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Memo

November 30, 2021

To: Consensus Standards Approval Committee (CSAC)

From: Patient Safety Project Team

Re: Patient Safety Spring 2021 Cycle

CSAC Action Required

The CSAC will review recommendations from the Patient Safety project at its November 30 and December 1, 2021 meeting and vote on whether to uphold the recommendations from the Committee.

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

> **Patient Safety Spring 2021 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.

Background

A goal of patient safety measurement efforts over the last two decades has been to focus healthcare organizations on quality improvement to enhance care delivery and outcomes for patients. Patient safety-related events occur across all settings, including hospitals and outpatient clinics as well as nursing homes, rehabilitation facilities, and others. These events include a variety of preventable outcomes, including healthcare-associated infections, falls, pressure ulcers, etc.

The Patient Safety Standing Committee oversees the NQF Patient Safety measure portfolio. On June 24 and 25, 2021, the 24-member Standing Committee evaluated two newly submitted measures and four measures undergoing maintenance review.

The Standing Committee recommended the following measures for endorsement:

- **#0500** Severe Sepsis and Septic Shock: Management Bundle (Henry Ford Hospital) (Maintenance)
- **#0674** Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay) (Centers for Medicare & Medicaid Services) (Maintenance)
- **#0679** Percent of High-Risk Residents With Pressure Ulcers (Long Stay) (Centers for Medicare & Medicaid Services) (New)
- **#3389** Concurrent Use of Opioids and Benzodiazepines (COB) (Pharmacy Quality Alliance) (Maintenance)
- **#3501e** Hospital Harm – Opioid-Related Adverse Events (Centers for Medicare & Medicaid Services/IMPAQ International, LLC) (Maintenance)

- **#3621** Composite Weighted Average for Computerized Tomography (CT) Exam Types: Overall Percent of CT exams for Which Dose Length Product Is at or Below the Size-Specific Diagnostic Reference Level (for CT Abdomen-Pelvis With Contrast/Single Phase Scan, CT Chest Without Contrast/Single (American College of Radiology [ACR]) (New)

Draft Report

The Patient Safety Spring 2021 draft report presents the results of the evaluation of six measures considered under the Consensus Development Process (CDP). All measures reviewed are recommended for endorsement.

The measures were evaluated against the 2019 version of the measure evaluation criteria.

Measures under Review	Maintenance	New	Total
Measures under review	4	2	6
Measures recommended for endorsement	2	2	6
Measures not recommended for endorsement or trial use	0	0	0
Reasons for not recommending	Importance - 0 Scientific Acceptability - 0 Use - 0 Overall - 0 Competing Measure - 0	Importance - 0 Scientific Acceptability - 0 Use - 0 Overall - 0 Competing Measure - 0	0

CSAC Action Required

Pursuant to the CDP, the CSAC is asked to consider endorsement of six candidate consensus measures.

Measures Recommended for Endorsement

- **#0500** Severe Sepsis and Septic Shock: Management Bundle (Henry Ford Hospital) [Maintenance]

  Overall Suitability for Endorsement: Y-14; N-3 (denominator = 17)

- **#0674** Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay) (Centers for Medicare & Medicaid Services) [Maintenance]

  Overall Suitability for Endorsement: Y-19; N-0 (denominator = 19)

- **#0679** Percent of High-Risk Residents With Pressure Ulcers (Long Stay) (Centers for Medicare & Medicaid Services) [New]

  Overall Suitability for Endorsement: Y-17; N-1 (denominator = 18)

- **#3389** Concurrent Use of Opioids and Benzodiazepines (COB) (Pharmacy Quality Alliance) [Maintenance]

Overall Suitability for Endorsement: Y-17; N-1 (denominator = 18)

- **#3501e** Hospital Harm – Opioid-Related Adverse Events (Centers for Medicare & Medicaid Services/IMPAQ International, LLC) [Maintenance]

  Overall Suitability for Endorsement: Yes-15; No-3 (denominator = 18)

- **#3621** Composite Weighted Average for Computerized Tomography (CT) Exam Types: Overall Percent of CT exams for Which Dose Length Product Is at or Below the Size-Specific Diagnostic Reference Level (for CT Abdomen-Pelvis With Contrast/Single Phase Scan, CT Chest Without Contrast/Single (American College of Radiology [ACR]) [New]

  Overall Suitability for Endorsement: Y-16; N-2 (denominator = 18)

Comments and Their Disposition

NQF received 15 comments from six organizations (including six member organizations) and individuals pertaining to the draft report and to the measures under review.

A comment narrative 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 Patient Safety project webpage.

Comment Themes and Committee Responses

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

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

Measure-Specific Comments

#0500 Severe Sepsis and Septic Shock: Management Bundle

In a joint comment, the Infectious Diseases Society of America, the American College of Emergency Physicians, American Hospital Association, Pediatric Infectious Disease Society, Society for Healthcare Epidemiology of America, Society of Hospital Medicine, and Society of Infectious Disease Pharmacists, suggest changing the measure to minimize antibiotic overuse and adverse effects by removing sepsis without shock from the measure, removing serial lactate measurements from the measure, and including a clear and reproduceable time-zero definition to minimize variability in abstraction. The commenter also suggested using electronic health records for data collection rather than chart abstraction to facilitate the reporting process and focus it on clinical outcomes.

The comment raised concerns that recent published literature indicates that the SEP-1 activities (broad spectrum antibiotics and lactate checks) have not improved outcomes for patients. The concern was that SEP-1's requirement to immediately administer antibiotic therapy to all patients with possible sepsis leads to increased use of unneeded antibiotics and antibiotic resistance. In relation to sepsis versus septic shock, the commenter states that while timely administration of antibiotics can reduce mortality from septic shock, mortality is not similarly reduced in the case of sepsis. The commenter further notes that the measure requires complex documentation of suspected infection, SIRS criteria, and one of more than eight potential organ dysfunction criteria within a limited time window. The

commenter states that due to the complexity of these requirements, there may be inconsistencies in abstraction and the measure may be applied to a wider patient population than necessary.

This comment additionally references and re-emphasizes comments submitted by the American Medical Association prior to Standing Committee evaluation over the measure's continued lack of alignment with the existing evidence base.

Measure Steward/Developer Response:

We genuinely appreciate the commentary submitted by the Infectious Diseases Society of America, the American College of Emergency Physicians, American Hospital Association, Pediatric Infectious Disease Society, Society for Healthcare Epidemiology of America, Society of Hospital Medicine, and Society of Infectious Disease Pharmacists. These remarks have been published elsewhere in a position paper by IDSA and their partner societies. This position paper was fully responded to by the CMS measure stewards. Please see: Townsend SR, Rivers EP, Duseja R. Centers for Medicare and Medicaid Services Measure Stewards' Assessment of the Infectious Diseases Society of America's Position Paper on SEP-1. *Clin Infect Dis.* 2021 Feb 16;72(4):553-555. doi: 10.1093/cid/ciaa458. PMID: 32374387.

We will summarize some of the most important fallacies and evidentiary deficiencies in the remarks above (and in the position paper) here for the sake of accessibility to the public.

In brief, the remarks above and the position paper assume that antibiotic resistance and other harms have been increasing after SEP-1 was launched. There is also an assumption that SEP-1 has directly caused increased antibiotic usage. These assumptions amount to rhetorical flourish because there is no credible evidence supporting the first assumption, and very low-quality evidence that the latter assumption is factual. Readers should not dismiss the significance of this absence of evidence: ungrounded arguments cannot drive policy-making considerations.

As to the first issue, IDSA and colleagues assume that resistant infections of all types have increased due to SEP-1's promotion of indiscriminate antibiotic usage across the United States since SEP-1 went into effect. In fact, as documented in two papers published by investigators from the Centers for Disease Control in the New England Journal of Medicine last year, most resistant infections of concern and rates of *Clostridium difficile* infections have decreased, including during the years since SEP-1 went into effect. Please see: Guh AY, Mu Y, Winston LG, et al. Trends in U.S. Burden of *Clostridioides difficile* Infection and Outcomes. *N Engl J Med*. 2020;382(14):1320-1330. Jernigan JA, Hatfield KM, Wolford H, et al. Multidrug-Resistant Bacterial Infections in U.S. Hospitalized Patients, 2012-2017. *N Engl J Med*. 2020;382(14):1309-1319.

As to the second issue, at the time of the publication of IDSA and colleagues' position paper, there were no published studies directly linking SEP-1 to increased antibiotic usage in the literature. The position paper referenced several low-quality studies with serious methodological flaws that were not studies of SEP-1 in an effort to indirectly establish this point. The table in the article by Townsend, Duseja and Rivers in *Clinical Infectious Diseases* cited above highlights the methodological flaws, confounding issues, and indirect nature of these studies.

Since that time, a single paper has been published in the literature that indicates that after SEP-1 was launched, *one hospital* experienced an increase in overly broad antibiotic therapy for

urinary tract infections (no other infections had increased usage observed). That paper was a retrospective review, did not control for changing resistance patterns, did not account for patient characteristics or comorbidities beyond that the patients had sepsis and were similar in age and gender, and established no harm from the observed changes, among other serious deficiencies: Miller J, Hall B, Wilson K, Cobian J. Impact of SEP-1 on broad-spectrum combination antibiotic therapy in the emergency department. *Am J Emerg Med*. 2020 Dec;38(12):2570-2573. doi: 10.1016/j.ajem.2019.12.045. Epub 2020 Jan 7. PMID: 31932126.

IDSA and its society partners express concerns about the reliability of time zero in SEP-1, but they do not fairly represent the details of the only two studies in the literature to consider this question. The first study by Rhee et al. provided just one hour of training for non-professional abstractors, including bedside clinicians, and compared their results to professionally trained abstractors before assessing inter-rater reliability. Such an approach sets up an unfair comparison wherein poor agreement should be expected rather than a surprise. It should be noted that Medicare, through its Clinical Data Abstraction Center, audits hospital abstractors for clinical competency in abstraction of its measures including SEP-1 and does not permit hospitals that do not attain passing scores to submit data to Medicare. A second study by Bauer et al., which IDSA and colleagues cite here, found fair agreement among trained abstractors in the first few months after SEP-1 was first launched but attained *perfect reliability and concordance between abstractors* after improvement efforts. Bauer et al. conclude that, "[a]bstraction by a dedicated team for SEP-1 can reduce variability and improve efficiency."

Rhee C, Brown SR, Jones TM, et al. Variability in determining sepsis time zero and bundle compliance rates for the Centers for Medicare and Medicaid services SEP-1 measure. *Infect Control Hosp Epidemiol*. 2018;39(8):994-996.

Department of Health and Human Services [Internet]. Baltimore: CMS.gov, QualityNet [cited 2019 Nov 8]. Chart-Abstracted Data Validation [about 2 screens]. Available from: https://qualitynet.org/inpatient/data-management/chart-abstracted-data-validation.

Bauer SR, Gonet JA, Rosario RF, Griffiths LA, Kingery T, Reddy AJ. Inter-rater Agreement for Abstraction of the Early Management Bundle, Severe Sepsis/Septic Shock (SEP-1) Quality Measure in a Multi-Hospital Health System. *Jt Comm J Qual Patient Saf*. 2019;45(2):108-111.

IDSA and colleagues point to a recent time-series analysis by Barbash et al. that found changes in processes of care but no changes in mortality among sepsis patients after SEP-1's inception. Barbash et al. studied patients that do not meet published definitions of sepsis, specifically studying patients with an order for a blood, urine, respiratory or other culture who exhibited a change in SOFA score of ≥ 2 in the first 6 hours of care in the emergency department. This definition does not conform to sepsis-2, sepsis-3, or the CDC's Adult Sepsis Events definitions and appears to be novel.

Average in-hospital mortality was low in Barbash et al. at 4.5% in Q3 2015, before SEP-1, and 4% in Q4 2017, after SEP-1's inception, despite median ages compatible with a Medicare population (72 and 71 years, respectively).This low mortality population stands in contrast to the CMS measure stewards and colleagues' study of actual SEP-1 cases cited immediately above with average 30-day mortality at 26.7%. Studying all Medicare beneficiaries from 2012 to 2018, Buchman et al. found one-week mortality ranged from 16.4%–20.5% in severe sepsis and 41.1%–42.4% in septic shock (Buchman TG, Simpson SQ, Sciarretta KL, et al. Sepsis Among

Medicare Beneficiaries: 1. The Burdens of Sepsis, 2012-2018. *Crit Care Med*. 2020;48(3):276-288).

The low mortality rates observed in Barbash et al. limit the generalizability of their findings and raise concerns that these patients may not have had sepsis by conventional definitions. In support of this belief, the mortality rate in Barbash et al. is similar to that of undifferentiated hospitalized patients (Shahian DM, Wolf RE, Iezzoni LI, Kirle L, Normand SL. Variability in the measurement of hospital-wide mortality rates [published correction appears in *N Engl J Med*. 2011 Apr 7;364(14):1382]. *N Engl J Med*. 2010;363(26):2530-2539).

The issues above as well as other concerns raised in IDSA and colleagues' remarks are substantively answered in the CMS measure stewards and colleagues' analysis of 333,770 verified SEP-1 patients from 3,241 U.S. hospitals. This study, carefully adjusted for possible confounding, found that compliance with SEP-1 is associated with substantial benefits including a reduction in 30-day mortality: 21.81% compliant care versus 27.48% non-compliant care, yielding an absolute risk reduction of 5.67% (95% confidence interval [CI]: 5.33–6.00; $P <$ 0.001). Townsend SR, Phillips GS, Duseja R, Tefera L, Cruikshank D, Dickerson R, Nguyen HB, Schorr CA, Levy MM, Dellinger RP, Conway WA, Browner WS, Rivers EP. Effects of Compliance with the Early Management Bundle (SEP-1) on Mortality Changes among Medicare Beneficiaries with Sepsis: A Propensity Score Matched Cohort Study. *Chest*. 2021 Aug 5:S0012-3692(21)03623-0. doi: 10.1016/j.chest.2021.07.2167. Epub ahead of print. PMID: 34364867.

In conclusion, the thrust of IDSA and colleagues' concerns results in their call for not requiring early antibiotic therapy for patients with severe sepsis and reserving these antibiotics for septic shock patients. We note that the study by Townsend, Phillips, Duseja et al. includes a super-majority of severe sepsis patients who appear to derive a notable benefit from early antibiotic therapy. We therefore believe IDSA and colleagues' request to not endorse SEP-1 is poorly grounded and insufficiently evidence-based.

Committee Response:

Thank you for your comment. The Standing Committee reviewed and considered this information during the post-comment meeting in conjunction with the developer's response. The Committee agrees that some of the concerns raised in this comment may require further examination and discussion in the future and may require modifications to the measure, but the Committee maintains that this measure is suitable for endorsement at the current time.

The Society for Healthcare Epidemiology of America (SHEA) SHEA expressed support for measurement and interventions that reduce harm to patients but does not believe NQF 0500 meets that standard. The commenter noted that sepsis and septic shock are not clinical diagnoses and therefore a patient may exhibit symptoms that are not of septic origin. Concerns were raised that the target population for this measure requires additional specificity and suggests that sepsis without shock should be removed from the measure. The commenter also discussed potential unintended consequences of this measure, including increased inappropriate antibiotic use which can lead to adverse effects such as renal insufficiency, C. difficile infection, MDRO colonization and infection. Another unintended consequence outlined in this measure was the amount time-consuming chart abstraction and a high level of effort expended by hospital employees. Commenters note that in many hospitals, there are full time employees whose sole responsibility is collection of data for the SEP-1 measure rather than implementing evidence-based initiatives known to improve sepsis care. The commenter suggests use of a more global measure such as hospital-onset bacteremia (HOB), rate of admissions to the ICU >48

hours after hospitalization, or ACEP-48 metric as alternatives to this measure because they address a more global audience.

Measure Steward/Developer Response:

We appreciate the opportunity to address the concerns of The Society for Healthcare Epidemiology of America (SHEA) regarding SEP-1. We note that the balance of the remarks by SHEA are based upon the analysis and conclusions drawn in the Infectious Diseases Society of America (IDSA) position paper on SEP-1. We would politely request that SHEA and readers of these remarks kindly review our response to IDSA and colleagues elsewhere in these commentaries.

Please also see our formal published response to IDSA and their society partners in Clinical Infectious Diseases, and the recent publication by the CMS measure stewards regarding SEP-1 and mortality changes among Medicare beneficiaries, if they have not already been reviewed: Townsend SR, Rivers EP, Duseja R. Centers for Medicare and Medicaid Services Measure Stewards' Assessment of the Infectious Diseases Society of America's Position Paper on SEP-1. Clin Infect Dis. 2021 Feb 16;72(4):553-555. doi: 10.1093/cid/ciaa458. PMID: 32374387. Townsend SR, Phillips GS, Duseja R, Tefera L, Cruikshank D, Dickerson R, Nguyen HB, Schorr CA, Levy MM, Dellinger RP, Conway WA, Browner WS, Rivers EP. Effects of Compliance with the Early Management Bundle (SEP-1) on Mortality Changes among Medicare Beneficiaries with Sepsis: A Propensity Score Matched Cohort Study. Chest. 2021 Aug 5:S0012-3692(21)03623-0. doi: 10.1016/j.chest.2021.07.2167. Epub ahead of print. PMID: 34364867.

A position paper's conclusions are only valid if it firmly establishes the assumptions the paper's conclusions and suggestions rest upon. Here, the position paper falls short in establishing:

- that SEP-1 has increased antibiotic usage in the United States (the Centers for Disease Control reports that including years after SEP-1's inception, inpatient antibiotic usage has remained stable, see Baggs J, Kazakova S, Hatfield KM et al. 2891.Trends in Inpatient Antibiotic Use in US Hospitals, 2012–2017, Open Forum Infectious Diseases, Volume 6, Issue Supplement_2, October 2019, Page S79.);
- that the hypothesized increase in antibiotic usage due to SEP-1 has resulted in harm in the form of increasing antibiotic resistance and promoted increases in C. difficile infections (see well-done studies by investigators at the Centers for Disease Control finding the opposite during the years SEP-1 has been in effect including Guh AY, Mu Y, Winston LG, et al. Trends in U.S. Burden of Clostridioides difficile Infection and Outcomes. N Engl J Med. 2020;382(14):1320-1330, and Jernigan JA, Hatfield KM, Wolford H, et al. Multidrug-Resistant Bacterial Infections in U.S. Hospitalized Patients, 2012-2017. N Engl J Med. 2020;382(14):1309-1319.)

In short, it would be a rush to judgment to accept the IDSA position paper as having established the necessary assumptions with proper evidence to advance the claims they wish to make without consideration of these other publications which substantially refute these assumptions.

As regards other concerns raised by SHEA, we welcome the opportunity to describe our understanding of these matters:

1. **Heterogeneity of the target population**
   - SHEA notes that sepsis and septic shock are a constellation of symptoms that may not have the same underlying diagnosis and that coded patients with sepsis may not have infections.
   - While we appreciate the sense and meaning of the statement that sepsis is a constellation of symptoms, most conventional definitions of sepsis (sepsis-3) or severe sepsis (sepsis-2, the entity treated by SEP-1 along with septic shock) would run counter to this remark by going beyond symptoms

and requiring documentation of a suspected infection and actual organ dysfunction.

- SEP-1 carefully specifies criteria for making a diagnosis of sepsis and does not rely on coding to verify those criteria. While the population may be drawn from coded cases, clinicians at hospitals review each case for the presence of 1) physician documented suspicion of infection; 2) the presence of 2 or more systemic inflammatory response criteria; 3) specific quantifiable organ dysfunction. If any of these criteria are not met, the case is not included in the measure sample. Therefore, the comment that "forty percent of patients coded as sepsis have a non-infectious cause for their symptoms" would not apply to the SEP-1 population because SEP-1 does not rely on coding to establish the diagnosis of sepsis and because clinician documented suspicion of infection is required.
- More generally, the concept that sepsis is a constellation of symptoms has not stopped substantial literature from developing about this entity or that it must be defined and treated somehow, since 270,000 patients die from this constellation of symptoms each year.

2. **Unintended consequences – antibiotics and resources**
   - SHEA is concerned about the unintended consequences of antibiotic administration, which we have addressed carefully in these commentaries elsewhere, and about diverting critical patient safety resources into data collection for SEP-1.
   - As regards the burdens of chart abstraction, we note SHEA is relying upon the characterization by IDSA regarding chart abstraction being overly burdensome. This characterization is unfortunately shorn from context.
   - Studying all Medicare beneficiaries from 2012 to 2018, Buchman et al. found one-week mortality ranged from 16.4%–20.5% in severe sepsis and 41.1%–42.4% in septic shock (Buchman TG, Simpson SQ, Sciarretta KL, et al. Sepsis Among Medicare Beneficiaries: 1. The Burdens of Sepsis, 2012-2018. Crit Care Med. 2020;48(3):276-288). This study found Medicare's costs for sepsis admissions and skilled nursing care exceeded $41.5 billion annually. This highly lethal condition represents the single most costly healthcare condition in the United States. Given this estimate and the severity of the disease, the burden of SEP-1 abstraction is contextually appropriate.
   - To quantify that burden realistically, SEP-1 permits hospitals to submit 20% of their cases each quarter (Department of Health and Human Services [Internet]. Baltimore: CMS.gov, QualityNet [cited 2020 May 28]. Hospital Inpatient Specifications Manuals; Version 5.8 - Specifications Manual for discharges 07/01/20 - 12/31/20 (Updated 04/2020) [about 2 screens]. Available from: https://www.qualitynet.org/inpatient/specifications-manuals).
   - Abstractors spend 30–120 minutes abstracting each chart citing the same evidence IDSA references (which other studies suggest decreases with experience). In the unusual circumstance that a hospital accrued 300 sepsis cases per quarter, abstraction would require less than one-quarter full-time employee (assuming 300 cases in 3 months, 20% sample, 120 minutes of abstraction time per case, 40-hour work week).
   - We would respectfully ask the question: is it a tenable position that hospitals should not dedicate a quarter of a full-time employee to measure

sepsis improvement activities, the costliest healthcare condition in the United States, with a mortality rate that is equally as concerning?

3. **Alternative measures**
   - SHEA has suggested several alternative measures. We appreciate any advancements in the field and recognize that other measures may have value. We also recognize that the devil is in the detail of any measure once scrutiny is applied and there are published critiques of each of the measures SHEA has noted in the literature.
   - Under NQF rules, any of the alternative measures suggested by SHEA could be brought before NQF for evaluation if the developers so choose. We encourage innovation in the field and welcome the opportunity to evaluate new approaches.

The Coalition for Improving Sepsis and Antibiotic Practice (CISAP) notes that an increasing body of peer-reviewed publications suggest that SEP-1 may not be the optimal way to do this. Appropriate biomarker-based diagnostic tests should be used to inform the management of sepsis and should focus on measures that have been proven to impact outcomes in real-world healthcare settings, not only in the initial randomized clinical trials with elaborate educational procedures and other controls.

Measure Steward/Developer Response:

We appreciate CISAP's reference to the Infectious Disease Society of America (IDSA) Position Paper on SEP-1 and encourage readers to review our remarks on this document elsewhere in our replies to public commentary.

In summary, we support CISAP's call for better diagnostics for sepsis and bacterial infection and, as this early science matures, we look forward to the opportunity to incorporate such approaches to sepsis quality of care measures.

Committee Response:

Thank you for your comment. The Standing Committee reviewed and considered this information during the post-comment meeting and agrees that some of the concerns raised in this comment may require further examination in the future, but the Committee maintains that this measure is suitable for endorsement at the current time.

Sepsis Alliance was joined by eight other organizations in expressing strong support of this measure due to timely diagnosis and early treatment of sepsis. The commenter thanked the Standing Committee for re-endorsing the measure and cited studies that show an association between performance metrics and patient outcomes such as decreased risk-adjusted sepsis mortality and increased hospital-level compliance with mandated public reporting. The commenter also notes there are sepsis screening programs at every hospital in the U.S. and stated that they respectfully disagree with those who continue to urge removal of this measure, noting that sepsis care is nuanced and no single test is yet sufficient, which is why the SEP-1 measure is so crucial to focus on improving the quality of care for the sepsis patient. The commenter support SEP-1's continued improvement to update the measure in response to updated evidence and provider feedback while in use.

Committee Response:

Thank you for your comment. The Standing Committee reviewed and considered this information during the post-comment meeting in conjunction with the developer's response. The Committee agrees that some of the concerns raised in this comment may require further examination in the future but the Committee maintains that this measure is suitable for endorsement at the current time.

The measure developer provided a recently published paper on national performance data on SEP-1, which not fully available at the time of consideration by the Patient Safety Standing Committee. Similar data was presented in the re-endorsement package. The developer states that the peer reviewed results confirm reductions in mortality with compliance with SEP-1 and decreased length of stay carefully adjusted for relevant confounding factors. They cite the following study: Townsend SR, Phillips GS, Duseja R, Tefera L, Cruikshank D, Dickerson R, Nguyen HB, Schorr CA, Levy MM, Dellinger RP, Conway WA, Browner WS, Rivers EP. Effects of Compliance with the Early Management Bundle (SEP-1) on Mortality Changes among Medicare Beneficiaries with Sepsis: A Propensity Score Matched Cohort Study. Chest. 2021 Aug 5:S0012-3692(21)03623-0. doi: 10.1016/j.chest.2021.07.2167. Epub ahead of print. PMID: 34364867.

Committee Response:

Thank you for your comment. The Standing Committee reviewed and considered this information during the post-comment meeting.

#3501e Hospital Harm – Opioid-Related Adverse Events

The American Society of Health-System Pharmacists (ASHP) raised concerns about balancing the public health impact of these measures with unintended consequences to patient care. Noting past concerns with measure 3501e, which was originally submitted for the fall 2019 cycle and underwent revisions, they believe that some but not all of these issues were addressed in the current submission. Issues addressed include expansion of the events to any opioid-related adverse outcome, removal of certain exclusions, and removal of doxapram and other respiratory stimulants from the measure.

However, the commenter felt that issues remain with the measure, especially as related to the performance gap. They question whether naloxone administration is an appropriate outcome and raised concerns about the disparity between states' event report rates and an overall low absolute rate reported from the measure's studies. Although the commenter recognizes the importance of opioid-related process measures to help curb the opioid epidemic, ASHP believes that potential unintended consequences could arise from measure implementation.

Measure Steward/Developer Response:

IMPAQ would like to thank the American Society of Health-System Pharmacists (ASHP) for their support of a measure that addresses an important medication safety gap related to opioid related overdose. Unfortunately, their comments do not appear to be relevant to the measure 3501e which was initially submitted to NQF for the Spring 2019 cycle and subsequently revised and resubmitted for the Spring 2021 cycle. Since IMPAQ acquired this measure under contract with CMS in 2019, there have been no exclusions for the use of naloxone within 2 hours of a procedure, nor did this measure address the use of doxapram or any other respiratory stimulant.

Based on feedback received from NQF during the 2019 Spring cycle, we made several substantive updates and re-tested the measure for the 2021 Spring cycle submission. Specifically, we:

- Updated the measure value sets to ensure that the most current codes for hospital administered opioids and naloxone are used and that the codes harmonize across other eCQMs in current CMS quality reporting programs;
- Limited the measure denominator to encounters where patients received at least one opioid during the hospitalization;

- Added a time constraint such that the opioid administration not only precedes the subsequent naloxone administration but also the time gap in between is no larger than 12 hours;
- Re-tested the refined measure for feasibility at 23 hospitals with four different EHR systems (Epic, Cerner, Meditech; and Allscripts); and
- Re-tested for the scientific acceptability of the measure's properties including reliability and validity at six implementation test sites.
- We would like to clarify that measure testing used de-identified EHR data from six hospitals with two different EHR systems (Cerner and Meditech). At no point did measure testing utilize state-based data.

We would also like to clarify that the NQF Standing Committee voted in favor of the appropriateness of naloxone as an opioid reversal agent typically used for severe opioid-related adverse events as they reached consensus in passing 3501e on the Evidence criterion. Empirically, we investigated the extent to which the measure as currently specified may suffer false positives and false negatives and found little evidence of the two. We refer the commenter to measure testing form of 3501e for details.

Lastly, we would like to remind the ASHP, the Patient Safety Standing Committee, and other readers of the substantial performance gap and variations in care which we identified. In addition to testing at six hospitals for reliability and validity, we collected frequency counts on the measure's numerators and denominators from 13 additional hospitals in CY 2019. The rate of ORAE, with the addition of 13 hospitals, ranges from 1.1 to 6.1 per 1,000 qualified inpatient encounters. Using the weighted average measure rate of 0.37%, we estimate that approximately 62,000 adult inpatients suffer ORAEs across the nation annually. While the absolute harm rate can appear small, these measures are of great value to the community both because there is so much room for quality improvement and because of the quality adjusted life years that could be gained. We also identified variability in performance by age, sex, race, ethnicity, and payer source, which following national implementation of the measure may uncover additional performance gaps among vulnerable populations. The literature also verifies that thousands of Americans experience severe adverse events related to hospital administered opioids each year (Herzig et al., 2014). Finally, we note that several NQF-endorsed "harm" measures are in the same frequency range as this eCQM (3501e).

Committee Response:

Thank you for your comment. The Standing Committee reviewed and discussed the comments presented and the developer's response during the post-comment meeting and determined that the measure is suitable for endorsement at the current time.

#3621 Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

The University of California San Francisco (UCSF) commented on the measure and raised a specific concern about the measure's success in measuring excessive radiation dose. The commenter notes that the measure assesses only single-phase CT scans and excludes double-phase scans, and cited evidence that most excessively dosed exams are double-phase scans (i.e. more phases deliver proportionally more radiation). Whether to perform a single- or double-phase scan is determined by the radiologist's choice of protocol. The commenter also cites that there is no evidence suggesting the higher phase protocol provides better diagnostic utility. Because the measure focuses on single-phase head, single-phase chest, and single-phase abdomen scans, the commenter feels that the measure misses an

important opportunity to measure variations in quality of care which are determined by radiologists' choice of protocol.

Additionally, UCSF raised a concern with the measure denominator's definition of the population to be measured. The measure population is defined as "all patients who require either a CT abdomen-pelvis exam with contrast (single-phase scans), a CT chest exam without contrast (single-phase scans), and/or a CT head/brain (single-phase scans) exam." However, the commenter cited research that their own registry's numbers suggests that "the denominator for this measure does not reflect a patient population who require these exams, but rather reflects the varying decisions of radiologists to assign patients to different protocols." Again, they assert that because physician choice is not taken into account in calculating the measure, known variations in practice associated with differing quality of care will be missed by the measure.

Measure Steward/Developer Response:

The ACR appreciates the concerns raised by Dr. Smith-Bindman on the endorsement of our measure, NQF #3621.

We agree that protocol selection that is appropriate for a clinical indication is an important component of radiation dose management, along with radiation dose optimization. Our measure addresses optimization but not whether the exam performed was appropriate for the clinical indication or any of the other aspects of protocol selection.

We believe that the protocol selection issue needs to be addressed as a different quality action because the level of standardization and availability of national benchmarks on that is much less further along than dose optimization. Dose optimization results in a quality action for facilities to adjust their protocols and is a responsibility of the team as a whole – physicists, technologists, and physicians who oversee the team at the facility. Protocol selection addresses the appropriateness of the exam for the clinical indication and other factors such as patient time on the scanner and optimal radiation dose.

The measure UCSF and Dr. Smith-Bindman have submitted to NQF for the Fall 2021 cycle conflates appropriateness of protocol for the clinical indication and radiation dose optimization, and disregards applicability.

A facility's protocol selection process may result in more multi-phase studies than needed, resulting in increased radiation exposure. The most accurate way to address that is to measure both the appropriateness of an exam and the radiation dose output (dose indices per exam) and look at the two separately or together. However, the UCSF measure combines the effect of dose optimization and appropriateness; from that, a facility may not be able to determine if its performance could be improved by adjusting protocols or by focusing on appropriateness of the ordered exam, and therefore improvement may be limited.

There are challenges with the implementation of an indications-based measure. Indications for exams do not have standardized language that could be used to track them. Most health and IT systems have just enough ICD-10 coding for reimbursement, but not enough to characterize the patient's condition and the resulting rationale for performing an imaging exam. Electronic Health Records (EHRs) are notoriously incomplete with this type of information and interoperability issues exist with other software systems that might contain such information. In pursuit of an indication-based measure, how would correct characterization of exam appropriateness be determined? A validated method for determining classification of studies using high-dose vs routine protocols appropriate to the indication must be incorporated into

such a measure. As benchmarks or guides to drive process improvement, indication-based benchmarks are ideal. We believe that the ACR measure is the first step in that process.

Furthermore, the claim that our measure amounts to as low as 1% exams is invalid. Head-Chest-Abdomen-Pelvis (HCAP) procedures account for nearly 75% of all CT exams, of which only 11% to 13% may be multiple-phase scans. [1]

The ACR will continue to work on a measure that looks at dose indices by indication, but that measure needs to be tested and gather consensus on groupings before it is usable for accountability.

1. National Council on Radiation Protection and Measurements (Ed.). (2019). Medical radiation exposure of patients in the United States: Recommendations of the National Council on Radiation Protection and Measurements. National Council on Radiation Protection and Measurements.

Committee Response:

Thank you for your comment. The Standing Committee reviewed and considered this information and the developer's response during the post-comment meeting and determined that the measure is suitable for endorsement at the current time.

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 review to inform the Committee's recommendations. Six NQF members provided their expression of support or non-support. Appendix C 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.	No	*
If a recommended measure is a related and/or competing measure, was a rationale provided for the Standing Committee's recommendation? If not, briefly explain.	Yes	*
Were any measurement gap areas addressed? If so, identify the areas.	No	*
Are there additional concerns that require CSAC discussion? If so, briefly explain.	Yes	During the post-comment meeting, the Standing Committee discussed new guidelines and evidence for NQF #0500 that had been brought to their attention that were not available at the time of the original discussion and may not be fully supportive of the current measure the Standing Committee had recommended for endorsement. A vote on whether to reopen #0500 for discussion was proposed by a Standing Committee member based upon this rationale. The Standing Committee voted not to reconsider the measure at this time.

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Appendix B: Measures Not Recommended for Endorsement

The Patient Safety Standing Committee recommended all candidate measure for endorsement.

Appendix C: NQF Member Expression of Support Results

Six NQF members provided their expressions of support/nonsupport. Three of six measures under review received support from NQF members. Results for each measure are provided below.

#0500: Severe Sepsis and Septic Shock: Management Bundle (Henry Ford Hospital)

Member Council	Support	Do Not Support	Total
Health Professional	2	1	3
Provider Organization	0	1	1

#3389: Concurrent Use of Opioids and Benzodiazepines (COB) (Pharmacy Quality Alliance)

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

#3501e: Hospital Harm – Opioid-Related Adverse Events (Centers for Medicare & Medicaid Services/IMPAQ International, LLC)

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

Appendix D: Details of Measure Evaluation

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

Note: Vote totals may differ between measure criteria and between measures as Standing Committee members often have to join calls late or leave calls early. NQF ensures that quorum is maintained for all live voting. All voting outcomes are calculated using the number of Standing Committee members present for that vote as the denominator. Quorum (16 out of 24 Standing Committee members) was reached and maintenance during the full measure evaluation meeting on June 24-25, 2021.

Measures Recommended

#0500 Severe Sepsis and Septic Shock: Management Bundle

Measure Worksheet

Description: This measure focuses on adults 18 years and older with a diagnosis of severe sepsis or septic shock. Consistent with Surviving Sepsis Campaign guidelines, it assesses measurement of lactate, obtaining blood cultures, administering broad spectrum antibiotics, fluid resuscitation, vasopressor administration, reassessment of volume status and tissue perfusion, and repeat lactate measurement. As reflected in the data elements and their definitions, the first three interventions should occur within three hours of presentation of severe sepsis, while the remaining interventions are expected to occur within six hours of presentation of septic shock.

Numerator Statement: Numerator Statement: Patients who received ALL of the following:

Within three hours of presentation of severe sepsis:

- Initial lactate level measurement
- Broad spectrum or other antibiotics administered
- Blood cultures drawn prior to antibiotics

AND received within six hours of presentation of severe sepsis. ONLY if the initial lactate is elevated:

- Repeat lactate level measurement

AND within three hours of initial hypotension:

- Resuscitation with 30 mL/kg crystalloid fluids

OR within three hours of septic shock:

- Resuscitation with 30 mL/kg crystalloid fluids

AND within six hours of septic shock presentation, ONLY if hypotension persists after fluid administration:

- Vasopressors are administered

AND within six hours of septic shock presentation, if hypotension persists after fluid administration or initial lactate >= 4 mmol/L:

- Repeat volume status and tissue perfusion assessment is performed

Denominator Statement: Inpatients age 18 and over with an ICD-10-CM Principal or Other Diagnosis Code of Sepsis, Severe Sepsis, or Septic Shock and not equal to U07.1 (COVID-19).

Exclusions: The following patients are excluded from the denominator:

- Patients with an ICD-10-CM Principal or Other Diagnosis Code of U07.1 (COVID-19)
- Directive for Comfort Care or Palliative Care within six hours of presentation of severe sepsis
- Directive for Comfort Care or Palliative Care within six hours of presentation of septic shock
- Administrative contraindication to care within six hours of presentation of severe sepsis
- Administrative contraindication to care within six hours of presentation of septic shock
- Length of Stay >120 days
- Transfer in from another acute care facility
- Patients enrolled in a clinical trial for sepsis, severe sepsis, or septic shock treatment or intervention

- Patients with severe sepsis who are discharged within six hours of presentation
- Patients with septic shock who are discharged within six hours of presentation
- Patients receiving IV antibiotics for more than 24 hours prior to presentation of severe sepsis

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Inpatient/Hospital

Type of Measure: Composite

Data Source: Electronic Health Data, Paper Medical Records

Measure Steward: Henry Ford Hospital

STANDING COMMITTEE MEETING June 24 and 25, 2021

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

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

1a. Evidence: **Total Votes-17; H-3**; **M-9**; **L-4**; **I-1**; 1b. Performance Gap: **Total Votes-17; H-6**; **M-9**; **L-2**; **I-0;**

Rationale:

- The Standing Committee reviewed the evidence supporting NQF #0500 (also known as SEP-1).
- SEP-1, and its components, was graded with regard to strength of recommendation and evidence (2016 Surviving Sepsis Guidelines)
    - Measure lactate levels and remeasure if initial lactate is ≥ 2 mmol/L (weak recommendation, low quality evidence)
    - Obtain blood cultures prior to antibiotics (best practice statement)
    - Administer broad-spectrum antibiotics (strong recommendation, moderate quality evidence)
    - Administer crystalloid for hypotension or lactate (strong recommendation, low quality evidence)
    - Vasopressors for hypotension that does not respond to initial fluid resuscitation (strong recommendation, moderate quality of evidence)
    - Reassess volume status and tissue perfusion after fluid administration (best practice statement)
- The Standing Committee also recognized that several scientific societies submitted statements that raised concerns over the variation in evidence, potential for unintended consequences including antibiotic overuse, and the potential harm to specific populations (i.e., fluid resuscitation of heart failure and renal insufficiency patients).
- The Standing Committee noted the definition of the NQF evidence criteria, specifically that an association between a process and outcome was what was under discussion.
- The Standing Committee noted that certain elements of the measure have clear evidence, such as the use of early antibiotics in the presence of severe infection, while others had less evidence. The developer commented that studies in the submission demonstrated that improved adherence to the guideline was associated with improved outcomes.
- Another Standing Committee member stated that liberal antibiotic use in the critically ill, even of viral etiologies, may be appropriate. Early de-escalation of antibiotics rather than avoiding early antibiotics may be a better strategy, which supports the measure.
- The Standing Committee also discussed the "weight" of evidence, comparing the risk and benefits of the measure. The developer then described that there were no studies that had quantified harm related to the measure. However, there had been studies showing a single-center study that demonstrated increased use of antibiotics in urinary tract infections. Another Standing Committee member described a patient who had died due to a delay in antibiotics. Therefore, early interventions are vital. While antibiotic stewardship is also important, this was not the situation where antibiotics should be restricted. Based on this discussion, the Standing Committee passed the measure on evidence.
- Based on this discussion the Standing Committee passed the measure on evidence.
- The Standing Committee then reviewed the performance gap of the measure.
- Q3 2018 July 1, 2018 – September 30, 2018, 3,222 hospitals, 114,827 cases after exclusions
    - Mean: 58%; Standard Deviation: 22%

- Q4 2018 October 1, 2018 – December 31, 2018; 3,235 hospitals, 118,925 cases after exclusions
    - Mean: 58% Standard Deviation: 23% Min: 0% Max: 100.0%.
- There were no other concerns about gap or composite construct and the measure passed both criteria.

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: **Total: 17; Y-17; N-0 (Accept SMP high rating);** 2b. Validity: **Total Votes-17; Y-17; N-0 (Accept SMP moderate rating);** Composite Construction**: Total votes: 17; Y-17; N-0 (Accept SMP moderate rating)**

Rationale:

- This measure was assessed by SMP, which passed the measure on reliability, (Total votes: 8; H-5; M-1; L-0; I-2), validity (Total votes-8; H-3; M-2; L-1; I-2) and composite construct (Total votes: 6; H-2; M-3; L-0; I-1). The Standing Committee reviewed the testing information for the measure.
- For reliability, the developer conducted measure score reliability using a beta-binomial model approach.
    - For all cases regardless of N, the reliability score was 0.92 (CI 0.41-1.00) for Q4 2015, 0.93 (CI 0.47 - 1.00) for Q1 2016, and 0.93 (CI 0.42 - 1.00) for Q2 2016.
    - There was a change between 2015 to 2016 which then remained stable.
    - For all facilities with >=10 cases, the results were 0.63-0.99 for Q4 2015, 0.64-0.99 for Q1 2016, and 0.65-0.99 for Q2 2016.
    - The overall reliability score is 0.92.
- For validity, the developer conducted data element validity testing by comparing submitted critical data elements to abstracted results by an independent group of trained medical record abstractors.
    - Data element validity testing found moderate to high agreement in a strong majority of the data elements (15 of 19)
    - The elements that had weaker agreement tended to be data elements that were rarer in nature.
- Score-level validity testing found a strong inverse relationship between facility mortality rate and measure pass rate. Seven out of ten percentile comparisons have a statistically significant difference between mortality rates at a significance level of 0.05.
- The Standing Committee did not raise any major concerns and accepted SMP's ratings for reliability, validity, and composite construction.

3. Feasibility: **Total Votes-17; H-3; M-13; 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 Standing Committee reviewed the feasibility information for the measure and acknowledged that data are abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)
- Some data elements are in electronic sources.
- All documentation required to report the SEP-1 (NQF #0500) measure cannot be captured electronically in discrete fields. Efforts are being made by hospitals to develop templates and workflows to facilitate the capture of electronic clinical data within the clinical workflow, gaps remain in the ability to electronically capture all of the required data in discrete fields. The SEP-1 (NQF #0500) measure is complex. To collect the data necessary for reporting the measure requires data abstractors to review documentation in various formats including narrative free-text and identify the specific information necessary to report the measure.
- Preliminary efforts to convert the SEP-1 (NQF 0500) measure to an eCQM within the current HQMF/QDM frameworks showed that the transition is not feasible.
- There were no major concerns from the Standing Committee, which voted moderate (passing) for feasibility.

4. Use and Usability

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

4a. Use: **Total Votes-17; Pass-17; No Pass-0** 4b. Usability: **Total Votes-17; H-10; M-5; L-2; I-0**

Rationale:

- The Standing Committee reviewed the use and usability information for this measure.
- This measure appears in public reporting programs and in value-based care:
    - Public Reporting Hospital IQR: Timely and Effective Care – Care Compare https://data.cms.gov/provider-data/dataset/yv7e-xc69
    - Payment Program Hospital IQR https://qualitynet.cms.gov/inpatient/iqr
- Data published on the Care Compare Timely and Effective Care National file (https://data.cms.gov/provider-data/dataset/isrn-hqyy) indicates improvement in the overall measure score over time from 50 % in 2017, to 60% in 2019 for hospitals with available SEP-1 data nationwide.
- There were also no concerns discussed about use or usability, which the Standing Committee gave a passing rating for use and a high rating for usability.

