NATIONAL QUALITY FORUM

Memo

May 1, 2018

To: Consensus Standards Approval Committee (CSAC)

From: Patient Safety

Re: Patient Safety, Fall Cycle, 2017

CSAC Action Required

The CSAC will review recommendations from the Patient Safety project at its May 8, 2018 meeting and vote on whether to uphold the recommendations from the Patient Safety Standing Committee.

This memo includes a summary of the project, recommended measures, and themes identified and responses to the public and member comments. The following documents accompany this memo:

1. **Patient Safety, Fall Cycle, 2017 draft report**. The draft report has been updated to reflect the changes made following the Standing Committee's discussion of public and member comments. The complete draft report and supplemental materials are available on the project webpage.
2. **Comment Table.** Staff has identified themes within the comments received. This table lists six comments received during the post-meeting comment period and the NQF/Standing Committee responses.

Background

Patient safety-related events occur across healthcare settings from hospitals to clinics to nursing homes and include healthcare-associated infections (HAIs), medication errors, falls, and other potentially avoidable occurrences. Medical errors are preventable patient safety events that are estimated to cause hundreds of thousands of preventable deaths each year in the United States. NQF's portfolio of patient safety measures spans various topic areas and is designed to measure and report on patient safety events and practices across a variety of settings. However, significant gaps remain in the measurement of patient safety and how providers approach minimizing the risk of patient safety events. There is also a recognized need to expand avoidable patient safety measures beyond the hospital setting, as well as harmonize safety measures across sites and settings of care.

NQF has over a 10-year history of focusing on patient safety. Through various projects, NQF previously endorsed over 100 consensus standards related to patient safety; these measures are important tools for tracking and improving patient performance.

The 25-member Patient Safety Standing Committee oversees the NQF Patient Safety measure portfolio. The Committee evaluates both newly submitted and previously endorsed measures against NQF's measure evaluation criteria, identifies gaps in the measurement portfolio,

provides feedback on how the portfolio should evolve, and serves on ad hoc or expedited projects in its designated topic areas.

On January 23, 2018, the Patient Safety Standing Committee evaluated one new measure: 3316e *Safe Use of Opioids – Concurrent Prescribing* (Centers for Medicare & Medicaid Services/Mathematica Policy Research). The Committee did not reach consensus on this measure during this web meeting. However, the Committee re-voted on the measure during its the post-comment web meeting on April 17, 2018 and ultimately recommended it for endorsement.

Draft Report

The Patient Safety, Fall Cycle, 2017 draft report presents the results of the evaluation of one measure considered under the Consensus Development Process (CDP). During the initial measure evaluation web meeting on January 23, 2018, the Committee did not reach consensus on whether the measure met NQF's standards for reliability, validity, and usability. After reviewing public comments on the measure and the developer's responses to those comments, the Patient Safety Standing Committee re-voted on the measure and recommended it for endorsement.

The measure was evaluated against the 2017 version of the measure evaluation criteria.

	Maintenance	New	Total
Measures under consideration	0	1	1
Measures recommended for endorsement	0	1	1
Measures recommended for inactive endorsement with reserve status	0	0	0
Measures approved for trial use	0	0	0
Measures not recommended for endorsement or trial use	0	0	0
Measures withdrawn from consideration	0	0	0
Reasons for not recommending	Importance – NA Scientific Acceptability - NA Overall - NA Competing Measure - NA	Importance - NA Scientific Acceptability - NA Overall - NA Competing Measure - NA	

CSAC Action Required

Pursuant to the CDP, the CSAC is asked to consider endorsement of one candidate consensus measure.

Measure Recommended for Endorsement

- 3316e Safe Use of Opioids – Concurrent Prescribing (Centers for Medicare & Medicaid Services/Mathematica Policy Research)

Overall Suitability for Endorsement: Yes-15; No-3

Comments and Their Disposition

NQF received six comments from six organizations (including six NQF member organizations) and individuals pertaining to the draft report and to the measure 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 developer, is posted to the Patient Safety project webpage.

