antidepressant Medication Management (AMM) (NCQA)

Member Council	Support	Do Not Support	Total
Consumer	0	0	0
Health Plan	0	0	0
Health Professional	0	0	0
Provider Organization	0	0	0
Public/Community Health Agency	0	0	0
Purchaser	0	0	0
QMRI	1	0	1
Supplier/Industry	0	0	0
All Councils	**1**	**0**	**1**

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

Member Council	Support	Do Not Support	Total
Consumer	0	0	0
Health Plan	0	0	0
Health Professional	0	0	0
Provider Organization	0	0	0
Public/Community Health Agency	0	0	0
Purchaser	0	0	0
QMRI	1	0	1
Supplier/Industry	0	0	0
All Councils	**1**	**0**	**1**

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

Member Council	Support	Do Not Support	Total
Consumer	0	0	0
Health Plan	0	0	0
Health Professional	0	0	0
Provider Organization	0	0	0
Public/Community Health Agency	0	0	0
Purchaser	0	0	0
QMRI	1	0	1
Supplier/Industry	0	0	0
All Councils	**1**	**0**	**1**

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

Member Council	Support	Do Not Support	Total
Consumer	0	0	0
Health Plan	0	0	0
Health Professional	0	0	0
Provider Organization	0	0	0
Public/Community Health Agency	0	0	0
Purchaser	0	0	0

Member Council	Support	Do Not Support	Total
QMRI	1	0	1
Supplier/Industry	0	0	0
All Councils	**1**	**0**	**1**

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

Member Council	Support	Do Not Support	Total
Consumer	0	0	0
Health Plan	0	0	0
Health Professional	0	0	0
Provider Organization	0	0	0
Public/Community Health Agency	0	0	0
Purchaser	0	0	0
QMRI	1	0	1
Supplier/Industry	0	0	0
All Councils	**1**	**0**	**1**

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

Member Council	Support	Do Not Support	Total
Consumer	0	0	0
Health Plan	0	0	0
Health Professional	0	0	0
Provider Organization	0	0	0
Public/Community Health Agency	0	0	0
Purchaser	0	0	0
QMRI	1	0	1
Supplier/Industry	0	0	0
All Councils	**1**	**0**	**1**

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

Member Council	Support	Do Not Support	Total
Consumer	0	0	0
Health Plan	0	0	0
Health Professional	1	0	1
Provider Organization	0	0	0
Public/Community Health Agency	0	0	0
Purchaser	0	0	0
QMRI		1	1
Supplier/Industry	0	0	0
All Councils	**1**	**1**	**2**

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

Member Council	Support	Do Not Support	Total
Consumer	0	0	0
Health Plan	0	0	0
Health Professional	0	1	1
Provider Organization	0	0	0
Public/Community Health Agency	0	0	0
Purchaser	0	0	0
QMRI	1	0	1
Supplier/Industry	0	0	0
All Councils	**1**	**1**	**2**