5. Related and Competing Measures

- NQF #0500 and NQF #3215, a related measure, have similar populations but are different measure types; NQF #0500 assesses the performance rates of sepsis care processes; NQF #3215 evaluates the impact sepsis care processes have on an outcome (mortality rates).

6. Standing Committee Recommendation for Endorsement: **Total Votes-17; Y-14**; **N-3**

- During the post-comment meeting, the Standing Committee discussed and voted on whether to reopen NQF #0500 for discussion and voting based upon the rationale that new guidelines and evidence had been brought to the Standing Committee's attention that were not available at the time of the original discussion. The Standing Committee voted not to reconsider the measure (Total Votes-16; Y-6; N-10).

7. Public and Member Comment

- NQF received 10 pre-evaluation comments in advance of the Standing Committee review and 15 post-evaluation comments on the Standing Committee recommendations and draft technical report.
    - In a joint comment, several professional associations expressed concerns regarding burden of chart abstraction; unintended consequences of including both sepsis and septic shock in measure; inclusion of serial lactate measurements due to lack of evidence of improved outcomes. The developer provided in depth responses highlighting areas of disagreements and citing additional evidence. During the post-comment meeting, the Standing Committee discussed the concerns and additional evidence about unintended harms brought forth by a committee member and conducted to vote to reconsider the measure which did not pass so the measure moved forward.
    - Several advocacy organizations wrote in support of this measure; cited studies in support of the measure. The commenter also notes there are sepsis screening programs at every hospital in the U.S. and note that sepsis care is nuanced, and no single test is yet sufficient, which is why the SEP-1 measure is so crucial to focus on improving the quality of care for the sepsis patient. Because this comment was in support of the measure, it did not require a response from the developer but was discussed by the standing committee due to the strong stakeholder support.

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

9. Appeals

#0674 Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay)

Measure Worksheet

Description: This measure reports the percentage of long-stay residents in a nursing home who have experienced one or more falls resulting in major injury (defined as bone fractures, joint dislocations, closed head injuries with altered consciousness, or subdural hematoma) reported in the look-back period no more than 275 days prior to the target assessment. The long stay nursing home population is defined as residents who have received 101 or more cumulative days of nursing home care by the end of the target assessment period. This measure is based on data obtained through the MDS 3.0 OBRA, PPS, and/or discharge assessments during the selected quarter(s).

Numerator Statement: The numerator is the number of long-stay residents with one or more look-back scan assessments that indicate one or more falls that resulted in major injury.

Denominator Statement: The denominator consists of all long-stay nursing home residents with one or more look-back scan assessments except those who meet the exclusion criteria.

Exclusions: A resident is excluded from the denominator of this quality measure if all look-back scan assessments indicate that data is missing from the data element assessing falls resulting in major injury during the look-back period preceding the target assessment.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Post-Acute Care

Type of Measure: Outcome

Data Source: Assessment Data

Measure Steward: Center for Medicare & Medicaid Services

STANDING COMMITTEE MEETING June 24 and 25, 2021

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

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

1a. Evidence: **Total Votes-18; Pass -18; No Pass-0;** 1b. Performance Gap: **Total Votes-18; H-1**; **M-17**; **L-0**; **I-0**

Rationale:

- The Standing Committee reviewed the evidence supporting the measure and recognized that injurious falls are important in the nursing home population because of the impact on health outcomes. Injurious falls are the leading causes of disability and death for nursing home residents. Falls with major injury also impact resident quality of life by introducing new functional limitations and psychosocial distress, while potentially influencing providers to increase the use of unwanted physical or chemical restraints.
- Some nursing home residents are at higher risk for experiencing falls, as certain resident characteristics and care-related factors influence the rate of falls in a facility.
- Falls are also associated with inappropriate or changing medications. Polypharmacy is a major risk factor for falls in the nursing home population.
- Several nursing home characteristics may influence the risk for experiencing a fall with major injury, including adequate staffing levels, staff education, and adequate levels of facility equipment, such as accessible computers used to complete assigned falls prevention tasks.
- Considering this information, the Standing Committee passed the measure on evidence.
- The Standing Committee reviewed the performance gap information for the measure.
- Using Q2 2019 data, 14,286 facilities (94%) and 1,012,706 (98%) of residents that met inclusion criteria. The facility-level mean score was 3.4% and the median score was 2.9%. The standard deviation was 2.9%, the minimum was 0%, and score at the 90th percentile was 7.1%. The interquartile range for this measure was 3.6%, indicating some room for improvement in this measure. Of the facilities with adequate sample size to report, 19.0% had perfect scores of 0.
- There was also a difference in the measure rate by age, race, and socioeconomic status. However, one Standing Committee member noted that the race disparities were somewhat counterintuitive, as the rates for minorities were lower than would be expected. The developer

thought that it could be due to staffing levels, and that there may an interaction with other effects that they could look into in the future.
- The Standing Committee voted moderate on performance gap.

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

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

2a. Reliability: **Total votes: 18; Y-17; N-1 (Accept SMP moderate rating)**; 2b. Validity: **Total votes-19; Y-19; N-0 (Accept SMP moderate rating).**

Rationale:

- The Standing Committee reviewed the testing information for this measure and acknowledged that this measure was assessed by NQF's SMP, which passed the measure on reliability (Total votes-9; H-0; M-6; L-2; I-1) and validity (total votes-8; H-1; M-6; L-1; I-0).
- Data element reliability was established by assessing agreement between gold-standard nurse abstractor and facility nurse abstractor. For performance score reliability, the developer calculated facility signal-to-noise reliability scores.
- The data for data element reliability testing were 15 years old.
- Data element testing:
    - Kappa for gold-standard to gold-standard on the MDS 3.0 item was 0.967
    - Kappa for gold-standard to facility-nurse agreement on the MDS 3.0 item was 0.945.
- Measure-score testing:
    - The average signal-to-noise reliability score was 0.45 but with 19% of facilities achieving a perfect score of 0.0%.
- It was mentioned by a Standing Committee member that it was not necessarily believable that any facility would have a zero rating for this measure. One Standing Committee member commented that this measure is not just looking at falls, but falls that result in a reportable injury, which may explain the zero event rate for some facilities.
- Regarding validity, performance score validity was established by correlations with other measure of nursing home quality. These included related MDS Quality Measures and Facility Five Star Ratings. Variations between states, seasonality, and stability of the measure scores was assessed.
    - There were low but positive correlations between facility performance on this measure and other quality measures. Almost all of the correlation values fell below 0.1.
- The lead discussant noted a validity concern with respect to reporting bias, as falls are self-reported by the facility. The Standing Committee considered evidence form the literature, which found that the Minimum Data Set (MDS) only identified 57 percent of falls in claims and that white patients had 60 percent of falls reported compared to 46 percent of non-white patients. It was recommended by a Standing Committee member that consideration should be given to assess underreporting or consider validating with claims data. The developer mentioned that they are planning to conduct quarterly monitoring to assess this in the future, linking MDS information to Medicare claims to assess the degree of underreporting. It was also mentioned that this would be difficult in the Medicaid population, as well as Medicare Advantage claims, which are not consistently reported.
- Moving to voting, the Standing Committee accepted the SMP's rating for both reliability (Total votes-18; Y-17; N-1) and validity (Total votes-19; Y-19; N-0).

3. Feasibility: Total Votes: 19; H-7; 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:

- The Standing Committee acknowledged that ALL data elements for this measure are in defined fields in electronic clinical data (e.g., clinical registry, nursing home MDS, home health OASIS).
- The general data collection method for the MDS 3.0 is currently in operational use and mandatory for all Medicare/Medicaid certified nursing facilities.
- The Standing Committee passed the measure on feasibility.

4. Use and Usability

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

4a. Use: **Total Votes: 18; Pass-18; No Pass-0** 4b. Usability: **Total Votes: 18; H-5; M-13; L-0; I-0**

Rationale:

- The Standing Committee reviewed the use and usability information for this measure.
- The measure is used for both public reporting and accountability programs.
  - Care Compare https://www.medicare.gov/care-compare/
  - Provider Data Catalog https://data.cms.gov/provider-data/
  - Certification and Survey Provider Enhanced Reports (CASPER) https://www.qtso.com/providernh.html
- The national facility-level mean and median scores demonstrate stability from quarter to quarter. National facility-level mean and median scores have decreased marginally and indicate a slight improvement in performance over time. The mean score for this measure was 3.5% in quarter 1 of 2017 and the median score was 3.0%. In Q2 2019, the mean and median were 3.4% and 2.9%, respectively.
- The Standing Committee did not raise any concerns and passed the measure on use and usability.

5. Related and Competing Measures

- Three related measures are listed below:
  - #0101 Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls
  - #0141 Patient Fall Rate
  - #0202 Falls with injury
- These measures were harmonized to the extent possible by the developer.

6. Standing Committee Recommendation for Endorsement: **Total Votes: 19; Y-19**; **N-0**

7. Public and Member Comment

- No public or member comments were received during the commenting period.

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

9. Appeals

#0679 Percent of High-Risk Residents With Pressure Ulcers (Long Stay)

Measure Worksheet

Description: This measure reports the percentage of long-stay, high-risk residents in a nursing home who have Stage II-IV or unstageable pressure ulcers on a selected target assessment in the target quarter. The long stay nursing home population is defined as residents who have received 101 or more cumulative days of nursing home care by the end of the target assessment period. A nursing home resident is defined as high-risk for pressure ulcer if they meet one or more of the following three criteria:

1. Impaired bed mobility or transfer
2. Comatose
3. Malnourished or at risk of malnutrition

This measure is based on data obtained through the Minimum Data Set (MDS) 3.0 OBRA, PPS, and/or discharge assessments during the selected quarter(s).

Numerator Statement: The numerator is the number of long-stay residents identified as high-risk with a selected MDS 3.0 target assessment (OBRA quarterly, annual or significant change/correction assessments, or discharge assessment with or without return anticipated) in an episode during the selected target quarter reporting one or more Stage II-IV or unstageable pressure ulcer(s) at the time of assessment. High-risk residents are those who are comatose (B0100 = [1]), or impaired in bed mobility (G0110A1 = [3, 4, 7, 8]) or transfer (G0110B1 = [3, 4, 7, 8]), or either experiencing malnutrition or at risk for malnutrition (I5600 = [1]). Unstageable pressure ulcers are pressure ulcers that are known to be present but are defined as unstageable due to either a non-removable dressing/device (M0300E1 = [1,

2, 3, 4, 5, 6, 7, 8, or 9]), slough or eschar (M0300F1 = [1, 2, 3, 4, 5, 6, 7, 8, or 9]), or a suspected deep tissue injury (M0300G1 = [1, 2, 3, 4, 5, 6, 7, 8, or 9]).

Denominator Statement: The denominator includes all long-stay nursing home residents who had a target assessment (ORBA, PPS, or discharge) during the selected quarter who were identified as high risk for pressure ulcer, and who do not meet the exclusion criteria.

Exclusions: A resident is excluded from the denominator if:

1. The target MDS assessment is an OBRA admission assessment or a PPS 5-day assessment or a PPS readmission/return assessment.
2. The resident did not meet the pressure ulcer conditions for the numerator and any Stage II, III, IV, or unstageable item is missing (M0300B1 = [-] or M0300C1 = [-] or M0300D1 = [-] or M0300E1 = [-] or M0300F1 = [-] or M0300G1 = [-]).

If the facility sample includes fewer than 20 residents, then the facility is excluded from public reporting because of small sample size.

Adjustment/Stratification: other

Level of Analysis: Facility

Setting of Care: Post-Acute Care

Type of Measure: Outcome

Data Source: Assessment Data

Measure Steward: Center for Medicare & Medicaid Services

STANDING COMMITTEE MEETING June 24 and 25, 2021

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

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

1a. Evidence: **Total Votes: 17; Pass-17; No Pass-0**; 1b. Performance Gap: **Total Votes: 17; H-10; M-7; L-0; I-0**

Rationale:

- The Standing Committee reviewed the evidence supporting the measure.
- The developer provided substantial literature demonstrating that interventions can be implemented to reduce pressure ulcers in nursing facilities. Several guidelines described recommended activities, including proper nutrition and hydration, repositioning, early mobilization (e.g., implementing ambulation schedules among residents on bedrest), preventing heel pressure injuries (e.g., regularly assessing the vulnerable heel area, prophylactic dressing of heels, etc.), providing support surfaces to redistribute pressure and provide a proper microclimate and more.
- Several processes to treat pressure ulcers were also described. These include: (1) assessing and monitoring of the wound, (2) managing pain, (3) supporting wound healing (e.g., promoting a well-vascularized wound bed, moisture balance, and infection and inflammation control), (4) cleansing and debridement (cleansing with normal saline at low pressure for 10 to 20 minutes was associated with greater reduction in pressure injury depth), (5) diagnosing microbial burdens or biofilms (if present) with tissue biopsies or microscopy, (6) administering antibiotics, (7) dressing wounds, (8) conducting biological wound dressing (e.g., skin substitutes, xenografts, collagen dressing, etc.), (9) using biophysical agents (e.g., electrical stimulation), (10) evaluating the need for surgery (usually on stage III or IV pressure injuries), and more.
- Based on this, the Standing Committee passed the measure on evidence.
- The Standing Committee considered the performance gap for the measure.
- The facility-level mean score for this measure in Quarter 4 (Q4) of 2019 was 7.5% and the median score was 6.8%. The standard deviation was 5.1%, the minimum was 0%, and score at the 90th percentile was 14.0%. The interquartile range for this measure was 6.4%, indicating room for improvement on this measure. Of the facilities with adequate sample size to report, 8.0% had perfect scores of 0.
- In Q4 2019, there were 13,219 facilities (87.5%) and 749,950 residents (97.0%) that met the denominator inclusion criteria. n (Facilities): 13,219 (Residents): 749,950.

- There was a question from a Standing Committee member as to why non-Medicaid patients were at higher risk. The developer stated that research shows that the older population may have lower function than others, which puts them at increased risk. In addition, these patients can have a longer healthcare stay and may be sicker. There was a request by the Standing Committee member that improved stratification could be done in future submissions, to which the developer agreed.
- Based upon this discussion, the Standing Committee voted high on performance gap.

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

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

2a. Reliability: **Total votes: 17; Y-17, N-0 (Accept SMP moderate rating)**; 2b. Validity: **Total votes: 18; Y-16; N-2 (Accept SMP moderate rating)**

Rationale:

- The Standing Committee reviewed the testing information for this measure and acknowledged that this measure was assessed by NQF's SMP, which passed the measure on reliability (Total votes: 8; H-0; M-6; L-2; I-0) and validity (Total votes: 8; H-2; M-4; L-2; I-0) Critical data element testing was performed on 71 community nursing facilities in 8 states (3,822 residents) and 19 VA nursing homes (764 residents). Agreement within gold-standard nurses and between gold-standard nurses and facility nurses both at the resident-level and the facility level. Kappa was 0.92 for the former and 0.97 for the latter.
- Performance measure score testing included nationwide nursing home facilities with an N greater than or equal to 20. Measure score reliability was assessed by split half testing and signal-to-noise analysis. The split-half correlation was 0.33 and 0.50 for the latter.
- Note the above data are old (>10 years). The developer did also describe a follow-up study showing similar data and the MDS form has not changed. Therefore, even though the data are old, the results should still be relevant.
- Performance score validity was assessed by correlation to other quality measures, specifically the Percent of SNF Residents with Pressure Ulcers) and Facility Five-Star Ratings. Variation by state, seasonality, stability analyses and confidence interval analyses were also utilized. Correlation was reported by spearman correlation and was significant for all.
- Spearman correlations ranged from -0.207 to +0.203 for the measure score with the other measures of quality mentioned above. 5.84% of the variation was between-state. Average inter-quartile range of state-level scores was 6.4 percentage points. Of interest was the note that 24.6% of facilities did not change deciles over, 25.7% changed one decile, 19.4% changed two deciles, and 30.4% changed 3 or more deciles.
- The Standing Committee accepted the NQF Scientific Methods Panel's rating for both reliability (Total votes-17; Y-17, N-0) and validity (Total votes-18; Y-16; N-2).

3. Feasibility: Total Votes: 18; H-13; M-5; L-0; I-0

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

Rationale:

- The Standing Committee acknowledged that ALL data elements for this measure are in defined fields in electronic clinical data (e.g., clinical registry, nursing home MDS, home health OASIS)
- The general data collection method for the MDS 3.0 is currently in operational use and mandatory for all Medicare/Medicaid certified nursing facilities.
- The Standing Committee passed the measure on feasibility.

4. Use and Usability

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

4a. Use: **Total Votes: 18; Pass-18; No Pass-0** 4b. Usability: **Total Votes: 18; H-4; M-12; L-2; I-0**

Rationale:

- The Standing Committee reviewed the use and usability information for this measure.

- This measure is used in both public reporting and for accountability:
  - Care Compare https://www.medicare.gov/care-compare/
  - Provider Data Catalog https://data.cms.gov/provider-data/
  - Certification and Survey Provider Enhanced Reports (CASPER) https://www.qtso.com/providernh.html
- The national facility-level mean and median scores demonstrate slight seasonal variation, with mean and median scores being higher in Quarter 1 and lower in Quarter 4 each year.
- The national facility-level mean and median scores have decreased marginally and indicate a slight improvement in performance over time. The mean score for this measure was 7.53% in quarter 4 of 2017 and the median score was 6.90%. In Q4 2019, the mean and median were 7.45% and 6.82%, respectively.
- Based on this, the Standing Committee passed the measure on use and usability.

5. Related and Competing Measures

- Three related measures are listed below:
  - #0201 Pressure ulcer prevalence (hospital acquired)
  - #0337 Pressure Ulcer Rate (PDI 2)
  - #0538 Pressure Ulcer Prevention and Care
- These were harmonized to the extent possible by the developer.

6. Standing Committee Recommendation for Endorsement: **Total Votes: 18; Y-17**; **N-1**

7. Public and Member Comment

- No public or member comments were received during the commenting period.

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

9. Appeals

#3389 Concurrent Use of Opioids and Benzodiazepines (COB)

Measure Worksheet

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

A lower rate indicates better performance.

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

Denominator Statement: The denominator includes individuals >=18 years of age with >= two prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Individuals with cancer, sickle cell disease, or in hospice are excluded.

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

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Health Plan

Setting of Care: Outpatient Services

Type of Measure: Process

Data Source: Claims, Enrollment Data

Measure Steward: PQA, Inc.

STANDING COMMITTEE MEETING June 24 and 25, 2021

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

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

1a. Evidence: **Total Votes: 18; H-6; M-12; L-0; I-0**; 1b. Performance Gap: **Total Votes: 18; H-11; M-6; L-1; I-0**

Rationale:

- The Standing Committee considered the evidence that was submitted by the developer in support of this process measure.

- The developer cited the CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016, which recommends clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible (Recommendation Category: A; Evidence Type: 3).
- Category A recommendation: Applies to all persons; most patients should receive the recommended course of action. Type 3 evidence: Observational studies or randomized clinical trials with notable limitations.
- The developer provided updated evidence since this measure's last review in 2018, which included four additional retrospective cohort studies, one case cohort study, and a technical brief from The Agency for Healthcare Research and Quality (AHRQ). The studies demonstrated the relationship between concurrent use of opioids and benzodiazepines and increased risk for overdose and other adverse events, as well as continued prevalence of concurrent use of opioids and benzodiazepines and room for improvement.
- The Standing Committee did not have any major concerns and voted to pass the measure on evidence.
- The Standing Committee reviewed the performance score distribution for this measure.
- The developer provided data, stratified by line of business (Medicare Advantage Prescription Drug Plan [MAPD], stand-alone Prescription Drug Plan [PDP]), inclusive of contracts with greater than 30 patients in the denominator.
    - 2018 Data (MAPD n=605), Mean: 19.44%, St. Dev: 6.72%
    - 2018 Data (PDP n=58), Mean: 19.36%, St. Dev: 4.78%
    - 2019 Data (MAPD n=618), Mean: 17.39%, St. Dev: 6.15%
    - 2019 Data (PDP n=57), Mean: 17.44%, St. Dev: 3.98%
- The developer also provided Medicaid data that included performance rates from 19 state Medicaid programs that reported on the measure for calendar year 2018, and one state that reported data from federal fiscal year 2018.
    - 2018 data (Medicaid N=20), Mean: 19.15%, St. Dev: 5.36%
- The developer also provided disparities data, which indicated differences in measure rates by age, gender, and between low-income subsidy (LIS) and non-LIS groups.
- The Standing Committee agreed that there remains a substantial gap and passed with measure on performance gap.

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

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

2a. Reliability: **Total Votes: 18; H-4; M-14; L-0; I-0;** 2b. Validity: **Total Votes: 18; H-3; M-14; L-1; I-0**

Rationale:

- This measure was not reviewed by the Scientific Methods Panel, as it is considered a non-complex measure.
- The Standing Committee reviewed the reliability testing for this measure.
- The developer conducted measure score reliability testing on data from the 2018 Part D Patient Safety Reports using the Adams beta-binomial methodology.
- Estimates were only computed for contracts with greater than 30 patients in the denominator.
- The developer reported a reliability score of 0.86 and 0.91 for MAPD and PDP plans with an interquartile range of 0.53 – 0.96 and 0.72 and 0.99, respectively.
- The Standing Committee did not raise any questions or concerns and voted to pass the measure with a moderate rating reliability.
- Moving to validity, the Standing Committee reviewed the validity testing results, including the potential threats to validity.
- The developer conducted measure score criterion validity testing. The developer evaluated the correlation between plan-level performance on the COB measure as specified and plan-level rates of a composite of inpatient stays and emergency department utilization due to opioid- and benzodiazepine-related adverse events (OBRAEs).
- The developer hypothesized an expected convergent relationship between measure rates and OBRAEs; the better a given plan performs on the COB measure (i.e., lower rate), the lower plan-level rates of OBRAEs are hypothesized to be.

- The developer reported that within the Medicare 5% sample, the Spearman's correlation coefficient was 0.45 within PDPs (moderate) [p<.0001] and .21 for MAPDs (weak) [p=.001].
- The Standing Committee acknowledged that this measure is not risk-adjusted, as it is a process measure.
- The Standing Committee did not raise any questions or concerns and voted to pass the measure with a moderate rating for validity.

3. Feasibility: Total Votes: 18; H-6; 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:

- This Standing Committee acknowledged that this measure uses medical claims data, prescription claims data, and Medicare enrollment data.
- Therefore, the developer indicated that all data elements are in defined fields in electronic claims.
- The Standing Committee did not have any concerns with feasibility and voted to pass the measure on feasibility.

4. Use and Usability

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

4a. Use: **Total Votes: 18; Pass-18; No Pass-0** 4b. Usability: **Total Votes: 18; H-11; M-7; L-0; I-0**

Rationale:

- The Standing Committee reviewed the measure's use.
- The developer reported that this measure is currently used in Medicare Part D Patient Safety Reports and in the Medicaid Adult Core Set. The developer stated that CMS will consider this measure for the 2023 Star Ratings (using 2021 data) pending rulemaking.
- The developer has received feedback from measure users suggesting that a palliative care and long-term care exclusions may be appropriate for the measure. As a result, the developer is evaluating the appropriateness of these exclusions for future updates to the measure.
- The Standing Committee did not have any questions or concerns and passed the measure on the use criterion.
- Moving to usability, the Standing Committee noted that this measure has seen improvements over time without any unintended consequences.
- Data from 2018 and 2019 in the Medicare Part D Patient Safety Reports demonstrate a downward trend across both the MAPD and PDP lines of business. In addition, the performance distributions demonstrate variation and room for improvement.
- The Standing Committee did not raise any concerns and passed the measure on the usability criterion.

5. Related and Competing Measures

- The Standing Committee observed that there are several related measures to this metric, but it did not consider these measures to be competing.
    - #2940 Use of Opioids at High Dosage in Persons Without Cancer
    - #2950 Use of Opioids from Multiple Providers in Persons Without Cancer
    - #2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer
    - #3316 Safe Use of Opioids – Concurrent Prescribing
    - #3541 Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)
    - #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

6. Standing Committee Recommendation for Endorsement: **Total Votes: 18; Y-17**; **N-1**

7. Public and Member Comment

- NQF received one pre-evaluation comment in advance of the Standing Committee review and five post-evaluation comments on the Standing Committee recommendations and draft technical report. The post-evaluation comment(s) were supportive of the measure.

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

9. Appeals

#3621 Composite Weighted Average for Three CT Exam Types: Overall Percent of CT exams for Which Dose Length Product Is at or Below the Size-Specific Diagnostic Reference Level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Measure Worksheet

Description: Measure title continued: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single phase scan and CT Head/Brain without contrast/single phase scan)

Description: Weighted average of 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single phase scan and CT Head/Brain without contrast/single phase scan)

Numerator Statement: Number of CT Abdomen-Pelvis exams with contrast (single phase scan), CT Chest exams without contrast (single phase scan), and CT Head/Brain exams without contrast (single phase scan) for which Dose Length Product is at or below the size-specific exam-specific diagnostic reference level

Denominator Statement: Number of CT Abdomen-pelvis exams with contrast (single phase scans), CT Chest exams without contrast (single phase scans), and CT Head/Brain (single phase scans)

Target population: all patients regardless of age.

Exclusions: No denominator exclusions

Adjustment/Stratification: Stratification by risk category/subgroup

Level of Analysis: Facility, Clinician : Group/Practice

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

Type of Measure: Composite

Data Source: Registry Data

Measure Steward: American College of Radiology

STANDING COMMITTEE MEETING June 24 and 25, 2021

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

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

1a. Evidence: **Total Votes: 19; H-0; M-15; L-3; I-1**; 1b. Performance Gap: **Total Votes: 18; H-0; M-18; L-0; I-0;** Composite - Quality Construct and Rationale**: Total Votes: 18; H-2; M-14; L-1; I-1**

Rationale:

- The Standing Committee reviewed the evidence supporting this measure.
- The measure goal is to decrease preventable harm through effective optimization of computed tomography (CT) protocols and resulting reduction in radiation dose to patients.
- The developer provided evidence for this intermediate clinical outcome measure from a systematic review (SR) of 56 studies that examined CT diagnostic reference levels for brain, chest, and abdominal examinations. (Garba, I., Zarb, F., McEntee, M. F., & Fabri, S. G. (2020). Computed tomography diagnostic reference levels for adult brain, chest, and abdominal examinations: A systematic review. Radiography, S1078817420301723)
- The study noted two- to three-fold variation in diagnostic reference levels (DRLs) between studies for the same procedure. The causes of variation are reported and include study design, scanner technology and the use of different dose indices.
- A Standing Committee member asked whether there was any linkage to actual outcomes. The developer clarified that if there is no adjustment of the dosing, there is the chance to over-radiate patients, but the developer did not specifically describe any link to other outcomes. A

Standing Committee member then clarified that the whole point is to limit the amount of radiation to patients to limit the risk of cancer. The developer clarified that the information linking radiation to cancer was primarily drawn from radiation exposure in World War 2 from Nagasaki, Japan.

- The Standing Committee also recognized a public comment for this measure, which stated the importance of exposure to ionizing radiation. Yet, there is unclear evidence that this impacted specific protocols within facilities. The developer clarified that the measure only included CT head, chest, and abdomen, and may not include other protocols such as perfusion studies.
- The Standing Committee agreed that this is an important measure and passed the measure on evidence.
- The Standing Committee then reviewed the performance gap information for this measure.
    - 2017: Performance Rate: 79.93, Mean: 80.17, # of patients: 1698254, # of groups: 173, Min: 11.01, Max: 100, Std Deviation: 16.82, Interquartile Range: 20.69
    - 2018: Performance Rate: 78.37, Mean: 78.61, # of patients: 1317898, # of groups: 189, Min: 11.01, Max: 100, Std. Deviation: 18.04, Interquartile Range: 22.87
    - 2019: Performance Rate: 79.86, Mean: 78.41, # of patients: 2832268, # of groups: 208, Min: 13.59, Max: 100, Std. Deviation: 18.74, Interquartile Range: 24.34
    - 2020: Performance Rate: 78.32, Mean: 78.47, # of patients: 2832268, # of groups: 205, Min: 13.60, Max: 100, Std. Deviation: 18.85, Interquartile Range: 21.73
- The Standing Committee did not raise any questions or concerns for performance gap and passed the measure on this criterion. The Standing Committee also passed the measure on the quality construct.

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: **Total votes: 18; Y-17; N-1 (Accept SMP high rating).** 2b. Committee Vote on Validity: **Total Votes: 17; H-0; M-12; L-3; I-2;** 2c. Composite Construct: **Total Votes: 18; Y-18; N-0 (Accept SMP moderate rating)**

Rationale:

- The Standing Committee reviewed the scientific acceptability for this measure and acknowledged that this measure was assessed by NQF's SMP, which passed the measure on reliability (total votes 8: H-5; M-2; L-0; I-1) and the composite construct (total votes-6; H-2; M-3; L-0; I-1). However, the SMP did not reach consensus for validity (Total votes: 8; H-0; M-4; L-2; I-2).
- The developer calculated a signal-to-noise ratio (SNR) using a Beta-Binomial model (as the event is pass/fail - DLP below benchmark), but calculated the testing only for physician groups, not facilities.
    - The reliability score was above .997 for all types of CT's and the composite weighted average. Confidence intervals included the same high reliability.
- There were no concerns from the Standing Committee regarding SMP's high reliability rating for the measure and voted to accept the SMP's reliability rating.
- Regarding validity, the developer conducted face validity for both group- and facility-level of analysis, which is the minimum acceptable testing for a new measure. The developer reports that:
    - 95% of the panel (20 members) agreed that monitoring radiation dose indices from clinical CT exams is a good and worthwhile activity for advancing or maintaining safety and quality
    - 71% of the panel (15 members) agreed that the measure components as described is a reasonable and appropriate way to assess performance quality of a facility or practice with regards to dose optimization
    - 62% of the panel (13 members) agreed that the scores obtained from the measure would differentiate clinical performance across providers
- Some SMP members questioned the level of analysis (clinician group versus facility), specifically whether face validity was conducted at the clinician group or facility level of analysis or both levels and why stratification was conducted at the clinical group level. The developer noted that

this was clarified within their submission and confirmed that face validity was conducted at both levels of analysis.
- There was a question from the Standing Committee as whether the measure would exclude certain types of patients, such as pregnant patients, to which the developer described that this is a very small population, which would not significantly impact the measure.
- Based upon this discussion, the Standing Committee voted to pass the measure on validity with a moderate rating. There were no concerns or discussion on the composite, and the Standing Committee voted to accept the SMP's rating of moderate for the quality construct.

3. Feasibility: Total Votes: 18; H-4; M-14; L-0; I-0

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

Rationale:
- The Standing Committee reviewed the feasibility information for this measure, recognizing that ALL data elements are in defined fields in a combination of electronic sources.
- The initial setup for submitting data requires the site to have staff resources for installing data collection software.
- Participation fee to participate in the registry, which is based on facility size, number of facilities, and number of radiologists in each practice. The fee is typically about $500-$1000 per year. The developer noted that fees charged by the American College of Radiology were for submitting the data for the Merit-based Incentive Payment System (MIPS).
- Based on this information, the Standing Committee passed the measure on feasibility.

4. Use and Usability

*(4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)*4a. Use: **Total Votes: 18; Pass-18; No Pass-0** 4b. Usability: **Total Votes: 18; H-4; M-14; L-0; I-0**

Rationale:
- The Standing Committee reviewed the use and usability information for this new measure.
- This is measure is an accountability program but not publicly reported:
  - Payment Program Merit-based Incentive Payment System qpp.cms.gov
  - Quality Improvement (Internal to the specific organization) ACR Dose Index Registry https://www.acr.org/Practice-Management-Quality-Informatics/Registries/Dose-Index-Registry
- Measure performance has remained steady in the 79-80% for this measure. There hasn't been a significant performance improvement.
- There were no concerns about use and usability, which received passing ratings for use and usability from the Standing Committee.

5. Related and Competing Measures
- One related measure is listed below:
  - #2820 Pediatric Computed Tomography (CT) Radiation Dose
- Harmonization to the extent possible is described by the developer.

6. Standing Committee Recommendation for Endorsement: **Total Votes: 18; Y-16**; **N-2**

7. Public and Member Comment
- NQF received one pre-evaluation comments in advance of the Standing Committee review and one post-evaluation comments on the Standing Committee recommendations and draft technical report. The comment raises concerns centered around physician's choice of protocol. They assert that because physician choice is not taken into account in calculating the measure, known variations in practice associated with differing quality of care will be missed by the measure.
  - In their response, the developer agrees with the commenter that protocol selection is an important component of radiation dose management but notes that that is not the focus of this measure and should be a separate quality action due to the level of standardization and availability of national benchmarks. The developer also noted that

they will continue to work on a measure that looks at the concerns the commenter highlights.
- The Standing Committee noted the commenter's concerns and the developer's response but had no further discussion.

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

9. Appeals

#3501e Hospital Harm – Opioid-Related Adverse Even

Measure Worksheet

Description: This measure assesses the proportion of inpatient hospital encounters where patients ages 18 years of age or older have been administered an opioid medication, subsequently suffer the harm of an opioid-related adverse event, and are administered an opioid antagonist (naloxone) within 12 hours. This measure excludes opioid antagonist (naloxone) administration occurring in the operating room setting.

Numerator Statement: Inpatient hospitalizations where an opioid antagonist (naloxone) was administered outside of the operating room and within 12 hours following administration of an opioid medication. Only one numerator event is counted per encounter.

Denominator Statement: Inpatient hospitalizations for patients 18 years or older during which at least one opioid medication was administered. An inpatient hospitalization includes time spent in the emergency department or in observation status when the patients are ultimately admitted to inpatient status.

Exclusions: N/A; there are no denominator exclusions

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Inpatient/Hospital

Type of Measure: Outcome

Data Source: Electronic Health Records

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING June 24 and 25, 2021

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

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

1a. Evidence: **Total Votes-16; Pass-10; No Pass-6**; 1b. Performance Gap: **Total Votes: 18; H-3; M-13; L-1; I-1**

Rationale:

- The Standing Committee reviewed the evidence supporting the measure.
- Several studies have demonstrated how naloxone administration is used to identify adverse drug events in the hospital, and there are healthcare actions that can be used to reduce opioid-related adverse events.
- The Standing Committee questioned whether naloxone administration is an appropriate outcome and whether naloxone administration is an actual adverse event as it may capture some appropriate medical care.
- The developer noted that nurse reviewers assessed why patients received the medication as well as the response, which was performed in most of the cases for respiratory depression, reduced arousal, related to opioids (98 percent of the time) and that it was given for opioid reversal and resulted in improvement in the patient's level of consciousness (76 percent of the time).
- The Standing Committee agreed that there was evidence to support this measure and passed the measure on this criterion.
- The Standing Committee discussed the gap in performance, particularly around the four-fold differences across the six sites tested (measure rates ranging from 0.11 to 0.45 percent).
- The Standing Committee expressed concern about the low absolute measure rate. The Standing Committee also questioned whether the low number of events showed differences across sites.

- As a result of these concerns, the Standing Committee did not reach consensus on the performance gap criterion (Total Votes-16; H-0; M-7; L-5; I-4).
- During the post-comment meeting, the Standing Committee passed this measure on performance gap (Total Votes-18; H-3; M-13; L-1; I-1.)

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: **Total vote: 16; Y-16; N-0; (Accept SMP moderate rating)**; 2b. Validity: **Total votes: 16; Y-10; N-6 (Accept SMP moderate rating)**

Rationale:

- The Standing Committee reviewed the scientific acceptability for this measure and acknowledged that the NQF SMP reviewed and passed the measure on reliability (Total votes-8; H-2; M-5; L-0; I-1) and validity (Total votes-8; H-1; M-6; L-1; I-0).
- For reliability, the developer provided data element reliability testing, comparing electronically extracted data to manually extracted data using k
- appa to quantify agreement.
- The Kappa coefficient was 0.98 at one site and 1.00 at all other sites for the six randomly selected sub-samples, comparing the electronically extracted EHR data to manually extracted EHR data for the same medical record.
- The Standing Committee did not have any major concerns with the reliability of the measure and voted to uphold the NQF SMP's moderate rating for reliability.
- For validity, the developer conducted inter-rater agreement testing by comparing the hospitals' EHR data to a clinical abstractor.
- Measure score validity was also assessed for this sample by positive predictive value (PPV), sensitivity, negative predictive value (NPV), and specificity. PPV was 100 percent, and sensitivity is 100 percent in all but one test site. NPV is also 100 percent. Specificity is 100 percent.
- The Standing Committee sought clarification on whether the clinical validity of this measure was being evaluated, this was confirmed by NQF staff.
- There was discussion around the exclusion of patients that were in the operating room, and how this was identified. In two of the 23 measure testing sites, there was an issue with detecting whether the patient was in the operating room. However, there were other proxies to measure this, such as the location of the administering provider.
- Based upon this discussion, the Standing Committee voted to uphold the SMP's assessment of validity.

3. Feasibility: Total Votes-18; H-7; M-11; L-0; I-0

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

Rationale:

- The Standing Committee commented that there may be some feasibility challenges with anesthesiologists documenting naloxone use on paper charts.
- Of all sites used for the measure feasibility assessment, some reported that their anesthesiologists document their activities on paper-based anesthesia records inside of the operating room (OR) rather than via the electronic medication administration record (eMAR). This suggests that, at this time, for these sites, opioid and naloxone administration inside of the OR will not be available for structured electronic extraction or appear in patient EHRs.
- For opioid and naloxone administration outside of OR suite, however, all test sites confirmed that they are documented in the eMARs, and available for electronic extraction.
- The Standing Committee voted to pass the measure with a moderate rating for feasibility.

4. Use and Usability

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

4a. Use: **Total Votes-18; Pass-17; No Pass-1** 4b. Usability: **Total Votes- 18; H-1; M-11; L-2; I-4**

Rationale:

- The Standing Committee acknowledged the developer's plan of using this in public programs in the future as this was a new measure.
- The Standing Committee recommended that the developer evaluate the unintended consequences with the future use of this measure.
- It was also mentioned that naloxone could be used as a trigger tool in hospitals to identify competing problems and target quality improvement efforts.
- Based on this discussion, the Standing Committee voted to pass the measure on the use and usability criteria.

5. Related and Competing Measures

- If the measure passes on performance gap and is recommended for endorsement during the October 2021 post-comment call, the Standing Committee will then proceed with a related and competing measure discussion.

6. Standing Committee Recommendation for Endorsement: Total Votes-18; Yes-15; No-3

Rationale

- During the post-comment meeting the Standing Committee discussed additional evidence provided by the measure developer and voted to pass this measure on performance gap and subsequently voted to recommend it for endorsement.

7. Public and Member Comment

- NQF received no pre-evaluation comments in advance of the Standing Committee review and five post-evaluation comments on the Standing Committee recommendations and draft technical report.
- The non-supportive public comment that required a response from the developer was generally in support of the measure but raised concerns about meeting performance gap while minimizing unintended consequences. In their response the developer notes that the comment may be referring to a version of the measure that was managed by a different developer and clarified other areas of concern for this measure. The Standing Committee noted the concern and the developer's response.

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

9. Appeals

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Patient Safety
Spring 2021 Review Cycle

CSAC Review

November 30 – December 1, 2021
Funded by the Centers for Medicare & Medicaid Services under contract HHSM-500-2017-00060I Task Order HHSM-500-T0001

Patient Safety Standing Committee Recommendations

- **Six measures reviewed for Spring 2021**
  - Four measures reviewed by the Scientific Methods Panel
    - #0674, #0679, and #3501e passed SMP on reliability and validity.
    - #3621 passed SMP on reliability and composite construct. SMP did not reach consensus on validity.
- **Six measures recommended for endorsement**
  - #0500 Severe Sepsis and Septic Shock: Management Bundle (Henry Ford Hospital) (Maintenance)
  - #0674 Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay) (Centers for Medicare & Medicaid Services) (Maintenance)
  - #0679 Percent of High-Risk Residents With Pressure Ulcers (Long Stay) (Centers for Medicare & Medicaid Services) (New)
  - #3389 Concurrent Use of Opioids and Benzodiazepines (COB) (Pharmacy Quality Alliance) (Maintenance)
  - #3501e Hospital Harm – Opioid-Related Adverse Events (Centers for Medicare & Medicaid Services/IMPAQ International, LLC) (Maintenance)
  - #3621 Composite Weighted Average for Computerized Tomography (CT) Exam Types: Overall Percent of CT exams for Which Dose Length Product Is at or Below the Size-Specific Diagnostic Reference Level (for CT Abdomen-Pelvis With Contrast/Single Phase Scan, CT Chest Without Contrast/Single (American College of Radiology [ACR]) (New)

Overarching Issues for Patient Safety Measures

- ***Importance of Evidence (NQF #3501e, NQF #3621, NQF #0500)***
  - For NQF #3501e, NQF #3621, NQF #0500, the Standing Committee raised concerns regarding whether the evidence showed that the process has a clear association or link to desired healthcare outcomes.
  - For NQF #0500, concerns were raised about whether naloxone administration was a true indicator of an opioid overdose rather than whether it was being used for other reasons, such as use of naloxone as a diagnostic tool in a patient who may be obtunded for other reasons.
- ***Performance Gap Concerns (NQF #3501e, NQF #0679, NQF #0674)***
  - For NQF #3501e, the Standing Committee discussed whether a four-fold difference in performance gap was sufficient in the naloxone measure for opioids, particularly using a small sample of six hospitals, and conditions in which the outcome was relatively rare. Consensus was not reached on performance gap, a must-pass criterion.
  - For NQF #0679 and NQF #0674, the Standing Committee focused on the need for a performance gap to still be established during maintenance endorsement review. This was particularly relevant for long-standing measures, such as these two measures, which had been in place in public programs for a long period of time.

Patient Safety: Public and Member Comment and Member Expressions of Support

- Fifteen comments received
  - Ten in support for measures under review (#0500, #3501e, #3621, #3389)
  - Four not supportive due to concerns about evidence and unintended consequences (#0500, #3501e)
  - One not supportive due to concerns about physician's choice of protocol (#3621)

- Six NQF members provided expressions of support and non-support for three measures under review
  - Two members expressed support of #0500 and two members expressed non-support
  - One member expressed support of #3501e and one member expressed non-support
  - Two members expressed support of #3389

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Patient Safety, Spring 2021 Cycle: CDP Report

DRAFT REPORT FOR CSAC REVIEW
NOVEMBER 30, 2021

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Contents

Executive Summary

Patient safety has been a central goal of the National Quality Forum (NQF) since its inception in 1999. Central to these efforts is NQF's Patient Safety Standing Committee, which consists of patient safety clinical leaders, patient representatives, and other thought leaders. The Standing Committee carefully vets new and existing patient safety measures and makes recommendations for endorsement. A goal of patient safety measurement efforts over the last two decades has been to focus healthcare organizations on quality improvement to improve care delivery and outcomes for patients. Examples include reductions in central line-associated blood stream infections (CLABSI), catheter-associated urinary tract infections (CAUTI), falls, pressure ulcers, in-patient mortality, and vital care processes for sepsis, medication reconciliation, and others.

In this project, the Standing Committee evaluated six measures against NQF's measure evaluation criteria. Measures focused on sepsis, pressure ulcers, falls, radiology, and medication use. The sepsis measure (also known as SEP-1 and NQF #0500) has been central to efforts in emergency departments (EDs) and hospitals to standardize sepsis care, employing the all-or-none measurement of a series of time-sensitive and evidence-based actions intended to reduce sepsis mortality. The pressure ulcers (#0679) and falls (#0674) measures assess outcomes in skilled nursing facilities, where interventions can prevent these complications, which cause considerable morbidity and mortality. The radiology measure (#3621) assesses the amount of radiation used when people undergo commonly performed computed tomography (CT) scans of the head, chest, and abdomen. Two measures pertained to medication use. First, measure #3389 assessed whether patients are receiving opioids and benzodiazepines together, which can cause adverse effects. A second measure (#3501e) was intended to reduce opioid-related adverse events in hospitals by measuring the rate of naloxone, which is used to reverse opioid overdose. NQF #3501e also uses data directly from electronic health records (EHRs).