Comment Themes and Committee Responses

Comments about specific measure specifications and rationale were forwarded to the developer, who was 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 topic areas with the most significant and recurring issues.

Themed Comments

Theme 1 – Potential Need for Additional Exclusions

Six commenters recommended potentially necessary exclusions, such as patients with sickle cell disease, patients undergoing chronic substance abuse treatment, patients with certain hematological and neurological conditions, and patients presenting to the emergency department with existing concurrent prescriptions.

Committee Response

The Committee reviewed these comments along with the developer's responses during their deliberations on the post-comment web meeting on April 17. The Committee then re-voted on the criteria where consensus was not reached and on the measure's overall suitability for endorsement. The Committee was satisfied by the developer's response and recommended the measure for endorsement.

Developer Response

We recognize that there may be some clinically necessary situations for concurrent prescriptions of opioids and benzodiazepines and we agree with the need to properly treat these patients. As recommended by our expert panels, we looked into single-condition exclusions, specifically sickle cell disease and substance use therapy and found that a very small portion of cases eligible for the numerator (0 to 3.4 percent) fell into

these [sic] category. Furthermore, after reviewing the testing results, clinicians from our expert workgroup recommended continuing to include patients for whom concurrent prescribing is medically necessary because experts stated these populations (1) have the highest risk of receiving concurrent prescriptions; and (2) can experience a lag in adverse events. In addition, there are currently no guidelines supporting exclusion of patients who may require concurrent prescriptions from the measure, other than cancer and palliative care. However, we will consider these comments and evaluate opportunities to refine the measure.

Theme 2 – Dosing Thresholds

One commenter recommended determining dosing thresholds to identify inappropriate versus appropriate concurrent prescribing.

Committee Response

Thank you for your comment, which the Committee reviewed along with the developer's responses during their deliberations on the post-comment web meeting on April 17. The Committee then re-voted on the criteria where consensus was not reached and on the measure's overall suitability for endorsement. The Committee was satisfied by the developer's response and recommended the measure for endorsement.

Developer Response

The existing professional organizations, states, and federal agency developed guidelines for opioid prescribing share some common elements, including dosing thresholds, cautious titration, and risk mitigation strategies such as using risk assessment tools, treatment contracts, and urine drug testing. However, there is considerable variability in the specific recommendations (e.g., range of dosing thresholds of 90 MME/day to 200 MME/day), audience (e.g., primary care clinicians versus specialists), use of evidence (e.g., systematic review, grading of evidence and recommendations, and role of expert opinion), and rigor of methods for addressing conflict of interest. There's currently not an evidence base strong enough to specify a certain threshold deemed safe for the inpatient setting so we did not include dosing thresholds in the specification.

Theme 3 – Unintended Consequences

Six commenters expressed concerns about potential unintended consequences of the measure, such as emergency physicians making changes to patients' medication regimens instead of outpatient physicians or primary care providers; potential incentives to reduce emphasis on pain control; and/or promoting rapid dose tapers that could be harmful to patients.

Committee Response

The Committee reviewed these comments, along with the developer's responses, during their deliberations on the post-comment web meeting on April 17. The Committee then re-voted on the criteria where consensus was not reached and on the measure's overall suitability for endorsement. The Committee was satisfied by the developer's response and recommended the measure for endorsement.

Developer Response

We recognize that there may be some clinically necessary situations for concurrent prescriptions of opioids and benzodiazepines and we agree with the need to properly treat these patients. As recommended by our expert panels, we looked into single-condition exclusions, specifically sickle cell disease and substance use therapy and found that a very small portion of cases eligible for the numerator (0 to 3.4 percent) fell into these category. Furthermore, after reviewing the testing results, clinicians from our expert workgroup recommended continuing to include patients for whom concurrent prescribing is medically necessary because experts stated these populations (1) have the highest risk of receiving concurrent prescriptions; and (2) can experience a lag in adverse events. In addition, there are currently no guidelines supporting exclusion of patients who may require concurrent prescriptions from the measure, other than cancer and palliative care. However, we will consider these comments and evaluate opportunities to refine the measure.