Two overarching themes emerged from the Standing Committee's discussion. One was the importance of evidence, and in particular, balancing concerns from external groups and ensuring care processes are linked to outcomes, which is an NQF must-pass criterion for endorsement. A second overarching issue was performance gap, another must-pass criterion, particularly when measuring rare events. The Standing Committee's concern with the performance gap of #3501e led to a "consensus not reached" vote for this criterion. Additionally, the importance of ensuring that performance gaps remain for maintenance measures was seen as vital, particularly when examining outcome measures, such as pressure ulcers and falls, which have been in use for some time.

For this project, two of the measures were newly submitted and four were undergoing maintenance review against NQF's standard evaluation criteria. Following the initial meeting, the Standing Committee recommended all measures for endorsement. The Standing Committee recommended the following measures for endorsement:

- **#0500** Severe Sepsis and Septic Shock: Management Bundle (Henry Ford Hospital)
- **#0674** Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay) (Centers for Medicare & Medicaid Services)

- **#0679** Percent of High-Risk Residents With Pressure Ulcers (Long Stay) (Centers for Medicare & Medicaid Services)
- **#3389** Concurrent Use of Opioids and Benzodiazepines (COB) (Pharmacy Quality Alliance)
- **#3501e** Hospital Harm – Opioid-Related Adverse Events (Centers for Medicare & Medicaid Services/IMPAQ International, LLC)
- **#3621** Composite Weighted Average for Computerized Tomography (CT) Exam Types: Overall Percent of CT exams for Which Dose Length Product Is at or Below the Size-Specific Diagnostic Reference Level (for CT Abdomen-Pelvis With Contrast/Single Phase Scan, CT Chest Without Contrast/Single (American College of Radiology [ACR])

Brief summaries of the measure evaluation proceedings are included in the body of this report. Detailed summaries of the Standing Committee's discussion and ratings of the criteria for each measure are in Appendix A.

Introduction

Improving patient safety has been central to the mission of NQF for more than two decades. The Patient Safety Standing Committee is vital to these efforts. The Standing Committee makes recommendations about endorsing NQF's portfolio of structure, process, and outcome measures pertaining to patient safety and complications across conditions and settings, including hospitals, rehabilitation centers, skilled nursing facilities, outpatient clinics, and in health plans. Measures within the NQF Patient Safety portfolio have been used in various accountability and public reporting programs, which have led to lower rates of complications, medical errors, mortality, and other patient safety events. The NQF Patient Safety portfolio includes various process measures, as well as patient safety outcome measures, such as mortality, pressure ulcers, falls, and others.

Measures reviewed in this cycle centered on several clinical areas, including sepsis; appropriate radiation dosing in diagnostic CT scans in hospitals; appropriate medication use, specifically the prescribing of opioids and benzodiazepines and adverse events related to opioid use; and two long-standing outcome measures used to measure the quality of skilled nursing facilities, pressure ulcers, and falls.

Sepsis Care

Sepsis is defined as life-threatening organ dysfunction caused by dysregulated host response to infection. A recent study on the global burden of diseases from 2017 estimated nearly 50 million cases of sepsis worldwide and 11 million sepsis-related deaths, representing nearly one in five global deaths.[1] The Centers for Medicare & Medicaid Services' (CMS) Severe Sepsis and Septic Shock Early Management Bundle (SEP-1 or NQF #0500) has made sepsis care a national priority through its inclusion in public programs and value-based purchasing. NQF #0500 involves the all-or-none measurement of a series of actions that must be taken early in the care of septic patients in the hospital, which includes early antibiotics, fluid resuscitation, specific laboratory testing, and reassessment. During this cycle, the Standing Committee evaluated NQF #0500 for maintenance endorsement review.

Radiation Dosing in Radiology

Computed tomography (CT) is a common diagnostic modality used around the world. It is estimated that approximately 75 million CTs are performed in the United States (U.S.) every year.[2] This is estimated to grow to 84 million per year by 2022. When CT is performed, a certain amount of radiation for each procedure is necessary to obtain images and should not be exceeded. This is called the diagnostic reference level (DRL). A recent systematic review of 54 studies identified great variation (two to three-fold) in the DRL between studies for the same procedure.[3] Because high levels of radiation have been shown to be harmful, standardization of DRL in CT imaging is an important measure of quality of care in radiology. The Standing Committee evaluated a new measure this cycle (#3621), which ensures that the proper DRLs are used in imaging of the head, chest, and abdomen.

Preventable Complications in Nursing Homes

Pressure ulcers and falls are two common complications that occur in long-term care facilities where patients have issues with mobility. The yearly incidence rate for pressure ulcers and falls has been estimated at 12 and 50 percent, respectively.[4,5] For both conditions, interventions can improve

outcomes. For example, pressure ulcer rates can be reduced through proper nutrition, using the correct types of mattresses, and using dressings over bony prominences.[6] For falls, characteristics of skilled nursing facilities can also influence the risk of experiencing an injurious fall, such as staffing levels, staff education, and levels of facility equipment, including computers used to complete assigned falls prevention tasks.[7] Measures of both pressure ulcers and injurious falls have been tracked by skilled nursing facilities in public programs for more than a decade and have been previously endorsed by NQF. Measures of pressure ulcers (#0679) and falls (#0674) were assessed by the Standing Committee during this cycle for maintenance endorsement review.

Proper Medication Use

Over the last decade, there has been an increasing crisis related to opioids in the U.S., with nearly 50,000 deaths in 2019 from opioid overdose.[8] Proper use of opioids is important to prevent complications and to reduce abuse and misuse. During this cycle, the Standing Committee assessed two measures related to opioids. The first was a measure of the rate of concurrent prescribing with benzodiazepines and opioids (#3389), which can be a harmful combination because it can lead to oversedation and respiratory depression. A second measure (#3501e), which is an electronic clinical quality measure (eCQM), assessed adverse events related to opioids in hospitals by measuring naloxone use.

NQF Portfolio of Performance Measures for Patient Safety Conditions

The Patient Safety Standing Committee (Appendix C) oversees NQF's portfolio of Patient Safety measures (Appendix B), which includes measures for various subtopics. This portfolio contains 58 measures: 35 outcome and resource use measures, 16 process measures, three composite measures, three structure measures, and one intermediate outcome measure (see table below).

Table 1. NQF Patient Safety Portfolio of Measures

Subtopic	Process	Outcome/Resource Use	Intermediate Outcome	Structure	Composite	Total
Medication Safety	8	1	0	0	0	9
Healthcare-Associated Infections	2	7	0	0	0	9
Perioperative Safety	0	7	0	0	0	7
Falls	1	3	0	0	0	4
Mortality	0	7	0	0	1	8
Venous Thromboembolism	0	1	0	0	0	1
Pressure Ulcers	0	3	0	0	0	3
Workforce	0	0	0	3	0	3
Radiation Safety	0	0	1	0	0	1

Subtopic	Process	Outcome/Resource Use	Intermediate Outcome	Structure	Composite	Total
Other	5	6	0	0	2	13
Total	16	35	1	3	3	58

Additional measures relevant to patient safety have been assigned to other portfolios. These include care coordination measures (Geriatrics and Palliative Care), imaging efficiency measures (Cost and Efficiency), and a variety of condition- or procedure-specific outcome measures (Cardiovascular, Cancer, Renal, etc.).

Patient Safety Measure Evaluation

From June 24–25, 2021, the Patient Safety Standing Committee evaluated four new measures and two measures undergoing maintenance review against NQF's standard measure evaluation criteria.

Table 2. Patient Safety Measure Evaluation Summary

Measure Summary	Maintenance	New	Total
Measures recommended for endorsement	4	2	6

Comments Received Prior to Standing Committee Evaluation

NQF accepts comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). In addition, NQF solicits comments for a continuous 16-week period during each evaluation cycle via an online tool located on the project webpage. For this evaluation cycle, the commenting period opened on April 22, 2021, and closed on September 9, 2021. Nine comments were submitted and shared with the Standing Committee prior to the measure evaluation meetings (Appendix F).

Comments Received After Committee Evaluation

The continuous 16-week public commenting period with NQF member support closed on June 9, 2021. Following the Committee's evaluation of the measures under review, NQF received 15 comments from six organizations (including six member organizations) and individuals pertaining to the draft report and to the measures under review (Appendix G).

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 during the commenting period. This expression of support (or not) during the commenting period replaces the member voting opportunity that was previously held subsequent to committee deliberations. Six NQF members expressed their support or non-support of the measures under review. Two members expressed support and two

members expressed non-support for #0500. Two members expressed support for #3389. One member expressed support and one member expressed non-support for measure #3501e.

Overarching Issues

During the Standing Committee's discussion of the measures, several overarching issues emerged that were factored into the Standing Committee's voting and recommendations for multiple measures and were not repeated in detail with each individual measure.

Importance of Evidence

During discussions of the measures for sepsis care (NQF #0500), radiation dosing (NQF #3621), and naloxone use (NQF 3501e), the Standing Committee raised concerns regarding evidence for process measures. Evidence is a must-pass criterion within the NQF measure evaluation criteria. To pass on this criterion for process measures, the evidence should show that the process has a clear association or link to desired healthcare outcomes. There were some concerns as to whether all elements of the composite sepsis measure (NQF #0500) were associated with outcomes. Some of the elements were clearly associated with improved outcomes, such as early antibiotics in septic shock, while others were based on expert consensus. In the discussion of radiation dosing, concerns were raised as to whether the radiation dosing itself had truly been linked to any outcome beyond older evidence that high radiation levels are harmful. During the discussion of the evidence that the opioid measure assessed with naloxone use, concerns were raised about whether naloxone administration was a true indicator of an opioid overdose rather than whether it was being used for other reasons, such as use of naloxone as a diagnostic tool in a patient who may be obtunded for other reasons. In addition to the evidence evaluation for these measures, the Standing Committee also assessed whether the evidence indicates that the benefits of the measure outweigh any potential risks. The Standing Committee recognized that these measures are important and add more benefit than risk. The Standing Committee proceeded to pass these measures on the evidence criterion.

Performance Gap Concerns

There was considerable discussion regarding the naloxone administration measure (NQF #3501e) and whether a four-fold difference in performance gap was sufficient in the naloxone measure for opioids (NQF #3501e), particularly using a small sample of six hospitals, and conditions in which the outcome was relatively rare. As a result of this discussion, the Standing Committee did not reach consensus on performance gap, a must-pass criterion. During the discussions about the two nursing home measures for pressure ulcers (NQF #0679) and falls (NQF #0674), increased emphasis was placed on the need for a performance gap to still be established during maintenance endorsement review. This was particularly relevant for long-standing measures, such as these two measures, which had been in place in public programs for a long period of time. The Standing Committee agreed that ensuring a performance gap still exists is important for keeping the measure relevant and for continued identification of a need for improvement.

Summary of Measure Evaluation

The following summaries of the measure evaluation highlight the major issues that the Standing Committee considered. Details of the Standing Committee's discussion and ratings of the criteria for each measure are included in Appendix A.

#0500 Severe Sepsis and Septic Shock: Management Bundle (Henry Ford Hospital): Recommended

Description: This measure focuses on adults 18 years of age and older with a diagnosis of severe sepsis or septic shock. Consistent with Surviving Sepsis Campaign guidelines, it assesses measurement of lactate, obtaining blood cultures, administering broad spectrum antibiotics, fluid resuscitation, vasopressor administration, reassessment of volume status and tissue perfusion, and repeat lactate measurement. As reflected in the data elements and their definitions, the first three interventions should occur within three hours of presentation of severe sepsis, while the remaining interventions are expected to occur within six hours of presentation of septic shock. **Measure Type**: Composite; **Level of Analysis**: Facility; **Setting of** Care**: Inpatient/Hospital;** Data Source**: Electronic Health Data, Paper Medical Records**

Since the last review of this measure in 2017 by the Infectious Disease Standing Committee, additional evidence has been added regarding many of the elements for this composite measure. In addition, to date, there have been no peer-reviewed reports of unintended consequences from this measure, except for a single-center study that demonstrated higher use of antibiotics for urinary tract infections (UTIs). Despite this fact, several groups have expressed concerns about the measure, particularly the start time (i.e., time zero) as well as concerns with promoting antibiotic overuse. In addition, concerns have been expressed regarding the amount of fluid administration recommended in the measure, specifically that it could be potentially harmful for certain types of patients, including those with congestive heart failure or chronic renal insufficiency.

During the Standing Committee meeting, these issues were considered and discussed along with concerns about the quality of the evidence for specific elements of the measure, such as rechecking lactate. It was noted that there is strong evidence that the early use of antibiotics improves outcomes, particularly in septic shock, which is one of the groups whose care is meaured. It was also discussed that the risks of withholding antibiotics exceed the risks of stewardship in this population, given the high rate of co-infection in patients with diagnosed viral infections, such as COVID-19. It was suggested that the more appropriate approach would be to use early antibiotics and later de-escalate because of the harms of delayed antibiotics in sepsis. It was also discussed that the association between the elements of the measure and mortality may be smaller than the relationship to observed morbidity and complications. Based upon this disucssion, the Standing Committee passed the measure on evidence.

The Standing Committee then discussed performance gap, disparities, and the composite construct, all of which generated no concerns. The Scientific Methods Panel (SMP) reviewed this measure for reliability, validity, and composite construction, all of which passed. The Standing Committee voted to uphold the SMP's votes. There were few concerns regarding the feasibility, use, and usablity of this measure. Ultimately, the Standing Committee recommended this measure for endorsement. The Standing Committee also observed that there are several related measures to this metric, but it did not consider these measures to be competing.

Public comments on this measure and the Standing Committee's decision were received from several groups including the Infectious Diseases Society of America, the American College of Emergency Physicians, American Hospital Association, Pediatric Infectious Disease Society, Society for Healthcare Epidemiology of America, Society of Hospital Medicine, and Society of Infectious Disease Pharmacists that expressed concerns about the measure and were discussed during the post comment meeting. They stated issues regarding the burden of chart abstraction as there is a considerable effort involved in the reporting of this measure. There were also concerns about the potential for the unintended consequences of including both sepsis and septic shock, as there is differing evidence supporting the clinical actions required in NQF #0500. In addition, there were concerns about the quality of the evidence for including serial lactate measurements as part of sepsis care. There were also supportive comments provided from several groups, including Sepsis Alliance, the Alliance for Aging Research, Americare CSS and Americare Inc, Home Care Association of New York State, the Leapfrog Group, MoMMA's Voices Coalition, NTM Info & Research, Peggy Lillis Foundation, and the Society to Improve Diagnosis in Medicine. Co-chair Dr. Thraen clarified that the concerns brought by specialty societies actually supported a sepsis measure and were focused on needed improvements to the measure, in contrast to being non-supportive. Another Standing Committee member disagreed, stating that several of the comments were actually not in support. The developer responded that the concerns of the specialty societies had been rebutted in their written responses, which were provided to the Standing Committee.

In addition, there were concerns about unintended harm to patients. A Standing Committee member brought forth another study that examined these unintended consequences and found that the onset of SEP-1 was associated with increased broad spectrum antibiotic use across 111 hospitals.[2] It was also mentioned that the measure may be out of step with current recommendations for a wait and see approach in some septic patients without giving antibiotics who are not in septic shock in the current Surviving Sepsis guideline. The developer clarified that this was fully addressed in the comments provided to the Standing Committee and that the measure is consistent with current sepsis care guidelines, and that the measure has evolved along with the science. The developer further stated that NQF permits a moderate level of evidence in support of a measure, including at least three observational studies that control for confounding factors. The developer sufficiently provided those studies as part of the evidence within their submission.

Additional concerns noted in comments include the burden of chart abstraction and the belief evidence to support inclusion of serial lactates was not sufficient. In response, the developer explained that measuring serial lactate is the single most important predictor of outcomes in sepsis care. A Standing Committee member then for an explanation of the definition of time zero for sepsis, as patients can develop sepsis while in the hospital and it may not be present on arrival. The developer clarified that the definition of time zero is currently in the measure specifications, and that if a more reliable time zero is identified it would be used in future versions of the measure.

NQF staff reminded the Standing Committee that the measure was recommended for endorsement during the June measure evaluation meeting; however, the Standing Committee does have the ability to choose to reconsider a measure they already passed. If the Standing Committee wanted to pursue this option they must provide a clear rationale that there is new information available that was

not available at the time of submission. If they presented this clear rationale, the Standing Committee could call for a vote to reconsider the measure. Another option available to the Standing Committee would be that new information could be used to propose an ad hoc review outside of a typical measure review cycle, especially if there are shown to be unintended consequences to a measure in current use. A Standing Committee member stated that there was new evidence, in particular the new Surviving Sepsis guidelines, and other literature that had not been discussed at the Spring 2021 meeting. The co-chair confirmed with the Standing Committee member that there is new information that was available since the time of the Standing Committee review, including new guidelines as well as other evidence, and that this Standing Committee member would like the Standing Committee to vote to reconsider the measure.

Following this discussion, a reconsideration vote was conducted for #0500 based upon the rationale that new guidelines and evidence had been brought to the Standing Committee's attention that were not available at the time of the original discussion. The Standing Committee voted not to reconsider the measure, with six Standing Committee members voting yes to reconsideration (38%) and 10 voting no to reconsideration (62%).

#0674 Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay) (Acumen LLC): Recommended

Description: This measure reports the percentage of long-stay residents in a nursing home who have experienced one or more falls resulting in major injury (defined as bone fractures, joint dislocations, closed head injuries with altered consciousness, or subdural hematoma) reported in the lookback period no more than 275 days prior to the target assessment. The long-stay nursing home population is defined as residents who have received 101 or more cumulative days of nursing home care by the end of the target assessment period. This measure is based on data obtained through the Minimum Data Set (MDS) 3.0 Omnibus Budget Reconciliation Act (OBRA), Palliative Performance Scale (PPS), and/or discharge assessments during the selected quarter(s). **Measure Type**: Outcome; **Level of Analysis**: Facility; **Setting of Care**: Post-Acute Care; **Data Source**: Assessment Data

Injurious falls are an important source of preventable morbidity and mortality in nursing homes. The developer presented data on several interventions that can be implemented to reduce falls with injury in nursing homes. This measure is a long-standing measure that has been captured in the MDS and is publicly reported in Nursing Home Compare. Since the last review of this measure, additional data were presented, specifically that other structural interventions may reduce the risk of falls in long-term care facilities, such as reducing the use of restraints. The Standing Committee passed the measure on evidence.

A performance gap was noted to still exist in this measure, and about one in five nursing homes have a rate of zero. The Standing Committee discussed some of the racial disparities for this measure, which were counterintuitive, demonstrating lower rates for minoritized individuals than expected. It was noted that these may represent interaction effects with other variables such as staffing, but this would be an area of future study. The Standing Committee passed the measure on performance gap.

There were some concerns that the reliability of the measure was low, which was likely due to the large number of zeros. The Standing Committee also expressed concern that a zero for facilities on this measure did not have good face validity, given that injurious falls are so common. Based on this discussion, the Standing Committee accepted the SMP's rating for reliability. Moving to validity, the Standing Committee discussed a study that found reporting bias, in which 57 percent of injurious falls in claims were reported by the MDS. In addition, disparities data showed that White patients had 60 percent of falls reported compared with 46 percent of non-White patients. The developer mentioned plans to conduct quarterly monitoring to assess this in the future, specifically linking MDS information to Medicare claims to assess the degree of underreporting. Based on this discussion, the Standing Committee accepted the SMP's moderate rating for validity.

The Standing Committee did not express any concerns regarding feasibility, usability, or use and voted to recommend the measure for endorsement. The Standing Committee also observed that there are several related measures to this metric, but it did not consider these measures to be competing.

During the public commenting period, no public comments were received, so no further action by the Standing Committee was required.

#0679 Percent of High-Risk Residents With Pressure Ulcers (Long Stay) (Acumen LLC): Recommended

Description: This measure reports the percentage of long-stay, high-risk residents in a nursing home who have Stage II-IV or unstageable pressure ulcers on a selected target assessment in the target quarter. The long-stay nursing home population is defined as residents who have received 101 or more cumulative days of nursing home care by the end of the target assessment period. A nursing home resident is defined as high risk for pressure ulcer if they meet one or more of the following three criteria:

1. Impaired bed mobility or transfer
2. Comatose
3. Malnourished or at risk of malnutrition

This measure is based on data obtained through the MDS 3.0 OBRA, PPS, and/or discharge assessments during the selected quarter(s). **Measure Type**: Outcome; **Level of Analysis**: Facility; **Setting of Care**: Post-Acute Care; **Data Source**: Assessment Data

Pressure ulcers are important adverse events that can occur in a variety of settings, including nursing homes. The incidence of pressure ulcers can be reduced by ensuring appropriate staffing. This has been a long-standing measure dating back to 2002. This measure is also publicly reported. The Standing Committee did not have concerns that pressure ulcers can be impacted by one or more healthcare actions and passed the measure on evidence. A considerable performance gap still exists for this measure even after many years of measurement, and certain groups are at higher risk, including older patients with lower degrees of mobility. The Standing Committee passed the measure on performance gap.

The SMP reviewed and passed this measure on both reliability and validity. There was some discussion about the reliability of grading pressure ulcers, and it was clarified that the measure includes stages 2 to 4 ulcers and unstageable ulcers, which are easier to detect than stage 1 ulcers. Additional concerns were

expressed that the reliability testing was old. However, the MDS, which is used to capture the data, has not changed since that testing; therefore, the reliability testing remained sufficient. Based on this information, the Standing Committee voted to uphold the SMP's decision to pass the measure.

Regarding validity, the measure was associated with other measures of nursing home quality, including the facility Star Ratings for Medicare. During the validity discussion, issues of risk adjustment and stratification were raised, as higher stages of ulcers are more harmful and patient factors can be associated with the incidence of ulcers, such as paraplegia or frailty. The developer did note the trade-off between simplicity and risk adjustment or stratification. The developer also described current efforts to respecify the MDS and that risk adjustment and stratification are under review in the future.

The Standing Committee did not have concerns about the feasibility, use, or usability for this measure and voted to recommend the measure for endorsement. The Standing Committee also observed that there are several related measures to this metric, but it did not consider these measures to be competing.

No public comments were received, so no action by the Standing Committee was required during the post-comment meeting.

#3621 Composite Weighted Average for Three CT Exam Types: Overall Percent of CT exams for Which Dose Length Product Is at or Below the Size-Specific Diagnostic Reference Level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single (American College of Radiology): Recommended

Description: Measure title continued: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single phase scan and CT Head/Brain without contrast/single phase scan). Weighted average of 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single phase scan and CT Head/Brain without contrast/single phase scan). **Measure Type**: Composite; **Level of Analysis**: Facility, Clinician: Group/Practice; **Setting of Care**: Emergency Department and Services, Inpatient/Hospital, Other, Outpatient Services; **Data Source**: Registry Data

CT scans are a very common diagnostic technology that is increasing in use. The intent of this measure is to optimize the manner in which CTs are performed by adjusting for DRLs and by the dose length. The goal is to safely reduce radiation exposure and ensure proper radiation dosing for commonly used CT scans (e.g., head, chest, and abdomen). Optimizing radiation is particularly important for people who receive multiple CT scans over time, as overuse or overexposure of radiation can increase their risk of cancer.

The Standing Committee discussed whether there was any evidence that linked the variation in diagnostic radiation with any outcome. It was clarified that the link between radiation and cancer is largely drawn from studies of radiation exposure in World War II in Nagasaki, Japan. The Standing Committee also discussed that this could potentially be limited to certain patients who are at higher risk of radiation exposure or harm from radiation exposure. In addition, questions were raised about

exclusions, such as trauma and stroke, in which optimizing radiation, which is commonly done through assessing a patient's weight, could delay care. The developer clarified that such cases would not have a large impact because these types of cases are relatively rare compared to larger use of CTs of the head, chest, and abdomen. Based on this discussion, the Standing Committee passed the measure on evidence.

When data on performance gap and composite construction were presented, the Standing Committee did not have any discussion and passed the measure on these two criteria. The SMP also passed this measure on reliability, and the Standing Committee voted to uphold the SMP's recommendation. The Standing Committee discussed validity, including concerns from the SMP about the level of analysis and how face validity was conducted. As a result, the SMP did not reach consensus on validity. The developer clarified the validity testing approach within their submission and that face validity was conducted at both levels of analysis. Following discussion of these concerns, the Standing Committee voted to pass the measure on validity. There were also no concerns about the composite construct; therefore, the Standing Committee voted to accept the SMP's rating for this criterion.

Lastly, the Standing Committee had no concerns with the feasibility, use, and usability of this measure. Ultimately, the Standing Committee voted to recommend this measure for endorsement. While several related measures do exist, the Standing Committee did not think any of them were competing, which would require harmonization.

During the post comment meeting the Standing Committee discussed public comments received on the measure and the Standing Committee's decisions. One public comment raised concerns about a physician's choice of protocol, and that it only includes only single-phase scans, not double phase scans. There were also concerns about the population denominator, as well as the lack of evidence that a higher phase protocol provides better diagnostic utility. The developer responded that single phase scans represent approximately 75% of overall scans. In addition, the developer described additional work that is in process to examine the indication for the exam; however, this information is limited due to variation in how indications are reported, which sometimes occurs in non-standardized ways. A Standing Committee member asked whether examining multiple-phase scans would be considered in the future. The developer responded that additional work needed to be done to examine the variation in dose length product with those CTs. There were no additional questions or comments by the Standing Committee.

#3389 Concurrent Use of Opioids and Benzodiazepines (COB) (PQA, Inc.): Recommended

Description: The percentage of individuals greater than or equal to 18 years of age with concurrent use of prescription opioids and benzodiazepines during the measurement year.

A lower rate indicates better performance. **Measure Type**: Process; **Level of Analysis**: Health Plan; **Setting of Care**: Outpatient Services; **Data Source**: Claims, Enrollment Data

The Standing Committee recommended this process measure for continued endorsement. The developer described the importance of this measure by highlighting the healthcare problems related to opioid overdose and the need for opioid-related measures. To address this matter, the Centers for

Disease Control and Prevention (CDC) issued a class A recommendation, and the U.S. Food and Drug Administration issued a black box warning against the use of opioids along with benzodiazepines, which can increase the risk of overdose. The developer mentioned that this measure had been used for public accountability and still has room for improvement.

In reviewing the evidence for this measure, the Standing Committee acknowledged the CDC's category A recommendation for this measure. The developer also provided additional studies that support its continued measurement. The Standing Committee also considered that the Medicare population was more adversely affected by opioid and benzodiazepine combination prescribing than other groups. The Standing Committee acknowledged that patients with sickle cell disease, cancer, and/or receiving hospice were not included in the denominator for the measure. The Standing Committee did not have any major concerns and voted to pass the measure on evidence.

Moving to performance gap, the Standing Committee agreed that a substantial gap remains and passed the measure on performance gap. Next, the Standing Committee considered the data on reliability and validity. The Standing Committee did not raise any questions or concerns and voted to pass the measure with a moderate rating for both reliability and validity. The Standing Committee also did not have any concerns with feasibility and voted to pass the measure on feasibility.

In reviewing the measure on use and usability, the Standing Committee noted that this measure has seen improvements over time and that the developer stated its future use in accountability programs. The Standing Committee did not raise any questions or concerns and passed the measure on use and usability. Lastly, the Standing Committee voted to recommend the measure for endorsement. The Standing Committee also observed that there are several related measures to this metric, but it did not consider these measures to be competing.

During the post comment period, five comments were received that expressed support for measure due to feasibility, evidence, and performance gap. There were no actions required by the Standing Committee since all comments were in support of the Standing Committee's decisions.

#3501e Hospital Harm – Opioid-Related Adverse Events (IMPAQ International, LLC): Recommended

Description: This measure assesses the proportion of inpatient hospital encounters where patients ages 18 years of age or older have been administered an opioid medication, subsequently suffer the harm of an opioid-related adverse event, and are administered an opioid antagonist (naloxone) within 12 hours. This measure excludes opioid antagonist (naloxone) administration occurring in the operating room setting. **Measure Type**: Outcome; **Level of Analysis**: Facility; **Setting of Care**: Inpatient/Hospital; **Data Source**: Electronic Health Records

The Standing Committee did not vote on the recommendation for endorsement for this outcome measure during the measure evaluation meeting because it did not reach consensus on performance gap—a must-pass criterion. The Standing Committee revoted and passed the measure on performance gap and voted to recommend the measure for endorsement during the post-comment web meeting on October 13, 2021.

Since this measure's last review in spring 2019, the developer made changes to the measure based on the feedback received from the Standing Committee during the spring 2019 evaluation. The specific changes include the following: (1) the denominator has been changed to those receiving at least one opioid during the hospitalization; (2) any naloxone administration needs to be preceded by an opioid with a time parameter; (3) measure value sets have been updated to include all opioids; and (4) determine whether there is sufficient variation across sites.

For the evidence criterion, several studies have demonstrated how naloxone administration is used to identify adverse drug events in the hospital. Some Standing Committee members questioned whether naloxone administration is an appropriate outcome and whether it is an actual adverse event, as it can be used for many other reasons beyond opioid overdose. The developer replied that nurse reviewers did assess why patients received the medication as well as the response, which was performed in most of the cases for respiratory depression and for reduced arousal related to opioid use (98 percent of the time), and that naloxone use did result in improvement in the patient's level of consciousness (76 percent of the time). Based on this discussion, the Standing Committee passed the measure on evidence.

The performance gap for the measure was tested in six hospitals with measure rates ranging from 0.11 to 0.45 percent. The Standing Committee questioned whether a performance gap truly exists because the absolute difference was low. Some Standing Committee members noted that a gap does exist due to four-fold differences across the six sites tested. It was also discussed whether the number of events, which were low, truly showed differences across sites. As a result of this discussion, the Standing Committee did not reach consensus on performance gap.

Reliability was tested using a comparison of electronically versus manually extracted data. The SMP reviewed the reliability testing and rated the measure's reliability as moderate (passing). The Standing Committee did not have any major concerns related to reliability and voted to accept the SMP's rating. Validity testing demonstrated excellent accuracy in detecting whether naloxone was given after an opioid administration. The SMP rated the measure's validity as moderate (passing). The Standing Committee discussed the exclusion of patients who were in the operating room and how this was identified. In two of the 23 measure testing sites, an issue occurred with detecting whether the patient was in the operating room. However, there were other proxy methods to measure this, such as the location of the administering provider. Ultimately, the Standing Committee voted to uphold the SMP's assessment of validity.

For the feasibility criterion, the Standing Committee commented that there may be some challenges with anesthesiologists documenting naloxone use on paper charts, but this did not present significant concerns. The Standing Committee voted to pass the measure with a moderate rating for feasibility. Regarding use and usability, the developer envisioned using this measure in public programs in the future since this was a new measure. The Standing Committee encouraged the developer to evaluate any potential unintended consequences as a result of the use of this measure. The Standing Committee also commented that naloxone could be used as a trigger tool in hospitals to identify problems and target quality improvement efforts. The Standing Committee passed the measure on use and rated the measure as moderate (passing) for usability.

Because consensus was not reached on performance gap, no vote was taken on the overall suitability for endorsement and no related and competing measure(s) discussion was held. If the measure passes on performance gap and is recommended for endorsement during the October 2021 post-comment call, the Standing Committee will then proceed with a related and competing measure(s) discussion.

During the post-comment meeting, NQF staff reminded the Standing Committee of the discussion that took place at the initial measure evaluation meeting related to validity. NQF staff then described the public comments that were received for the measure. These comments expressed concerns about the unintended consequences of the measure as well as concerns about the performance gap. The developer then clarified that among the public comments, several were supportive that it did meet the performance gap criteria by NQF. The developer went on to emphasize two points: first, testing data showed a four-fold difference, which does represent a large gap in performance; second, since the spring 2021 discussion, data had been gathered from 13 additional hospitals. Data from these hospitals demonstrated an even larger performance gap, varying from 0.11% to 0.61%, which is a six-fold difference. Finally, in terms of the total number of harms, these numbers are actually not low. An extrapolation exercise was performed that estimated that >60,000 patients per year in the US likely experience such an event. After this comment, there was no further discussion by the Standing Committee.

NQF staff reminded the Standing Committee how to evaluate the performance gap criterion and they re-voted. The Standing Committee passed the measure on performance gap. There were no further comments or discussion by the Standing Committee, and the Standing Committee then voted to recommend the measure for endorsement.

There were two related measures to #3501e discussed by the Standing Committee: NQF #3316 Safe Use of Current Opioids – Concurrent Prescribing, and NQF #3389 – Concurrent Use of Opioids and Benzodiazepines. Both of these measures were seen to be related but not directly competing with NQF #3501e, and the Standing Committee accepted the developer's rationale for how the three measures were different, and how they had been harmonized. There was no further discussion by the Standing Committee.

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Appendix A: Details of Measure Evaluation

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

Note: Vote totals may differ between measure criteria and between measures as Standing Committee members often have to join calls late or leave calls early. NQF ensures that quorum is maintained for all live voting. All voting outcomes are calculated using the number of Standing Committee members present for that vote as the denominator. Quorum (16 out of 24 Standing Committee members) was reached and maintenance during the full measure evaluation meeting on June 24-25, 2021.

Measures Recommended

#0500 Severe Sepsis and Septic Shock: Management Bundle

Measure Worksheet | Specifications

Description: This measure focuses on adults 18 years and older with a diagnosis of severe sepsis or septic shock. Consistent with Surviving Sepsis Campaign guidelines, it assesses measurement of lactate, obtaining blood cultures, administering broad spectrum antibiotics, fluid resuscitation, vasopressor administration, reassessment of volume status and tissue perfusion, and repeat lactate measurement. As reflected in the data elements and their definitions, the first three interventions should occur within three hours of presentation of severe sepsis, while the remaining interventions are expected to occur within six hours of presentation of septic shock.

Numerator Statement: Numerator Statement: Patients who received ALL of the following:

Within three hours of presentation of severe sepsis:

- Initial lactate level measurement
- Broad spectrum or other antibiotics administered
- Blood cultures drawn prior to antibiotics

AND received within six hours of presentation of severe sepsis. ONLY if the initial lactate is elevated:

- Repeat lactate level measurement

AND within three hours of initial hypotension:

- Resuscitation with 30 mL/kg crystalloid fluids

OR within three hours of septic shock:

- Resuscitation with 30 mL/kg crystalloid fluids

AND within six hours of septic shock presentation, ONLY if hypotension persists after fluid administration:

- Vasopressors are administered

AND within six hours of septic shock presentation, if hypotension persists after fluid administration or initial lactate >= 4 mmol/L:

- Repeat volume status and tissue perfusion assessment is performed

Denominator Statement: Inpatients age 18 and over with an ICD-10-CM Principal or Other Diagnosis Code of Sepsis, Severe Sepsis, or Septic Shock and not equal to U07.1 (COVID-19).

Exclusions: The following patients are excluded from the denominator:

- Patients with an ICD-10-CM Principal or Other Diagnosis Code of U07.1 (COVID-19)
- Directive for Comfort Care or Palliative Care within six hours of presentation of severe sepsis
- Directive for Comfort Care or Palliative Care within six hours of presentation of septic shock
- Administrative contraindication to care within six hours of presentation of severe sepsis
- Administrative contraindication to care within six hours of presentation of septic shock
- Length of Stay >120 days
- Transfer in from another acute care facility

- Patients enrolled in a clinical trial for sepsis, severe sepsis, or septic shock treatment or intervention
- Patients with severe sepsis who are discharged within six hours of presentation
- Patients with septic shock who are discharged within six hours of presentation
- Patients receiving IV antibiotics for more than 24 hours prior to presentation of severe sepsis

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Inpatient/Hospital

Type of Measure: Composite

Data Source: Electronic Health Data, Paper Medical Records

Measure Steward: Henry Ford Hospital

STANDING COMMITTEE MEETING June 24 and 25, 2021

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

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

1a. Evidence: **Total Votes-17; H-3**; **M-9**; **L-4**; **I-1**; 1b. Performance Gap: **Total Votes-17; H-6**; **M-9**; **L-2**; **I-0;**

Rationale:

- The Standing Committee reviewed the evidence supporting NQF #0500 (also known as SEP-1).
- SEP-1, and its components, was graded with regard to strength of recommendation and evidence (2016 Surviving Sepsis Guidelines)
    - Measure lactate levels and remeasure if initial lactate is ≥ 2 mmol/L (weak recommendation, low quality evidence)
    - Obtain blood cultures prior to antibiotics (best practice statement)
    - Administer broad-spectrum antibiotics (strong recommendation, moderate quality evidence)
    - Administer crystalloid for hypotension or lactate (strong recommendation, low quality evidence)
    - Vasopressors for hypotension that does not respond to initial fluid resuscitation (strong recommendation, moderate quality of evidence)
    - Reassess volume status and tissue perfusion after fluid administration (best practice statement)
- The Standing Committee also recognized that several scientific societies submitted statements that raised concerns over the variation in evidence, potential for unintended consequences including antibiotic overuse, and the potential harm to specific populations (i.e., fluid resuscitation of heart failure and renal insufficiency patients).
- The Standing Committee noted the definition of the NQF evidence criteria, specifically that an association between a process and outcome was what was under discussion.
- The Standing Committee noted that certain elements of the measure have clear evidence, such as the use of early antibiotics in the presence of severe infection, while others had less evidence. The developer commented that studies in the submission demonstrated that improved adherence to the guideline was associated with improved outcomes.
- Another Standing Committee member stated that liberal antibiotic use in the critically ill, even of viral etiologies, may be appropriate. Early de-escalation of antibiotics rather than avoiding early antibiotics may be a better strategy, which supports the measure.
- The Standing Committee also discussed the “weight” of evidence, comparing the risk and benefits of the measure. The developer then described that there were no studies that had quantified harm related to the measure. However, there had been studies showing a single-center study that demonstrated increased use of antibiotics in urinary tract infections. Another Standing Committee member described a patient who had died due to a delay in antibiotics. Therefore, early interventions are vital. While antibiotic stewardship is also important, this was not the situation where antibiotics should be restricted. Based on this discussion, the Standing Committee passed the measure on evidence.
- Based on this discussion the Standing Committee passed the measure on evidence.

- The Standing Committee then reviewed the performance gap of the measure.
- Q3 2018 July 1, 2018 – September 30, 2018, 3,222 hospitals, 114,827 cases after exclusions
    - Mean: 58%; Standard Deviation: 22%
- Q4 2018 October 1, 2018 – December 31, 2018; 3,235 hospitals, 118,925 cases after exclusions
    - Mean: 58% Standard Deviation: 23% Min: 0% Max: 100.0%.
- There were no other concerns about gap or composite construct and the measure passed both criteria.

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: **Total: 17; Y-17; N-0 (Accept SMP high rating);** 2b. Validity: **Total Votes-17; Y-17; N-0 (Accept SMP moderate rating);** Composite Construction**: Total votes: 17; Y-17; N-0 (Accept SMP moderate rating)**

Rationale:

- This measure was assessed by SMP, which passed the measure on reliability, (Total votes: 8; H-5; M-1; L-0; I-2), validity (Total votes-8; H-3; M-2; L-1; I-2) and composite construct (Total votes: 6; H-2; M-3; L-0; I-1). The Standing Committee reviewed the testing information for the measure.
- For reliability, the developer conducted measure score reliability using a beta-binomial model approach.
    - For all cases regardless of N, the reliability score was 0.92 (CI 0.41-1.00) for Q4 2015, 0.93 (CI 0.47 - 1.00) for Q1 2016, and 0.93 (CI 0.42 - 1.00) for Q2 2016.
    - There was a change between 2015 to 2016 which then remained stable.
    - For all facilities with >=10 cases, the results were 0.63-0.99 for Q4 2015, 0.64-0.99 for Q1 2016, and 0.65-0.99 for Q2 2016.
    - The overall reliability score is 0.92.
- For validity, the developer conducted data element validity testing by comparing submitted critical data elements to abstracted results by an independent group of trained medical record abstractors.
    - Data element validity testing found moderate to high agreement in a strong majority of the data elements (15 of 19)
    - The elements that had weaker agreement tended to be data elements that were rarer in nature.
- Score-level validity testing found a strong inverse relationship between facility mortality rate and measure pass rate. Seven out of ten percentile comparisons have a statistically significant difference between mortality rates at a significance level of 0.05.
- The Standing Committee did not raise any major concerns and accepted SMP's ratings for reliability, validity, and composite construction.

3. Feasibility: **Total Votes-17; H-3; M-13; 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 Standing Committee reviewed the feasibility information for the measure and acknowledged that data are abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)
- Some data elements are in electronic sources.
- All documentation required to report the SEP-1 (NQF #0500) measure cannot be captured electronically in discrete fields. Efforts are being made by hospitals to develop templates and workflows to facilitate the capture of electronic clinical data within the clinical workflow, gaps remain in the ability to electronically capture all of the required data in discrete fields. The SEP-1 (NQF #0500) measure is complex. To collect the data necessary for reporting the measure requires data abstractors to review documentation in various formats including narrative free-text and identify the specific information necessary to report the measure.

- Preliminary efforts to convert the SEP-1 (NQF 0500) measure to an eCQM within the current HQMF/QDM frameworks showed that the transition is not feasible.
- There were no major concerns from the Standing Committee, which voted moderate (passing) for feasibility.

4. Use and Usability

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

4a. Use: **Total Votes-17; Pass-17; No Pass-0** 4b. Usability: **Total Votes-17; H-10; M-5; L-2; I-0**

Rationale:

- The Standing Committee reviewed the use and usability information for this measure.
- This measure appears in public reporting programs and in value-based care:
    - Public Reporting Hospital IQR: Timely and Effective Care – Care Compare https://data.cms.gov/provider-data/dataset/yv7e-xc69
    - Payment Program Hospital IQR https://qualitynet.cms.gov/inpatient/iqr
- Data published on the Care Compare Timely and Effective Care National file (https://data.cms.gov/provider-data/dataset/isrn-hqyy) indicates improvement in the overall measure score over time from 50 % in 2017, to 60% in 2019 for hospitals with available SEP-1 data nationwide.
- There were also no concerns discussed about use or usability, which the Standing Committee gave a passing rating for use and a high rating for usability.

5. Related and Competing Measures

- NQF #0500 and NQF #3215, a related measure, have similar populations but are different measure types; NQF #0500 assesses the performance rates of sepsis care processes; NQF #3215 evaluates the impact sepsis care processes have on an outcome (mortality rates).

6. Standing Committee Recommendation for Endorsement: **Total Votes-17; Y-14**; **N-3**

- During the post-comment meeting, the Standing Committee discussed and voted on whether to reopen NQF #0500 for discussion and voting based upon the rationale that new guidelines and evidence had been brought to the Standing Committee's attention that were not available at the time of the original discussion. The Standing Committee voted not to reconsider the measure (Total Votes-16; Y-6; N-10).

7. Public and Member Comment

- NQF received 10 pre-evaluation comments in advance of the Standing Committee review and 15 post-evaluation comments on the Standing Committee recommendations and draft technical report.
    - In a joint comment, several professional associations expressed concerns regarding burden of chart abstraction; unintended consequences of including both sepsis and septic shock in measure; inclusion of serial lactate measurements due to lack of evidence of improved outcomes. The developer provided in depth responses highlighting areas of disagreements and citing additional evidence. During the post-comment meeting, the Standing Committee discussed the concerns and additional evidence about unintended harms brought forth by a committee member and conducted to vote to reconsider the measure which did not pass so the measure moved forward.
    - Several advocacy organizations wrote in support of this measure; cited studies in support of the measure. The commenter also notes there are sepsis screening programs at every hospital in the U.S. and note that sepsis care is nuanced, and no single test is yet sufficient, which is why the SEP-1 measure is so crucial to focus on improving the quality of care for the sepsis patient. Because this comment was in support of the measure, it did not require a response from the developer but was discussed by the standing committee due to the strong stakeholder support.

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

9. Appeals

#0674 Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay)

Measure Worksheet| Specifications

Description: This measure reports the percentage of long-stay residents in a nursing home who have experienced one or more falls resulting in major injury (defined as bone fractures, joint dislocations, closed head injuries with altered consciousness, or subdural hematoma) reported in the look-back period no more than 275 days prior to the target assessment. The long stay nursing home population is defined as residents who have received 101 or more cumulative days of nursing home care by the end of the target assessment period. This measure is based on data obtained through the MDS 3.0 OBRA, PPS, and/or discharge assessments during the selected quarter(s).

Numerator Statement: The numerator is the number of long-stay residents with one or more look-back scan assessments that indicate one or more falls that resulted in major injury.

Denominator Statement: The denominator consists of all long-stay nursing home residents with one or more look-back scan assessments except those who meet the exclusion criteria.

Exclusions: A resident is excluded from the denominator of this quality measure if all look-back scan assessments indicate that data is missing from the data element assessing falls resulting in major injury during the look-back period preceding the target assessment.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Post-Acute Care

Type of Measure: Outcome

Data Source: Assessment Data

Measure Steward: Center for Medicare & Medicaid Services

STANDING COMMITTEE MEETING June 24 and 25, 2021

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

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

1a. Evidence: **Total Votes-18; Pass -18; No Pass-0;** 1b. Performance Gap: **Total Votes-18; H-1**; **M-17**; **L-0**; **I-0**

Rationale:

- The Standing Committee reviewed the evidence supporting the measure and recognized that injurious falls are important in the nursing home population because of the impact on health outcomes. Injurious falls are the leading causes of disability and death for nursing home residents. Falls with major injury also impact resident quality of life by introducing new functional limitations and psychosocial distress, while potentially influencing providers to increase the use of unwanted physical or chemical restraints.
- Some nursing home residents are at higher risk for experiencing falls, as certain resident characteristics and care-related factors influence the rate of falls in a facility.
- Falls are also associated with inappropriate or changing medications. Polypharmacy is a major risk factor for falls in the nursing home population.
- Several nursing home characteristics may influence the risk for experiencing a fall with major injury, including adequate staffing levels, staff education, and adequate levels of facility equipment, such as accessible computers used to complete assigned falls prevention tasks.
- Considering this information, the Standing Committee passed the measure on evidence.
- The Standing Committee reviewed the performance gap information for the measure.
- Using Q2 2019 data, 14,286 facilities (94%) and 1,012,706 (98%) of residents that met inclusion criteria. The facility-level mean score was 3.4% and the median score was 2.9%. The standard deviation was 2.9%, the minimum was 0%, and score at the 90th percentile was 7.1%. The interquartile range for this measure was 3.6%, indicating some room for improvement in this measure. Of the facilities with adequate sample size to report, 19.0% had perfect scores of 0.
- There was also a difference in the measure rate by age, race, and socioeconomic status. However, one Standing Committee member noted that the race disparities were somewhat

counterintuitive, as the rates for minorities were lower than would be expected. The developer thought that it could be due to staffing levels, and that there may an interaction with other effects that they could look into in the future.
- The Standing Committee voted moderate on performance gap.

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

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

2a. Reliability: **Total votes: 18; Y-17; N-1 (Accept SMP moderate rating)**; 2b. Validity: **Total votes-19; Y-19; N-0 (Accept SMP moderate rating).**

Rationale:

- The Standing Committee reviewed the testing information for this measure and acknowledged that this measure was assessed by NQF's SMP, which passed the measure on reliability (Total votes-9; H-0; M-6; L-2; I-1) and validity (total votes-8; H-1; M-6; L-1; I-0).
- Data element reliability was established by assessing agreement between gold-standard nurse abstractor and facility nurse abstractor. For performance score reliability, the developer calculated facility signal-to-noise reliability scores.
- The data for data element reliability testing were 15 years old.
- Data element testing:
    - Kappa for gold-standard to gold-standard on the MDS 3.0 item was 0.967
    - Kappa for gold-standard to facility-nurse agreement on the MDS 3.0 item was 0.945.
- Measure-score testing:
    - The average signal-to-noise reliability score was 0.45 but with 19% of facilities achieving a perfect score of 0.0%.
- It was mentioned by a Standing Committee member that it was not necessarily believable that any facility would have a zero rating for this measure. One Standing Committee member commented that this measure is not just looking at falls, but falls that result in a reportable injury, which may explain the zero event rate for some facilities.
- Regarding validity, performance score validity was established by correlations with other measure of nursing home quality. These included related MDS Quality Measures and Facility Five Star Ratings. Variations between states, seasonality, and stability of the measure scores was assessed.
    - There were low but positive correlations between facility performance on this measure and other quality measures. Almost all of the correlation values fell below 0.1.
- The lead discussant noted a validity concern with respect to reporting bias, as falls are self-reported by the facility. The Standing Committee considered evidence form the literature, which found that the Minimum Data Set (MDS) only identified 57 percent of falls in claims and that white patients had 60 percent of falls reported compared to 46 percent of non-white patients. It was recommended by a Standing Committee member that consideration should be given to assess underreporting or consider validating with claims data. The developer mentioned that they are planning to conduct quarterly monitoring to assess this in the future, linking MDS information to Medicare claims to assess the degree of underreporting. It was also mentioned that this would be difficult in the Medicaid population, as well as Medicare Advantage claims, which are not consistently reported.
- Moving to voting, the Standing Committee accepted the SMP's rating for both reliability (Total votes-18; Y-17; N-1) and validity (Total votes-19; Y-19; N-0).

3. Feasibility: Total Votes: 19; H-7; 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:

- The Standing Committee acknowledged that ALL data elements for this measure are in defined fields in electronic clinical data (e.g., clinical registry, nursing home MDS, home health OASIS).
- The general data collection method for the MDS 3.0 is currently in operational use and mandatory for all Medicare/Medicaid certified nursing facilities.

- The Standing Committee passed the measure on feasibility.

4. Use and Usability

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

4a. Use: **Total Votes: 18; Pass-18; No Pass-0** 4b. Usability: **Total Votes: 18; H-5; M-13; L-0; I-0**

Rationale:

- The Standing Committee reviewed the use and usability information for this measure.
- The measure is used for both public reporting and accountability programs.
    - Care Compare https://www.medicare.gov/care-compare/
    - Provider Data Catalog https://data.cms.gov/provider-data/
    - Certification and Survey Provider Enhanced Reports (CASPER) https://www.qtso.com/providernh.html
- The national facility-level mean and median scores demonstrate stability from quarter to quarter. National facility-level mean and median scores have decreased marginally and indicate a slight improvement in performance over time. The mean score for this measure was 3.5% in quarter 1 of 2017 and the median score was 3.0%. In Q2 2019, the mean and median were 3.4% and 2.9%, respectively.
- The Standing Committee did not raise any concerns and passed the measure on use and usability.

5. Related and Competing Measures

- Three related measures are listed below:
    - #0101 Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls
    - #0141 Patient Fall Rate
    - #0202 Falls with injury
- These measures were harmonized to the extent possible by the developer.

6. Standing Committee Recommendation for Endorsement: **Total Votes: 19; Y-19**; **N-0**

7. Public and Member Comment

- No public or member comments were received during the commenting period.

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

9. Appeals

#0679 Percent of High-Risk Residents With Pressure Ulcers (Long Stay)

Measure Worksheet | Specifications

Description: This measure reports the percentage of long-stay, high-risk residents in a nursing home who have Stage II-IV or unstageable pressure ulcers on a selected target assessment in the target quarter. The long stay nursing home population is defined as residents who have received 101 or more cumulative days of nursing home care by the end of the target assessment period. A nursing home resident is defined as high-risk for pressure ulcer if they meet one or more of the following three criteria:

1. Impaired bed mobility or transfer
2. Comatose
3. Malnourished or at risk of malnutrition

This measure is based on data obtained through the Minimum Data Set (MDS) 3.0 OBRA, PPS, and/or discharge assessments during the selected quarter(s).

Numerator Statement: The numerator is the number of long-stay residents identified as high-risk with a selected MDS 3.0 target assessment (OBRA quarterly, annual or significant change/correction assessments, or discharge assessment with or without return anticipated) in an episode during the selected target quarter reporting one or more Stage II-IV or unstageable pressure ulcer(s) at the time of assessment. High-risk residents are those who are comatose (B0100 = [1]), or impaired in bed mobility (G0110A1 = [3, 4, 7, 8]) or transfer (G0110B1 = [3, 4, 7, 8]), or either experiencing malnutrition or at risk

for malnutrition (I5600 = [1]). Unstageable pressure ulcers are pressure ulcers that are known to be present but are defined as unstageable due to either a non-removable dressing/device (M0300E1 = [1, 2, 3, 4, 5, 6, 7, 8, or 9]), slough or eschar (M0300F1 = [1, 2, 3, 4, 5, 6, 7, 8, or 9]), or a suspected deep tissue injury (M0300G1 = [1, 2, 3, 4, 5, 6, 7, 8, or 9]).

Denominator Statement: The denominator includes all long-stay nursing home residents who had a target assessment (ORBA, PPS, or discharge) during the selected quarter who were identified as high risk for pressure ulcer, and who do not meet the exclusion criteria.

Exclusions: A resident is excluded from the denominator if:

1. The target MDS assessment is an OBRA admission assessment or a PPS 5-day assessment or a PPS readmission/return assessment.
2. The resident did not meet the pressure ulcer conditions for the numerator and any Stage II, III, IV, or unstageable item is missing (M0300B1 = [-] or M0300C1 = [-] or M0300D1 = [-] or M0300E1 = [-] or M0300F1 = [-] or M0300G1 = [-]).

If the facility sample includes fewer than 20 residents, then the facility is excluded from public reporting because of small sample size.

Adjustment/Stratification: other

Level of Analysis: Facility

Setting of Care: Post-Acute Care

Type of Measure: Outcome

Data Source: Assessment Data

Measure Steward: Center for Medicare & Medicaid Services

STANDING COMMITTEE MEETING June 24 and 25, 2021

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

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

1a. Evidence: **Total Votes: 17; Pass-17; No Pass-0**; 1b. Performance Gap: **Total Votes: 17; H-10; M-7; L-0; I-0**

Rationale:

- The Standing Committee reviewed the evidence supporting the measure.
- The developer provided substantial literature demonstrating that interventions can be implemented to reduce pressure ulcers in nursing facilities. Several guidelines described recommended activities, including proper nutrition and hydration, repositioning, early mobilization (e.g., implementing ambulation schedules among residents on bedrest), preventing heel pressure injuries (e.g., regularly assessing the vulnerable heel area, prophylactic dressing of heels, etc.), providing support surfaces to redistribute pressure and provide a proper microclimate and more.
- Several processes to treat pressure ulcers were also described. These include: (1) assessing and monitoring of the wound, (2) managing pain, (3) supporting wound healing (e.g., promoting a well-vascularized wound bed, moisture balance, and infection and inflammation control), (4) cleansing and debridement (cleansing with normal saline at low pressure for 10 to 20 minutes was associated with greater reduction in pressure injury depth), (5) diagnosing microbial burdens or biofilms (if present) with tissue biopsies or microscopy, (6) administering antibiotics, (7) dressing wounds, (8) conducting biological wound dressing (e.g., skin substitutes, xenografts, collagen dressing, etc.), (9) using biophysical agents (e.g., electrical stimulation), (10) evaluating the need for surgery (usually on stage III or IV pressure injuries), and more.
- Based on this, the Standing Committee passed the measure on evidence.
- The Standing Committee considered the performance gap for the measure.
- The facility-level mean score for this measure in Quarter 4 (Q4) of 2019 was 7.5% and the median score was 6.8%. The standard deviation was 5.1%, the minimum was 0%, and score at the 90th percentile was 14.0%. The interquartile range for this measure was 6.4%, indicating room for improvement on this measure. Of the facilities with adequate sample size to report, 8.0% had perfect scores of 0.

- In Q4 2019, there were 13,219 facilities (87.5%) and 749,950 residents (97.0%) that met the denominator inclusion criteria. n (Facilities): 13,219 (Residents): 749,950.
- There was a question from a Standing Committee member as to why non-Medicaid patients were at higher risk. The developer stated that research shows that the older population may have lower function than others, which puts them at increased risk. In addition, these patients can have a longer healthcare stay and may be sicker. There was a request by the Standing Committee member that improved stratification could be done in future submissions, to which the developer agreed.
- Based upon this discussion, the Standing Committee voted high on performance gap.

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

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

2a. Reliability: **Total votes: 17; Y-17, N-0 (Accept SMP moderate rating)**; 2b. Validity: **Total votes: 18; Y-16; N-2 (Accept SMP moderate rating)**

Rationale:

- The Standing Committee reviewed the testing information for this measure and acknowledged that this measure was assessed by NQF's SMP, which passed the measure on reliability (Total votes: 8; H-0; M-6; L-2; I-0) and validity (Total votes: 8; H-2; M-4; L-2; I-0) Critical data element testing was performed on 71 community nursing facilities in 8 states (3,822 residents) and 19 VA nursing homes (764 residents). Agreement within gold-standard nurses and between gold-standard nurses and facility nurses both at the resident-level and the facility level. Kappa was 0.92 for the former and 0.97 for the latter.
- Performance measure score testing included nationwide nursing home facilities with an N greater than or equal to 20. Measure score reliability was assessed by split half testing and signal-to-noise analysis. The split-half correlation was 0.33 and 0.50 for the latter.
- Note the above data are old (>10 years). The developer did also describe a follow-up study showing similar data and the MDS form has not changed. Therefore, even though the data are old, the results should still be relevant.
- Performance score validity was assessed by correlation to other quality measures, specifically the Percent of SNF Residents with Pressure Ulcers) and Facility Five-Star Ratings. Variation by state, seasonality, stability analyses and confidence interval analyses were also utilized. Correlation was reported by spearman correlation and was significant for all.
- Spearman correlations ranged from -0.207 to +0.203 for the measure score with the other measures of quality mentioned above. 5.84% of the variation was between-state. Average inter-quartile range of state-level scores was 6.4 percentage points. Of interest was the note that 24.6% of facilities did not change deciles over, 25.7% changed one decile, 19.4% changed two deciles, and 30.4% changed 3 or more deciles.
- The Standing Committee accepted the NQF Scientific Methods Panel's rating for both reliability (Total votes-17; Y-17, N-0) and validity (Total votes-18; Y-16; N-2).

3. Feasibility: Total Votes: 18; H-13; M-5; L-0; I-0

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

Rationale:

- The Standing Committee acknowledged that ALL data elements for this measure are in defined fields in electronic clinical data (e.g., clinical registry, nursing home MDS, home health OASIS)
- The general data collection method for the MDS 3.0 is currently in operational use and mandatory for all Medicare/Medicaid certified nursing facilities.
- The Standing Committee passed the measure on feasibility.

4. Use and Usability

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

4a. Use: **Total Votes: 18; Pass-18; No Pass-0** 4b. Usability: **Total Votes: 18; H-4; M-12; L-2; I-0**

Rationale:

- The Standing Committee reviewed the use and usability information for this measure.
- This measure is used in both public reporting and for accountability:
  - Care Compare https://www.medicare.gov/care-compare/
  - Provider Data Catalog https://data.cms.gov/provider-data/
  - Certification and Survey Provider Enhanced Reports (CASPER) https://www.qtso.com/providernh.html
- The national facility-level mean and median scores demonstrate slight seasonal variation, with mean and median scores being higher in Quarter 1 and lower in Quarter 4 each year.
- The national facility-level mean and median scores have decreased marginally and indicate a slight improvement in performance over time. The mean score for this measure was 7.53% in quarter 4 of 2017 and the median score was 6.90%. In Q4 2019, the mean and median were 7.45% and 6.82%, respectively.
- Based on this, the Standing Committee passed the measure on use and usability.

5. Related and Competing Measures

- Three related measures are listed below:
  - #0201 Pressure ulcer prevalence (hospital acquired)
  - #0337 Pressure Ulcer Rate (PDI 2)
  - #0538 Pressure Ulcer Prevention and Care
- These were harmonized to the extent possible by the developer.

6. Standing Committee Recommendation for Endorsement: **Total Votes: 18; Y-17**; **N-1**

7. Public and Member Comment

- No public or member comments were received during the commenting period.

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

9. Appeals

#3389 Concurrent Use of Opioids and Benzodiazepines (COB)

Measure Worksheet | Specifications

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

A lower rate indicates better performance.

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

Denominator Statement: The denominator includes individuals >=18 years of age with >= two prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Individuals with cancer, sickle cell disease, or in hospice are excluded.

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

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Health Plan

Setting of Care: Outpatient Services

Type of Measure: Process

Data Source: Claims, Enrollment Data

Measure Steward: PQA, Inc.

STANDING COMMITTEE MEETING June 24 and 25, 2021

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

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

1a. Evidence: **Total Votes: 18; H-6; M-12; L-0; I-0**; 1b. Performance Gap: **Total Votes: 18; H-11; M-6; L-1; I-0**

Rationale:

- The Standing Committee considered the evidence that was submitted by the developer in support of this process measure.
- The developer cited the CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016, which recommends clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible (Recommendation Category: A; Evidence Type: 3).
- Category A recommendation: Applies to all persons; most patients should receive the recommended course of action. Type 3 evidence: Observational studies or randomized clinical trials with notable limitations.
- The developer provided updated evidence since this measure's last review in 2018, which included four additional retrospective cohort studies, one case cohort study, and a technical brief from The Agency for Healthcare Research and Quality (AHRQ). The studies demonstrated the relationship between concurrent use of opioids and benzodiazepines and increased risk for overdose and other adverse events, as well as continued prevalence of concurrent use of opioids and benzodiazepines and room for improvement.
- The Standing Committee did not have any major concerns and voted to pass the measure on evidence.
- The Standing Committee reviewed the performance score distribution for this measure.
- The developer provided data, stratified by line of business (Medicare Advantage Prescription Drug Plan [MAPD], stand-alone Prescription Drug Plan [PDP]), inclusive of contracts with greater than 30 patients in the denominator.
    - 2018 Data (MAPD n=605), Mean: 19.44%, St. Dev: 6.72%
    - 2018 Data (PDP n=58), Mean: 19.36%, St. Dev: 4.78%
    - 2019 Data (MAPD n=618), Mean: 17.39%, St. Dev: 6.15%
    - 2019 Data (PDP n=57), Mean: 17.44%, St. Dev: 3.98%
- The developer also provided Medicaid data that included performance rates from 19 state Medicaid programs that reported on the measure for calendar year 2018, and one state that reported data from federal fiscal year 2018.
    - 2018 data (Medicaid N=20), Mean: 19.15%, St. Dev: 5.36%
- The developer also provided disparities data, which indicated differences in measure rates by age, gender, and between low-income subsidy (LIS) and non-LIS groups.
- The Standing Committee agreed that there remains a substantial gap and passed with measure on performance gap.

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

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

2a. Reliability: **Total Votes: 18; H-4; M-14; L-0; I-0;** 2b. Validity: **Total Votes: 18; H-3; M-14; L-1; I-0**

Rationale:

- This measure was not reviewed by the Scientific Methods Panel, as it is considered a non-complex measure.
- The Standing Committee reviewed the reliability testing for this measure.
- The developer conducted measure score reliability testing on data from the 2018 Part D Patient Safety Reports using the Adams beta-binomial methodology.
- Estimates were only computed for contracts with greater than 30 patients in the denominator.
- The developer reported a reliability score of 0.86 and 0.91 for MAPD and PDP plans with an interquartile range of 0.53 – 0.96 and 0.72 and 0.99, respectively.
- The Standing Committee did not raise any questions or concerns and voted to pass the measure with a moderate rating reliability.
- Moving to validity, the Standing Committee reviewed the validity testing results, including the potential threats to validity.
- The developer conducted measure score criterion validity testing. The developer evaluated the correlation between plan-level performance on the COB measure as specified and plan-level rates of a composite of inpatient stays and emergency department utilization due to opioid- and benzodiazepine-related adverse events (OBRAEs).

- The developer hypothesized an expected convergent relationship between measure rates and OBRAEs; the better a given plan performs on the COB measure (i.e., lower rate), the lower plan-level rates of OBRAEs are hypothesized to be.
- The developer reported that within the Medicare 5% sample, the Spearman's correlation coefficient was 0.45 within PDPs (moderate) [p<.0001] and .21 for MAPDs (weak) [p=.001].
- The Standing Committee acknowledged that this measure is not risk-adjusted, as it is a process measure.
- The Standing Committee did not raise any questions or concerns and voted to pass the measure with a moderate rating for validity.

3. Feasibility: Total Votes: 18; H-6; 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:

- This Standing Committee acknowledged that this measure uses medical claims data, prescription claims data, and Medicare enrollment data.
- Therefore, the developer indicated that all data elements are in defined fields in electronic claims.
- The Standing Committee did not have any concerns with feasibility and voted to pass the measure on feasibility.

4. Use and Usability

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

4a. Use: **Total Votes: 18; Pass-18; No Pass-0** 4b. Usability: **Total Votes: 18; H-11; M-7; L-0; I-0**

Rationale:

- The Standing Committee reviewed the measure's use.
- The developer reported that this measure is currently used in Medicare Part D Patient Safety Reports and in the Medicaid Adult Core Set. The developer stated that CMS will consider this measure for the 2023 Star Ratings (using 2021 data) pending rulemaking.
- The developer has received feedback from measure users suggesting that a palliative care and long-term care exclusions may be appropriate for the measure. As a result, the developer is evaluating the appropriateness of these exclusions for future updates to the measure.
- The Standing Committee did not have any questions or concerns and passed the measure on the use criterion.
- Moving to usability, the Standing Committee noted that this measure has seen improvements over time without any unintended consequences.
- Data from 2018 and 2019 in the Medicare Part D Patient Safety Reports demonstrate a downward trend across both the MAPD and PDP lines of business. In addition, the performance distributions demonstrate variation and room for improvement.
- The Standing Committee did not raise any concerns and passed the measure on the usability criterion.

5. Related and Competing Measures

- The Standing Committee observed that there are several related measures to this metric, but it did not consider these measures to be competing.
    - #2940 Use of Opioids at High Dosage in Persons Without Cancer
    - #2950 Use of Opioids from Multiple Providers in Persons Without Cancer
    - #2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer
    - #3316 Safe Use of Opioids – Concurrent Prescribing
    - #3541 Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)
    - #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

6. Standing Committee Recommendation for Endorsement: **Total Votes: 18; Y-17**; **N-1**

7. Public and Member Comment

- NQF received one pre-evaluation comment in advance of the Standing Committee review and five post-evaluation comments on the Standing Committee recommendations and draft technical report. The post-evaluation comment(s) were supportive of the measure.

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

9. Appeals

#3621 Composite Weighted Average for Three CT Exam Types: Overall Percent of CT exams for Which Dose Length Product Is at or Below the Size-Specific Diagnostic Reference Level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Measure Worksheet | Specifications

Description: Measure title continued: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single phase scan and CT Head/Brain without contrast/single phase scan)

Description: Weighted average of 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single phase scan and CT Head/Brain without contrast/single phase scan)

Numerator Statement: Number of CT Abdomen-Pelvis exams with contrast (single phase scan), CT Chest exams without contrast (single phase scan), and CT Head/Brain exams without contrast (single phase scan) for which Dose Length Product is at or below the size-specific exam-specific diagnostic reference level

Denominator Statement: Number of CT Abdomen-pelvis exams with contrast (single phase scans), CT Chest exams without contrast (single phase scans), and CT Head/Brain (single phase scans)

Target population: all patients regardless of age.

Exclusions: No denominator exclusions

Adjustment/Stratification: Stratification by risk category/subgroup

Level of Analysis: Facility, Clinician : Group/Practice

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

Type of Measure: Composite

Data Source: Registry Data

Measure Steward: American College of Radiology

STANDING COMMITTEE MEETING June 24 and 25, 2021

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

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

1a. Evidence: **Total Votes: 19; H-0; M-15; L-3; I-1**; 1b. Performance Gap: **Total Votes: 18; H-0; M-18; L-0; I-0;** Composite - Quality Construct and Rationale**: Total Votes: 18; H-2; M-14; L-1; I-1**

Rationale:

- The Standing Committee reviewed the evidence supporting this measure.
- The measure goal is to decrease preventable harm through effective optimization of computed tomography (CT) protocols and resulting reduction in radiation dose to patients.
- The developer provided evidence for this intermediate clinical outcome measure from a systematic review (SR) of 56 studies that examined CT diagnostic reference levels for brain, chest, and abdominal examinations. (Garba, I., Zarb, F., McEntee, M. F., & Fabri, S. G. (2020). Computed tomography diagnostic reference levels for adult brain, chest, and abdominal examinations: A systematic review. Radiography, S1078817420301723)
- The study noted two- to three-fold variation in diagnostic reference levels (DRLs) between studies for the same procedure. The causes of variation are reported and include study design, scanner technology and the use of different dose indices.
- A Standing Committee member asked whether there was any linkage to actual outcomes. The developer clarified that if there is no adjustment of the dosing, there is the chance to over-

radiate patients, but the developer did not specifically describe any link to other outcomes. A Standing Committee member then clarified that the whole point is to limit the amount of radiation to patients to limit the risk of cancer. The developer clarified that the information linking radiation to cancer was primarily drawn from radiation exposure in World War 2 from Nagasaki, Japan.

- The Standing Committee also recognized a public comment for this measure, which stated the importance of exposure to ionizing radiation. Yet, there is unclear evidence that this impacted specific protocols within facilities. The developer clarified that the measure only included CT head, chest, and abdomen, and may not include other protocols such as perfusion studies.
- The Standing Committee agreed that this is an important measure and passed the measure on evidence.
- The Standing Committee then reviewed the performance gap information for this measure.
    - 2017: Performance Rate: 79.93, Mean: 80.17, # of patients: 1698254, # of groups: 173, Min: 11.01, Max: 100, Std Deviation: 16.82, Interquartile Range: 20.69
    - 2018: Performance Rate: 78.37, Mean: 78.61, # of patients: 1317898, # of groups: 189, Min: 11.01, Max: 100, Std. Deviation: 18.04, Interquartile Range: 22.87
    - 2019: Performance Rate: 79.86, Mean: 78.41, # of patients: 2832268, # of groups: 208, Min: 13.59, Max: 100, Std. Deviation: 18.74, Interquartile Range: 24.34
    - 2020: Performance Rate: 78.32, Mean: 78.47, # of patients: 2832268, # of groups: 205, Min: 13.60, Max: 100, Std. Deviation: 18.85, Interquartile Range: 21.73
- The Standing Committee did not raise any questions or concerns for performance gap and passed the measure on this criterion. The Standing Committee also passed the measure on the quality construct.

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: **Total votes: 18; Y-17; N-1 (Accept SMP high rating).** 2b. Committee Vote on Validity: **Total Votes: 17; H-0; M-12; L-3; I-2;** 2c. Composite Construct: **Total Votes: 18; Y-18; N-0 (Accept SMP moderate rating)**

Rationale:

- The Standing Committee reviewed the scientific acceptability for this measure and acknowledged that this measure was assessed by NQF's SMP, which passed the measure on reliability (total votes 8: H-5; M-2; L-0; I-1) and the composite construct (total votes-6; H-2; M-3; L-0; I-1). However, the SMP did not reach consensus for validity (Total votes: 8; H-0; M-4; L-2; I-2).
- The developer calculated a signal-to-noise ratio (SNR) using a Beta-Binomial model (as the event is pass/fail - DLP below benchmark), but calculated the testing only for physician groups, not facilities.
    - The reliability score was above .997 for all types of CT's and the composite weighted average. Confidence intervals included the same high reliability.
- There were no concerns from the Standing Committee regarding SMP's high reliability rating for the measure and voted to accept the SMP's reliability rating.
- Regarding validity, the developer conducted face validity for both group- and facility-level of analysis, which is the minimum acceptable testing for a new measure. The developer reports that:
    - 95% of the panel (20 members) agreed that monitoring radiation dose indices from clinical CT exams is a good and worthwhile activity for advancing or maintaining safety and quality
    - 71% of the panel (15 members) agreed that the measure components as described is a reasonable and appropriate way to assess performance quality of a facility or practice with regards to dose optimization
    - 62% of the panel (13 members) agreed that the scores obtained from the measure would differentiate clinical performance across providers
- Some SMP members questioned the level of analysis (clinician group versus facility), specifically whether face validity was conducted at the clinician group or facility level of analysis or both

levels and why stratification was conducted at the clinical group level. The developer noted that this was clarified within their submission and confirmed that face validity was conducted at both levels of analysis.
- There was a question from the Standing Committee as whether the measure would exclude certain types of patients, such as pregnant patients, to which the developer described that this is a very small population, which would not significantly impact the measure.
- Based upon this discussion, the Standing Committee voted to pass the measure on validity with a moderate rating. There were no concerns or discussion on the composite, and the Standing Committee voted to accept the SMP's rating of moderate for the quality construct.

3. Feasibility: Total Votes: 18; H-4; M-14; L-0; I-0

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

Rationale:
- The Standing Committee reviewed the feasibility information for this measure, recognizing that ALL data elements are in defined fields in a combination of electronic sources.
- The initial setup for submitting data requires the site to have staff resources for installing data collection software.
- Participation fee to participate in the registry, which is based on facility size, number of facilities, and number of radiologists in each practice. The fee is typically about $500-$1000 per year. The developer noted that fees charged by the American College of Radiology were for submitting the data for the Merit-based Incentive Payment System (MIPS).
- Based on this information, the Standing Committee passed the measure on feasibility.

4. Use and Usability

*(4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)*4a. Use: **Total Votes: 18; Pass-18; No Pass-0** 4b. Usability: **Total Votes: 18; H-4; M-14; L-0; I-0**

Rationale:
- The Standing Committee reviewed the use and usability information for this new measure.
- This is measure is an accountability program but not publicly reported:
  - Payment Program Merit-based Incentive Payment System qpp.cms.gov
  - Quality Improvement (Internal to the specific organization) ACR Dose Index Registry https://www.acr.org/Practice-Management-Quality-Informatics/Registries/Dose-Index-Registry
- Measure performance has remained steady in the 79-80% for this measure. There hasn't been a significant performance improvement.
- There were no concerns about use and usability, which received passing ratings for use and usability from the Standing Committee.

5. Related and Competing Measures
- One related measure is listed below:
  - #2820 Pediatric Computed Tomography (CT) Radiation Dose
- Harmonization to the extent possible is described by the developer.

6. Standing Committee Recommendation for Endorsement: **Total Votes: 18; Y-16**; **N-2**

7. Public and Member Comment
- NQF received one pre-evaluation comments in advance of the Standing Committee review and one post-evaluation comments on the Standing Committee recommendations and draft technical report. The comment raises concerns centered around physician's choice of protocol. They assert that because physician choice is not taken into account in calculating the measure, known variations in practice associated with differing quality of care will be missed by the measure.
  - In their response, the developer agrees with the commenter that protocol selection is an important component of radiation dose management but notes that that is not the focus of this measure and should be a separate quality action due to the level of

standardization and availability of national benchmarks. The developer also noted that they will continue to work on a measure that looks at the concerns the commenter highlights.
    - The Standing Committee noted the commenter's concerns and the developer's response but had no further discussion.

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

9. Appeals

#3501e Hospital Harm – Opioid-Related Adverse Even

Measure Worksheet | Specifications

Description: This measure assesses the proportion of inpatient hospital encounters where patients ages 18 years of age or older have been administered an opioid medication, subsequently suffer the harm of an opioid-related adverse event, and are administered an opioid antagonist (naloxone) within 12 hours. This measure excludes opioid antagonist (naloxone) administration occurring in the operating room setting.

Numerator Statement: Inpatient hospitalizations where an opioid antagonist (naloxone) was administered outside of the operating room and within 12 hours following administration of an opioid medication. Only one numerator event is counted per encounter.

Denominator Statement: Inpatient hospitalizations for patients 18 years or older during which at least one opioid medication was administered. An inpatient hospitalization includes time spent in the emergency department or in observation status when the patients are ultimately admitted to inpatient status.

Exclusions: N/A; there are no denominator exclusions

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Inpatient/Hospital

Type of Measure: Outcome

Data Source: Electronic Health Records

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING June 24 and 25, 2021

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

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

1a. Evidence: **Total Votes-16; Pass-10; No Pass-6**; 1b. Performance Gap: **Total Votes: 18; H-3; M-13; L-1; I-1**

Rationale:

- The Standing Committee reviewed the evidence supporting the measure.
- Several studies have demonstrated how naloxone administration is used to identify adverse drug events in the hospital, and there are healthcare actions that can be used to reduce opioid-related adverse events.
- The Standing Committee questioned whether naloxone administration is an appropriate outcome and whether naloxone administration is an actual adverse event as it may capture some appropriate medical care.
- The developer noted that nurse reviewers assessed why patients received the medication as well as the response, which was performed in most of the cases for respiratory depression, reduced arousal, related to opioids (98 percent of the time) and that it was given for opioid reversal and resulted in improvement in the patient's level of consciousness (76 percent of the time).
- The Standing Committee agreed that there was evidence to support this measure and passed the measure on this criterion.
- The Standing Committee discussed the gap in performance, particularly around the four-fold differences across the six sites tested (measure rates ranging from 0.11 to 0.45 percent).

- The Standing Committee expressed concern about the low absolute measure rate. The Standing Committee also questioned whether the low number of events showed differences across sites.
- As a result of these concerns, the Standing Committee did not reach consensus on the performance gap criterion (Total Votes-16; H-0; M-7; L-5; I-4).
- During the post-comment meeting, the Standing Committee passed this measure on performance gap (Total Votes-18; H-3; M-13; L-1; I-1.)

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: **Total vote: 16; Y-16; N-0; (Accept SMP moderate rating)**; 2b. Validity: **Total votes: 16; Y-10; N-6 (Accept SMP moderate rating)**

Rationale:

- The Standing Committee reviewed the scientific acceptability for this measure and acknowledged that the NQF SMP reviewed and passed the measure on reliability (Total votes-8; H-2; M-5; L-0; I-1) and validity (Total votes-8; H-1; M-6; L-1; I-0).
- For reliability, the developer provided data element reliability testing, comparing electronically extracted data to manually extracted data using k
- appa to quantify agreement.
- The Kappa coefficient was 0.98 at one site and 1.00 at all other sites for the six randomly selected sub-samples, comparing the electronically extracted EHR data to manually extracted EHR data for the same medical record.
- The Standing Committee did not have any major concerns with the reliability of the measure and voted to uphold the NQF SMP's moderate rating for reliability.
- For validity, the developer conducted inter-rater agreement testing by comparing the hospitals' EHR data to a clinical abstractor.
- Measure score validity was also assessed for this sample by positive predictive value (PPV), sensitivity, negative predictive value (NPV), and specificity. PPV was 100 percent, and sensitivity is 100 percent in all but one test site. NPV is also 100 percent. Specificity is 100 percent.
- The Standing Committee sought clarification on whether the clinical validity of this measure was being evaluated, this was confirmed by NQF staff.
- There was discussion around the exclusion of patients that were in the operating room, and how this was identified. In two of the 23 measure testing sites, there was an issue with detecting whether the patient was in the operating room. However, there were other proxies to measure this, such as the location of the administering provider.
- Based upon this discussion, the Standing Committee voted to uphold the SMP's assessment of validity.

3. Feasibility: Total Votes-18; H-7; M-11; L-0; I-0

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

Rationale:

- The Standing Committee commented that there may be some feasibility challenges with anesthesiologists documenting naloxone use on paper charts.
- Of all sites used for the measure feasibility assessment, some reported that their anesthesiologists document their activities on paper-based anesthesia records inside of the operating room (OR) rather than via the electronic medication administration record (eMAR). This suggests that, at this time, for these sites, opioid and naloxone administration inside of the OR will not be available for structured electronic extraction or appear in patient EHRs.
- For opioid and naloxone administration outside of OR suite, however, all test sites confirmed that they are documented in the eMARs, and available for electronic extraction.
- The Standing Committee voted to pass the measure with a moderate rating for feasibility.

4. Use and Usability

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

4a. Use: **Total Votes-18; Pass-17; No Pass-1** 4b. Usability: **Total Votes- 18; H-1; M-11; L-2; I-4**

Rationale:

- The Standing Committee acknowledged the developer's plan of using this in public programs in the future as this was a new measure.
- The Standing Committee recommended that the developer evaluate the unintended consequences with the future use of this measure.
- It was also mentioned that naloxone could be used as a trigger tool in hospitals to identify competing problems and target quality improvement efforts.
- Based on this discussion, the Standing Committee voted to pass the measure on the use and usability criteria.

5. Related and Competing Measures

- If the measure passes on performance gap and is recommended for endorsement during the October 2021 post-comment call, the Standing Committee will then proceed with a related and competing measure discussion.

6. Standing Committee Recommendation for Endorsement: Total Votes-18; Yes-15; No-3

Rationale

- During the post-comment meeting the Standing Committee discussed additional evidence provided by the measure developer and voted to pass this measure on performance gap and subsequently voted to recommend it for endorsement.

7. Public and Member Comment

- NQF received no pre-evaluation comments in advance of the Standing Committee review and five post-evaluation comments on the Standing Committee recommendations and draft technical report.
- The non-supportive public comment that required a response from the developer was generally in support of the measure but raised concerns about meeting performance gap while minimizing unintended consequences. In their response the developer notes that the comment may be referring to a version of the measure that was managed by a different developer and clarified other areas of concern for this measure. The Standing Committee noted the concern and the developer's response.

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

9. Appeals

Appendix B: Patient Safety Portfolio—Use in Federal Programs[a]

NQF #	Title	Federal Programs: Finalized or Implemented as of June 30, 2021
0022	Use of High-Risk Medications in Older Adults	Merit-Based Incentive Payment System (MIPS) Program (Implemented 2018)
0097	Medication Reconciliation Post-Discharge	Medicare Part C Star Rating (Implemented 2019) Physician Compare (Implemented 2007)
0101	Falls: (Plan of Care, Risk Assessment, and Screening for Future Fall Risk)	Merit-Based Incentive Payment System (MIPS) Program (Implemented 2018) Medicare Shared Savings Program (Implemented 2012)
0138	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure	Hospital Acquired Condition Reduction Program (Implemented 2014) Hospital Compare (Implemented 2018) Hospital Value-Based Purchasing (Implemented 2016) Inpatient Rehabilitation Facility Quality Reporting (Implemented 2014) Long-Term Care Hospital Quality Reporting (Implemented 2013) Prospective Payment System-Exempt Cancer Hospital Quality Reporting (Implemented 2013) Inpatient Rehabilitation Facility Compare (Implemented 2011) Long-Term Care Hospital Compare (Implemented 2011)
0139	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	Hospital Acquired Condition Reduction Program (Implemented 2014) Hospital Compare (Implemented 2018) Hospital Value-Based Purchasing (Implemented 2016) Long-Term Care Hospital Quality Reporting (Implemented 2013) Prospective Payment System-Exempt Cancer Hospital Quality Reporting (Implemented 2013) Long-Term Care Hospital Compare (Implemented 2011)
0419	Documentation of Current Medications in the Medical Record	Merit-Based Incentive Payment System (MIPS) Program (Implemented 2018) Medicaid Promoting Interoperability Program for Eligible Professionals (Implemented 2019)
0468	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization	Hospital Compare (Implemented 2010) Hospital Value-Based Purchasing (Implemented 2014)

[a] Per CMS Measures Inventory Tool as of 07/13/21

NQF #	Title	Federal Programs: Finalized or Implemented as of June 30, 2021
0531	[CMS] [Recalibrated] Patient Safety and Adverse Events Composite	Hospital Compare (Implemented 2020) Hospital Acquired Condition Reduction Program (Implemented 2017) Hospital Compare (Implemented 2014)
0537	Multifactor Fall Risk Assessment Conducted for All Patients Who Can Ambulate	Home Health Compare (Implemented 2020)
0553	Care for Older Adults Medication Review	Medicare Part C Star Rating (Implemented 2017)
0555	International Normalized Ratio Monitoring for Individuals on Warfarin (INR)	Marketplace Quality Rating System (QRS) (Implemented 2020)
0674	Application of Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay)	Home Health Compare (Implemented 2020) Nursing Home Compare (Implemented 2020) Nursing Home Quality Initiative (Implemented 2017) Long-Term Care Hospital Quality Reporting (Implemented 2016) Skilled Nursing Facility Quality Reporting (Implemented 2017) Long-Term Care Hospital Compare (Implemented 2013)
0684	Percent of Residents With a Urinary Tract Infection (Long Stay)	Nursing Home Compare (Implemented 2020) Nursing Home Quality Initiative (Implemented 2017)
0686	Percent of Residents Who Have/Had a Catheter Inserted and Left in Their Bladder (Long Stay)	Nursing Home Compare (Implemented 2020) Nursing Home Quality Initiative (Implemented 2017)
0753	American College of Surgeons Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	Hospital Value-Based Purchasing (Implemented 2016) Hospital Acquired Condition Reduction Program (Implemented 2015) Hospital Compare (Implemented 2014) Prospective Payment System-Exempt Cancer Hospital Quality Reporting (Implemented 2014)
1716	National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia Outcome Measure	Hospital Acquired Condition Reduction Program (Implemented 2016) Hospital Compare (Implemented 2016) Hospital Value-Based Purchasing (Implemented 2016) Prospective Payment System-Exempt Cancer Hospital Quality Reporting (Implemented 2017)

NQF #	Title	Federal Programs: Finalized or Implemented as of June 30, 2021
1717	National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Clostridium Difficile Infection (CDI) Outcome Measure	Hospital Acquired Condition Reduction Program (Implemented 2016) Hospital Compare (Implemented 2016) Hospital Value-Based Purchasing (Implemented 2016) Inpatient Rehabilitation Facility Quality Reporting (Implemented 2016) Long-Term Care Hospital Quality Reporting (Implemented 2016) Prospective Payment System-Exempt Cancer Hospital Quality Reporting (Implemented 2017) Inpatient Rehabilitation Facility Compare (Implemented 2014) Long-Term Care Hospital Compare (Implemented 2013)
1893	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization	Hospital Value-Based Purchasing (Implemented 2020) Hospital Compare (Implemented 2015)
2720	National Healthcare Safety Network (NHSN) Antimicrobial Use Measure	None
2726	Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections	Merit-Based Incentive Payment System (MIPS) Program (Implemented 2018)
2940	Use of Opioids at High Dosage in Persons Without Cancer (OHD-AD)	None
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities	None

Appendix C: Patient Safety Standing Committee and NQF Staff

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Appendix D: Measure Specifications

0500 Severe Sepsis and Septic Shock: Management Bundle

Steward

Henry Ford Hospital

Description

This measure focuses on adults 18 years and older with a diagnosis of severe sepsis or septic shock. Consistent with Surviving Sepsis Campaign guidelines, it assesses measurement of lactate, obtaining blood cultures, administering broad spectrum antibiotics, fluid resuscitation, vasopressor administration, reassessment of volume status and tissue perfusion, and repeat lactate measurement. As reflected in the data elements and their definitions, the first three interventions should occur within three hours of presentation of severe sepsis, while the remaining interventions are expected to occur within six hours of presentation of septic shock.

Type

Composite

Data Source

Electronic Health Data, Paper Medical Records Electronic data collection software are available for purchase or under contract from vendors. Alternatively, facilities can download the free CMS Abstraction & Reporting Tool (CART). Paper tools for manual abstraction, which are posted on www.QualityNet.org, are also available for the CART tool. These tools are posted on www.QualityNet.org at this URL: https://qualitynet.cms.gov/inpatient/data-management/cart.