Theme 4 – Limited Testing

Two commenters expressed concern about the limited testing conducted for this measure, with one commenter suggesting that the testing should be expanded beyond two EHR systems, and another suggesting that rural and nonacademic hospitals should have been included.

Committee Response

The Committee reviewed these comments, along with the developer's responses, during their deliberations on the post-comment web meeting on April 17. The Committee then re-voted on the criteria where consensus was not reached and on the measure's overall suitability for endorsement. The Committee was satisfied by the developer's response and recommended the measure for endorsement.

Developer Response

We agree that voluntary data collected by this measure, as it is currently specified, could potentially serve as a useful starting point for hospitals and clinicians and may be advantageous for performance improvement. Data collected at the national level during the initial implementation phase may offer more evidence for actionable refinements than retesting the measure at only a few hospitals.

We agree that it is important to understand performance in rural and non-academic hospitals. We attempted to recruit a broad variety of hospitals and, in accordance with NQF guidelines, include data from at least two different EHR systems.

Overall, performance rates from site were on par with the literature. Field testing also showed that overall concurrent prescribing rate of 18.2% in the inpatient setting and 6.1% in ED settings, which aligned with the literature, that is, studies of multiple claims and prescription databases have shown that among patients who receive opioids in an inpatient or outpatient hospital setting, 5 to 15 percent of patients receive concurrent opioid prescriptions, and 5 to 20 percent receive concurrent opioid and benzodiazepine prescriptions.

Theme 5 – Measurement Period Timeframe

One commenter expressed concern that the measurement period timeframe is not clearly specified, suggesting that it is unclear whether CMS and others would implement the measure using a 12-month, 24-month, or other period. A two-year timeframe was used for the opportunity for improvement information and in testing; however, the specifications and Health Quality Measures Format (HQMF) do not require this two-year period.

Committee Response

Thank you for your comment which the Committee reviewed along with the developer's responses during their deliberations on the post-comment web meeting on April 17. The Committee then re-voted on the criteria where consensus was not reached and on the measure's overall suitability for endorsement. The Committee was satisfied by the developer's response and recommended the measure for endorsement.

Developer Response

We developed the Safe Use of Opioids—Concurrent Prescribing measure for the Hospital Inpatient Quality Reporting (IQR) and Hospital Outpatient Quality Reporting (OQR) programs. CMS will determine the proposed measurement period at a future date if the measure is implemented.

Theme 6 – Need for Voluntary Data Collection Before Implementation in Accountability Programs

While noting that the measure may be useful for quality improvement and information-gathering purposes, some commenters recommended collecting data voluntarily for one to two years before the measure is implemented for accountability purposes (such as payment or public reporting programs).

Committee Response

The Committee reviewed these comments, along with the developer's responses, during their deliberations on the post-comment web meeting on April 17. The Committee then re-voted on the criteria where consensus was not reached and on the measure's overall suitability for endorsement. The Committee was satisfied by the developer's response and recommended the measure for endorsement.

Developer Response

We agree that voluntary data collected by this measure, as it is currently specified, could potentially serve as a useful starting point for hospitals and clinicians and may be advantageous for performance improvement. Data collected at the national level during the initial implementation phase may offer more evidence for actionable refinements than retesting the measure at only a few hospitals.

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 indicated that they did not support the measure. Appendix B details the expression of support.

Appendix A: CSAC Checklist

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

Key Consideration	Yes/No	Notes
Were there any process concerns raised during the CDP project? If so, briefly explain.	No	
Did the Standing Committee receive requests for reconsideration? If so, briefly explain.	No	
Did the Standing Committee overturn any of the Scientific Methods Panel's ratings of Scientific Acceptability? If so, state the measure and why the measure was overturned.	N/A	No measures were reviewed by the Scientific Methods Panel during the Fall Cycle, 2017.
If a recommended measure is a related and/or competing measure, was a rationale provided for the Standing Committee's recommendation? If not, briefly explain.	Yes	Three measures were identified as related to measure 3316e, as they focus on measuring and reducing inappropriate opioid prescriptions. However, the three related measures are specified for the outpatient setting, whereas 3316e focuses on emergency department (ED) visits and inpatient admissions. Committee members noted that it would be desirable for these measures to have some linkage and continuity with each other, but recognized that the health care system may not currently be capable of achieving such linkages.
Were any measurement gap areas addressed? If so, identify the areas.	Yes	Measure 3316e seeks to address inappropriate prescribing of opioids and benzodiazepines.

Key Consideration	Yes/No	Notes
Are there additional concerns that require CSAC discussion? If so, briefly explain.	Yes	During the January 2018 measure evaluation web meeting, the Standing Committee did not reach consensus on the measure 3316e, primarily of out of concern for the measure specifications and potential for unintended consequences. Specifically, there were concerns that providers in the ED and hospital may feel pressured to change existing medication regimens for patients, even if those medications have been prescribed appropriately by primary care physicians. This concern was also reflected in some of the comments. However, during the April 2018 post-comment web meeting, the Committee decided that the developer adequately addressed all of these concerns, as its expert panel had explicitly discussed these issues and determined that the populations of concern to the Committee only represented a small proportion of patients (<3%) for whom the measure would apply. Based upon this reasoning as well as other information, the Committee voted to pass the measure with >60% votes on all the measure elements that had not achieved consensus (reliability, validity, usability & use, and overall suitability for endorsement).

Appendix B: NQF Member Expression of Support Results

Measure 3316e did not receive support from NQF members. Results for measure 3316e are provided below.

3316e Safe Use of Opioids – Concurrent Prescribing (Centers for Medicare & Medicaid Services/Mathematica Policy Research)

Member Council	Support	Do Not Support	Total
Health Professional	0	2	2
Supplier/Industry	0	1	1

Appendix C: Details of Measure Evaluation

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

Measure Recommended for Endorsement

3316e Safe Use of Opioids – Concurrent Prescribing

Submission

Description: 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)

Numerator Statement: Patients prescribed two or more opioids or an opioid and benzodiazepine at discharge.

Denominator Statement: Patients age 18 years and older prescribed an opioid or a benzodiazepine at discharge from a hospital-based encounter (inpatient stay less than or equal to 120 days or emergency department encounters, including observation stays) during the measurement period.

Exclusions: Denominator exclusions: The following encounters are excluded from the denominator:

- Encounters for patients with an active diagnosis of cancer during the encounter
- Encounters for patients who are ordered for palliative care during the encounter
- Inpatient encounters with length of stay greater than 120 days

Denominator exceptions: None.

Adjustment/Stratification: N/A

Level of Analysis: Facility

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

Type of Measure: Process

Data Source: Electronic Health Records

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING [01/23/2018]

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

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

1a. Evidence: **H-4**; **M-16**; **L-0**; **I-1** 1b. Performance Gap: **H-2**; **M-15**; **L-0**; **I-3**

Rationale:

- The developer provided a clinical practice guideline from the 2016 CDC Guidelines for Prescribing Opioids for Chronic Pain to support the avoidance of prescribing opioid pain medication and benzodiazepines concurrently whenever possible. The developer also summarized a systematic review of the evidence suggesting an increased risk of overdose events associated with opioid use and co-prescription of opioids with benzodiazepines.

- Committee members agreed that there is strong evidence linking the use of opioids and benzodiazepines with adverse drug events. However, members noted that the evidence does not appear to directly address concurrent prescription of opioids and benzodiazepines.
- Committee members were concerned about whether there were sufficient data to demonstrate that this is a sensitive measure of "inappropriate" prescriptions. Members pointed out that there are many cases where prescribing two opioids together or an opioid and a benzodiazepine together may be appropriate.
- Overall, the Committee agreed that the measure meets the evidence subcriterion.
- The developer presented performance data for eight testing hospitals from three large tertiary health systems, in three states. Performance rates observed during testing aligned with those in the literature; between 5 to 15 percent of patients receiving concurrent opioid prescriptions, and 5 to 20 percent receiving concurrent opioid-benzodiazepine prescription in an inpatient or outpatient hospital setting. The developer reports that there were higher rates of concurrent prescribing in the inpatient setting compared to the emergency department (ED) setting across test sites.
- The Committee did not express any major concerns with the performance gap data.