Level

Facility

Setting

Inpatient/Hospital

Numerator Statement

Numerator Statement: Patients who received ALL of the following:

Within three hours of presentation of severe sepsis:

- Initial lactate level measurement
- Broad spectrum or other antibiotics administered
- Blood cultures drawn prior to antibiotics

AND received within six hours of presentation of severe sepsis. ONLY if the initial lactate is elevated:

- Repeat lactate level measurement

AND within three hours of initial hypotension:

- Resuscitation with 30 mL/kg crystalloid fluids

OR within three hours of septic shock:

- Resuscitation with 30 mL/kg crystalloid fluids

AND within six hours of septic shock presentation, ONLY if hypotension persists after fluid administration:

- Vasopressors are administered

AND within six hours of septic shock presentation, if hypotension persists after fluid administration or initial lactate >= 4 mmol/L:

- Repeat volume status and tissue perfusion assessment is performed

Numerator Details

The following variables are used to calculate the numerator:

- Blood Culture Collection
- Blood Culture Collection Acceptable Delay
- Blood Culture Collection Date

- Blood Culture Collection Time
- Broad Spectrum or Other Antibiotic Administration
- Broad Spectrum or Other Antibiotic Administration Date
- Broad Spectrum or Other Antibiotic Administration Selection
- Broad Spectrum or Other Antibiotic Administration Time
- Crystalloid Fluid Administration
- Crystalloid Fluid Administration Date
- Crystalloid Fluid Administration Time
- Initial Hypotension
- Initial Hypotension Date
- Initial Hypotension Time
- Initial Lactate Level Collection
- Initial Lactate Level Date
- Initial Lactate Level Result
- Initial Lactate Level Time
- Persistent Hypotension
- Repeat Lactate Level Collection
- Repeat Lactate Level Date
- Repeat Lactate Level Time
- Repeat Volume Status and Tissue Perfusion Assessment Performed
- Repeat Volume Status and Tissue Perfusion Assessment Performed Date
- Repeat Volume Status and Tissue Perfusion Assessment Performed Time
- Septic Shock Present
- Septic Shock Presentation Date
- Septic Shock Presentation Time
- Severe Sepsis Present
- Severe Sepsis Presentation Date
- Severe Sepsis Presentation Time
- Vasopressor Administration
- Vasopressor Administration Date
- Vasopressor Administration Time

Denominator Statement

Inpatients age 18 and over with an ICD-10-CM Principal or Other Diagnosis Code of Sepsis, Severe Sepsis, or Septic Shock and not equal to U07.1 (COVID-19).

Denominator Details

Discharges age 18 and over with an ICD-10-CM Principal or Other Diagnosis Code of Sepsis, Severe Sepsis, or Septic Shock as defined in the table below:

ICD-10-CM Code	Code Description
A021	Salmonella sepsis
A227	Anthrax sepsis
A267	Erysipelothrix sepsis
A327	Listerial sepsis
A400	Sepsis due to streptococcus, group A
A401	Sepsis due to streptococcus, group B
A403	Sepsis due to Streptococcus pneumoniae
A408	Other streptococcal sepsis
A409	Streptococcal sepsis, unspecified

A4101 Sepsis due to Methicillin susceptible Staphylococcus aureus
A4102 Sepsis due to Methicillin resistant Staphylococcus aureus
A411 Sepsis due to other specified staphylococcus
A412 Sepsis due to unspecified staphylococcus
A413 Sepsis due to Hemophilus influenzae
A414 Sepsis due to anaerobes
A4150 Gram-negative sepsis, unspecified
A4151 Sepsis due to Escherichia coli [E. coli]
A4152 Sepsis due to Pseudomonas
A4153 Sepsis due to Serratia
A4159 Other Gram-negative sepsis
A4181 Sepsis due to Enterococcus
A4189 Other specified sepsis
A419 Sepsis, unspecified organism
A427 Actinomycotic sepsis
A5486 Gonococcal sepsis
R6520 Severe sepsis without septic shock
R6521 Severe sepsis with septic shock

Data elements required to calculate the denominator (in alphabetical order):

- Administrative Contraindication to Care, Septic Shock
- Administrative Contraindication to Care, Severe Sepsis
- Admission Date
- Birthdate
- Clinical Trial
- Directive for Comfort Care or Palliative Care, Septic Shock
- Directive for Comfort Care or Palliative Care, Severe Sepsis
- Discharge Date
- Discharge Disposition
- Discharge Time
- Transfer From Another Hospital or ASC

Exclusions

The following patients are excluded from the denominator:

- Patients with an ICD-10-CM Principal or Other Diagnosis Code of U07.1 (COVID-19)
- Directive for Comfort Care or Palliative Care within six hours of presentation of severe sepsis
- Directive for Comfort Care or Palliative Care within six hours of presentation of septic shock
- Administrative contraindication to care within six hours of presentation of severe sepsis
- Administrative contraindication to care within six hours of presentation of septic shock
- Length of Stay >120 days
- Transfer in from another acute care facility
- Patients enrolled in a clinical trial for sepsis, severe sepsis or septic shock treatment or intervention
- Patients with severe sepsis who are discharged within six hours of presentation
- Patients with septic shock who are discharged within six hours of presentation
- Patients receiving IV antibiotics for more than 24 hours prior to presentation of severe sepsis

Exclusion details

The following data elements are used to determine the denominator exclusions:

- Administrative Contraindication to Care, Septic Shock
- Administrative Contraindication to Care, Severe Sepsis

- Admission Date
- Birthdate
- Clinical Trial
- Directive for Comfort Care or Palliative Care, Septic Shock
- Directive for Comfort Care or Palliative Care, Severe Sepsis
- Discharge Date
- Discharge Disposition
- Discharge Time
- Transfer From Another Hospital or ASC

To determine the length of stay, the admission date and discharge date are used. If the result of the calculation subtracting the admission date from the discharge date is greater than 120 days, the patient is excluded from the measure.

Risk Adjustment

No risk adjustment or risk stratification

Stratification

N/A. This measure is not stratified.

Type Score

Rate/proportion better quality = higher score

Algorithm

The detailed measure algorithm for SEP-1 is available in the Measure Information Form (file named 2b SEP-1(508)1) in the measure specifications (found at the link referenced in S.1). Below is a high-level summary of the measure logic:

1. Identify the target population by checking whether cases have the appropriate ICD-10 CM Principal or Other Diagnosis Codes on table 4.01 of the manual (see attached code book), are 18 years or older, and have a length of stay of less than or equal to 120 days, and does not have the COVID-19 code.
2. Of the patients who meet the initial target population criteria, find the patients who qualify for the denominator by assessing for initial exclusions (Transfer From Another Hospital or ASC, Clinical Trial, Severe Sepsis not Present, Administrative Contraindication to Care, Severe Sepsis, Directive for Comfort Care or Palliative Care, Severe Sepsis, Discharge within 6 hours of Severe Sepsis Presentation).
3. Assess for completion of the following actions within 3 hours of presentation of severe sepsis:
    a. Broad Spectrum or Other Antibiotic Administration within 3 hours after Severe Sepsis Presentation Date and Time (Cases for which Broad Spectrum Antibiotic Timing is more than 24 hours before Severe Sepsis Presentation Date and Time are excluded from the measure).
    b. Blood Culture Collection Date and Time within 48 hours before to 3 hours after Severe Sepsis Presentation Date and Time and before the Broad Spectrum Administration Date and Time and Time or Blood Culture Collection Acceptable Delay = 1
    c. Initial Lactate Level Collection in the time frame between 6 hours before to 3 hours after Severe Sepsis Presentation Date and Time.
4. If the Initial Lactate Level Result is elevated (> 2 mmol/L), assess for Repeat Lactate Level Collection within 6 hours of Severe Sepsis Presentation Date and Time.
5. Assess for Septic Shock (as determined by Initial Hypotension or Initial Lactate Level Result of 4 mmol/L or higher or documentation as described by the Septic Shock Present data element). For patients with Septic Shock Present, assess for exclusions including Administrative Contraindication to Care, Septic Shock; Directive for Comfort Care or Palliative Care, Septic Shock; or Discharge Date and Time within 6 hours of Septic Shock Presentation Date and Time.
    a. For patients with Septic Shock, assess for Crystalloid Fluid Administration within 3 hours after the triggering event (Initial Hypotension Date and Time or Septic Shock Presentation Date and Time).
    b. For patients with Persistent Hypotension after fluids have been completely infused, assess for Vasopressor Administration within six hours of Septic Shock Presentation Date and Time and Repeat

Volume Status and Tissue Perfusion Assessment Performed within 6 hours of Septic Shock Presentation Date and Time

c. For patients without Persistent Hypotension after fluids have been completely infused, assess for Repeat Volume Status and Tissue Perfusion Assessment Performed within 6 hours of Septic Shock Presentation Date and Time

Cases must comply with all of the above numerator components (as applicable) in order to meet the numerator criteria. 108452| 137864| 135810| 138817| 150289

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0674 Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

Steward

Center for Medicare & Medicaid Services

Description

This measure reports the percentage of long-stay residents in a nursing home who have experienced one or more falls resulting in major injury (defined as bone fractures, joint dislocations, closed head injuries with altered consciousness, or subdural hematoma) reported in the look-back period no more than 275 days prior to the target assessment. The long stay nursing home population is defined as residents who have received 101 or more cumulative days of nursing home care by the end of the target assessment period. This measure is based on data obtained through the Minimum Data Set (MDS) 3.0 OBRA, PPS, and/or discharge assessments during the selected quarter(s).

Type

Outcome

Data Source

Assessment Data The data source is the Minimum Data Set (MDS) 3.0, and the collection instrument is the Resident Assessment Instrument (RAI). For MDS 3.0 item sets used to calculate the quality measure, please see: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIMDS30TechnicalInformation.

Level

Facility

Setting

Post-Acute Care

Numerator Statement

The numerator is the number of long-stay residents with one or more look-back scan assessments that indicate one or more falls that resulted in major injury.

Numerator Details

The numerator is the number of long-stay residents with one or more look-back scan assessments that indicate one or more falls that resulted in major injury (J1900C = [01, 02]). The selection period for the look-back scan consists of all qualifying Reason for Assessments (RFAs) (A0310A = [01, 02, 03, 04, 05, 06] or A0310B = [01] or A0310F = [10, 11]) within the current episode that have target dates no more than 275 days prior to the target assessment. A 275-day time period is used to include up to three quarterly OBRA assessments. The earliest of these assessments would have a look-back period of up to 93 days, which would cover a total of about one year. The look-back scan includes the target assessment and all qualifying earlier assessments in the scan. An earlier assessment should only be included in the scan if it meets all of the following conditions: (a) it is contained within the resident's episode, (b) it has a qualifying RFA, (c) its target date is on or before the target date for the target assessment, and (d) its target date is no more than 275 days prior to the target date of the target assessment. The Centers for Medicare & Medicaid Services (CMS) then scans the target assessment and qualifying earlier assessments to calculate the measure.

Residents are counted in the numerator if they are long-stay residents, defined as residents who have had 101 or more cumulative days of nursing home care by the end of the target period. Residents who return to the nursing home following a hospital discharge will not have their cumulative days in facility reset to zero.

An episode is defined as a period of time spanning one or more stays. An episode begins with an admission and ends with either (a) a discharge, or (b) the end of the target period, whichever comes first. Data are publicly reported on the Nursing Home Compare website and are weighted on an average of four target periods.

Denominator Statement

The denominator consists of all long-stay nursing home residents with one or more look-back scan assessments except those who meet the exclusion criteria.

Denominator Details

Residents are counted in the denominator if they are long-stay residents with one or more look-back scan assessments no more than 275 days prior to the target assessment, except those with exclusions (specified in S.8 and S.9). Long-stay residents are defined as residents who have had 101 or more cumulative days of nursing home care by the end of the target assessment period. Residents who return to the nursing home following a hospital discharge will not have their cumulative days in facility reset to zero. Target assessments may be an OBRA admission, quarterly, annual or significant change/correction assessment (A0310A = [01, 02, 03, 04, 05, 06]); or PPS 5-day assessments (A0310B = [01]); or discharge assessment with or without anticipated return (A0310F = [10, 11]).

A description of the time period for the data included in this measure is provided in S.5 above.

Exclusions

A resident is excluded from the denominator of this quality measure if all look-back scan assessments indicate that data is missing from the data element assessing falls resulting in major injury during the look-back period preceding the target assessment.

Exclusion details

A resident is excluded from the denominator if the following is true for all look-back scan assessments:

1. The number of falls with major injury was not coded (J1900C = [-]).

If the facility sample includes fewer than 20 residents after all other resident-level exclusions are applied, then the facility is suppressed from public reporting because of small sample size.

Risk Adjustment

No risk adjustment or risk stratification

Stratification

This is not applicable because this measure is not stratified.

Type Score

Rate/proportion better quality = lower score

Algorithm

Step 1: Identify the total number of long-stay residents with a qualifying target assessment (OBRA, PPS, or discharge), one or more look-back scan assessments, and who do not meet the exclusion criteria (i.e., if J1900C = [-] on the target assessment or other qualifying assessments).

Step 2: Starting with the set of residents identified in Step 1, determine the total number of long-stay residents with one or more look-back scan assessments that indicate one or more falls that resulted in major injury (J1900C = [1, 2]).

Step 3: Divide the results of step 2 by the results of step 1.

Step 4: Multiply the result of step 3 by 100 to obtain a percent value.

A description of the time period for the data included in this measure is provided in S.5 above. 141015| 151431| 152468| 150289

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n/a

0679 Percent of High Risk Residents with Pressure Ulcers (Long Stay)

Steward

Center for Medicare & Medicaid Services

Description

This measure reports the percentage of long-stay, high-risk, residents in a nursing home who have Stage II-IV or unstageable pressure ulcers on a selected target assessment in the target quarter. The long stay nursing home population is defined as residents who have received 101 or more cumulative days of nursing home care by the end of the target assessment period. A nursing home resident is defined as high-risk for pressure ulcer if they meet one or more of the following three criteria:

1. Impaired bed mobility or transfer
2. Comatose
3. Malnourished or at risk of malnutrition

This measure is based on data obtained through the Minimum Data Set (MDS) 3.0 OBRA, PPS, and/or discharge assessments during the selected quarter(s).

Type

Outcome

Data Source

Assessment Data The data source is the Minimum Data Set (MDS) 3.0, and the collection instrument is the Resident Assessment Instrument (RAI). For MDS 3.0 item sets used to calculate the quality measure, please see "MDS3.0_Final_Item_Sets_v1.17.2 for October 1 2020 zip (ZIP)" under the "Downloads" section of the following webpage:

https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIMDS30TechnicalInformation

Level

Facility

Setting

Post-Acute Care

Numerator Statement

The numerator is the number of long-stay residents identified as high-risk with a selected MDS 3.0 target assessment (OBRA quarterly, annual or significant change/correction assessments or discharge assessment with or without return anticipated) in an episode during the selected target quarter reporting one or more Stage II-IV or unstageable pressure ulcer(s) at the time of assessment. . High-risk residents are those who are comatose (B0100 = [1]), or impaired in bed mobility (G0110A1 = [3, 4, 7, 8]) or transfer (G0110B1 = [3, 4, 7, 8]), or either experiencing malnutrition or at risk for malnutrition (I5600 = [1]). Unstageable pressure ulcers are pressure ulcers that are known to be present but are defined as unstageable due to either a non-removable dressing/device (M0300E1 = [1, 2, 3, 4, 5, 6, 7, 8, or 9]), slough or eschar (M0300F1 = [1, 2, 3, 4, 5, 6, 7, 8, or 9]), or a suspected deep tissue injury (M0300G1 = [1, 2, 3, 4, 5, 6, 7, 8, or 9]).

Numerator Details

Residents are counted in the numerator if they are long-stay residents, defined as residents whose length of stay is 101 days or more, and identified as at high risk for pressure ulcer(s). Residents who return to the nursing home following a hospital discharge may not have their length of stay within the episode of care reset to zero. The numerator is the number of long-stay residents with a selected target assessment (OBRA quarterly, annual or significant change/correction assessments or discharge assessment with or without return anticipated) that meets both of the following conditions:

1. There is a high risk for pressure ulcers, where high-risk is defined in the denominator definition below.
2. Stage II-IV or unstageable pressure ulcers are present, as indicated by any of the following six conditions:

2.1 Current number of unhealed Stage II ulcers (M0300B1) = [1, 2, 3, 4, 5, 6, 7, 8, 9, or more] or

2.2 Current number of unhealed Stage III ulcers (M0300C1) = [1, 2, 3, 4, 5, 6, 7, 8, 9, or more] or

2.3 Current number of unhealed Stage IV ulcers (M0300D1) = [1, 2, 3, 4, 5, 6, 7, 8, 9, or more] or

2.4 Current number of unstageable ulcers due to non-removable dressing/device (M0300E1) = [1, 2, 3, 4, 5, 6, 7, 8, 9, or more] or

2.5 Current number of unstageable ulcers due to wound bed being covered by slough and/or eschar (M0300F1) = [1, 2, 3, 4, 5, 6, 7, 8, 9, or more] or

2.6 Current number of unstageable ulcers presenting as deep tissue injury (M0300G1) = [1, 2, 3, 4, 5, 6, 7, 8, 9, or more]

Stage 1 pressure ulcers are not included in this measure because studies have identified difficulties in objectively measuring them across different populations (Lynn et al., 2007).

Stage 2 pressure ulcer: Partial thickness loss or dermis presenting as shallow open ulcer with red or pink wound bed, without slough. May also present as an intact or open/ruptured blister.

Stage 3 pressure ulcer: Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon, or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining or tunneling.

Stage 4 pressure ulcer: Full thickness tissue loss with exposed bone or tendon, or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining or tunneling.

Non-removable dressing/device: Includes, for example, a primary surgical dressing that cannot be removed, an orthopedic device, or cast.

Slough tissue: Non-viable yellow, tan, gray, green or brown tissue; usually moist, can be soft, stringy and mucinous in texture. Slough may be adherent to the base of the wound or present in clumps throughout the wound bed.

Eschar tissue: Dead or devitalized tissue that is hard or soft in texture; usually black, brown, or tan in color, and may appear scab-like. Necrotic tissue and eschar are usually firmly adherent to the base of the wound and often the sides/ edges of the wound.

Suspected deep tissue injury: Purple or maroon area of discolored intact skin due to damage of underlying soft tissue. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

(Target assessments may be OBRA quarterly, annual or significant change/correction assessments (A0310A = 02, 03, 04, 05, 06) or discharge assessment with or without return anticipated (A0310F = 10, 11)).

Reference

1. Lynn J, West J, Hausmann S, Gifford D, Nelson R, McGann P, Bergstrom N, Ryan JA (2007). Collaborative clinical quality improvement for pressure ulcers in nursing homes. Journal of the American Geriatrics Society, 55(10), 1663-9.

Denominator Statement

The denominator includes all long-stay nursing home residents who had a target assessment (ORBA, PPS, or discharge) during the selected quarter who were identified as high risk for pressure ulcer, and who do not meet the exclusion criteria.

Denominator Details

Residents are counted in the denominator if they are long-stay residents, defined as residents whose length of stay is 101 days or more. Residents who return to the nursing home following a hospital discharge may not have their length of stay within the episode of care reset to zero. The denominator is the number of long-stay residents with a selected target assessment (assessment types include: a quarterly, annual, significant change/correction admission OBRA assessment (A0310A = 02, 03, 04, 05, 06); or discharge with or without return anticipated (A0310F = 10, 11)) during the selected quarter, except those with exclusions. Residents must be high risk for pressure ulcer where high risk is defined by meeting one of the following criteria on the selected target assessment:

1. Impaired bed mobility or transfer:

1.1 This is indicated by a level of assistance reported on either item G0110A1, Bed mobility (self-performance) or G0110B1 Transfer (self-performance) at the level of: extensive assistance (3), total dependence (4), activity occurred only once or twice (7) OR activity or any part of the ADL was not performed by resident or staff at all over the entire 7 day period (8), or

2. Comatose (B0100 = [1] (yes)), or

3. Malnutrition [protein or calorie] or at risk for malnutrition (I5600 = [1])

Exclusions

A resident is excluded from the denominator if:

1. The target MDS assessment is an OBRA admission assessment or a PPS 5-day assessment or a PPS readmission/return assessment.
2. The resident did not meet the pressure ulcer conditions for the numerator and any Stage II, III, IV, or unstageable item is missing (M0300B1 = [-] or M0300C1 = [-] or M0300D1 = [-] or M0300E1 = [-] or M0300F1 = [-] or M0300G1 = [-]).

If the facility sample includes fewer than 20 residents, then the facility is excluded from public reporting because of small sample size.

Exclusion details

A long-stay resident is excluded from the denominator if the MDS assessment in the current quarter is an OBRA admission assessment or a PPS 5-day assessment:

1. OBRA admission assessment (A0310A = [01]), or
2. 5-Day PPS assessment (A0310B = [01]), or

In addition, a resident is excluded if the resident did not meet the pressure ulcer conditions for the numerator AND any of the following conditions are true:

1. M0300B1 (Current number of unhealed Stage II ulcers) = [-] (missing)
2. M0300C1 (Current number of unhealed Stage III ulcers) = [-] (missing)
3. M0300D1 (Current number of unhealed Stage IV ulcers) = [-] (missing)
4. M0300E1 (Current number of unstageable ulcers due to non-removable dressing/device) = [-] (missing)
5. M0300F1 (Current number of unstageable ulcers due to coverage of wound bed by slough or eschar) = [-] (missing)
6. M0300G1 (Current number of unstageable ulcers with suspected deep tissue injury in evolution) = [-] (missing)

Nursing homes are excluded from public reporting because of small sample size if their sample includes fewer than 20 residents.

Risk Adjustment

Other Other: Sample restriction - this measure is restricted to residents who are at high risk for pressure ulcers. Residents are identified as high risk if they meet any of the following three criteria: 1. Impaired in bed mobility or transfer, or 2. Comatose, or 3. Active diagnosis of malnutrition [protein or calorie] identified, or resident is at risk for malnutrition. (See denominator details for more information) This measure was originally developed as one of a pair of stratified pressure ulcer measures – one low-risk and one high-risk. The low-risk measure is no longer reported or maintained.

Stratification

This measure is not stratified.

Type Score

Rate/proportion better quality = lower score

Algorithm

Step 1: For each facility, identify the total number (sum) of high risk long-stay residents with a target assessment meeting the denominator criteria.

Step 2: Starting with the set of residents identified in Step 1, determine the number of high-risk long-stay residents in the numerator (i.e. the total number with stage II, III, IV, or unstageable ulcers at target assessment).

Step 3: Divide the result of Step 2 by the result of Step 1. 151431| 152468

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3389 Concurrent Use of Opioids and Benzodiazepines (COB)

Steward

PQA, Inc.

Description

The percentage of individuals >=18 years of age with concurrent use of prescription opioids and benzodiazepines during the measurement year.

A lower rate indicates better performance.

Type

Process

Data Source

Claims, Enrollment Data Administrative claims: prescription claims, medical claims, enrollment data

Level

Health Plan

Setting

Outpatient Services

Numerator Statement

The number of individuals from the denominator with concurrent use of opioids and benzodiazepines for >=30 cumulative days during the measurement year.

Numerator Details

The number of individuals from the denominator with:

- >=2 prescription claims for any benzodiazepine with different dates of service, AND
- Concurrent use of opioids and benzodiazepines for >=30 cumulative days.

Complete the steps below to identify individuals with concurrent use of opioids and benzodiazepines:

Step 1: From the denominator population, identify individuals with >=2 prescription claims with different dates of service for any benzodiazepine (Table COB-B, below) during the measurement year.

Step 2: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

NOTE:

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 3: Count the individuals with concurrent use for >=30 cumulative days. This is the numerator.

Table COB-B: Benzodiazepines:

Alprazolam, chlordiazepoxide, clobazam, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, triazolam

(Note: excludes injectable formulations, includes combination products)

Denominator Statement

The denominator includes individuals >=18 years of age with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Individuals with cancer, sickle cell disease, or in hospice are excluded.

Denominator Details

The denominator includes individuals 18 years and older by the first day of the measurement year with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Use Table COB-A: Opioids, below, to identify the opioid medications for the measure.

Complete the steps below to determine the denominator:

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Table COB-A: Opioids:

Benzhydrocodone, buprenorphine, butorphanol, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol

(note: includes combination products and prescription opioid cough medications. Excludes the following: injectable formulations; sublingual sufentanil (used in a supervised setting); and single-agent and combination buprenorphine products used to treat opioid use disorder (i.e., buprenorphine sublingual tablets, Probuphine® Implant kit subcutaneous implant, and all buprenorphine/naloxone combination products).

Exclusions

Individuals with cancer, sickle cell disease, or in hospice at any point during the measurement year are excluded from the denominator.

Exclusion details

Hospice exclusion: Exclude any individual in hospice during the measurement year. To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

Cancer exclusion: Exclude any individuals with cancer during the measurement year. To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

Sickle Cell Disease exclusion: Exclude any individual with sickle cell disease during the measurement year.

- =1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

Risk Adjustment

No risk adjustment or risk stratification

Stratification

Type Score

Rate/proportion better quality = lower score

Algorithm

A. Target population (denominator):

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Step 5: Identify individuals with cancer, sickle cell disease or in hospice during the measurement year.

To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g., Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

To identify individuals with sickle cell disease:

- >=1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

Step 6: Exclude individuals with cancer, sickle cell disease, or in hospice (Step 5) from those identified in Step 4. This is the denominator.

B. Numerator Population:

Step 7: From the denominator population, identify individuals with >=2 prescriptions claims with different dates of service for any benzodiazepines (Table COB-B, below) during the measurement year.

Step 8: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the

measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

- Note: When identifying days' supply for opioids (or benzodiazepines):
- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 9: Count the number of individuals with concurrent use of opioids and benzodiazepines for >=30 cumulative days. This is the numerator.

C. Measure Rate:

Step 10: Divide the number of individuals in the numerator (Step 9) by the denominator (Step 6) and multiply by 100. This is the measure rate reported as a percentage.

- Report the rates separately by line of business (e.g. Medicare, Medicaid, Commercial). 135614| 141015| 139698

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3621 Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Steward

American College of Radiology

Description

Measure title continued: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single phase scan and CT Head/Brain without contrast/single phase scan)

Description: Weighted average of 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single phase scan and CT Head/Brain without contrast/single phase scan)

Type

Composite

Data Source

Registry Data Clinical data registry (ACR National Radiology Data Registry - Dose Index Registry)

Level

Facility, Clinician : Group/Practice

Setting

Emergency Department and Services, Inpatient/Hospital, Other, Outpatient Services Dialysis Facility

Numerator Statement

Number of CT Abdomen-Pelvis exams with contrast (single phase scan), CT Chest exams without contrast (single phase scan), and CT Head/Brain exams without contrast (single phase scan) for which Dose Length Product is at or below the size-specific exam-specific diagnostic reference level

Numerator Details

Dose length product; CTDIw Phantom Type; Effective Diameter (calculated from localizer image); size specific exam-specific diagnostic reference level.

These components capture how well radiation exposure from the scanner is adjusted for patient size, using size-specific exam-level diagnostic reference levels and how well total radiation exposure to a patient from an exam is optimized based on the CT dose index dose-length product (DLP).

Denominator Statement

Number of CT Abdomen-pelvis exams with contrast (single phase scans), CT Chest exams without contrast (single phase scans), and CT Head/Brain (single phase scans)

Target population: all patients regardless of age.

Denominator Details

Study description; Exam date; Acquisition protocol

Target population: all patients who require either a CT Abdomen-pelvis exam with contrast (single phase scans), a CT Chest exam without contrast (single phase scans), and/or a CT Head/Brain (single phase scans) exam regardless of age.

Exclusions

No denominator exclusions

Exclusion details

No denominator exclusions

Risk Adjustment

Stratification by risk category/subgroup

Stratification

The measure calculation is stratified by patient size. The results are not reported separately by the stratification variable.

Type Score

Rate/proportion better quality = higher score

Algorithm

Target population is all patients regardless of age.

To calculate the denominator for each of the measures we include all exams that are mapped to a standardized exam name/study description that corresponds to one of the three exam types used for measures, has a localizer image to permit size assessment, and has non-zero values for dose indices.

To calculate the numerator:

Head exams are categorized using lateral thickness (size) from scout images submitted by facilities. Body exams (chest and abdomen/pelvis) are categorized using the effective diameter (size) that ACR calculates from scout images. The numerator consists of the total number of exams among the denominator that are at or below the size specific DRL.

To calculate the performance rate, the numerator (Total number of exams among the denominator that are at or below the size specific DRL) is divided by the denominator (submitted eligible records) and multiplied by 100 to indicate the percentage. Physician groups/facilities may compare their performance to other facilities using aggregate registry level benchmarks.

Step 1: Denominator: Total number of exams that were mapped to one of the 3 exam names, had a non-zero DLP and a non-zero CTDIvol, CTDIvol<DLP, age was not missing, and patient size is available

Step 2: Numerator: Total number of exams among the denominator that are at or below the size specific DRL

Step 3: Percentage at or below size-specific DRL for each body part: (Numerator/Denominator)*100

Step 4: Percentage of all exams at or below size-specific DRL. Alternately, calculate weighted average of component measures, where weight is number of records for each body part.

Composite score:

Each component measure percentile score is weighted by the denominator count. The weighted scores are summed then divided by the sum of weights of all 3. Alternatively, the numerator and denominator counts for each measure can be totaled then averaged by 3.

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Example:

	Numerator	Denominator	Rate
Head	3000	8000	38%
Abdomen/Pelvis	5000	10000	50%
Chest	2000	5000	40%
All	10000	23000	43%
Weighted average			43%

Weighted average = (Weight Head x Rate Head) + (Weight Abdomen/Pelvis x Rate Abdomen/Pelvis) + (Weight Chest x Rate Chest)))/Sum of weights of all 3 145989| 151468

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n/a

3501e Hospital Harm – Opioid-Related Adverse Events

Steward

Centers for Medicare & Medicaid Services

Description

This measure assesses the proportion of inpatient hospital encounters where patients ages 18 years of age or older have been administered an opioid medication, subsequently suffer the harm of an opioid-related adverse event, and are administered an opioid antagonist (naloxone) within 12 hours. This measure excludes opioid antagonist (naloxone) administration occurring in the operating room setting.

Type

Outcome

Data Source

Electronic Health Records Hospitals collect EHR data using certified electronic health record technology (CEHRT). The MAT output, which includes the human readable and XML artifacts of the clinical quality language (CQL) for the measure are contained in the eCQM specifications attached. No additional tools are used for data collection for eCQMs.

Level

Facility

Setting

Inpatient/Hospital

Numerator Statement

Inpatient hospitalizations where an opioid antagonist (naloxone) was administered outside of the operating room and within 12 hours following administration of an opioid medication. Only one numerator event is counted per encounter.

Numerator Details

This is an eCQM, and therefore uses electronic health record data to calculate the measure score. The time period for data collection is during an inpatient hospitalization, beginning at hospital arrival (whether through emergency department, observation stay, or directly admitted as inpatient).

All data elements necessary to calculate this measure are defined within value sets available in the Value Set Authority Center (VSAC), and listed below.

The Opioid antagonist (naloxone) is defined by the value set Opioid Antagonist (2.16.840.1.113752.1.4.1179.1).

Opioids are defined by the value set Opioids, All (2.16.840.1.113762.1.4.1196.226).

The location for opioid administration is defined by the code Operating Room/Suite (HSLOC Code 1096-7).

To access the value sets for the measure, please visit the Value Set Authority Center (VSAC), sponsored by the National Library of Medicine, at https://vsac.nlm.nih.gov/.

Denominator Statement

Inpatient hospitalizations for patients 18 years or older during which at least one opioid medication was administered. An inpatient hospitalization includes time spent in the emergency department or in observation status when the patients are ultimately admitted to inpatient status.

Denominator Details

This measure includes all patients aged 18 years and older at the time of admission, and all payers. Measurement period is one year. This measure is at the hospital admission level; only one numerator event is counted per encounter.

Inpatient Encounters are represented using the value set of Encounter Inpatient (2.16.840.1.113883.3.666.5.307).

Emergency Department visits are represented using the value set of Emergency Department Visit (2.16.840.1.113883.3.117.1.7.1.292).

Patients whom had observation encounters are represented using the value set of Observation Services (2.16.840.1.113762.1.4.1111.143).

Opioids are defined by the value set Opioids, All (2.16.840.1.113762.1.4.1196.226).

To access the value sets for the measure, please visit the Value Set Authority Center, sponsored by the National Library of Medicine, at https://vsac.nlm.nih.gov/.

Exclusions

N/A; there are no denominator exclusions

Exclusion details

N/A

Risk Adjustment

No risk adjustment or risk stratification

Stratification

N/A; this measure is not stratified.

Type Score

Rate/proportion better quality = lower score

Algorithm

This measure defines the indication of a harm for an opioid-related adverse event by assessing administration of an opioid antagonist (naloxone).

To calculate the hospital-level measure result, divide the total numerator events by the total number of qualifying encounters (denominator).

Qualifying encounters (denominator) include all patients 18 years of age or older at the start of the encounter with at least one opioid medication administered during the encounter.

To create the numerator:

1. First, start with those encounters meeting denominator criteria
2. Next, remove all events where an opioid antagonist (naloxone) was only administered in the operating room.

Opioid antagonist administrations in the operating room are excluded because they could be part be part of the sedation plan as administered by an anesthesiologist. Encounters that include use of opioid antagonists for procedures and recovery outside of the operating room (e.g., bone marrow biopsy and PACU) are included in the numerator, as it would indicate the patient was over-sedated. Note that should a facility not utilize temporary patient locations, alternative times may be used to determine whether a patient is in the operating room during opioid antagonist administration. Since anesthesia end time could represent the time the anesthesiologist signed off, and thus may include the patient's time in the PACU, this should be avoided.

3. Finally, remove all administrations of naloxone that were given greater than 12 hours following hospital administration of an opioid medication .

This eCQM is an episode-based measure.

This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. 144762| 146433| 149896| 149897| 110874| 150289

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Appendix E: Related and Competing Measures

Comparison of NQF #0500 and NQF #3215

0500: Severe Sepsis and Septic Shock: Management Bundle
3215: Adult Inpatient Risk Adjusted Sepsis Mortality

Steward

0500: Severe Sepsis and Septic Shock: Management Bundle

Henry Ford Hospital

3215: Adult Inpatient Risk Adjusted Sepsis Mortality

New York State Department of Health, Office of Quality and Patient Safety

Description

0500: Severe Sepsis and Septic Shock: Management Bundle

This measure focuses on adults 18 years and older with a diagnosis of severe sepsis or septic shock. Consistent with Surviving Sepsis Campaign guidelines, it assesses measurement of lactate, obtaining blood cultures, administering broad spectrum antibiotics, fluid resuscitation, vasopressor administration, reassessment of volume status and tissue perfusion, and repeat lactate measurement. As reflected in the data elements and their definitions, the first three interventions should occur within three hours of presentation of severe sepsis, while the remaining interventions are expected to occur within six hours of presentation of septic shock.

3215: Adult Inpatient Risk Adjusted Sepsis Mortality

Annual risk adjusted inpatient mortality rate for adult patients (aged 18 and over) admitted to acute care hospitals with diagnosis of severe sepsis or septic shock. The measure includes patients in acute care hospital settings over one year timeframe who had, either on admission, or during their hospital stay, a clinical diagnosis of severe sepsis (now referred to as 'sepsis') or septic shock using criteria described in the International Sepsis Definitions (Sepsis-2)

Hospitals were required to submit a protocol for early identification and treatment of severe sepsis or septic shock. Subsequent to protocol submission, hospitals were required to submit 100% of their patient cases to a data collection portal using a standardized data dictionary (see relevant sections for details). Numerous data elements including patient demographics and comorbidities among other patient care details were reported. A random sample of the data submissions were validated for accuracy. The full adult data for discharges within calendar year 2015 was used to generate statewide and hospital-specific risk adjusted mortality rates for the calendar year.

Type

0500: Severe Sepsis and Septic Shock: Management Bundle

Composite

3215: Adult Inpatient Risk Adjusted Sepsis Mortality

Outcome

Data Source

0500: Severe Sepsis and Septic Shock: Management Bundle

Electronic Health Data, Paper Medical Records Electronic data collection software are available for purchase or under contract from vendors. Alternatively, facilities can download the free CMS Abstraction & Reporting Tool (CART). Paper tools for manual abstraction, which are posted on www.QualityNet.org, are also available for the CART tool. These tools are posted on www.QualityNet.org at this URL: https://qualitynet.cms.gov/inpatient/data-management/cart.

No data collection instrument provided Attachment Appendix-A1_v5.9.xls

3215: Adult Inpatient Risk Adjusted Sepsis Mortality

Assessment Data, Claims, Electronic Health Data, Management Data, Paper Medical Records, Registry Data Data collection is performed via a standardized clinical data dictionary (see Appendix) with set specified data fields which may be electronically extracted via custom record abstraction queries and/or manually abstracted, all of which conclude with a plain-text comma-delimited file. The file is submitted over a secure encrypted connection to an electronic data collection portal (https://ny.sepsis.ipro.org) that validates all data and all conditional bounds of data subject to an electronic machine-readable version of the data dictionary which parses not only valid data but also ensures that all "if then" statements are conditionally valid, e.g. ""left_ed_datetime cannot be before triage_datetime"". All required data elements must be completed for the submission to be accepted by the portal. Data errors such as conditional logic failures or missing data are returned to the submitter for correction prior to data acceptance. The portal maintains valid dictionaries for all reporting periods such that historical data may be submitted and validated against historical versions of the data dictionary.

Valid data is passed on to the analytic process, invalid data is destroyed and an error returned to the submitter with detailed failure reasons and a requirement to resubmit the data upon correction. Full data submission is validated through facility volume comparison charts across prior data quarters and years.

Available in attached appendix at A.1 Attachment Sepsis_Data_Dictionary_3.0_pub-636214687710592961.pdf

Level

0500: Severe Sepsis and Septic Shock: Management Bundle

Facility

3215: Adult Inpatient Risk Adjusted Sepsis Mortality

Facility

Setting

0500: Severe Sepsis and Septic Shock: Management Bundle

Inpatient/Hospital

3215: Adult Inpatient Risk Adjusted Sepsis Mortality

Inpatient/Hospital

Numerator Statement

0500: Severe Sepsis and Septic Shock: Management Bundle

Numerator Statement: Patients who received ALL of the following:

Within three hours of presentation of severe sepsis:

- Initial lactate level measurement
- Broad spectrum or other antibiotics administered
- Blood cultures drawn prior to antibiotics

AND received within six hours of presentation of severe sepsis. ONLY if the initial lactate is elevated:

- Repeat lactate level measurement

AND within three hours of initial hypotension:

- Resuscitation with 30 mL/kg crystalloid fluids

OR within three hours of septic shock:

- Resuscitation with 30 mL/kg crystalloid fluids

AND within six hours of septic shock presentation, ONLY if hypotension persists after fluid administration:

- Vasopressors are administered

AND within six hours of septic shock presentation, if hypotension persists after fluid administration or initial lactate >= 4 mmol/L:

- Repeat volume status and tissue perfusion assessment is performed

3215: Adult Inpatient Risk Adjusted Sepsis Mortality

Outcome is risk adjusted inpatient mortality rate for adult patients (18 and over) admitted to an acute care hospital with a diagnosis of severe sepsis or septic shock or who develop severe sepsis or septic shock during their hospital stay.

Numerator Details

0500: Severe Sepsis and Septic Shock: Management Bundle

The following variables are used to calculate the numerator:

- Blood Culture Collection
- Blood Culture Collection Acceptable Delay
- Blood Culture Collection Date
- Blood Culture Collection Time
- Broad Spectrum or Other Antibiotic Administration
- Broad Spectrum or Other Antibiotic Administration Date
- Broad Spectrum or Other Antibiotic Administration Selection
- Broad Spectrum or Other Antibiotic Administration Time
- Crystalloid Fluid Administration
- Crystalloid Fluid Administration Date
- Crystalloid Fluid Administration Time
- Initial Hypotension
- Initial Hypotension Date
- Initial Hypotension Time

- Initial Lactate Level Collection
- Initial Lactate Level Date
- Initial Lactate Level Result
- Initial Lactate Level Time
- Persistent Hypotension
- Repeat Lactate Level Collection
- Repeat Lactate Level Date
- Repeat Lactate Level Time
- Repeat Volume Status and Tissue Perfusion Assessment Performed
- Repeat Volume Status and Tissue Perfusion Assessment Performed Date
- Repeat Volume Status and Tissue Perfusion Assessment Performed Time
- Septic Shock Present
- Septic Shock Presentation Date
- Septic Shock Presentation Time
- Severe Sepsis Present
- Severe Sepsis Presentation Date
- Severe Sepsis Presentation Time
- Vasopressor Administration
- Vasopressor Administration Date
- Vasopressor Administration Time

3215: Adult Inpatient Risk Adjusted Sepsis Mortality

Inpatient mortality is noted on data submission from hospital. Clinical variables needed for risk adjustment including demographics, co-morbidities, severity, and potential exclusions are reported by hospital as described in the data dictionary.

Denominator Statement

0500: Severe Sepsis and Septic Shock: Management Bundle

Inpatients age 18 and over with an ICD-10-CM Principal or Other Diagnosis Code of Sepsis, Severe Sepsis, or Septic Shock and not equal to U07.1 (COVID-19).

3215: Adult Inpatient Risk Adjusted Sepsis Mortality

All adult patient discharges (18 and over) in a calendar year with a diagnosis of severe sepsis or septic shock on admission or at any time during their hospital stay. This may include multiple admissions of the same patient during the measurement year. Denominator includes all cases identified using any means (administrative, registry, electronic health records, billing data, etc.), either prospectively, retrospectively, or both, that meet the International consensus definition (Sepsis- 2) of severe sepsis or septic shock.

Denominator Details

0500: Severe Sepsis and Septic Shock: Management Bundle

Discharges age 18 and over with an ICD-10-CM Principal or Other Diagnosis Code of Sepsis, Severe Sepsis, or Septic Shock as defined in the table below:

ICD-10-CM Code Code Description

A021	Salmonella sepsis
A227	Anthrax sepsis
A267	Erysipelothrix sepsis
A327	Listerial sepsis
A400	Sepsis due to streptococcus, group A
A401	Sepsis due to streptococcus, group B
A403	Sepsis due to Streptococcus pneumoniae
A408	Other streptococcal sepsis
A409	Streptococcal sepsis, unspecified
A4101	Sepsis due to Methicillin susceptible Staphylococcus aureus
A4102	Sepsis due to Methicillin resistant Staphylococcus aureus
A411	Sepsis due to other specified staphylococcus
A412	Sepsis due to unspecified staphylococcus
A413	Sepsis due to Hemophilus influenzae
A414	Sepsis due to anaerobes
A4150	Gram-negative sepsis, unspecified
A4151	Sepsis due to Escherichia coli [E. coli]
A4152	Sepsis due to Pseudomonas
A4153	Sepsis due to Serratia
A4159	Other Gram-negative sepsis
A4181	Sepsis due to Enterococcus
A4189	Other specified sepsis
A419	Sepsis, unspecified organism
A427	Actinomycotic sepsis
A5486	Gonococcal sepsis
R6520	Severe sepsis without septic shock
R6521	Severe sepsis with septic shock

Data elements required to calculate the denominator (in alphabetical order):

- Administrative Contraindication to Care, Septic Shock
- Administrative Contraindication to Care, Severe Sepsis
- Admission Date
- Birthdate
- Clinical Trial
- Directive for Comfort Care or Palliative Care, Septic Shock
- Directive for Comfort Care or Palliative Care, Severe Sepsis
- Discharge Date
- Discharge Disposition
- Discharge Time
- Transfer From Another Hospital or ASC

3215: Adult Inpatient Risk Adjusted Sepsis Mortality

All adult patients meeting International consensus definition (Sepsis-2) for Severe Sepsis/Septic shock identified through combination of any relevant hospital clinical and/or administrative databases, prospectively or retrospectively.

Exclusions

0500: Severe Sepsis and Septic Shock: Management Bundle

The following patients are excluded from the denominator:

- Patients with an ICD-10-CM Principal or Other Diagnosis Code of U07.1 (COVID-19)
- Directive for Comfort Care or Palliative Care within six hours of presentation of severe sepsis
- Directive for Comfort Care or Palliative Care within six hours of presentation of septic shock
- Administrative contraindication to care within six hours of presentation of severe sepsis
- Administrative contraindication to care within six hours of presentation of septic shock
- Length of Stay >120 days
- Transfer in from another acute care facility
- Patients enrolled in a clinical trial for sepsis, severe sepsis or septic shock treatment or intervention
- Patients with severe sepsis who are discharged within six hours of presentation
- Patients with septic shock who are discharged within six hours of presentation
- Patients receiving IV antibiotics for more than 24 hours prior to presentation of severe sepsis

3215: Adult Inpatient Risk Adjusted Sepsis Mortality

Patients with advanced directives in place prior to episode of sepsis which specifically restrict any hospital specific sepsis protocol interventions or who decline (or their proxy declines) treatment for sepsis. Patients who have been transferred from one acute care hospital to another are excluded.

Exclusion Details

0500: Severe Sepsis and Septic Shock: Management Bundle

The following data elements are used to determine the denominator exclusions:

- Administrative Contraindication to Care, Septic Shock
- Administrative Contraindication to Care, Severe Sepsis
- Admission Date
- Birthdate
- Clinical Trial
- Directive for Comfort Care or Palliative Care, Septic Shock
- Directive for Comfort Care or Palliative Care, Severe Sepsis
- Discharge Date
- Discharge Disposition
- Discharge Time

- Transfer From Another Hospital or ASC

To determine the length of stay, the admission date and discharge date are used. If the result of the calculation subtracting the admission date from the discharge date is greater than 120 days, the patient is excluded from the measure.

3215: Adult Inpatient Risk Adjusted Sepsis Mortality

Patients who have any of the following characteristics, reported on data variables fully described in the data dictionary, are excluded from the calculation of risk adjusted mortality rates for a specific hospital:

1. Advanced Directives in place prior to diagnosis of severe sepsis or septic shock that specifically preclude active treatment according to that hospital's protocol for severe sepsis and septic shock.
2. Patient or patient proxy refusal of treatment for severe sepsis or septic shock according to that hospital's protocol for severe sepsis and septic shock.
3. Patients who were transferred between acute care hospitals.

Risk Adjustment

0500: Severe Sepsis and Septic Shock: Management Bundle

No risk adjustment or risk stratification

3215: Adult Inpatient Risk Adjusted Sepsis Mortality

Statistical risk model

Stratification

0500: Severe Sepsis and Septic Shock: Management Bundle

N/A. This measure is not stratified.

3215: Adult Inpatient Risk Adjusted Sepsis Mortality

Stratification

The analysis was not stratified for different populations since there was only a single population studied: patients with sepsis. However in the risk adjusted logistic regression model there are categorical variables that represent either patient demographics or patient clinical characteristics. This mix of variables generates the probability of mortality across the levels of the categorical variable. For example septic shock diagnosis is in the model so a probability of hospital mortality could be generated for both severe sepsis and for septic shock.

Type Score

0500: Severe Sepsis and Septic Shock: Management Bundle

Rate/proportion better quality = higher score

3215: Adult Inpatient Risk Adjusted Sepsis Mortality

Rate/proportion better quality = lower score

Algorithm

0500: Severe Sepsis and Septic Shock: Management Bundle

The detailed measure algorithm for SEP-1 is available in the Measure Information Form (file named 2b SEP-1(508)1) in the measure specifications (found at the link referenced in S.1). Below is a high-level summary of the measure logic:

1. Identify the target population by checking whether cases have the appropriate ICD-10 CM Principal or Other Diagnosis Codes on table 4.01 of the manual (see attached code book), are 18 years or older, and have a length of stay of less than or equal to 120 days, and does not have the COVID-19 code.
2. Of the patients who meet the initial target population criteria, find the patients who qualify for the denominator by assessing for initial exclusions (Transfer From Another Hospital or ASC, Clinical Trial, Severe Sepsis not Present, Administrative Contraindication to Care, Severe Sepsis, Directive for Comfort Care or Palliative Care, Severe Sepsis, Discharge within 6 hours of Severe Sepsis Presentation).
3. Assess for completion of the following actions within 3 hours of presentation of severe sepsis:
    a. Broad Spectrum or Other Antibiotic Administration within 3 hours after Severe Sepsis Presentation Date and Time (Cases for which Broad Spectrum Antibiotic Timing is more than 24 hours before Severe Sepsis Presentation Date and Time are excluded from the measure).
    b. Blood Culture Collection Date and Time within 48 hours before to 3 hours after Severe Sepsis Presentation Date and Time and before the Broad Spectrum Administration Date and Time and Time or Blood Culture Collection Acceptable Delay = 1
    c. Initial Lactate Level Collection in the time frame between 6 hours before to 3 hours after Severe Sepsis Presentation Date and Time.
4. If the Initial Lactate Level Result is elevated (> 2 mmol/L), assess for Repeat Lactate Level Collection within 6 hours of Severe Sepsis Presentation Date and Time.
5. Assess for Septic Shock (as determined by Initial Hypotension or Initial Lactate Level Result of 4 mmol/L or higher or documentation as described by the Septic Shock Present data element). For patients with Septic Shock Present, assess for exclusions including Administrative Contraindication to Care, Septic Shock; Directive for Comfort Care or Palliative Care, Septic Shock; or Discharge Date and Time within 6 hours of Septic Shock Presentation Date and Time.
    a. For patients with Septic Shock, assess for Crystalloid Fluid Administration within 3 hours after the triggering event (Initial Hypotension Date and Time or Septic Shock Presentation Date and Time).
    b. For patients with Persistent Hypotension after fluids have been completely infused, assess for Vasopressor Administration within six hours of Septic Shock Presentation Date and Time and Repeat Volume Status and Tissue Perfusion Assessment Performed within 6 hours of Septic Shock Presentation Date and Time
    c. For patients without Persistent Hypotension after fluids have been completely infused, assess for Repeat Volume Status and Tissue Perfusion Assessment Performed within 6 hours of Septic Shock Presentation Date and Time

Cases must comply with all of the above numerator components (as applicable) in order to meet the numerator criteria.

3215: Adult Inpatient Risk Adjusted Sepsis Mortality

Setting

The study objective was to develop a logistic regression model to estimate the probability of hospital mortality among septic patients entering 179 New York State hospitals over the period of January 1, 2015 through December 31, 2015. The a priori analysis plan eliminated

any patient with an advanced directive or who declined interventions. When a patient was discharged from a hospital as “transfer to acute care”, only the patient’s data from the receiving hospital was used in the dataset. If a patient was in the dataset multiple times for sepsis, only the final admission was used. This preserved the outcome of interest (mortality) and observation independence in the data file for developing logistic regression models. This resulted in a database total of 43,204 septic patients. The a priori analysis used only patient demographics, comorbidities, and admission characteristics to estimate the probability of hospital mortality. Specifically treatment variables were not used in the model.

Septic patients

All subjects entered into the model met the admitting hospital’s criteria for severe sepsis or septic shock. Severe sepsis was defined as a suspected or confirmed infection, at least two systemic manifestations of infection and one or more acute organ dysfunctions. Septic shock was defined as severe sepsis where at least one organ dysfunction with sustained hypotension after a fluid challenge. For this paper, the term sepsis or septic represents the dataset population of severe sepsis and septic shock patients. Mortality is defined as in-hospitals deaths.

Statistical Methods

Logistic regression developed a model to estimate the probability of mortality for patients with severe sepsis or septic shock during their hospital stay. A list of the possible predictor variables and definitions are given in Table 1. Maximum likelihood was used to estimate model coefficients and associated standard errors. The hierarchical nature of the data supports random-effects logistic regression use since patients are nested within the 179 hospitals. However, the 179 random-effect coefficients would have made the resulting model specific only to those 179 New York hospitals and would not be generalizable to patients outside these specific hospitals. A random sample of 10% (N = 4,319) of the observations were set aside and the logistic regression model was developed on the remaining 90% (38,884 observations). The final model was validated on the 10% of observations that were set aside. Patient comorbidities were generated using the list shown in supplemental Table S1. We generated a variable called mechanical ventilation (MV) severity that indicated a severity of illness relating to mechanical ventilation. This dichotomous variable was defined when a patient was admitted to the hospital already mechanically ventilated or requiring mechanical ventilation within 6 hours post admission. Initial serum lactate was not measured in 2,528 (5.9%) patients and was imputed using single imputation. Specifically, truncated linear regression was used during the imputation procedure where the lower limit of left truncation was set at a serum lactate level 0.1 mmol/L (1st percentile) and the upper limit of the right truncation was set at 30.0 mmol/L (99th percentile). A list of predictor variables is shown in supplemental Table S2.

A multivariable logistic regression model was built using the developmental dataset and starting with all possible covariates in the model. Using an iterative procedure, variables were removed from the model, one by one, if their p-values were not significant at 0.05 level until a parsimonious model was reached. Variables removed during the development procedure were added back into the model if their p-values were significant at the 0.05 level and if model calibration (Hosmer-Lemeshow goodness of fit) was improved through their inclusion. We then assessed the scale of the 3 continuous variables (patient age, first serum lactate, and the count of the number of comorbidities) remaining in the model. Specifically, we were interested in determining whether these variables had a linear relationship with mortality. Using the method of fractional polynomials patient age was

included in the model as a linear term, the number of comorbidities was transformed by taking the square root of the number of comorbidities, and first serum lactate was entered into the model as a quadratic expression (linear and a squared term). Model calibration was further improved by adding the following interactions to the model: lower respiratory infection (LRI) and MV severity, patient age and the square root of the number of comorbidities, and first serum lactate and the square root of the number of comorbidities.

Model calibration was assessed using the Hosmer-Lemeshow goodness of fit on both the developmental and the validation datasets. Group sizes of 10, 100, 500, and 1,000 were chosen for the large, developmental, dataset while group sizes of 10, 50, 100, and 150 were chosen for the smaller validation dataset. Model discrimination was assessed using the area under the receiver operating characteristic (ROC) curve for both the developmental and validation datasets.

The estimated probability of mortality was generated using the model coefficients and the specific patient attributes. If the patient attribute is defined by a categorical variable, then the possible values are either a 0 or 1. If the attribute is defined by a continuous variable, then the specific value is used such as the patient's age. Interaction values are generated by multiplying the values of each of the two individual variables defined by the interaction. The product of the coefficient and the patient's value for all of the variables in the model are generated. Next the logit is defined as the sum of the above products. Finally, the probability of mortality for a specific patient is generated using the follow equation:

Probability of mortality= exp(logit)/(1+exp(logit))

Submission items

0500: Severe Sepsis and Septic Shock: Management Bundle

5.1 Identified measures: 3215 : Adult Inpatient Risk Adjusted Sepsis Mortality

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: The two measures, NQF 0500 and NQF 3215, have similar populations but are different measure types; NQF 0500 assesses the performance rates of sepsis care processes and NQF 3215 evaluates the impact sepsis care processes have on an outcome, mortality rates. NQF 3215 uses NQF0500 data elements for many of its measure process adherence variables. NQF 3215 collects additional demographic variables (e.g., Source of Admission, Pregnancy Status), the actual lactate value and variables for severity adjustment and morbidity, which are used for risk adjustment. The New York State Sepsis Improvement Initiative adult composite bundle and NQF 0500 include many identical data elements and several similar data elements, which are harmonized with version 5.7 of the SEP-1 measure specifications. Key differences include that the New York State measure requires that hospitals in New York report all cases of severe sepsis and septic shock and does not exclude cases transferred to other hospitals. The New York State measure also requires that hospitals report the actual lactate level numerically rather than categorically as in SEP-1 and has one variation in the types of blood cultures accepted for the Blood Culture Acceptable Delay data element.

5b.1 If competing, why superior or rationale for additive value: Not applicable; there are no competing measures for evaluation.

3215: Adult Inpatient Risk Adjusted Sepsis Mortality

5.1 Identified measures:

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value:

Comparison of NQF #0674 and NQF #0101

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)
0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Steward

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

Center for Medicare & Medicaid Services

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

National Committee for Quality Assurance

Description

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

This measure reports the percentage of long-stay residents in a nursing home who have experienced one or more falls resulting in major injury (defined as bone fractures, joint dislocations, closed head injuries with altered consciousness, or subdural hematoma) reported in the look-back period no more than 275 days prior to the target assessment. The long stay nursing home population is defined as residents who have received 101 or more cumulative days of nursing home care by the end of the target assessment period. This measure is based on data obtained through the Minimum Data Set (MDS) 3.0 OBRA, PPS, and/or discharge assessments during the selected quarter(s).

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates:

A) Screening for Future Fall Risk:

Percentage of patients aged 65 years and older who were screened for future fall risk at least once within 12 months

B) Falls Risk Assessment:

Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months

C) Plan of Care for Falls:

Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months

Type

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

Outcome

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Process

Data Source

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

Assessment Data The data source is the Minimum Data Set (MDS) 3.0, and the collection instrument is the Resident Assessment Instrument (RAI). For MDS 3.0 item sets used to

calculate the quality measure, please see: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIMDS30TechnicalInformation.

Available at measure-specific web page URL identified in S.1 No data dictionary

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Claims, Electronic Health Records, Paper Medical Records This measure is based on administrative claims to identify the eligible population and medical record documentation collected in the course of providing care to patients to identify the numerator.

In the Physician Quality Reporting System (PQRS) program this measure is coded using CPT Category II specific to quality measurement.

No data collection instrument provided No data dictionary

Level

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

Facility

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Clinician : Group/Practice, Clinician : Individual

Setting

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

Post-Acute Care

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Outpatient Services, Post-Acute Care

Numerator Statement

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

The numerator is the number of long-stay residents with one or more look-back scan assessments that indicate one or more falls that resulted in major injury.

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

This measure has three rates. The numerators for the three rates are as follows:

A) Screening for Future Fall Risk: Patients who were screened for future fall risk* at last once within 12 months

B) Falls Risk Assessment: Patients who had a risk assessment** for falls completed within 12 months

C) Plan of Care for Falls: Patients with a plan of care*** for falls documented within 12 months.

*Screening for Future Fall Risk: Assessment of whether an individual has experienced a fall or problems with gait or balance. A specific screening tool is not required for this measure, however potential screening tools include the Morse Fall Scale and the timed Get-Up-And-Go test.

**Risk assessment is comprised of balance/gait assessment AND one or more of the following assessments: postural blood pressure, vision, home fall hazards, and documentation on whether medications are a contributing factor or not to falls within the past 12 months.

***Plan of care must include exercise therapy or referral to an exercise.

Numerator Details

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

The numerator is the number of long-stay residents with one or more look-back scan assessments that indicate one or more falls that resulted in major injury (J1900C = [01, 02]). The selection period for the look-back scan consists of all qualifying Reason for Assessments (RFAs) (A0310A = [01, 02, 03, 04, 05, 06] or A0310B = [01] or A0310F = [10, 11]) within the current episode that have target dates no more than 275 days prior to the target assessment. A 275-day time period is used to include up to three quarterly OBRA assessments. The earliest of these assessments would have a look-back period of up to 93 days, which would cover a total of about one year. The look-back scan includes the target assessment and all qualifying earlier assessments in the scan. An earlier assessment should only be included in the scan if it meets all of the following conditions: (a) it is contained within the resident's episode, (b) it has a qualifying RFA, (c) its target date is on or before the target date for the target assessment, and (d) its target date is no more than 275 days prior to the target date of the target assessment. The Centers for Medicare & Medicaid Services (CMS) then scans the target assessment and qualifying earlier assessments to calculate the measure.

Residents are counted in the numerator if they are long-stay residents, defined as residents who have had 101 or more cumulative days of nursing home care by the end of the target period. Residents who return to the nursing home following a hospital discharge will not have their cumulative days in facility reset to zero.

An episode is defined as a period of time spanning one or more stays. An episode begins with an admission and ends with either (a) a discharge, or (b) the end of the target period, whichever comes first. Data are publicly reported on the Nursing Home Compare website and are weighted on an average of four target periods.

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

This measure has three rates. The numerator for each rate is met by documentation in the medical record as follows:

A) Screening for Future Fall Risk: Documentation of an evaluation completed in the 12-month measurement period of whether the adult has experienced a fall or problems with balance or gait. A specific screening tool is not required for this measure.

B) Falls Risk Assessment: Documentation of a falls risk assessment completed in the 12 month measurement period comprised of balance/gait AND one or more of the following: postural blood pressure, vision, home fall hazards, and documentation on whether medications are a contributing factor or not to falls within the past 12 months. All components do not need to be completed during a single patient visit, but should be documented in the medical record as having been performed within the past 12 months.

Balance/gait: (1) Documentation of observed transfer and walking, or (2) Use of a standardized scale (eg, Get Up & Go, Berg, Tinetti), or (3) Documentation of referral for assessment of balance/gait

Postural blood pressure: Documentation of blood pressure values in standing and supine positions

Vision: (1) Documentation that patient is functioning well with vision or not functioning well with vision based on discussion with the patient, or (2) Use of a standardized scale or assessment tool (eg, Snellen), or (3) Documentation of referral for assessment of vision

Home fall hazards: (1) Documentation of counseling on home falls hazards, or (2) Documentation of inquiry of home fall hazards, or (3) referral for evaluation of home fall hazards.

Medications: Documentation of whether the patient's current medications may or may not contribute to falls.

C) Plan of Care to Prevent Future Falls: Documentation of a plan of care completed in the 12-month measurement period, which includes at a minimum exercise therapy or referral to an exercise. Documentation of exercise therapy may include any of the following:

- Documentation of exercise provided or referral to an exercise program
- Balance/gait training or instructions provided or referral for balance/gait training
- Physical therapy provided or referral to physical therapy
- Occupational therapy provided or referral for occupational therapy

This measure is also collected in the Quality Payment Program using CPT Category II codes specific to the quality measure rates:

3288F: Falls risk assessment documented

0518F: Falls plan of care documented

Denominator Statement

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

The denominator consists of all long-stay nursing home residents with one or more look-back scan assessments except those who meet the exclusion criteria.

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

A) Screening for Future Fall Risk: All patients aged 65 years and older seen by an eligible provider in the past year.

B & C) Falls Risk Assessment & Plan of Care for Falls: All patients aged 65 years and older seen by an eligible provider in the past year with a history of falls (history of falls is defined as 2 or more falls in the past year or any fall with injury in the past year).

Denominator Details

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

Residents are counted in the denominator if they are long-stay residents with one or more look-back scan assessments no more than 275 days prior to the target assessment, except those with exclusions (specified in S.8 and S.9). Long-stay residents are defined as residents who have had 101 or more cumulative days of nursing home care by the end of the target assessment period. Residents who return to the nursing home following a hospital discharge will not have their cumulative days in facility reset to zero. Target assessments may be an OBRA admission, quarterly, annual or significant change/correction assessment (A0310A = [01, 02, 03, 04, 05, 06]); or PPS 5-day assessments (A0310B = [01]); or discharge assessment with or without anticipated return (A0310F = [10, 11]).

A description of the time period for the data included in this measure is provided in S.5 above.

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

The Screening for Futures Fall Rate is used to identify the denominator for the remaining two rates, Falls Risk Assessment and Falls Plan of Care.

A) Screening for Future Fall Risk: Patients are included in the denominator if they have been seen by a healthcare practitioner during the measurement period. Use the following CPT codes to identify encounters that meet inclusion criteria:

92540, 92541, 92542, 92548, 97001, 97002, 97003, 97004, 99201, 99202, 99203, 99204, 99205,99211, 99212, 99213, 99214, 99215, , 99304, 99305, 99306, 99307, 99308, 99309, 99310, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350, G0344, G0402, G0438, G0439

B & C) Falls Risk Assessment & Plan of Care for Falls: Patients are included in the denominator if they have been seen by a healthcare practitioner during the measurement period and have a documented history of falls (two or more falls or one fall with injury in the past year). Documentation of patient reported history of falls is sufficient. Use the following CPT codes to identify encounters that meet inclusion criteria:

92540, 92541, 92542, 92548, 97001, 97002, 97003, 97004, 99201, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99304, 99305, 99306, 99307, 99308, 99309, 99310, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350, G0402, G0438, G0439

This measure is also collected in the Quality Payment Program using a CPT Category II code specific to the quality measure to identify the denominator for Falls Risk Assessment & Plan of Care for Falls:

1100F: Patient screened for future fall risk; documentation of two or more falls in the past year.

Exclusions

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

A resident is excluded from the denominator of this quality measure if all look-back scan assessments indicate that data is missing from the data element assessing falls resulting in major injury during the look-back period preceding the target assessment.

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Adults who are not ambulatory are excluded from all 3 rates of this measure.

Exclude members who use hospice services during the measurement period.

Exclude members who use hospice services during the measurement period.

Exclusion Details

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

A resident is excluded from the denominator if the following is true for all look-back scan assessments:

1. The number of falls with major injury was not coded (J1900C = [-]).

If the facility sample includes fewer than 20 residents after all other resident-level exclusions are applied, then the facility is suppressed from public reporting because of small sample size.

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Adults who are not ambulatory, bed ridden, immobile, confined to chair, wheelchair users that are dependent on helper pushing wheelchair, or independent in wheelchair, or require minimal help in wheelchair are excluded from all 3 rates of this measure. These adults are excluded because the assessments and corresponding plans of care for these individuals would address a different set of falls risk factors and interventions than those addressed in this measure.

In the CMS Quality Payment Program CPT Category II codes specific to the quality measure are used to identify exclusions:

3288F with 1P: Documentation of medical reason(s) for not completing a risk assessment for falls

0518F with 1P: Documentation of medical reason(s) for no plan of care for falls

Exclude patients who used hospice services during the measurement period.

G9718 (Falls Risk Assessment)

G9720 (Falls Plan of Care)

Risk Adjustment

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

No risk adjustment or risk stratification

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

No risk adjustment or risk stratification

Stratification

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

This is not applicable because this measure is not stratified.

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

N/A

Type Score

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

Rate/proportion better quality = lower score

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Rate/proportion better quality = higher score

Algorithm

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

Step 1: Identify the total number of long-stay residents with a qualifying target assessment (OBRA, PPS, or discharge), one or more look-back scan assessments, and who do not meet the exclusion criteria (i.e., if J1900C = [-] on the target assessment or other qualifying assessments).

Step 2: Starting with the set of residents identified in Step 1, determine the total number of long-stay residents with one or more look-back scan assessments that indicate one or more falls that resulted in major injury (J1900C = [1, 2]).

Step 3: Divide the results of step 2 by the results of step 1.

Step 4: Multiply the result of step 3 by 100 to obtain a percent value.

A description of the time period for the data included in this measure is provided in S.5 above.

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

This measure is reported at three rates calculated by creating a fraction with the following components: Denominator, Numerator, and Exclusions.

Step 1: Determine the eligible population. The eligible population is all patients aged 65 years and older.

Step 2: Determine number of patients meeting the denominator criteria for Rate 1- Screening specified in Section S.7 above. The denominator includes all patients 65 and up seen by a health care provider in the 12-month measurement period.

Step 3: Identify patients with valid exclusions and remove from the denominator (step 2). Adults who are not ambulatory are excluded from this measure (see Exclusion details above).

Step 4. Identify the number of adults who meet the numerator criteria for Rate 1 - Screening specified in section S.5 above. The numerator includes all adults in Step 3 who were screened for fall risk as least once within the 12-month measurement period.

Step 5. Divide the number of adults in Step 4 by the number of adults in Step 3 to calculate Rate 1 – Screening.

Step 6. From adults identified in Step 4, identify adults who have a documented history of falls (at least two falls or one fall with injury in the past year).

Step 7. From the adults identified in Step 6, identify the number of adults who meet the numerator criteria for Rate 2 - Risk Assessment for falls as specified in section S.5 above. The numerator includes all adults in Step 6 who received a risk assessment within the 12-month measurement period.

Step 8. Divide the number of adults in Step 7 by the number of adults in Step 6 to calculate Rate 2 – Risk Assessment.

Step 9. From the adults identified in step 6, identify the number of adults who meet the numerator criteria for Rate 3 – Plan of Care as specified in section S.5 above. The numerator includes all adults in Step 6 with a documented plan of care for falls within the 12-month measurement period.

Step 10. Divide the number of adults in Step 8 by the number of adults in Step 9 to calculate Rate 3 – Plan of Care.

Submission items

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

5.1 Identified measures: 0101 : Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

0141 : Patient Fall Rate

0202 : Falls with injury

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: #0202 Falls with Injury - Acute Care Prevention of Falls (rate of inpatient falls with injury per 1,000 patient days): This measure has a similar focus as NQF #0674, but it is different because it focuses on adult acute care inpatient and adult rehabilitation patients and is reported as a rate

rather than a percentage. Additionally, this measure includes any injury from minor to major. This is an important distinction. Focusing on falls with minor injury could potentially create inappropriate incentives for nursing homes to reduce resident opportunity for mobility and independence. The selection of the outcome of falls with major injury for NQF #0674 was deliberate to reduce this potential adverse unintended consequence. #0101 Falls Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls: This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates: 1) screening: percentage of patients aged 65 years of age and older who were screened for future fall risk at least once within 12 months; 2) falls risk assessment: percentage of patients aged 65 years of age and older with a history of falls who had a risk assessment for falls completed within 12 months; and 3) plan of care for falls: percentage of patients aged 65 years of age and older with a history of falls who had a plan of care for falls documented within 12 months. This measure is different in that it is a process measure, rather than an outcome measure. #0141 Patient Fall Rate (Total number of patient falls [with or without injury to the patient and whether or not assisted by a staff member] by hospital unit during the calendar month X 1000): This measure has a similar focus as NQF #0674, but it is different because it focuses on the adult acute care inpatient and adult rehabilitation patients and does not discriminate between falls with and without injuries, which is an important distinction. Focusing on falls with minor injury could potentially create inappropriate incentives for nursing homes to reduce resident opportunity for mobility. The selection of the outcome of falls with major injury for NQF #0674 was deliberate to reduce this potential adverse unintended consequence.

5b.1 If competing, why superior or rationale for additive value: This is not applicable. There are no competing measures.

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

5.1 Identified measures: 0035 : Fall Risk Management (FRM)

0141 : Patient Fall Rate

0202 : Falls with injury

0537 : Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: See 5b.1. for more information.

5b.1 If competing, why superior or rationale for additive value: NQF# 0141 measures patient fall rate in the hospital setting during one month. This measure is related but not competing. The target population is different (#0141 – adults in the hospital setting) and the measure concept is different (#0141 rate of falls outcome measure).

NQF #0202 measures patient fall with injury rate in the hospital setting. This measure is related but not competing. The target population is different (#0202 – adults in the hospital setting) and the measure concept is different (#0202 – rate of falls with injury outcome measure).

NQF #0537 measures risk assessment for falls in the home health setting. This measure is related but not competing. The target populations overlap; however the level of analysis and data source are different. NQF #0537 focuses on patient in the home health setting and uses a survey data sources (OASIS) that is not available for patients in the outpatient ambulatory care setting.

NQF #0035 measures falls risk management for all older adults across all settings. This measure is related but not competing. The target population is the same; however the

level of analysis and data source are different. NQF #0035 is a health plan level measure and uses patient reported information. Measure #0035 is currently under review to conceptually harmonize the measure elements with #0101 where appropriate.

5b.1.No competing measures.

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Steward

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

Center for Medicare & Medicaid Services

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

National Committee for Quality Assurance

Description

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

This measure reports the percentage of long-stay residents in a nursing home who have experienced one or more falls resulting in major injury (defined as bone fractures, joint dislocations, closed head injuries with altered consciousness, or subdural hematoma) reported in the look-back period no more than 275 days prior to the target assessment. The long stay nursing home population is defined as residents who have received 101 or more cumulative days of nursing home care by the end of the target assessment period. This measure is based on data obtained through the Minimum Data Set (MDS) 3.0 OBRA, PPS, and/or discharge assessments during the selected quarter(s).

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates:

A) Screening for Future Fall Risk:

Percentage of patients aged 65 years and older who were screened for future fall risk at least once within 12 months

B) Falls Risk Assessment:

Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months

C) Plan of Care for Falls:

Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months

Type

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

Outcome

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Process

Data Source

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

Assessment Data The data source is the Minimum Data Set (MDS) 3.0, and the collection instrument is the Resident Assessment Instrument (RAI). For MDS 3.0 item sets used to calculate the quality measure, please see: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIMDS30TechnicalInformation.

Available at measure-specific web page URL identified in S.1 No data dictionary

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Claims, Electronic Health Records, Paper Medical Records This measure is based on administrative claims to identify the eligible population and medical record documentation collected in the course of providing care to patients to identify the numerator.

In the Physician Quality Reporting System (PQRS) program this measure is coded using CPT Category II specific to quality measurement.

No data collection instrument provided No data dictionary

Level

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

Facility

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Clinician : Group/Practice, Clinician : Individual

Setting

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

Post-Acute Care

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Outpatient Services, Post-Acute Care

Numerator Statement

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

The numerator is the number of long-stay residents with one or more look-back scan assessments that indicate one or more falls that resulted in major injury.

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

This measure has three rates. The numerators for the three rates are as follows:

A) Screening for Future Fall Risk: Patients who were screened for future fall risk* at last once within 12 months

B) Falls Risk Assessment: Patients who had a risk assessment** for falls completed within 12 months

C) Plan of Care for Falls: Patients with a plan of care*** for falls documented within 12 months.

*Screening for Future Fall Risk: Assessment of whether an individual has experienced a fall or problems with gait or balance. A specific screening tool is not required for this measure, however potential screening tools include the Morse Fall Scale and the timed Get-Up-And-Go test.

**Risk assessment is comprised of balance/gait assessment AND one or more of the following assessments: postural blood pressure, vision, home fall hazards, and documentation on whether medications are a contributing factor or not to falls within the past 12 months.

***Plan of care must include exercise therapy or referral to an exercise.

Numerator Details

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

The numerator is the number of long-stay residents with one or more look-back scan assessments that indicate one or more falls that resulted in major injury (J1900C = [01, 02]). The selection period for the look-back scan consists of all qualifying Reason for Assessments (RFAs) (A0310A = [01, 02, 03, 04, 05, 06] or A0310B = [01] or A0310F = [10, 11]) within the current episode that have target dates no more than 275 days prior to the target assessment. A 275-day time period is used to include up to three quarterly OBRA assessments. The earliest of these assessments would have a look-back period of up to 93 days, which would cover a total of about one year. The look-back scan includes the target assessment and all qualifying earlier assessments in the scan. An earlier assessment should only be included in the scan if it meets all of the following conditions: (a) it is contained within the resident's episode, (b) it has a qualifying RFA, (c) its target date is on or before the target date for the target assessment, and (d) its target date is no more than 275 days prior to the target date of the target assessment. The Centers for Medicare & Medicaid Services (CMS) then scans the target assessment and qualifying earlier assessments to calculate the measure.

Residents are counted in the numerator if they are long-stay residents, defined as residents who have had 101 or more cumulative days of nursing home care by the end of the target period. Residents who return to the nursing home following a hospital discharge will not have their cumulative days in facility reset to zero.

An episode is defined as a period of time spanning one or more stays. An episode begins with an admission and ends with either (a) a discharge, or (b) the end of the target period, whichever comes first. Data are publicly reported on the Nursing Home Compare website and are weighted on an average of four target periods.

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

This measure has three rates. The numerator for each rate is met by documentation in the medical record as follows:

A) Screening for Future Fall Risk: Documentation of an evaluation completed in the 12-month measurement period of whether the adult has experienced a fall or problems with balance or gait. A specific screening tool is not required for this measure.

B) Falls Risk Assessment: Documentation of a falls risk assessment completed in the 12 month measurement period comprised of balance/gait AND one or more of the following: postural blood pressure, vision, home fall hazards, and documentation on whether medications are a contributing factor or not to falls within the past 12 months. All components do not need to be completed during a single patient visit, but should be documented in the medical record as having been performed within the past 12 months.

Balance/gait: (1) Documentation of observed transfer and walking, or (2) Use of a standardized scale (eg, Get Up & Go, Berg, Tinetti), or (3) Documentation of referral for assessment of balance/gait

Postural blood pressure: Documentation of blood pressure values in standing and supine positions

Vision: (1) Documentation that patient is functioning well with vision or not functioning well with vision based on discussion with the patient, or (2) Use of a standardized scale or assessment tool (eg, Snellen), or (3) Documentation of referral for assessment of vision

Home fall hazards: (1) Documentation of counseling on home falls hazards, or (2) Documentation of inquiry of home fall hazards, or (3) referral for evaluation of home fall hazards.

Medications: Documentation of whether the patient's current medications may or may not contribute to falls.

C) Plan of Care to Prevent Future Falls: Documentation of a plan of care completed in the 12-month measurement period, which includes at a minimum exercise therapy or referral to an exercise. Documentation of exercise therapy may include any of the following:

- Documentation of exercise provided or referral to an exercise program
- Balance/gait training or instructions provided or referral for balance/gait training
- Physical therapy provided or referral to physical therapy
- Occupational therapy provided or referral for occupational therapy

This measure is also collected in the Quality Payment Program using CPT Category II codes specific to the quality measure rates:

3288F: Falls risk assessment documented

0518F: Falls plan of care documented

Denominator Statement

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

The denominator consists of all long-stay nursing home residents with one or more look-back scan assessments except those who meet the exclusion criteria.

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

A) Screening for Future Fall Risk: All patients aged 65 years and older seen by an eligible provider in the past year.

B & C) Falls Risk Assessment & Plan of Care for Falls: All patients aged 65 years and older seen by an eligible provider in the past year with a history of falls (history of falls is defined as 2 or more falls in the past year or any fall with injury in the past year).

Denominator Details

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

Residents are counted in the denominator if they are long-stay residents with one or more look-back scan assessments no more than 275 days prior to the target assessment, except those with exclusions (specified in S.8 and S.9). Long-stay residents are defined as residents who have had 101 or more cumulative days of nursing home care by the end of the target assessment period. Residents who return to the nursing home following a hospital discharge will not have their cumulative days in facility reset to zero. Target assessments may be an OBRA admission, quarterly, annual or significant change/correction assessment (A0310A = [01, 02, 03, 04, 05, 06]); or PPS 5-day assessments (A0310B = [01]); or discharge assessment with or without anticipated return (A0310F = [10, 11]).

A description of the time period for the data included in this measure is provided in S.5 above.

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

The Screening for Futures Fall Rate is used to identify the denominator for the remaining two rates, Falls Risk Assessment and Falls Plan of Care.

A) Screening for Future Fall Risk: Patients are included in the denominator if they have been seen by a healthcare practitioner during the measurement period. Use the following CPT codes to identify encounters that meet inclusion criteria:

92540, 92541, 92542, 92548, 97001, 97002, 97003, 97004, 99201, 99202, 99203, 99204, 99205,99211, 99212, 99213, 99214, 99215, , 99304, 99305, 99306, 99307, 99308, 99309, 99310, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350, G0344, G0402, G0438, G0439

B & C) Falls Risk Assessment & Plan of Care for Falls: Patients are included in the denominator if they have been seen by a healthcare practitioner during the measurement period and have a documented history of falls (two or more falls or one fall with injury in the past year). Documentation of patient reported history of falls is sufficient. Use the following CPT codes to identify encounters that meet inclusion criteria:

92540, 92541, 92542, 92548, 97001, 97002, 97003, 97004, 99201, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99304, 99305, 99306, 99307, 99308, 99309, 99310, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350, G0402, G0438, G0439

This measure is also collected in the Quality Payment Program using a CPT Category II code specific to the quality measure to identify the denominator for Falls Risk Assessment & Plan of Care for Falls:

1100F: Patient screened for future fall risk; documentation of two or more falls in the past year.

Exclusions

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

A resident is excluded from the denominator of this quality measure if all look-back scan assessments indicate that data is missing from the data element assessing falls resulting in major injury during the look-back period preceding the target assessment.

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Adults who are not ambulatory are excluded from all 3 rates of this measure.

Exclude members who use hospice services during the measurement period.

Exclude members who use hospice services during the measurement period.

Exclusion Details

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

A resident is excluded from the denominator if the following is true for all look-back scan assessments:

1. The number of falls with major injury was not coded (J1900C = [-]).

If the facility sample includes fewer than 20 residents after all other resident-level exclusions are applied, then the facility is suppressed from public reporting because of small sample size.

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Adults who are not ambulatory, bed ridden, immobile, confined to chair, wheelchair users that are dependent on helper pushing wheelchair, or independent in wheelchair, or require minimal help in wheelchair are excluded from all 3 rates of this measure. These adults are excluded because the assessments and corresponding plans of care for these individuals would address a different set of falls risk factors and interventions than those addressed in this measure.

In the CMS Quality Payment Program CPT Category II codes specific to the quality measure are used to identify exclusions:

3288F with 1P: Documentation of medical reason(s) for not completing a risk assessment for falls

0518F with 1P: Documentation of medical reason(s) for no plan of care for falls

Exclude patients who used hospice services during the measurement period.

G9718 (Falls Risk Assessment)

G9720 (Falls Plan of Care)

Risk Adjustment

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

No risk adjustment or risk stratification

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

No risk adjustment or risk stratification

Stratification

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

This is not applicable because this measure is not stratified.

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

N/A

Type Score

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

Rate/proportion better quality = lower score

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Rate/proportion better quality = higher score

Algorithm

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

Step 1: Identify the total number of long-stay residents with a qualifying target assessment (OBRA, PPS, or discharge), one or more look-back scan assessments, and who do not meet the exclusion criteria (i.e., if J1900C = [-] on the target assessment or other qualifying assessments).

Step 2: Starting with the set of residents identified in Step 1, determine the total number of long-stay residents with one or more look-back scan assessments that indicate one or more falls that resulted in major injury (J1900C = [1, 2]).

Step 3: Divide the results of step 2 by the results of step 1.

Step 4: Multiply the result of step 3 by 100 to obtain a percent value.

A description of the time period for the data included in this measure is provided in S.5 above.

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

This measure is reported at three rates calculated by creating a fraction with the following components: Denominator, Numerator, and Exclusions.

Step 1: Determine the eligible population. The eligible population is all patients aged 65 years and older.

Step 2: Determine number of patients meeting the denominator criteria for Rate 1- Screening specified in Section S.7 above. The denominator includes all patients 65 and up seen by a health care provider in the 12-month measurement period.

Step 3: Identify patients with valid exclusions and remove from the denominator (step 2). Adults who are not ambulatory are excluded from this measure (see Exclusion details above).

Step 4. Identify the number of adults who meet the numerator criteria for Rate 1 - Screening specified in section S.5 above. The numerator includes all adults in Step 3 who were screened for fall risk as least once within the 12-month measurement period.

Step 5. Divide the number of adults in Step 4 by the number of adults in Step 3 to calculate Rate 1 – Screening.

Step 6. From adults identified in Step 4, identify adults who have a documented history of falls (at least two falls or one fall with injury in the past year).

Step 7. From the adults identified in Step 6, identify the number of adults who meet the numerator criteria for Rate 2 - Risk Assessment for falls as specified in section S.5 above. The numerator includes all adults in Step 6 who received a risk assessment within the 12-month measurement period.

Step 8. Divide the number of adults in Step 7 by the number of adults in Step 6 to calculate Rate 2 – Risk Assessment.

Step 9. From the adults identified in step 6, identify the number of adults who meet the numerator criteria for Rate 3 – Plan of Care as specified in section S.5 above. The numerator includes all adults in Step 6 with a documented plan of care for falls within the 12-month measurement period.

Step 10. Divide the number of adults in Step 8 by the number of adults in Step 9 to calculate Rate 3 – Plan of Care.

Submission items

0674: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

5.1 Identified measures: 0101 : Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

0141 : Patient Fall Rate

0202 : Falls with injury

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: #0202 Falls with Injury - Acute Care Prevention of Falls (rate of inpatient falls with injury per 1,000 patient days): This measure has a similar focus as NQF #0674, but it is different because it focuses on adult acute care inpatient and adult rehabilitation patients and is reported as a rate rather than a percentage. Additionally, this measure includes any injury from minor to major. This is an important distinction. Focusing on falls with minor injury could potentially create inappropriate incentives for nursing homes to reduce resident opportunity for mobility and independence. The selection of the outcome of falls with major injury for NQF #0674 was deliberate to reduce this potential adverse unintended consequence. #0101 Falls Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls: This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates: 1) screening: percentage of patients aged 65 years of age and older who were screened for future fall risk at least once within 12 months; 2) falls risk assessment: percentage of patients aged 65 years of age and older with a history of falls who had a risk assessment for falls completed within 12 months; and 3) plan of care for falls: percentage of patients aged 65 years of age and older with a history of falls who had a plan of care for falls documented within 12 months. This measure is different in that it is a process measure, rather than an outcome measure. #0141 Patient Fall Rate (Total number of patient falls [with or without injury to the patient and whether or not assisted by a staff member] by hospital unit during the calendar month X 1000): This measure has a similar focus as NQF #0674, but it is different because it focuses on the adult acute care inpatient and adult rehabilitation patients and does not discriminate between falls with and without injuries, which is an important distinction. Focusing on falls with minor injury could potentially create inappropriate incentives for nursing homes to reduce resident opportunity for mobility. The selection of the outcome of falls with major injury for NQF #0674 was deliberate to reduce this potential adverse unintended consequence.

5b.1 If competing, why superior or rationale for additive value: This is not applicable. There are no competing measures.

0101: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

5.1 Identified measures: 0035 : Fall Risk Management (FRM)

0141 : Patient Fall Rate

0202 : Falls with injury

0537 : Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: See 5b.1. for more information.

5b.1 If competing, why superior or rationale for additive value: NQF# 0141 measures patient fall rate in the hospital setting during one month. This measure is related but not competing. The target population is different (#0141 – adults in the hospital setting) and the measure concept is different (#0141 rate of falls outcome measure).

NQF #0202 measures patient fall with injury rate in the hospital setting. This measure is related but not competing. The target population is different (#0202 – adults in the hospital setting) and the measure concept is different (#0202 – rate of falls with injury outcome measure).

NQF #0537 measures risk assessment for falls in the home health setting. This measure is related but not competing. The target populations overlap; however the level of analysis and data source are different. NQF #0537 focuses on patient in the home health setting

and uses a survey data sources (OASIS) that is not available for patients in the outpatient ambulatory care setting.

NQF #0035 measures falls risk management for all older adults across all settings. This measure is related but not competing. The target population is the same; however the level of analysis and data source are different. NQF #0035 is a health plan level measure and uses patient reported information. Measure #0035 is currently under review to conceptually harmonize the measure elements with #0101 where appropriate.

5b.1.No competing measures.

Comparison of NQF #3389 and NQF #2940

3389: Concurrent Use of Opioids and Benzodiazepines (COB)
2940: Use of Opioids at High Dosage in Persons Without Cancer

Steward

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

PQA, Inc.

2940: Use of Opioids at High Dosage in Persons Without Cancer

Pharmacy Quality Alliance

Description

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The percentage of individuals >=18 years of age with concurrent use of prescription opioids and benzodiazepines during the measurement year.

A lower rate indicates better performance.

2940: Use of Opioids at High Dosage in Persons Without Cancer

The percentage of individuals >=18 years of age who received prescriptions for opioids with an average daily dosage of >=90 morphine milligram equivalents (MME) over a period of >=90 days.

A lower rate indicates better performance.

Type

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Process

2940: Use of Opioids at High Dosage in Persons Without Cancer

Process

Data Source

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Claims, Enrollment Data Administrative claims: prescription claims, medical claims, enrollment data

No data collection instrument provided Attachment pqa_meas_yr_2019_cob_value_sets_20200729_NQF.xlsx

2940: Use of Opioids at High Dosage in Persons Without Cancer

Claims, Electronic Health Data, Enrollment Data Health Plan Medical and Pharmacy Claims. Health Plan member enrollment information.

No data collection instrument provided Attachment Cancer_Exclusion_Codes.xlsx

Level

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Health Plan

2940: Use of Opioids at High Dosage in Persons Without Cancer

Health Plan, Other, Population : Regional and State

Setting

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Outpatient Services

2940: Use of Opioids at High Dosage in Persons Without Cancer

Other, Outpatient Services The level of analysis for this measure is the prescription drug health plan, but it contains claims data from multiple care settings, including ambulatory, skilled nursing facility, pharmacy etc.

Numerator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with concurrent use of opioids and benzodiazepines for >=30 cumulative days during the measurement year.

2940: Use of Opioids at High Dosage in Persons Without Cancer

The numerator includes individuals from the denominator with an average daily dosage >=90 MME during the opioid episode.