---

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

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

2a. Reliability: **H-1**; **M-14**; **L-1**; **I-1** 2b. Validity: **M-11**; **L-5**; **I-1**

<u>Rationale</u>:

- Data element testing was used to support the reliability and validity of this measure. The assessment included EHR-extracted data from each of three test sites (eight hospitals in total) for the time frame October 1, 2013, to September 30, 2015.
- A split-half sample approach was used to estimate the reliability of the performance rate. The measure's reliability coefficient across eight hospitals was 0.99. A reliability score of 0.00 implies that all the variability in a measure is attributable to measurement error. A reliability of 1.00 implies that all the variability is attributable to real differences in performance. The higher the reliability score, the greater the confidence of distinguishing the performance of one provider from another. This is an appropriate test for measure score reliability.
- In addition to data element testing, face validity of the measure score was systematically assessed to support the validity of this measure. Twelve expert work group members and three testing site affiliated staff (N = 15 respondents) evaluated the face validity of the measure and measure score through a survey. Seventy-three percent of respondents strongly agreed or agreed that the measure will likely reduce the incidence of concurrent prescribing of opioid-opioid and opioid-benzodiazepines at discharge in the inpatient and emergency department (ED) settings.
- Members again noted that there are many cases where prescribing two opioids together or an opioid and a benzodiazepine together may be appropriate, but denominator exclusions did not adequately address such cases. For example, there are several patient populations with chronic pain—such as patients with sickle cell disease—

for which a prescription for both a short-acting and long-acting opioid may be appropriate care.

- In addition, because this is a measure meant to assess inpatient and emergency department (ED) settings, some Committee members were concerned that the measure specifications were too broad and did not include any assessment of whether there was a pre-existing prescription (i.e., present on admission exclusions) for the medication combinations of opioid-opioid or opioid-benzodiazepines.
- Committee members also noted that the measure could potentially cause unintentional consequences, particularly if facilities are compelled to change existing outpatient regimens to meet the measure rather than customizing individualized medication regimens that may be appropriate for certain patients.
- Due to concerns about the specifications and potential threats to validity noted above, the Committee initially did not reach consensus on the reliability and validity subcriteria on this measure during the January 23, 2018 measure evaluation web meeting. Specifically, the Committee was primarily concerned about the measure specifications and potential for unintended consequences. There were concerns that providers in the ED and hospital may decide to change existing medication regimens for patients who are on combinations of medications that meet measure criteria (e.g. a sickle cell patient who is on two opioids), and that these patients would not be excluded from the measure. This concern was also echoed by some of the public commenters. The Committee, however, re-voted on the measure during the post-comment web meeting on April 17, 2018 and the measure passed the reliability and validity criteria. The Committee believed that the developer was able to adequately address all of the earlier concerns with input from their expert panel that had explicitly discussed these issues. The Panel noted that the populations of concern to the Committee only represented a small proportion of patients (<3%) for whom the measure would apply.

---

3. Feasibility: H-6; M-12; L-2; I-1

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

- The measure is constructed using electronic health records. All data elements are available in defined fields in electronic health records (EHRs). Upon a vote, the Committee agreed the measure met this criterion.

---

4. Use and Usability

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

4a. Use**: Pass-18; No Pass-2** 4b. Usability: **H-1; M-10; L-6; I-1**

Rationale:

- Although not currently used in an accountability program, the developer has submitted the measure through the Measures Under Consideration process for the CMS Hospital Inpatient and Outpatient Quality Reporting Programs.