Numerator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with:

- >=2 prescription claims for any benzodiazepine with different dates of service, AND
- Concurrent use of opioids and benzodiazepines for >=30 cumulative days.

Complete the steps below to identify individuals with concurrent use of opioids and benzodiazepines:

Step 1: From the denominator population, identify individuals with >=2 prescription claims with different dates of service for any benzodiazepine (Table COB-B, below) during the measurement year.

Step 2: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

NOTE:

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 3: Count the individuals with concurrent use for >=30 cumulative days. This is the numerator.

Table COB-B: Benzodiazepines:

Alprazolam, chlordiazepoxide, clobazam, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, triazolam

(Note: excludes injectable formulations, includes combination products)

2940: Use of Opioids at High Dosage in Persons Without Cancer

The numerator includes individuals from the denominator with an average daily dosage >=90 MME during the opioid episode.

1. For each individual in the denominator population, identify all opioid prescription claims (Table Opioid-A) during the opioid episode.
2. Calculate the daily MME for each opioid prescription claim during the opioid episode, using the following equation: [Strength * (Quantity Dispensed / Days' Supply)] * MME conversion factor. The strength and MME conversion factor are provided for each NDC code in the NDC file.

Examples:

10 mg oxycodone tablets X (120 tablets / 30 days) X 1.5 = 60 MME/day

25 µg/hr fentanyl patch X (10 patches / 30 days) X 7.2 = 60 MME/day

3. Apply the MME for each opioid prescription claim to the days from the date of service to the date of the last dose (date of service + days' supply - 1).

NOTE:

- If multiple prescriptions for opioids are dispensed on the same day or on different days with overlapping days' supply, do not adjust for overlap, and calculate the daily MME using the days' supply for each prescription claim.
- Apply the MME through to the last day of the opioid episode, i.e., do not include days that extend beyond the end of the opioid episode.

4. For each individual, sum the MMEs across all days during the opioid episode.

5. Calculate the average MME across all days during the opioid episode. The average daily MME = total MME/days in opioid episode. Calculate the average daily MME to 2 decimal places (e.g. 89.98).
6. Count the individuals with an average daily dosage >=90.00 MME during the opioid episode.

Table Opioid-A: Opioid Medications (MME conversion factor)

butorphanol (7)

codeine (0.15)

dihydrocodeine (0.25)

fentanyl buccal or SL tablets, or lozenze/troche (0.13)

fentanyl film or oral spray (0.18)

fentanyl nasal spray (0.16)

fentanyl patch (7.2)

hydrocodone (1)

hydromorphone (4)

levorphanol (11)

meperidine (0.1)

methadone (3)

morphine (1)

opium (1)

oxycodone (1.5)

oxymorphone (3)

pentazocine (0.37)

tapentadol (0.4)

tramadol (0.1)

*Note: Excludes injectable formulations and opioid cough and cold products. Excludes all buprenorphine products, as buprenorphine, as a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.

Denominator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals >=18 years of age with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Individuals with cancer, sickle cell disease, or in hospice are excluded.

2940: Use of Opioids at High Dosage in Persons Without Cancer

Individuals 18 years and older with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Individuals with cancer or in hospice are excluded.

Denominator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals 18 years and older by the first day of the measurement year with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Use Table COB-A: Opioids, below, to identify the opioid medications for the measure.

Complete the steps below to determine the denominator:

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Table COB-A: Opioids:

Benzhydrocodone, buprenorphine, butorphanol, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol

(note: includes combination products and prescription opioid cough medications. Excludes the following: injectable formulations; sublingual sufentanil (used in a supervised setting); and single-agent and combination buprenorphine products used to treat opioid use disorder (i.e., buprenorphine sublingual tablets, Probuphine® Implant kit subcutaneous implant, and all buprenorphine/naloxone combination products).

2940: Use of Opioids at High Dosage in Persons Without Cancer

Individuals 18 years and older with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Individuals with cancer or in hospice are excluded.

1. Identify individuals aged >=18 years as of the first day of the measurement year.
2. Identify individuals meeting the continuous enrollment criteria.
    - To be continuously enrolled, an individual may have no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in

coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

3. Identify individuals with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescriptions with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.

4. Identify individuals with an index prescription start date (IPSD) from January 1 – October 3 of the measurement year.
5. Identify individuals with an opioid episode >=90 days during the measurement year.

NOTE:

- The opioid episode start date is the IPSD; the opioid episode end date is the maximum of the date of service + days' supply - 1, or the end of the measurement year, whichever occurs first.

Table Opioid-A: Opioid Medications

butorphanol

codeine

dihydrocodeine

fentanyl

hydrocodone

hydromorphone

levorphanol

meperidine

methadone

morphine

opium

oxycodone

oxymorphone

pentazocine

tapentadol

tramadol

*Note: Excludes injectable formulations and opioid cough and cold products. Excludes all buprenorphine products, as buprenorphine, as a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.

Exclusions

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Individuals with cancer, sickle cell disease, or in hospice at any point during the measurement year are excluded from the denominator.

2940: Use of Opioids at High Dosage in Persons Without Cancer

Exclude individuals who met at least one of the following during the measurement year:

- Hospice
- Cancer Diagnosis

Exclusion Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Hospice exclusion: Exclude any individual in hospice during the measurement year. To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

Cancer exclusion: Exclude any individuals with cancer during the measurement year. To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

Sickle Cell Disease exclusion: Exclude any individual with sickle cell disease during the measurement year.

- =1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

2940: Use of Opioids at High Dosage in Persons Without Cancer

Hospice Exclusion: Any individual in hospice during the measurement year.

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or
- Use place of service code 34 or type of service code 35 where a hospice indicator is not available (e.g. Commercial, Medicaid).

Cancer Diagnosis Exclusion: Any individual with a cancer diagnosis during the measurement year.

- See PQA ICD Code Value Sets, Cancer Exclusion
- A cancer diagnosis is defined as having at least one claim with any of the listed cancer diagnoses, including primary diagnosis or any other diagnosis fields during the measurement year.
- Medicare Data (if ICD codes note available): RxHCCs 15, 16, 17, 18, 19 for Payment Year 2017 or 2018.

Risk Adjustment

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

No risk adjustment or risk stratification

2940: Use of Opioids at High Dosage in Persons Without Cancer

No risk adjustment or risk stratification

Stratification

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

2940: Use of Opioids at High Dosage in Persons Without Cancer

Commercial, Medicaid, Medicare (report each product line separately). Low income subsidy (LIS) population (report rates for LIS population and non-LIS population separately.

Type Score

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Rate/proportion better quality = lower score

2940: Use of Opioids at High Dosage in Persons Without Cancer

Rate/proportion better quality = lower score

Algorithm

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

A. Target population (denominator):

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Step 5: Identify individuals with cancer, sickle cell disease or in hospice during the measurement year.

To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g., Medicare); or

- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

To identify individuals with sickle cell disease:

- >=1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

Step 6: Exclude individuals with cancer, sickle cell disease, or in hospice (Step 5) from those identified in Step 4. This is the denominator.

B. Numerator Population:

Step 7: From the denominator population, identify individuals with >=2 prescriptions claims with different dates of service for any benzodiazepines (Table COB-B, below) during the measurement year.

Step 8: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

Note: When identifying days' supply for opioids (or benzodiazepines):

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 9: Count the number of individuals with concurrent use of opioids and benzodiazepines for >=30 cumulative days. This is the numerator.

C. Measure Rate:

Step 10: Divide the number of individuals in the numerator (Step 9) by the denominator (Step 6) and multiply by 100. This is the measure rate reported as a percentage.

- Report the rates separately by line of business (e.g. Medicare, Medicaid, Commercial).

2940: Use of Opioids at High Dosage in Persons Without Cancer

DENOMINATOR

1. Identify individuals aged >=18 years as of the first day of the measurement year.
2. Identify individuals meeting the continuous enrollment criteria.
3. Identify individuals with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescriptions with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.

4. Identify individuals with an index prescription start date (IPSD) from January 1 – October 3 of the measurement year.
5. Identify individuals with an opioid episode >=90 days during the measurement year.

NOTE:

- The opioid episode start date is the IPSD; the opioid episode end date is the maximum of the date of service + days' supply - 1, or the end of the measurement year, whichever occurs first.

6. Exclude individuals who met at least one of the following during the measurement year:
   - Hospice
   - Cancer Diagnosis

This is the denominator population.

NUMERATOR

7. For each individual in the denominator population, identify all opioid prescription claims (Table Opioid-A) during the opioid episode.
8. Calculate the daily MME for each opioid prescription claim during the opioid episode, using the following equation: [Strength * (Quantity Dispensed / Days' Supply)] * MME conversion factor. The strength and MME conversion factor are provided for each NDC code in the NDC file.

Examples:

10 mg oxycodone tablets X (120 tablets / 30 days) X 1.5 = 60 MME/day

25 µg/hr fentanyl patch X (10 patches / 30 days) X 7.2 = 60 MME/day

9. Apply the MME for each opioid prescription claim to the days from the date of service to the date of the last dose (date of service + days' supply - 1).

NOTE:

- If multiple prescriptions for opioids are dispensed on the same day or on different days with overlapping days' supply, do not adjust for overlap, and calculate the daily MME using the days' supply for each prescription claim.
- Apply the MME through to the last day of the opioid episode, i.e., do not include days that extend beyond the end of the opioid episode.

10. For each individual, sum the MMEs across all days during the opioid episode.

11. Calculate the average MME across all days during the opioid episode. The average daily MME = total MME/days in opioid episode. Calculate the average daily MME to 2 decimal places (e.g. 89.98).
12. Count the individuals with an average daily dosage >=90.00 MME during the opioid episode. This is the numerator population.

MEASURE RATE

13. Divide the numerator by the denominator and multiply by 100. This is the measure rate.

Table Opioid-A: Opioid Medications (MME conversion factor)

butorphanol (7)

codeine (0.15)

dihydrocodeine (0.25)

fentanyl buccal or SL tablets, or lozenze/troche (0.13)

fentanyl film or oral spray (0.18)

fentanyl nasal spray (0.16)

fentanyl patch (7.2)

hydrocodone (1)

hydromorphone (4)

levorphanol (11)

meperidine (0.1)

methadone (3)

morphine (1)

opium (1)

oxycodone (1.5)

oxymorphone (3)

pentazocine (0.37)

tapentadol (0.4)

tramadol (0.1)

*Note: Excludes injectable formulations and opioid cough and cold products. Excludes all buprenorphine products, as buprenorphine, as a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.

Submission items

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

5.1 Identified measures: 2940 : Use of Opioids at High Dosage in Persons Without Cancer

2950 : Use of Opioids from Multiple Providers in Persons Without Cancer

2951 : Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

3316 : Safe Use of Opioids – Concurrent Prescribing

3541 : Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

3558 : Initial Opioid Prescribing for Long Duration (IOP-LD)

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: ---UPDATED FOR MAINTENANCE--- At time of maintenance, PQA has also identified the 3316e: Safe Use of Opioids – Concurrent Prescribing measure as related. Although the area of focus overlaps, 3316e is specified at the facility level as an eCQM, as opposed to 3389, which is specified at the health plan level and is claims-based. PQA identified the 3558: Initial Opioid Prescribing

for Long Duration and 3541: Annual Monitoring for Persons on Long-Term Opioid Therapy) measures as related to opioid prescribing, although the areas of focus (initial opioid prescribing and annual monitoring) are different than 3389 (concurrent use of opioids and benzodiazepines).

5b.1 If competing, why superior or rationale for additive value: There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

---UPDATED FOR MAINTENANCE---

There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

2940: Use of Opioids at High Dosage in Persons Without Cancer

5.1 Identified measures:

5a.1 Are specs completely harmonized?

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value: N/A

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

2940: Use of Opioids at High Dosage in Persons Without Cancer

2940: Use of Opioids at High Dosage in Persons Without Cancer

Steward

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

PQA, Inc.

2940: Use of Opioids at High Dosage in Persons Without Cancer

Pharmacy Quality Alliance

Description

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The percentage of individuals >=18 years of age with concurrent use of prescription opioids and benzodiazepines during the measurement year.

A lower rate indicates better performance.

2940: Use of Opioids at High Dosage in Persons Without Cancer

The percentage of individuals >=18 years of age who received prescriptions for opioids with an average daily dosage of >=90 morphine milligram equivalents (MME) over a period of >=90 days.

A lower rate indicates better performance.

Type

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Process

2940: Use of Opioids at High Dosage in Persons Without Cancer

Process

Data Source

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Claims, Enrollment Data Administrative claims: prescription claims, medical claims, enrollment data

No data collection instrument provided Attachment pqa_meas_yr_2019_cob_value_sets_20200729_NQF.xlsx

2940: Use of Opioids at High Dosage in Persons Without Cancer

Claims, Electronic Health Data, Enrollment Data Health Plan Medical and Pharmacy Claims. Health Plan member enrollment information.

No data collection instrument provided Attachment Cancer_Exclusion_Codes.xlsx

Level

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Health Plan

2940: Use of Opioids at High Dosage in Persons Without Cancer

Health Plan, Other, Population : Regional and State

Setting

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Outpatient Services

2940: Use of Opioids at High Dosage in Persons Without Cancer

Other, Outpatient Services The level of analysis for this measure is the prescription drug health plan, but it contains claims data from multiple care settings, including ambulatory, skilled nursing facility, pharmacy etc.

Numerator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with concurrent use of opioids and benzodiazepines for >=30 cumulative days during the measurement year.

2940: Use of Opioids at High Dosage in Persons Without Cancer

The numerator includes individuals from the denominator with an average daily dosage >=90 MME during the opioid episode.

Numerator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with:

- >=2 prescription claims for any benzodiazepine with different dates of service, AND
- Concurrent use of opioids and benzodiazepines for >=30 cumulative days.

Complete the steps below to identify individuals with concurrent use of opioids and benzodiazepines:

Step 1: From the denominator population, identify individuals with >=2 prescription claims with different dates of service for any benzodiazepine (Table COB-B, below) during the measurement year.

Step 2: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

NOTE:

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 3: Count the individuals with concurrent use for >=30 cumulative days. This is the numerator.

Table COB-B: Benzodiazepines:

Alprazolam, chlordiazepoxide, clobazam, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, triazolam

(Note: excludes injectable formulations, includes combination products)

2940: Use of Opioids at High Dosage in Persons Without Cancer

The numerator includes individuals from the denominator with an average daily dosage >=90 MME during the opioid episode.

1. For each individual in the denominator population, identify all opioid prescription claims (Table Opioid-A) during the opioid episode.
2. Calculate the daily MME for each opioid prescription claim during the opioid episode, using the following equation: [Strength * (Quantity Dispensed / Days' Supply)] * MME conversion factor. The strength and MME conversion factor are provided for each NDC code in the NDC file.

Examples:

10 mg oxycodone tablets X (120 tablets / 30 days) X 1.5 = 60 MME/day

25 µg/hr fentanyl patch X (10 patches / 30 days) X 7.2 = 60 MME/day

3. Apply the MME for each opioid prescription claim to the days from the date of service to the date of the last dose (date of service + days' supply - 1).

NOTE:

- If multiple prescriptions for opioids are dispensed on the same day or on different days with overlapping days' supply, do not adjust for overlap, and calculate the daily MME using the days' supply for each prescription claim.
- Apply the MME through to the last day of the opioid episode, i.e., do not include days that extend beyond the end of the opioid episode.

4. For each individual, sum the MMEs across all days during the opioid episode.

5. Calculate the average MME across all days during the opioid episode. The average daily MME = total MME/days in opioid episode. Calculate the average daily MME to 2 decimal places (e.g. 89.98).
6. Count the individuals with an average daily dosage >=90.00 MME during the opioid episode.

Table Opioid-A: Opioid Medications (MME conversion factor)

butorphanol (7)

codeine (0.15)

dihydrocodeine (0.25)

fentanyl buccal or SL tablets, or lozenze/troche (0.13)

fentanyl film or oral spray (0.18)

fentanyl nasal spray (0.16)

fentanyl patch (7.2)

hydrocodone (1)

hydromorphone (4)

levorphanol (11)

meperidine (0.1)

methadone (3)

morphine (1)

opium (1)

oxycodone (1.5)

oxymorphone (3)

pentazocine (0.37)

tapentadol (0.4)

tramadol (0.1)

*Note: Excludes injectable formulations and opioid cough and cold products. Excludes all buprenorphine products, as buprenorphine, as a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.

Denominator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals >=18 years of age with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Individuals with cancer, sickle cell disease, or in hospice are excluded.

2940: Use of Opioids at High Dosage in Persons Without Cancer

Individuals 18 years and older with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Individuals with cancer or in hospice are excluded.

Denominator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals 18 years and older by the first day of the measurement year with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Use Table COB-A: Opioids, below, to identify the opioid medications for the measure.

Complete the steps below to determine the denominator:

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Table COB-A: Opioids:

Benzhydrocodone, buprenorphine, butorphanol, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol

(note: includes combination products and prescription opioid cough medications. Excludes the following: injectable formulations; sublingual sufentanil (used in a supervised setting); and single-agent and combination buprenorphine products used to treat opioid use disorder (i.e., buprenorphine sublingual tablets, Probuphine® Implant kit subcutaneous implant, and all buprenorphine/naloxone combination products).

2940: Use of Opioids at High Dosage in Persons Without Cancer

Individuals 18 years and older with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Individuals with cancer or in hospice are excluded.

1. Identify individuals aged >=18 years as of the first day of the measurement year.
2. Identify individuals meeting the continuous enrollment criteria.
    - To be continuously enrolled, an individual may have no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in

coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

3. Identify individuals with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescriptions with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.

4. Identify individuals with an index prescription start date (IPSD) from January 1 – October 3 of the measurement year.
5. Identify individuals with an opioid episode >=90 days during the measurement year.

NOTE:

- The opioid episode start date is the IPSD; the opioid episode end date is the maximum of the date of service + days' supply - 1, or the end of the measurement year, whichever occurs first.

Table Opioid-A: Opioid Medications

butorphanol

codeine

dihydrocodeine

fentanyl

hydrocodone

hydromorphone

levorphanol

meperidine

methadone

morphine

opium

oxycodone

oxymorphone

pentazocine

tapentadol

tramadol

*Note: Excludes injectable formulations and opioid cough and cold products. Excludes all buprenorphine products, as buprenorphine, as a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.

Exclusions

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Individuals with cancer, sickle cell disease, or in hospice at any point during the measurement year are excluded from the denominator.

2940: Use of Opioids at High Dosage in Persons Without Cancer

Exclude individuals who met at least one of the following during the measurement year:

- Hospice
- Cancer Diagnosis

Exclusion Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Hospice exclusion: Exclude any individual in hospice during the measurement year. To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

Cancer exclusion: Exclude any individuals with cancer during the measurement year. To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

Sickle Cell Disease exclusion: Exclude any individual with sickle cell disease during the measurement year.

- =1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

2940: Use of Opioids at High Dosage in Persons Without Cancer

Hospice Exclusion: Any individual in hospice during the measurement year.

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or
- Use place of service code 34 or type of service code 35 where a hospice indicator is not available (e.g. Commercial, Medicaid).

Cancer Diagnosis Exclusion: Any individual with a cancer diagnosis during the measurement year.

- See PQA ICD Code Value Sets, Cancer Exclusion
- A cancer diagnosis is defined as having at least one claim with any of the listed cancer diagnoses, including primary diagnosis or any other diagnosis fields during the measurement year.
- Medicare Data (if ICD codes note available): RxHCCs 15, 16, 17, 18, 19 for Payment Year 2017 or 2018.

Risk Adjustment

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

No risk adjustment or risk stratification

2940: Use of Opioids at High Dosage in Persons Without Cancer

No risk adjustment or risk stratification

Stratification

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

2940: Use of Opioids at High Dosage in Persons Without Cancer

Commercial, Medicaid, Medicare (report each product line separately). Low income subsidy (LIS) population (report rates for LIS population and non-LIS population separately.

Type Score

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Rate/proportion better quality = lower score

2940: Use of Opioids at High Dosage in Persons Without Cancer

Rate/proportion better quality = lower score

Algorithm

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

A. Target population (denominator):

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Step 5: Identify individuals with cancer, sickle cell disease or in hospice during the measurement year.

To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g., Medicare); or

- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

To identify individuals with sickle cell disease:

- >=1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

Step 6: Exclude individuals with cancer, sickle cell disease, or in hospice (Step 5) from those identified in Step 4. This is the denominator.

B. Numerator Population:

Step 7: From the denominator population, identify individuals with >=2 prescriptions claims with different dates of service for any benzodiazepines (Table COB-B, below) during the measurement year.

Step 8: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

Note: When identifying days' supply for opioids (or benzodiazepines):

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 9: Count the number of individuals with concurrent use of opioids and benzodiazepines for >=30 cumulative days. This is the numerator.

C. Measure Rate:

Step 10: Divide the number of individuals in the numerator (Step 9) by the denominator (Step 6) and multiply by 100. This is the measure rate reported as a percentage.

- Report the rates separately by line of business (e.g. Medicare, Medicaid, Commercial).

2940: Use of Opioids at High Dosage in Persons Without Cancer

DENOMINATOR

1. Identify individuals aged >=18 years as of the first day of the measurement year.
2. Identify individuals meeting the continuous enrollment criteria.
3. Identify individuals with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescriptions with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.

4. Identify individuals with an index prescription start date (IPSD) from January 1 – October 3 of the measurement year.
5. Identify individuals with an opioid episode >=90 days during the measurement year.

NOTE:

- The opioid episode start date is the IPSD; the opioid episode end date is the maximum of the date of service + days' supply - 1, or the end of the measurement year, whichever occurs first.

6. Exclude individuals who met at least one of the following during the measurement year:
   - Hospice
   - Cancer Diagnosis

This is the denominator population.

NUMERATOR

7. For each individual in the denominator population, identify all opioid prescription claims (Table Opioid-A) during the opioid episode.
8. Calculate the daily MME for each opioid prescription claim during the opioid episode, using the following equation: [Strength * (Quantity Dispensed / Days' Supply)] * MME conversion factor. The strength and MME conversion factor are provided for each NDC code in the NDC file.

Examples:

10 mg oxycodone tablets X (120 tablets / 30 days) X 1.5 = 60 MME/day

25 µg/hr fentanyl patch X (10 patches / 30 days) X 7.2 = 60 MME/day

9. Apply the MME for each opioid prescription claim to the days from the date of service to the date of the last dose (date of service + days' supply - 1).

NOTE:

- If multiple prescriptions for opioids are dispensed on the same day or on different days with overlapping days' supply, do not adjust for overlap, and calculate the daily MME using the days' supply for each prescription claim.
- Apply the MME through to the last day of the opioid episode, i.e., do not include days that extend beyond the end of the opioid episode.

10. For each individual, sum the MMEs across all days during the opioid episode.

11. Calculate the average MME across all days during the opioid episode. The average daily MME = total MME/days in opioid episode. Calculate the average daily MME to 2 decimal places (e.g. 89.98).
12. Count the individuals with an average daily dosage >=90.00 MME during the opioid episode. This is the numerator population.

MEASURE RATE

13. Divide the numerator by the denominator and multiply by 100. This is the measure rate.

Table Opioid-A: Opioid Medications (MME conversion factor)

butorphanol (7)

codeine (0.15)

dihydrocodeine (0.25)

fentanyl buccal or SL tablets, or lozenze/troche (0.13)

fentanyl film or oral spray (0.18)

fentanyl nasal spray (0.16)

fentanyl patch (7.2)

hydrocodone (1)

hydromorphone (4)

levorphanol (11)

meperidine (0.1)

methadone (3)

morphine (1)

opium (1)

oxycodone (1.5)

oxymorphone (3)

pentazocine (0.37)

tapentadol (0.4)

tramadol (0.1)

*Note: Excludes injectable formulations and opioid cough and cold products. Excludes all buprenorphine products, as buprenorphine, as a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.

Submission items

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

5.1 Identified measures: 2940 : Use of Opioids at High Dosage in Persons Without Cancer

2950 : Use of Opioids from Multiple Providers in Persons Without Cancer

2951 : Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

3316 : Safe Use of Opioids – Concurrent Prescribing

3541 : Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

3558 : Initial Opioid Prescribing for Long Duration (IOP-LD)

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: ---UPDATED FOR MAINTENANCE--- At time of maintenance, PQA has also identified the 3316e: Safe Use of Opioids – Concurrent Prescribing measure as related. Although the area of focus overlaps, 3316e is specified at the facility level as an eCQM, as opposed to 3389, which is specified at the health plan level and is claims-based. PQA identified the 3558: Initial Opioid Prescribing

for Long Duration and 3541: Annual Monitoring for Persons on Long-Term Opioid Therapy) measures as related to opioid prescribing, although the areas of focus (initial opioid prescribing and annual monitoring) are different than 3389 (concurrent use of opioids and benzodiazepines).

5b.1 If competing, why superior or rationale for additive value: There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

---UPDATED FOR MAINTENANCE---

There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

2940: Use of Opioids at High Dosage in Persons Without Cancer

5.1 Identified measures:

5a.1 Are specs completely harmonized?

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value: N/A

Comparison of NQF #3389 and NQF #2950

3389: Concurrent Use of Opioids and Benzodiazepines (COB)
2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Steward

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

PQA, Inc.

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Pharmacy Quality Alliance

Description

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The percentage of individuals >=18 years of age with concurrent use of prescription opioids and benzodiazepines during the measurement year.

A lower rate indicates better performance.

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

The percentage of individuals >=18 years of age who received prescriptions for opioids from >=4 prescribers AND >=4 pharmacies within <=180 days.

A lower rate indicates better performance.

Type

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Process

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Process

Data Source

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Claims, Enrollment Data Administrative claims: prescription claims, medical claims, enrollment data

No data collection instrument provided Attachment pqa_meas_yr_2019_cob_value_sets_20200729_NQF.xlsx

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Claims, Electronic Health Data, Enrollment Data Health Plan Medical and Pharmacy Claims. Health Plan member enrollment information.

No data collection instrument provided Attachment Cancer_Exclusion_Codes-637267041490070087.xlsx

Level

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Health Plan

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Health Plan, Other, Population : Regional and State

Setting

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Outpatient Services

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Other, Outpatient Services The level of analysis for this measure is the prescription drug health plan, but it contains claims data from multiple care settings, including ambulatory, skilled nursing facility, pharmacy etc.

Numerator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with concurrent use of opioids and benzodiazepines for >=30 cumulative days during the measurement year.

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Individuals from the denominator with opioid prescription claims from >=4 prescribers AND >=4 pharmacies within <=180 days during the opioid episode.

Numerator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with:

- >=2 prescription claims for any benzodiazepine with different dates of service, AND

- Concurrent use of opioids and benzodiazepines for >=30 cumulative days.

Complete the steps below to identify individuals with concurrent use of opioids and benzodiazepines:

Step 1: From the denominator population, identify individuals with >=2 prescription claims with different dates of service for any benzodiazepine (Table COB-B, below) during the measurement year.

Step 2: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

NOTE:

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 3: Count the individuals with concurrent use for >=30 cumulative days. This is the numerator.

Table COB-B: Benzodiazepines:

Alprazolam, chlordiazepoxide, clobazam, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, triazolam

(Note: excludes injectable formulations, includes combination products)

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

1. For each individual in the denominator population, identify all opioid prescription claims during the opioid episode.

Each date of service for >=1 opioid prescription claims represents the beginning of a numerator evaluation period of <=180 days during the opioid episode.

2. For each individual, starting with each unique date of service (for >=1 opioid prescriptions), identify the number of unique prescribers by NPI occurring within <=180 days or through the end of the opioid episode, whichever is shorter.
3. For each individual, starting with each unique date of service (for >=1 opioid prescriptions), identify the number of unique pharmacies by NPI occurring within <=180 days or through the end of the opioid episode, whichever is shorter.
4. Count the unique number of individuals with any numerator evaluation periods with opioid prescription claims from >=4 prescribers AND >=4 pharmacies during the opioid episode.

Table Opioid-A: Opioid Medications

butorphanol

codeine

dihydrocodeine

fentanyl
hydrocodone
hydromorphone
levorphanol
meperidine
methadone
morphine
opium
oxycodone
oxymorphone
pentazocine
tapentadol
tramadol

*Note: Excludes injectable formulations and opioid cough and cold products. Excludes all buprenorphine products, as buprenorphine, as a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.

Denominator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals >=18 years of age with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Individuals with cancer, sickle cell disease, or in hospice are excluded.

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Individuals 18 years and older with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Individuals with cancer or in hospice are excluded.

Denominator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals 18 years and older by the first day of the measurement year with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Use Table COB-A: Opioids, below, to identify the opioid medications for the measure.

Complete the steps below to determine the denominator:

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Table COB-A: Opioids:

Benzhydrocodone, buprenorphine, butorphanol, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol

(note: includes combination products and prescription opioid cough medications. Excludes the following: injectable formulations; sublingual sufentanil (used in a supervised setting); and single-agent and combination buprenorphine products used to treat opioid use disorder (i.e., buprenorphine sublingual tablets, Probuphine® Implant kit subcutaneous implant, and all buprenorphine/naloxone combination products).

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

1. Identify individuals aged >=18 years as of the first day of the measurement year.
2. Identify individuals meeting the continuous enrollment criteria.
3. Identify individuals with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescriptions with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.

4. Identify individuals with an index prescription start date (IPSD) from January 1 – October 3 of the measurement year.
5. Identify individuals with an opioid episode >=90 days during the measurement year.

NOTE:

- The opioid episode start date is the IPSD; the opioid episode end date is the maximum of the date of service + days' supply - 1, or the end of the measurement year, whichever occurs first.

Table Opioid-A: Opioid Medications

butorphanol

codeine
dihydrocodeine
fentanyl
hydrocodone
hydromorphone
levorphanol
meperidine
methadone
morphine
opium
oxycodone
oxymorphone
pentazocine
tapentadol
tramadol

*Note: Excludes injectable formulations and opioid cough and cold products. Excludes all buprenorphine products, as buprenorphine, as a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.

Exclusions

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Individuals with cancer, sickle cell disease, or in hospice at any point during the measurement year are excluded from the denominator.

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Exclude individuals who met at least one of the following during the measurement year:

- Hospice
- Cancer Diagnosis

Exclusion Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Hospice exclusion: Exclude any individual in hospice during the measurement year. To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

Cancer exclusion: Exclude any individuals with cancer during the measurement year. To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

Sickle Cell Disease exclusion: Exclude any individual with sickle cell disease during the measurement year.

- =1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Hospice Exclusion: Any individual in hospice during the measurement year.

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or
- Use place of service code 34 or type of service code 35 where a hospice indicator is not available (e.g. Commercial, Medicaid).

Cancer Diagnosis Exclusion: Any individual with a cancer diagnosis during the measurement year.

- See PQA ICD Code Value Sets, Cancer Exclusion
- A cancer diagnosis is defined as having at least one claim with any of the listed cancer diagnoses, including primary diagnosis or any other diagnosis fields during the measurement year.
- Medicare Data (if ICD codes note available): RxHCCs 15, 16, 17, 18, 19 for Payment Year 2017 or 2018.

Risk Adjustment

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

No risk adjustment or risk stratification

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

No risk adjustment or risk stratification

Stratification

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Commercial, Medicaid, Medicare (report each product line separately). Low income subsidy (LIS) population (report rates for LIS population and non-LIS population separately.

Type Score

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Rate/proportion better quality = lower score

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Rate/proportion better quality = lower score

Algorithm

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

A. Target population (denominator):

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual

may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Step 5: Identify individuals with cancer, sickle cell disease or in hospice during the measurement year.

To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g., Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

To identify individuals with sickle cell disease:

- >=1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

Step 6: Exclude individuals with cancer, sickle cell disease, or in hospice (Step 5) from those identified in Step 4. This is the denominator.

B. Numerator Population:

Step 7: From the denominator population, identify individuals with >=2 prescriptions claims with different dates of service for any benzodiazepines (Table COB-B, below) during the measurement year.

Step 8: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

Note: When identifying days' supply for opioids (or benzodiazepines):

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 9: Count the number of individuals with concurrent use of opioids and benzodiazepines for >=30 cumulative days. This is the numerator.

C. Measure Rate:

Step 10: Divide the number of individuals in the numerator (Step 9) by the denominator (Step 6) and multiply by 100. This is the measure rate reported as a percentage.

- Report the rates separately by line of business (e.g. Medicare, Medicaid, Commercial).

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

DENOMINATOR

1. Identify individuals aged >=18 years as of the first day of the measurement year.
2. Identify individuals meeting the continuous enrollment criteria.
3. Identify individuals with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescriptions with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.

4. Identify individuals with an index prescription start date (IPSD) from January 1 – October 3 of the measurement year.
5. Identify individuals with an opioid episode >=90 days during the measurement year.

NOTE:

- The opioid episode start date is the IPSD; the opioid episode end date is the maximum of the date of service + days' supply - 1, or the end of the measurement year, whichever occurs first.

6. Exclude individuals who met at least one of the following during the measurement year:
   - Hospice
   - Cancer Diagnosis

This is the denominator population.

NUMERATOR

7. For each individual in the denominator population, identify all opioid prescription claims during the opioid episode.

Each date of service for >=1 opioid prescription claims represents the beginning of a numerator evaluation period of <=180 days during the opioid episode.

8. For each individual, starting with each unique date of service (for >=1 opioid prescriptions), identify the number of unique prescribers by NPI occurring within <=180 days or through the end of the opioid episode, whichever is shorter.
9. For each individual, starting with each unique date of service (for >=1 opioid prescriptions), identify the number of unique pharmacies by NPI occurring within <=180 days or through the end of the opioid episode, whichever is shorter.
10. Count the unique number of individuals with any numerator evaluation periods with opioid prescription claims from >=4 prescribers AND >=4 pharmacies during the opioid episode. This is the numerator population.

MEASURE RATE

11. Divide the numerator by the denominator and multiply by 100. This is the measure rate.

Table Opioid-A: Opioid Medications

butorphanol

codeine

dihydrocodeine

fentanyl

hydrocodone

hydromorphone

levorphanol

meperidine

methadone

morphine

opium

oxycodone

oxymorphone

pentazocine

tapentadol

tramadol

Note: Excludes injectable formulations and opioid cough and cold products. Excludes all buprenorphine products, as buprenorphine, as a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.

Submission items

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

5.1 Identified measures: 2940 : Use of Opioids at High Dosage in Persons Without Cancer

2950 : Use of Opioids from Multiple Providers in Persons Without Cancer

2951 : Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

3316 : Safe Use of Opioids – Concurrent Prescribing

3541 : Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

3558 : Initial Opioid Prescribing for Long Duration (IOP-LD)

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: ---UPDATED FOR MAINTENANCE--- At time of maintenance, PQA has also identified the 3316e: Safe Use of Opioids – Concurrent Prescribing measure as related. Although the area of focus overlaps, 3316e is specified at the facility level as an eCQM, as opposed to 3389, which is specified at the health plan level and is claims-based. PQA identified the 3558: Initial Opioid Prescribing for Long Duration and 3541: Annual Monitoring for Persons on Long-Term Opioid Therapy) measures as related to opioid prescribing, although the areas of focus (initial opioid prescribing and annual monitoring) are different than 3389 (concurrent use of opioids and benzodiazepines).

5b.1 If competing, why superior or rationale for additive value: There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

---UPDATED FOR MAINTENANCE---

There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

5.1 Identified measures:

5a.1 Are specs completely harmonized?

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value: N/A

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Steward

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

PQA, Inc.

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Pharmacy Quality Alliance

Description

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The percentage of individuals >=18 years of age with concurrent use of prescription opioids and benzodiazepines during the measurement year.

A lower rate indicates better performance.

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

The percentage of individuals >=18 years of age who received prescriptions for opioids from >=4 prescribers AND >=4 pharmacies within <=180 days.

A lower rate indicates better performance.

Type

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Process

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Process

Data Source

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Claims, Enrollment Data Administrative claims: prescription claims, medical claims, enrollment data

No data collection instrument provided Attachment pqa_meas_yr_2019_cob_value_sets_20200729_NQF.xlsx

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Claims, Electronic Health Data, Enrollment Data Health Plan Medical and Pharmacy Claims. Health Plan member enrollment information.

No data collection instrument provided Attachment Cancer_Exclusion_Codes-637267041490070087.xlsx

Level

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Health Plan

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Health Plan, Other, Population : Regional and State

Setting

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Outpatient Services

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Other, Outpatient Services The level of analysis for this measure is the prescription drug health plan, but it contains claims data from multiple care settings, including ambulatory, skilled nursing facility, pharmacy etc.

Numerator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with concurrent use of opioids and benzodiazepines for >=30 cumulative days during the measurement year.

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Individuals from the denominator with opioid prescription claims from >=4 prescribers AND >=4 pharmacies within <=180 days during the opioid episode.

Numerator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with:

- >=2 prescription claims for any benzodiazepine with different dates of service, AND

- Concurrent use of opioids and benzodiazepines for >=30 cumulative days.

Complete the steps below to identify individuals with concurrent use of opioids and benzodiazepines:

Step 1: From the denominator population, identify individuals with >=2 prescription claims with different dates of service for any benzodiazepine (Table COB-B, below) during the measurement year.

Step 2: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

NOTE:

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 3: Count the individuals with concurrent use for >=30 cumulative days. This is the numerator.

Table COB-B: Benzodiazepines:

Alprazolam, chlordiazepoxide, clobazam, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, triazolam

(Note: excludes injectable formulations, includes combination products)

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

1. For each individual in the denominator population, identify all opioid prescription claims during the opioid episode.

Each date of service for >=1 opioid prescription claims represents the beginning of a numerator evaluation period of <=180 days during the opioid episode.

2. For each individual, starting with each unique date of service (for >=1 opioid prescriptions), identify the number of unique prescribers by NPI occurring within <=180 days or through the end of the opioid episode, whichever is shorter.
3. For each individual, starting with each unique date of service (for >=1 opioid prescriptions), identify the number of unique pharmacies by NPI occurring within <=180 days or through the end of the opioid episode, whichever is shorter.
4. Count the unique number of individuals with any numerator evaluation periods with opioid prescription claims from >=4 prescribers AND >=4 pharmacies during the opioid episode.

Table Opioid-A: Opioid Medications

butorphanol

codeine

dihydrocodeine

fentanyl

hydrocodone

hydromorphone

levorphanol

meperidine

methadone

morphine

opium

oxycodone

oxymorphone

pentazocine

tapentadol

tramadol

*Note: Excludes injectable formulations and opioid cough and cold products. Excludes all buprenorphine products, as buprenorphine, as a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.

Denominator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals >=18 years of age with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Individuals with cancer, sickle cell disease, or in hospice are excluded.

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Individuals 18 years and older with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Individuals with cancer or in hospice are excluded.

Denominator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals 18 years and older by the first day of the measurement year with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Use Table COB-A: Opioids, below, to identify the opioid medications for the measure.

Complete the steps below to determine the denominator:

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Table COB-A: Opioids:

Benzhydrocodone, buprenorphine, butorphanol, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol

(note: includes combination products and prescription opioid cough medications. Excludes the following: injectable formulations; sublingual sufentanil (used in a supervised setting); and single-agent and combination buprenorphine products used to treat opioid use disorder (i.e., buprenorphine sublingual tablets, Probuphine® Implant kit subcutaneous implant, and all buprenorphine/naloxone combination products).

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

1. Identify individuals aged >=18 years as of the first day of the measurement year.
2. Identify individuals meeting the continuous enrollment criteria.
3. Identify individuals with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescriptions with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.

4. Identify individuals with an index prescription start date (IPSD) from January 1 – October 3 of the measurement year.
5. Identify individuals with an opioid episode >=90 days during the measurement year.

NOTE:

- The opioid episode start date is the IPSD; the opioid episode end date is the maximum of the date of service + days' supply - 1, or the end of the measurement year, whichever occurs first.

Table Opioid-A: Opioid Medications

butorphanol

codeine
dihydrocodeine
fentanyl
hydrocodone
hydromorphone
levorphanol
meperidine
methadone
morphine
opium
oxycodone
oxymorphone
pentazocine
tapentadol
tramadol

*Note: Excludes injectable formulations and opioid cough and cold products. Excludes all buprenorphine products, as buprenorphine, as a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.

Exclusions

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Individuals with cancer, sickle cell disease, or in hospice at any point during the measurement year are excluded from the denominator.

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Exclude individuals who met at least one of the following during the measurement year:

- Hospice
- Cancer Diagnosis

Exclusion Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Hospice exclusion: Exclude any individual in hospice during the measurement year. To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

Cancer exclusion: Exclude any individuals with cancer during the measurement year. To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

Sickle Cell Disease exclusion: Exclude any individual with sickle cell disease during the measurement year.

- =1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Hospice Exclusion: Any individual in hospice during the measurement year.

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or
- Use place of service code 34 or type of service code 35 where a hospice indicator is not available (e.g. Commercial, Medicaid).

Cancer Diagnosis Exclusion: Any individual with a cancer diagnosis during the measurement year.

- See PQA ICD Code Value Sets, Cancer Exclusion
- A cancer diagnosis is defined as having at least one claim with any of the listed cancer diagnoses, including primary diagnosis or any other diagnosis fields during the measurement year.
- Medicare Data (if ICD codes note available): RxHCCs 15, 16, 17, 18, 19 for Payment Year 2017 or 2018.

Risk Adjustment

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

No risk adjustment or risk stratification

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

No risk adjustment or risk stratification

Stratification

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Commercial, Medicaid, Medicare (report each product line separately). Low income subsidy (LIS) population (report rates for LIS population and non-LIS population separately.

Type Score

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Rate/proportion better quality = lower score

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Rate/proportion better quality = lower score

Algorithm

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

A. Target population (denominator):

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual

may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Step 5: Identify individuals with cancer, sickle cell disease or in hospice during the measurement year.

To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g., Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

To identify individuals with sickle cell disease:

- >=1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

Step 6: Exclude individuals with cancer, sickle cell disease, or in hospice (Step 5) from those identified in Step 4. This is the denominator.

B. Numerator Population:

Step 7: From the denominator population, identify individuals with >=2 prescriptions claims with different dates of service for any benzodiazepines (Table COB-B, below) during the measurement year.

Step 8: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

Note: When identifying days' supply for opioids (or benzodiazepines):

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 9: Count the number of individuals with concurrent use of opioids and benzodiazepines for >=30 cumulative days. This is the numerator.

C. Measure Rate:

Step 10: Divide the number of individuals in the numerator (Step 9) by the denominator (Step 6) and multiply by 100. This is the measure rate reported as a percentage.

- Report the rates separately by line of business (e.g. Medicare, Medicaid, Commercial).

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

DENOMINATOR

1. Identify individuals aged >=18 years as of the first day of the measurement year.
2. Identify individuals meeting the continuous enrollment criteria.
3. Identify individuals with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescriptions with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.

4. Identify individuals with an index prescription start date (IPSD) from January 1 – October 3 of the measurement year.
5. Identify individuals with an opioid episode >=90 days during the measurement year.

NOTE:

- The opioid episode start date is the IPSD; the opioid episode end date is the maximum of the date of service + days' supply - 1, or the end of the measurement year, whichever occurs first.

6. Exclude individuals who met at least one of the following during the measurement year:
   - Hospice
   - Cancer Diagnosis

This is the denominator population.

NUMERATOR

7. For each individual in the denominator population, identify all opioid prescription claims during the opioid episode.

Each date of service for >=1 opioid prescription claims represents the beginning of a numerator evaluation period of <=180 days during the opioid episode.

8. For each individual, starting with each unique date of service (for >=1 opioid prescriptions), identify the number of unique prescribers by NPI occurring within <=180 days or through the end of the opioid episode, whichever is shorter.
9. For each individual, starting with each unique date of service (for >=1 opioid prescriptions), identify the number of unique pharmacies by NPI occurring within <=180 days or through the end of the opioid episode, whichever is shorter.
10. Count the unique number of individuals with any numerator evaluation periods with opioid prescription claims from >=4 prescribers AND >=4 pharmacies during the opioid episode. This is the numerator population.