- The developer collected feedback from clinical quality/data analytics staff, as well as other providers and some physicians at the test site locations. Providers at the test sites were unsurprised by their measure performance scores, which aligned with their expectations of the rate of concurrent prescribing at their hospitals during the measurement period. Some Committee members questioned whether or not providers see discontinuing the practice of concurrent prescribing as an important issue to measure.
- Overall, the Committee agreed that the measure meets the use subcriterion.
- Committee members were concerned about potential unintended consequences, such as a patient who legitimately benefited from dual opioid (e.g. long and short acting for intractable or inoperable pain) or opioid and benzodiazepine (e.g. migraine) might be deprived of helpful treatment. There were also concerns with the harm associated with withdrawal of medications.
- A Committee member stated that the measure directly addresses an area of high-risk prescribing. The emphasis in this type of measure is in understanding that some patients may justifiably need the therapy; therefore, from a system level analysis, the goal is not zero but a defendable low rate.
- Although not a must-pass subcriterion, the Committee did not initially reach consensus on usability, due to concerns with potential unintended consequences; however, the Committee re-voted on the measure during the post-comment web meeting on April 17, 2018 and the measure passed the usability criteria following input from the developer .

---

5. Related and Competing Measures

- This measure is related to #2940: Use of Opioids at High Dosage in Persons Without Cancer, #2950: Use of Opioids from Multiple Providers in Persons Without Cancer, and #2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer.
- Three measures were identified as related to measure 3316e, as they focus on measuring and reducing inappropriate opioid prescriptions; however, the three related measures are specified outpatient setting, whereas 3316e focuses on emergency department (ED) visits and inpatient admissions. Committee members noted that it would be desirable for these measures to have some linkage and continuity with each other, but recognized that the health care system may not currently be capable of achieving such linkages.

---

6. Standing Committee Recommendation for Endorsement: **Y-15**; **N-3** **Recommended for Endorsement**

Rationale

The Standing Committee initially did not reach consensus on the reliability, validity, and usability subcriteria and overall recommendation of endorsement. The Committee indicated its strong support of measures that addresses the opioid crisis. However, Committee members had concerns about how this particular measure was specified. The Committee was particularly concerned that the measure was too broad and resulted in unintended consequences. However, the Committee re-voted on the measure during the post-comment web meeting on April 17, 2018 and the measure is now recommended for endorsement. Initial concerns about the

specifications and unintended consequences were addressed by the developer. Ultimately, the Committee recommended the measure for endorsement.

---

7. Public and Member Comment

- Six commenters recommended potentially necessary exclusions, such as patients with sickle cell disease, patients undergoing chronic substance abuse treatment, patients with certain hematological and neurological conditions, and patients presenting to the ED with existing concurrent prescriptions.
    - Developer Response: We recognize that there may be some clinically necessary situations for concurrent prescriptions of opioids and benzodiazepines and we agree with the need to properly treat these patients. As recommended by our expert panels, we looked into single-condition exclusions, specifically sickle cell disease and substance use therapy, and found that a very small portion of cases eligible for the numerator (0 to 3.4 percent) fell into these category. Furthermore, after reviewing the testing results, clinicians from our expert workgroup recommended continuing to include patients for whom concurrent prescribing is medically necessary because experts stated these populations (1) have the highest risk of receiving concurrent prescriptions; and (2) can experience a lag in adverse events. In addition, there are currently no guidelines supporting exclusion of patients who may require concurrent prescriptions from the measure, other than cancer and palliative care. However, we will consider these comments and evaluate opportunities to refine the measure.
- One commenter recommended determining dosing thresholds to identify inappropriate versus appropriate concurrent prescribing.
    - Developer Response: The existing professional organizations, states, and federal agency developed guidelines for opioid prescribing share some common elements, including dosing thresholds, cautious titration, and risk mitigation strategies such as using risk assessment tools, treatment contracts, and urine drug testing. However, there is considerable variability in the specific recommendations (e.g., range of dosing thresholds of 90 MME/day to 200 MME/day), audience (e.g., primary care clinicians versus specialists), use of evidence (e.g., systematic review, grading of evidence and recommendations, and role of expert opinion), and rigor of methods for addressing conflict of interest. There's currently not an evidence base strong enough to specify a certain threshold deemed safe for the inpatient setting so we did not include dosing thresholds in the specification.
- Six commenters expressed concerns about potential unintended consequences of the measure, such as emergency physicians making changes to patients' medication regimens instead of outpatient physicians or primary care providers, potential incentives to reduce emphasis on pain control, and/or promoting rapid dose tapers that could be harmful to patients.
    - Developer Response: We recognize that there may be some clinically necessary situations for concurrent prescriptions of opioids and benzodiazepines and we agree with the need to properly treat these patients. As recommended by our expert panels, we looked into single-condition exclusions, specifically sickle cell

disease and substance use therapy and found that a very small portion of cases eligible for the numerator (0 to 3.4 percent) fell into these category. Furthermore, after reviewing the testing results, clinicians from our expert workgroup recommended continuing to include patients for whom concurrent prescribing is medically necessary because experts stated these populations (1) have the highest risk of receiving concurrent prescriptions; and (2) can experience a lag in adverse events. In addition, there are currently no guidelines supporting exclusion of patients who may require concurrent prescriptions from the measure, other than cancer and palliative care. However, we will consider these comments and evaluate opportunities to refine the measure.

---

7. Public and Member Comment (continued)

- Two commenters expressed concern about the limited testing conducted for this measure, with one commenter suggesting that the testing should be expanded beyond two EHR systems, and another suggesting that rural and nonacademic hospitals should have been included.
    - Developer Response: We agree that voluntary data collected by this measure, as it is currently specified, could potentially serve as a useful starting point for hospitals and clinicians and may be advantageous for performance improvement. Data collected at the national level during the initial implementation phase may offer more evidence for actionable refinements than retesting the measure at only a few hospitals.

      We agree that it is important to understand performance in rural and non-academic hospitals. We attempted to recruit a broad variety of hospitals and, in accordance with NQF guidelines, include data from at least two different EHR systems.

      Overall, performance rates from site were on par with the literature. Field testing also showed that overall concurrent prescribing rate of 18.2% in the inpatient setting and 6.1% in ED settings, which aligned with the literature, that is, studies of multiple claims and prescription databases have shown that among patients who receive opioids in an inpatient or outpatient hospital setting, 5 to 15 percent of patients receive concurrent opioid prescriptions, and 5 to 20 percent receive concurrent opioid and benzodiazepine prescriptions.
- One commenter expressed concern that the measurement period timeframe is not clearly specified, suggesting that it is unclear whether CMS and others would implement the measure using a 12-month, 24-month, or other period. A two-year timeframe was used for the opportunity for improvement information and in testing; however, the specifications and Health Quality Measures Format (HQMF) do not require this two-year period.
    - Developer Response: We developed the Safe Use of Opioids—Concurrent Prescribing measure for the Hospital Inpatient Quality Reporting (IQR) and Hospital Outpatient Quality Reporting (OQR) programs. CMS will determine the proposed measurement period at a future date if the measure is implemented.

- While noting that the measure may be useful for quality improvement and information-gathering purposes, some commenters recommended collecting data voluntarily for one to two years before the measure is implemented for accountability purposes (such as payment or public reporting programs).
    - Developer Response: We agree that voluntary data collected by this measure, as it is currently specified, could potentially serve as a useful starting point for hospitals and clinicians and may be advantageous for performance improvement. Data collected at the national level during the initial implementation phase may offer more evidence for actionable refinements than retesting the measure at only a few hospitals.

- The Committee reviewed all the received public and member comments, as well as the developer's responses and responded accordingly:
    - Committee Response: The Committee reviewed these comments, along with the developer's responses, during their deliberations on the post-comment web meeting on April 17. The Committee then re-voted on the criteria where consensus was not reached and on the measure's overall suitability for endorsement. The Committee was satisfied by the developer's response and recommended the measure for endorsement.

---

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

9. Appeals