MEASURE RATE

11. Divide the numerator by the denominator and multiply by 100. This is the measure rate.

Table Opioid-A: Opioid Medications

butorphanol

codeine

dihydrocodeine

fentanyl

hydrocodone

hydromorphone

levorphanol

meperidine

methadone

morphine

opium

oxycodone

oxymorphone

pentazocine

tapentadol

tramadol

Note: Excludes injectable formulations and opioid cough and cold products. Excludes all buprenorphine products, as buprenorphine, as a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.

Submission items

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

5.1 Identified measures: 2940 : Use of Opioids at High Dosage in Persons Without Cancer

2950 : Use of Opioids from Multiple Providers in Persons Without Cancer

2951 : Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

3316 : Safe Use of Opioids – Concurrent Prescribing

3541 : Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

3558 : Initial Opioid Prescribing for Long Duration (IOP-LD)

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: ---UPDATED FOR MAINTENANCE--- At time of maintenance, PQA has also identified the 3316e: Safe Use of Opioids – Concurrent Prescribing measure as related. Although the area of focus overlaps, 3316e is specified at the facility level as an eCQM, as opposed to 3389, which is specified at the health plan level and is claims-based. PQA identified the 3558: Initial Opioid Prescribing for Long Duration and 3541: Annual Monitoring for Persons on Long-Term Opioid Therapy) measures as related to opioid prescribing, although the areas of focus (initial opioid prescribing and annual monitoring) are different than 3389 (concurrent use of opioids and benzodiazepines).

5b.1 If competing, why superior or rationale for additive value: There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

---UPDATED FOR MAINTENANCE---

There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

2950: Use of Opioids from Multiple Providers in Persons Without Cancer

5.1 Identified measures:

5a.1 Are specs completely harmonized?

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value: N/A

Comparison of NQF #3389 and NQF #2951

3389: Concurrent Use of Opioids and Benzodiazepines (COB)
2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Steward

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

PQA, Inc.

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Pharmacy Quality Alliance

Description

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The percentage of individuals >=18 years of age with concurrent use of prescription opioids and benzodiazepines during the measurement year.

A lower rate indicates better performance.

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

The percentage of individuals >=18 years of age who received prescriptions for opioids with an average daily dosage of >=90 morphine milligram equivalents (MME) AND who received prescriptions for opioids from >=4 prescribers AND >=4 pharmacies.

A lower rate indicates better performance.

Type

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Process

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Process

Data Source

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Claims, Enrollment Data Administrative claims: prescription claims, medical claims, enrollment data

No data collection instrument provided Attachment pqa_meas_yr_2019_cob_value_sets_20200729_NQF.xlsx

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Claims, Electronic Health Data, Enrollment Data Health Plan Medical and Pharmacy Claims. Health Plan member enrollment information.

No data collection instrument provided Attachment Cancer_Exclusion_Codes-637267044680747732.xlsx

Level

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Health Plan

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Health Plan, Other, Population : Regional and State

Setting

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Outpatient Services

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Other, Outpatient Services The level of analysis for this measure is the prescription drug health plan, but it contains claims data from multiple care settings, including ambulatory, skilled nursing facility, pharmacy etc.

Numerator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with concurrent use of opioids and benzodiazepines for >=30 cumulative days during the measurement year.

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Individuals from the denominator with an average daily dosage >=90 MME during the opioid episode AND with opioid prescription claims from >=4 prescribers AND >=4 pharmacies within <=180 days during the opioid episode.

Numerator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with:

- >=2 prescription claims for any benzodiazepine with different dates of service, AND
- Concurrent use of opioids and benzodiazepines for >=30 cumulative days.

Complete the steps below to identify individuals with concurrent use of opioids and benzodiazepines:

Step 1: From the denominator population, identify individuals with >=2 prescription claims with different dates of service for any benzodiazepine (Table COB-B, below) during the measurement year.

Step 2: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

NOTE:

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 3: Count the individuals with concurrent use for >=30 cumulative days. This is the numerator.

Table COB-B: Benzodiazepines:

Alprazolam, chlordiazepoxide, clobazam, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, triazolam

(Note: excludes injectable formulations, includes combination products)

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

1. For each individual in the denominator population, identify all opioid prescription claims during the opioid episode.
2. Calculate the daily MME for each opioid prescription claim during the opioid episode, using the following equation: [Strength * (Quantity Dispensed / Days' Supply)] * MME conversion factor.

The strength and MME conversion factor are provided for each NDC code in the NDC file.

Examples:

10 mg oxycodone tablets X (120 tablets / 30 days) X 1.5 = 60 MME/day

25 µg/hr fentanyl patch X (10 patches / 30 days) X 7.2 = 60 MME/day

3. Apply the MME for each opioid prescription claim to the days from the date of service to the date of the last dose (date of service + days' supply - 1).

NOTE:

- If multiple prescriptions for opioids are dispensed on the same day or on different days with overlapping days' supply, do not adjust for overlap, and calculate the daily MME using the days' supply for each prescription claim.
- Apply the MME through to the last day of the opioid episode, i.e., do not include days that extend beyond the end of the opioid episode.

4. For each individual, sum the MMEs across all days during the opioid episode.

5. For each individual, calculate the average MME across all days during the opioid episode. The average daily MME = total MME/days in opioid episode. Calculate the average daily MME to 2 decimal places (e.g. 89.98).
6. Identify individuals with an average daily dosage >=90.00 MME during the opioid episode.
7. For each individual identified in step 6, starting with each unique date of service (for >=1 opioid prescriptions) within the opioid episode, identify the number of unique prescribers by NPI occurring within <=180 days or through the end of the opioid episode, whichever is shorter.

Each date of service for >=1 opioid prescription claims represents the beginning of a numerator evaluation period of <=180 days during the opioid episode.

8. For each individual in step 7, starting with each unique date of service (for >=1 opioid prescriptions) within the opioid episode, identify the number of unique pharmacies by NPI occurring within <=180 days or through the end of the opioid episode, whichever is shorter.

9. Count the individuals from step 8 with any numerator evaluation periods with opioid prescription claims from >=4 prescribers AND >=4 pharmacies during the opioid episode.

Table Opioid-A: Opioid Medications (MME conversion factor)

butorphanol (7)

codeine (0.15)

dihydrocodeine (0.25)

fentanyl buccal or SL tablets, or lozenze/troche (0.13)

fentanyl film or oral spray (0.18)

fentanyl nasal spray (0.16)

fentanyl patch (7.2)

hydrocodone (1)

hydromorphone (4)

levorphanol (11)

meperidine (0.1)

methadone (3)

morphine (1)

opium (1)

oxycodone (1.5)

oxymorphone (3)

pentazocine (0.37)

tapentadol (0.4)

tramadol (0.1)

Denominator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals >=18 years of age with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Individuals with cancer, sickle cell disease, or in hospice are excluded.

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Individuals 18 years and older with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Individuals with cancer or in hospice are excluded.

Denominator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals 18 years and older by the first day of the measurement year with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Use Table COB-A: Opioids, below, to identify the opioid medications for the measure.

Complete the steps below to determine the denominator:

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Table COB-A: Opioids:

Benzhydrocodone, buprenorphine, butorphanol, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol

(note: includes combination products and prescription opioid cough medications. Excludes the following: injectable formulations; sublingual sufentanil (used in a supervised setting); and single-agent and combination buprenorphine products used to treat opioid use disorder (i.e., buprenorphine sublingual tablets, Probuphine® Implant kit subcutaneous implant, and all buprenorphine/naloxone combination products).

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Individuals 18 years and older with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Individuals with cancer or in hospice are excluded.

1. Identify individuals aged >=18 years as of the first day of the measurement year.
2. Identify individuals meeting the continuous enrollment criteria.
    - To be continuously enrolled, an individual may have no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).
3. Identify individuals with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescriptions with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.

4. Identify individuals with an index prescription start date (IPSD) from January 1 – October 3 of the measurement year.
5. Identify individuals with an opioid episode >=90 days during the measurement year.

NOTE:

- The opioid episode start date is the IPSD; the opioid episode end date is the maximum of the date of service + days' supply - 1, or the end of the measurement year, whichever occurs first.

Table Opioid-A: Opioid Medications

butorphanol

codeine

dihydrocodeine

fentanyl

hydrocodone

hydromorphone

levorphanol

meperidine

methadone

morphine

opium

oxycodone

oxymorphone

pentazocine

tapentadol

tramadol

*Note: Excludes injectable formulations and opioid cough and cold products. Excludes all buprenorphine products, as buprenorphine, as a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.

Exclusions

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Individuals with cancer, sickle cell disease, or in hospice at any point during the measurement year are excluded from the denominator.

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Exclude individuals who met at least one of the following during the measurement year:

- Hospice
- Cancer Diagnosis

Exclusion Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Hospice exclusion: Exclude any individual in hospice during the measurement year. To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

Cancer exclusion: Exclude any individuals with cancer during the measurement year. To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

Sickle Cell Disease exclusion: Exclude any individual with sickle cell disease during the measurement year.

- =1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Hospice Exclusion: Any individual in hospice during the measurement year.

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or

- Use place of service code 34 or type of service code 35 where a hospice indicator is not available (e.g. Commercial, Medicaid).

Cancer Diagnosis Exclusion: Any individual with a cancer diagnosis during the measurement year.

- See PQA ICD Code Value Sets, Cancer Exclusion
- A cancer diagnosis is defined as having at least one claim with any of the listed cancer diagnoses, including primary diagnosis or any other diagnosis fields during the measurement year.
- Medicare Data (if ICD codes note available): RxHCCs 15, 16, 17, 18, 19 for Payment Year 2017 or 2018.

Risk Adjustment

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

No risk adjustment or risk stratification

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

No risk adjustment or risk stratification

Stratification

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Commercial, Medicaid, Medicare (report each product line separately). Low income subsidy (LIS) population (report rates for LIS population and non-LIS population separately.

Type Score

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Rate/proportion better quality = lower score

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Rate/proportion better quality = lower score

Algorithm

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

A. Target population (denominator):

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Step 5: Identify individuals with cancer, sickle cell disease or in hospice during the measurement year.

To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g., Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

To identify individuals with sickle cell disease:

- >=1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

Step 6: Exclude individuals with cancer, sickle cell disease, or in hospice (Step 5) from those identified in Step 4. This is the denominator.

B. Numerator Population:

Step 7: From the denominator population, identify individuals with >=2 prescriptions claims with different dates of service for any benzodiazepines (Table COB-B, below) during the measurement year.

Step 8: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

Note: When identifying days' supply for opioids (or benzodiazepines):

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 9: Count the number of individuals with concurrent use of opioids and benzodiazepines for >=30 cumulative days. This is the numerator.

C. Measure Rate:

Step 10: Divide the number of individuals in the numerator (Step 9) by the denominator (Step 6) and multiply by 100. This is the measure rate reported as a percentage.

- Report the rates separately by line of business (e.g. Medicare, Medicaid, Commercial).

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

DENOMINATOR

1. Identify individuals aged >=18 years as of the first day of the measurement year.
2. Identify individuals meeting the continuous enrollment criteria.
3. Identify individuals with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescriptions with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.

4. Identify individuals with an index prescription start date (IPSD) from January 1 – October 3 of the measurement year.
5. Identify individuals with an opioid episode >=90 days during the measurement year.

NOTE:

- The opioid episode start date is the IPSD; the opioid episode end date is the maximum of the date of service + days' supply - 1, or the end of the measurement year, whichever occurs first.

6. Exclude individuals who met at least one of the following during the measurement year:
   - Hospice
   - Cancer Diagnosis

This is the denominator population.

NUMERATOR

7. For each individual in the denominator population, identify all opioid prescription claims during the opioid episode.
8. Calculate the daily MME for each opioid prescription claim during the opioid episode, using the following equation: [Strength * (Quantity Dispensed / Days' Supply)] * MME conversion factor.

The strength and MME conversion factor are provided for each NDC code in the NDC file.

Examples:

10 mg oxycodone tablets X (120 tablets / 30 days) X 1.5 = 60 MME/day

25 µg/hr fentanyl patch X (10 patches / 30 days) X 7.2 = 60 MME/day

9. Apply the MME for each opioid prescription claim to the days from the date of service to the date of the last dose (date of service + days' supply - 1).

NOTE:

- If multiple prescriptions for opioids are dispensed on the same day or on different days with overlapping days' supply, do not adjust for overlap, and calculate the daily MME using the days' supply for each prescription claim.
- Apply the MME through to the last day of the opioid episode, i.e., do not include days that extend beyond the end of the opioid episode.

10. For each individual, sum the MMEs across all days during the opioid episode.

11. For each individual, calculate the average MME across all days during the opioid episode. The average daily MME = total MME/days in opioid episode. Calculate the average daily MME to 2 decimal places (e.g. 89.98).
12. Identify individuals with an average daily dosage >=90.00 MME during the opioid episode.
13. For each individual identified in step 12, starting with each unique date of service (for >=1 opioid prescriptions) within the opioid episode, identify the number of unique prescribers by NPI occurring within <=180 days or through the end of the opioid episode, whichever is shorter.

Each date of service for >=1 opioid prescription claims represents the beginning of a numerator evaluation period of <=180 days during the opioid episode.

14. For each individual in step 13, starting with each unique date of service (for >=1 opioid prescriptions) within the opioid episode, identify the number of unique pharmacies by NPI occurring within <=180 days or through the end of the opioid episode, whichever is shorter.

15. Count the individuals from step 14 with any numerator evaluation periods with opioid prescription claims from >=4 prescribers AND >=4 pharmacies during the opioid episode. This is the numerator population.

MEASURE RATE

16. Divide the numerator by the denominator and multiply by 100. This is the measure rate.

Table Opioid-A: Opioid Medications (MME conversion factor)

butorphanol (7)

codeine (0.15)

dihydrocodeine (0.25)

fentanyl buccal or SL tablets, or lozenze/troche (0.13)

fentanyl film or oral spray (0.18)

fentanyl nasal spray (0.16)

fentanyl patch (7.2)

hydrocodone (1)

hydromorphone (4)

levorphanol (11)

meperidine (0.1)

methadone (3)

morphine (1)

opium (1)

oxycodone (1.5)

oxymorphone (3)

pentazocine (0.37)

tapentadol (0.4)

tramadol (0.1)

Submission items

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

5.1 Identified measures: 2940 : Use of Opioids at High Dosage in Persons Without Cancer

2950 : Use of Opioids from Multiple Providers in Persons Without Cancer

2951 : Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

3316 : Safe Use of Opioids – Concurrent Prescribing

3541 : Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

3558 : Initial Opioid Prescribing for Long Duration (IOP-LD)

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: ---UPDATED FOR MAINTENANCE--- At time of maintenance, PQA has also identified the 3316e: Safe Use of Opioids – Concurrent Prescribing measure as related. Although the area of focus overlaps, 3316e is specified at the facility level as an eCQM, as opposed to 3389, which is specified at the health plan level and is claims-based. PQA identified the 3558: Initial Opioid Prescribing for Long Duration and 3541: Annual Monitoring for Persons on Long-Term Opioid Therapy) measures as related to opioid prescribing, although the areas of focus (initial opioid prescribing and annual monitoring) are different than 3389 (concurrent use of opioids and benzodiazepines).

5b.1 If competing, why superior or rationale for additive value: There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

---UPDATED FOR MAINTENANCE---

There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

5.1 Identified measures:

5a.1 Are specs completely harmonized?

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value: N/A

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Steward

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

PQA, Inc.

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Pharmacy Quality Alliance

Description

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The percentage of individuals >=18 years of age with concurrent use of prescription opioids and benzodiazepines during the measurement year.

A lower rate indicates better performance.

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

The percentage of individuals >=18 years of age who received prescriptions for opioids with an average daily dosage of >=90 morphine milligram equivalents (MME) AND who received prescriptions for opioids from >=4 prescribers AND >=4 pharmacies.

A lower rate indicates better performance.

Type

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Process

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Process

Data Source

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Claims, Enrollment Data Administrative claims: prescription claims, medical claims, enrollment data

No data collection instrument provided Attachment pqa_meas_yr_2019_cob_value_sets_20200729_NQF.xlsx

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Claims, Electronic Health Data, Enrollment Data Health Plan Medical and Pharmacy Claims. Health Plan member enrollment information.

No data collection instrument provided Attachment Cancer_Exclusion_Codes-637267044680747732.xlsx

Level

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Health Plan

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Health Plan, Other, Population : Regional and State

Setting

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Outpatient Services

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Other, Outpatient Services The level of analysis for this measure is the prescription drug health plan, but it contains claims data from multiple care settings, including ambulatory, skilled nursing facility, pharmacy etc.

Numerator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with concurrent use of opioids and benzodiazepines for >=30 cumulative days during the measurement year.

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Individuals from the denominator with an average daily dosage >=90 MME during the opioid episode AND with opioid prescription claims from >=4 prescribers AND >=4 pharmacies within <=180 days during the opioid episode.

Numerator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with:

- >=2 prescription claims for any benzodiazepine with different dates of service, AND
- Concurrent use of opioids and benzodiazepines for >=30 cumulative days.

Complete the steps below to identify individuals with concurrent use of opioids and benzodiazepines:

Step 1: From the denominator population, identify individuals with >=2 prescription claims with different dates of service for any benzodiazepine (Table COB-B, below) during the measurement year.

Step 2: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

NOTE:

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 3: Count the individuals with concurrent use for >=30 cumulative days. This is the numerator.

Table COB-B: Benzodiazepines:

Alprazolam, chlordiazepoxide, clobazam, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, triazolam

(Note: excludes injectable formulations, includes combination products)

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

1. For each individual in the denominator population, identify all opioid prescription claims during the opioid episode.
2. Calculate the daily MME for each opioid prescription claim during the opioid episode, using the following equation: [Strength * (Quantity Dispensed / Days' Supply)] * MME conversion factor.

The strength and MME conversion factor are provided for each NDC code in the NDC file.

Examples:

10 mg oxycodone tablets X (120 tablets / 30 days) X 1.5 = 60 MME/day

25 µg/hr fentanyl patch X (10 patches / 30 days) X 7.2 = 60 MME/day

3. Apply the MME for each opioid prescription claim to the days from the date of service to the date of the last dose (date of service + days' supply - 1).

NOTE:

- If multiple prescriptions for opioids are dispensed on the same day or on different days with overlapping days' supply, do not adjust for overlap, and calculate the daily MME using the days' supply for each prescription claim.
- Apply the MME through to the last day of the opioid episode, i.e., do not include days that extend beyond the end of the opioid episode.

4. For each individual, sum the MMEs across all days during the opioid episode.

5. For each individual, calculate the average MME across all days during the opioid episode. The average daily MME = total MME/days in opioid episode. Calculate the average daily MME to 2 decimal places (e.g. 89.98).
6. Identify individuals with an average daily dosage >=90.00 MME during the opioid episode.
7. For each individual identified in step 6, starting with each unique date of service (for >=1 opioid prescriptions) within the opioid episode, identify the number of unique prescribers by NPI occurring within <=180 days or through the end of the opioid episode, whichever is shorter.

Each date of service for >=1 opioid prescription claims represents the beginning of a numerator evaluation period of <=180 days during the opioid episode.

8. For each individual in step 7, starting with each unique date of service (for >=1 opioid prescriptions) within the opioid episode, identify the number of unique pharmacies by NPI occurring within <=180 days or through the end of the opioid episode, whichever is shorter.

9. Count the individuals from step 8 with any numerator evaluation periods with opioid prescription claims from >=4 prescribers AND >=4 pharmacies during the opioid episode.

Table Opioid-A: Opioid Medications (MME conversion factor)

butorphanol (7)

codeine (0.15)

dihydrocodeine (0.25)

fentanyl buccal or SL tablets, or lozenze/troche (0.13)

fentanyl film or oral spray (0.18)

fentanyl nasal spray (0.16)

fentanyl patch (7.2)

hydrocodone (1)

hydromorphone (4)

levorphanol (11)

meperidine (0.1)

methadone (3)

morphine (1)

opium (1)

oxycodone (1.5)

oxymorphone (3)

pentazocine (0.37)

tapentadol (0.4)

tramadol (0.1)

Denominator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals >=18 years of age with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Individuals with cancer, sickle cell disease, or in hospice are excluded.

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Individuals 18 years and older with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Individuals with cancer or in hospice are excluded.

Denominator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals 18 years and older by the first day of the measurement year with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Use Table COB-A: Opioids, below, to identify the opioid medications for the measure.

Complete the steps below to determine the denominator:

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Table COB-A: Opioids:

Benzhydrocodone, buprenorphine, butorphanol, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol

(note: includes combination products and prescription opioid cough medications. Excludes the following: injectable formulations; sublingual sufentanil (used in a supervised setting); and single-agent and combination buprenorphine products used to treat opioid use disorder (i.e., buprenorphine sublingual tablets, Probuphine® Implant kit subcutaneous implant, and all buprenorphine/naloxone combination products).

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Individuals 18 years and older with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Individuals with cancer or in hospice are excluded.

1. Identify individuals aged >=18 years as of the first day of the measurement year.
2. Identify individuals meeting the continuous enrollment criteria.
    - To be continuously enrolled, an individual may have no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).
3. Identify individuals with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescriptions with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.

4. Identify individuals with an index prescription start date (IPSD) from January 1 – October 3 of the measurement year.

5. Identify individuals with an opioid episode >=90 days during the measurement year.

NOTE:

- The opioid episode start date is the IPSD; the opioid episode end date is the maximum of the date of service + days' supply - 1, or the end of the measurement year, whichever occurs first.

Table Opioid-A: Opioid Medications

butorphanol

codeine

dihydrocodeine

fentanyl

hydrocodone

hydromorphone

levorphanol

meperidine

methadone

morphine

opium

oxycodone

oxymorphone

pentazocine

tapentadol

tramadol

*Note: Excludes injectable formulations and opioid cough and cold products. Excludes all buprenorphine products, as buprenorphine, as a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.

Exclusions

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Individuals with cancer, sickle cell disease, or in hospice at any point during the measurement year are excluded from the denominator.

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Exclude individuals who met at least one of the following during the measurement year:

- Hospice
- Cancer Diagnosis

Exclusion Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Hospice exclusion: Exclude any individual in hospice during the measurement year. To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or

- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

Cancer exclusion: Exclude any individuals with cancer during the measurement year. To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

Sickle Cell Disease exclusion: Exclude any individual with sickle cell disease during the measurement year.

- =1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Hospice Exclusion: Any individual in hospice during the measurement year.

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or
- Use place of service code 34 or type of service code 35 where a hospice indicator is not available (e.g. Commercial, Medicaid).

Cancer Diagnosis Exclusion: Any individual with a cancer diagnosis during the measurement year.

- See PQA ICD Code Value Sets, Cancer Exclusion
- A cancer diagnosis is defined as having at least one claim with any of the listed cancer diagnoses, including primary diagnosis or any other diagnosis fields during the measurement year.
- Medicare Data (if ICD codes note available): RxHCCs 15, 16, 17, 18, 19 for Payment Year 2017 or 2018.

Risk Adjustment

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

No risk adjustment or risk stratification

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

No risk adjustment or risk stratification

Stratification

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Commercial, Medicaid, Medicare (report each product line separately). Low income subsidy (LIS) population (report rates for LIS population and non-LIS population separately.

Type Score

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Rate/proportion better quality = lower score

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Rate/proportion better quality = lower score

Algorithm

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

A. Target population (denominator):

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Step 5: Identify individuals with cancer, sickle cell disease or in hospice during the measurement year.

To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g., Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

To identify individuals with sickle cell disease:

- >=1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

Step 6: Exclude individuals with cancer, sickle cell disease, or in hospice (Step 5) from those identified in Step 4. This is the denominator.

B. Numerator Population:

Step 7: From the denominator population, identify individuals with >=2 prescriptions claims with different dates of service for any benzodiazepines (Table COB-B, below) during the measurement year.

Step 8: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

Note: When identifying days' supply for opioids (or benzodiazepines):

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 9: Count the number of individuals with concurrent use of opioids and benzodiazepines for >=30 cumulative days. This is the numerator.

C. Measure Rate:

Step 10: Divide the number of individuals in the numerator (Step 9) by the denominator (Step 6) and multiply by 100. This is the measure rate reported as a percentage.

- Report the rates separately by line of business (e.g. Medicare, Medicaid, Commercial).

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

DENOMINATOR

1. Identify individuals aged >=18 years as of the first day of the measurement year.
2. Identify individuals meeting the continuous enrollment criteria.
3. Identify individuals with >=2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply >=15 during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescriptions with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.

4. Identify individuals with an index prescription start date (IPSD) from January 1 – October 3 of the measurement year.
5. Identify individuals with an opioid episode >=90 days during the measurement year.

NOTE:

- The opioid episode start date is the IPSD; the opioid episode end date is the maximum of the date of service + days' supply - 1, or the end of the measurement year, whichever occurs first.

6. Exclude individuals who met at least one of the following during the measurement year:
   - Hospice
   - Cancer Diagnosis

This is the denominator population.

NUMERATOR

7. For each individual in the denominator population, identify all opioid prescription claims during the opioid episode.
8. Calculate the daily MME for each opioid prescription claim during the opioid episode, using the following equation: [Strength * (Quantity Dispensed / Days' Supply)] * MME conversion factor.

The strength and MME conversion factor are provided for each NDC code in the NDC file.

Examples:

10 mg oxycodone tablets X (120 tablets / 30 days) X 1.5 = 60 MME/day

25 µg/hr fentanyl patch X (10 patches / 30 days) X 7.2 = 60 MME/day

9. Apply the MME for each opioid prescription claim to the days from the date of service to the date of the last dose (date of service + days' supply - 1).

NOTE:

- If multiple prescriptions for opioids are dispensed on the same day or on different days with overlapping days' supply, do not adjust for overlap, and calculate the daily MME using the days' supply for each prescription claim.
- Apply the MME through to the last day of the opioid episode, i.e., do not include days that extend beyond the end of the opioid episode.

10. For each individual, sum the MMEs across all days during the opioid episode.
11. For each individual, calculate the average MME across all days during the opioid episode. The average daily MME = total MME/days in opioid episode. Calculate the average daily MME to 2 decimal places (e.g. 89.98).
12. Identify individuals with an average daily dosage >=90.00 MME during the opioid episode.
13. For each individual identified in step 12, starting with each unique date of service (for >=1 opioid prescriptions) within the opioid episode, identify the number of unique prescribers by NPI occurring within <=180 days or through the end of the opioid episode, whichever is shorter.

Each date of service for >=1 opioid prescription claims represents the beginning of a numerator evaluation period of <=180 days during the opioid episode.

14. For each individual in step 13, starting with each unique date of service (for >=1 opioid prescriptions) within the opioid episode, identify the number of unique pharmacies by NPI occurring within <=180 days or through the end of the opioid episode, whichever is shorter.
15. Count the individuals from step 14 with any numerator evaluation periods with opioid prescription claims from >=4 prescribers AND >=4 pharmacies during the opioid episode. This is the numerator population.

MEASURE RATE

16. Divide the numerator by the denominator and multiply by 100. This is the measure rate.

Table Opioid-A: Opioid Medications (MME conversion factor)

butorphanol (7)

codeine (0.15)

dihydrocodeine (0.25)

fentanyl buccal or SL tablets, or lozenze/troche (0.13)

fentanyl film or oral spray (0.18)

fentanyl nasal spray (0.16)

fentanyl patch (7.2)

hydrocodone (1)

hydromorphone (4)

levorphanol (11)

meperidine (0.1)

methadone (3)

morphine (1)

opium (1)

oxycodone (1.5)

oxymorphone (3)

pentazocine (0.37)

tapentadol (0.4)

tramadol (0.1)

Submission items

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

5.1 Identified measures: 2940 : Use of Opioids at High Dosage in Persons Without Cancer

2950 : Use of Opioids from Multiple Providers in Persons Without Cancer

2951 : Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

3316 : Safe Use of Opioids – Concurrent Prescribing

3541 : Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

3558 : Initial Opioid Prescribing for Long Duration (IOP-LD)

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: ---UPDATED FOR MAINTENANCE--- At time of maintenance, PQA has also identified the 3316e: Safe Use of Opioids – Concurrent Prescribing measure as related. Although the area of focus overlaps, 3316e is specified at the facility level as an eCQM, as opposed to 3389, which is specified at the health plan level and is claims-based. PQA identified the 3558: Initial Opioid Prescribing for Long Duration and 3541: Annual Monitoring for Persons on Long-Term Opioid Therapy) measures as related to opioid prescribing, although the areas of focus (initial opioid prescribing and annual monitoring) are different than 3389 (concurrent use of opioids and benzodiazepines).

5b.1 If competing, why superior or rationale for additive value: There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

---UPDATED FOR MAINTENANCE---

There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

5.1 Identified measures:

5a.1 Are specs completely harmonized?

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value: N/A

Comparison of NQF #3389 and NQF #3316e

3389: Concurrent Use of Opioids and Benzodiazepines (COB)
3316e: Safe Use of Opioids – Concurrent Prescribing

Steward

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

PQA, Inc.

3316e: Safe Use of Opioids – Concurrent Prescribing

Centers for Medicare & Medicaid Services

Description

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The percentage of individuals >=18 years of age with concurrent use of prescription opioids and benzodiazepines during the measurement year.

A lower rate indicates better performance.

3316e: Safe Use of Opioids – Concurrent Prescribing

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)

Type

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Process

3316e: Safe Use of Opioids – Concurrent Prescribing

Process

Data Source

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Claims, Enrollment Data Administrative claims: prescription claims, medical claims, enrollment data

No data collection instrument provided Attachment pqa_meas_yr_2019_cob_value_sets_20200729_NQF.xlsx

3316e: Safe Use of Opioids – Concurrent Prescribing

Electronic Health Records Hospitals collect EHR data using certified electronic health record technology (CEHRT). The human readable and XML artifacts of the health quality measures format (HQMF) of the measure are contained in the eCQM specifications attached in question S.2a. No additional tools are used for data collection for eCQMs.

No data collection instrument provided Attachment Opioids_ValueSets.xlsx

Level

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Health Plan

3316e: Safe Use of Opioids – Concurrent Prescribing

Facility

Setting

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Outpatient Services

3316e: Safe Use of Opioids – Concurrent Prescribing

Emergency Department and Services, Inpatient/Hospital

Numerator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with concurrent use of opioids and benzodiazepines for >=30 cumulative days during the measurement year.

3316e: Safe Use of Opioids – Concurrent Prescribing

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

Numerator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with:

- >=2 prescription claims for any benzodiazepine with different dates of service, AND
- Concurrent use of opioids and benzodiazepines for >=30 cumulative days.

Complete the steps below to identify individuals with concurrent use of opioids and benzodiazepines:

Step 1: From the denominator population, identify individuals with >=2 prescription claims with different dates of service for any benzodiazepine (Table COB-B, below) during the measurement year.

Step 2: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

NOTE:

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 3: Count the individuals with concurrent use for >=30 cumulative days. This is the numerator.

Table COB-B: Benzodiazepines:

Alprazolam, chlordiazepoxide, clobazam, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, triazolam

(Note: excludes injectable formulations, includes combination products)

3316e: Safe Use of Opioids – Concurrent Prescribing

Presence of two or more new opioids at discharge resulting in concurrent therapy is represented by QDM datatype and value set of Medication, Discharge: Schedule II and Schedule III Opioids (2.16.840.1.113762.1.4.1125.2).

Presence of a new opioid and a new benzodiazepine prescription at discharge resulting in concurrent therapy is represented by QDM datatype and value sets of Medication, Discharge: Schedule II and Schedule III Opioids (2.16.840.1.113762.1.4.1125.2) and Medication, Discharge: Benzodiazepines (2.16.840.1.113762.1.4.1125.1).

Presence of an existing opioid and a new opioid or benzodiazepine prescription at discharge resulting in concurrent therapy is represented by QDM datatypes and value sets of Medication, Active: Schedule II and Schedule III Opioids (2.16.840.1.113762.1.4.1125.2) and Medication, Discharge: Benzodiazepines (2.16.840.1.113762.1.4.1125.1) or Medication, Discharge: Schedule II and Schedule III Opioids (2.16.840.1.113762.1.4.1125.2).

Presence of an existing benzodiazepine and a new opioid prescription at discharge resulting in concurrent therapy is represented by QDM datatypes and value sets of Medication, Active: Benzodiazepines (2.16.840.1.113762.1.4.1125.1) and Medication, Discharge: Schedule II and Schedule III Opioids (2.16.840.1.113762.1.4.1125.2).

Presence of an existing benzodiazepine and an existing opioid prescription at discharge resulting in concurrent therapy is represented by QDM datatype and value sets of Medication, Active: Benzodiazepines (2.16.840.1.113762.1.4.1125.1) and Medication, Active: Schedule II and Schedule III Opioids (2.16.840.1.113762.1.4.1125.2).

Presence of two or more existing opioids at discharge resulting in concurrent therapy is represented by QDM datatype and value set of Medication, Active: Schedule II and Schedule III Opioids (2.16.840.1.113762.1.4.1125.2).

To access the value sets for the measure, please visit the Value Set Authority Center (VSAC), sponsored by the National Library of Medicine, at https://vsac.nlm.nih.gov/.

Denominator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals >=18 years of age with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Individuals with cancer, sickle cell disease, or in hospice are excluded.

3316e: Safe Use of Opioids – Concurrent Prescribing

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.

Denominator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals 18 years and older by the first day of the measurement year with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Use Table COB-A: Opioids, below, to identify the opioid medications for the measure.

Complete the steps below to determine the denominator:

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Table COB-A: Opioids:

Benzhydrocodone, buprenorphine, butorphanol, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol

(note: includes combination products and prescription opioid cough medications. Excludes the following: injectable formulations; sublingual sufentanil (used in a supervised setting); and single-agent and combination buprenorphine products used to treat opioid use

disorder (i.e., buprenorphine sublingual tablets, Probuphine® Implant kit subcutaneous implant, and all buprenorphine/naloxone combination products).

3316e: Safe Use of Opioids – Concurrent Prescribing

Inpatient Encounters are represented using the QDM datatype and value set of Encounter, Performed: Encounter Inpatient (OID: 2.16.840.1.113883.3.666.5.307). Length of stay is calculated within the measure based on encounter start and end dates. ED Encounters including observation stay are represented using the QDM datatype and value set of Encounter, Performed: Encounter ED and Observation Stay (OID: 2.16.840.1.113883.3.3157.1002.81).

Patients with an opioid or a benzodiazepine active on admission and continued at discharge are represented by the following QDM datatype and value sets:

- Medication, Active: Schedule II and Schedule III Opioids (OID: 2.16.840.1.113762.1.4.1125.2)
- Medication, Active: Benzodiazepines (OID: 2.16.840.1.113762.1.4.1125.1)

Patients who received a new opioid or benzodiazepine prescription at discharge from a qualifying encounter, not those patients who were given an opioid or benzodiazepine as part of their encounter treatment, are represented by the following QDM datatype and value sets:

- Medication, Discharge: Schedule II and Schedule III Opioids (OID: 2.16.840.1.113762.1.4.1125.2)
- Medication, Discharge: Benzodiazepines (OID: 2.16.840.1.113762.1.4.1125.1)

To access the value sets for the measure, please visit the Value Set Authority Center, sponsored by the National Library of Medicine, at https://vsac.nlm.nih.gov/. A list of value sets for the measure is attached in the Excel workbook provided for question S.2b.

Exclusions

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Individuals with cancer, sickle cell disease, or in hospice at any point during the measurement year are excluded from the denominator.

3316e: Safe Use of Opioids – Concurrent Prescribing

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.

Exclusion Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Hospice exclusion: Exclude any individual in hospice during the measurement year. To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

Cancer exclusion: Exclude any individuals with cancer during the measurement year. To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

Sickle Cell Disease exclusion: Exclude any individual with sickle cell disease during the measurement year.

- =1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

3316e: Safe Use of Opioids – Concurrent Prescribing

Active cancer diagnosis or palliative care order during the encounter are represented using the QDM datatype and following value sets:

- Diagnosis: Cancer (2.16.840.1.113883.3.526.3.1010)
- Intervention, Performed: Palliative care (2.16.840.1.113762.1.4.1125.3)
- Intervention, Order: Palliative care (2.16.840.1.113762.1.4.1125.3)

Risk Adjustment

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

No risk adjustment or risk stratification

3316e: Safe Use of Opioids – Concurrent Prescribing

No risk adjustment or risk stratification

Stratification

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

3316e: Safe Use of Opioids – Concurrent Prescribing

Not applicable; this measure is not stratified.

Type Score

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Rate/proportion better quality = lower score

3316e: Safe Use of Opioids – Concurrent Prescribing

Rate/proportion better quality = lower score

Algorithm

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

A. Target population (denominator):

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Step 5: Identify individuals with cancer, sickle cell disease or in hospice during the measurement year.

To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g., Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

To identify individuals with sickle cell disease:

- >=1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

Step 6: Exclude individuals with cancer, sickle cell disease, or in hospice (Step 5) from those identified in Step 4. This is the denominator.

B. Numerator Population:

Step 7: From the denominator population, identify individuals with >=2 prescriptions claims with different dates of service for any benzodiazepines (Table COB-B, below) during the measurement year.

Step 8: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

Note: When identifying days' supply for opioids (or benzodiazepines):

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.

- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 9: Count the number of individuals with concurrent use of opioids and benzodiazepines for >=30 cumulative days. This is the numerator.

C. Measure Rate:

Step 10: Divide the number of individuals in the numerator (Step 9) by the denominator (Step 6) and multiply by 100. This is the measure rate reported as a percentage.

- Report the rates separately by line of business (e.g. Medicare, Medicaid, Commercial).

3316e: Safe Use of Opioids – Concurrent Prescribing

Please see the attached HQMF specifications for the complete measure logic. Additionally, a flow diagram of the denominator and numerator logic is attached to the NQF submission form as a supplemental document in response to question A.1, 'Opioids_LogicFlow_for S.14 response.pdf'.

Submission items

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

5.1 Identified measures: 2940 : Use of Opioids at High Dosage in Persons Without Cancer

2950 : Use of Opioids from Multiple Providers in Persons Without Cancer

2951 : Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

3316 : Safe Use of Opioids – Concurrent Prescribing

3541 : Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

3558 : Initial Opioid Prescribing for Long Duration (IOP-LD)

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: ---UPDATED FOR MAINTENANCE--- At time of maintenance, PQA has also identified the 3316e: Safe Use of Opioids – Concurrent Prescribing measure as related. Although the area of focus overlaps, 3316e is specified at the facility level as an eCQM, as opposed to 3389, which is specified at the health plan level and is claims-based. PQA identified the 3558: Initial Opioid Prescribing for Long Duration and 3541: Annual Monitoring for Persons on Long-Term Opioid Therapy) measures as related to opioid prescribing, although the areas of focus (initial opioid prescribing and annual monitoring) are different than 3389 (concurrent use of opioids and benzodiazepines).

5b.1 If competing, why superior or rationale for additive value: There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

---UPDATED FOR MAINTENANCE---

There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

3316e: Safe Use of Opioids – Concurrent Prescribing

5.1 Identified measures: 2940 : Use of Opioids at High Dosage in Persons Without Cancer

2950 : Use of Opioids from Multiple Providers in Persons Without Cancer

2951 : Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: This proposed measure is a new measure. The list of Schedule II and III opioids and denominator exclusions are harmonized, where feasible, with NQF-endorsed PQA measures 2940, 2950, and 2951. The measure specifications of the proposed measure are not completely harmonized with these PQA measures as they do not include benzodiazepines in the measure focus. Below we describe the differences between the proposed measure and NQF #2940, #2950, and #2951: The eligible population for the Concurrent Prescribing measure captures not only patients prescribed at least one opioid at discharge, but also patients prescribed at least one benzodiazepine at discharge per the measure focus. Experts stressed the importance of including both opioids and benzodiazepines in the denominator to ensure that the measure takes into consideration any iatrogenic risk from co-prescribing for both populations already on opioids or benzodiazepines; Only Schedule II and Schedule III opioids are in scope of the Concurrent Prescribing measure per expert consensus. The PQA measures also include Schedule IV opioids; The Concurrent Prescribing measure assesses patients across the hospital inpatients and outpatient settings (ED, including observation stays) per the programs in which the measure will be proposed for implementation. The PQA measure focuses on the prescription drug health plan level.

5b.1 If competing, why superior or rationale for additive value: Not applicable

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

3316e: Safe Use of Opioids – Concurrent Prescribing

3316e: Safe Use of Opioids – Concurrent Prescribing

Steward

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

PQA, Inc.

3316e: Safe Use of Opioids – Concurrent Prescribing

Centers for Medicare & Medicaid Services

Description

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The percentage of individuals >=18 years of age with concurrent use of prescription opioids and benzodiazepines during the measurement year.

A lower rate indicates better performance.

3316e: Safe Use of Opioids – Concurrent Prescribing

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)

Type

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Process

3316e: Safe Use of Opioids – Concurrent Prescribing

Process

Data Source

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Claims, Enrollment Data Administrative claims: prescription claims, medical claims, enrollment data

No data collection instrument provided Attachment pqa_meas_yr_2019_cob_value_sets_20200729_NQF.xlsx

3316e: Safe Use of Opioids – Concurrent Prescribing

Electronic Health Records Hospitals collect EHR data using certified electronic health record technology (CEHRT). The human readable and XML artifacts of the health quality measures format (HQMF) of the measure are contained in the eCQM specifications attached in question S.2a. No additional tools are used for data collection for eCQMs.

No data collection instrument provided Attachment Opioids_ValueSets.xlsx

Level

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Health Plan

3316e: Safe Use of Opioids – Concurrent Prescribing

Facility

Setting

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Outpatient Services

3316e: Safe Use of Opioids – Concurrent Prescribing

Emergency Department and Services, Inpatient/Hospital

Numerator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with concurrent use of opioids and benzodiazepines for >=30 cumulative days during the measurement year.

3316e: Safe Use of Opioids – Concurrent Prescribing

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

Numerator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with:

- >=2 prescription claims for any benzodiazepine with different dates of service, AND
- Concurrent use of opioids and benzodiazepines for >=30 cumulative days.

Complete the steps below to identify individuals with concurrent use of opioids and benzodiazepines:

Step 1: From the denominator population, identify individuals with >=2 prescription claims with different dates of service for any benzodiazepine (Table COB-B, below) during the measurement year.

Step 2: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

NOTE:

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 3: Count the individuals with concurrent use for >=30 cumulative days. This is the numerator.

Table COB-B: Benzodiazepines:

Alprazolam, chlordiazepoxide, clobazam, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, triazolam

(Note: excludes injectable formulations, includes combination products)

3316e: Safe Use of Opioids – Concurrent Prescribing

Presence of two or more new opioids at discharge resulting in concurrent therapy is represented by QDM datatype and value set of Medication, Discharge: Schedule II and Schedule III Opioids (2.16.840.1.113762.1.4.1125.2).

Presence of a new opioid and a new benzodiazepine prescription at discharge resulting in concurrent therapy is represented by QDM datatype and value sets of Medication, Discharge: Schedule II and Schedule III Opioids (2.16.840.1.113762.1.4.1125.2) and Medication, Discharge: Benzodiazepines (2.16.840.1.113762.1.4.1125.1).

Presence of an existing opioid and a new opioid or benzodiazepine prescription at discharge resulting in concurrent therapy is represented by QDM datatypes and value sets of Medication, Active: Schedule II and Schedule III Opioids (2.16.840.1.113762.1.4.1125.2) and Medication, Discharge: Benzodiazepines (2.16.840.1.113762.1.4.1125.1) or Medication, Discharge: Schedule II and Schedule III Opioids (2.16.840.1.113762.1.4.1125.2).

Presence of an existing benzodiazepine and a new opioid prescription at discharge resulting in concurrent therapy is represented by QDM datatypes and value sets of Medication, Active: Benzodiazepines (2.16.840.1.113762.1.4.1125.1) and Medication, Discharge: Schedule II and Schedule III Opioids (2.16.840.1.113762.1.4.1125.2).

Presence of an existing benzodiazepine and an existing opioid prescription at discharge resulting in concurrent therapy is represented by QDM datatype and value sets of Medication, Active: Benzodiazepines (2.16.840.1.113762.1.4.1125.1) and Medication, Active: Schedule II and Schedule III Opioids (2.16.840.1.113762.1.4.1125.2).

Presence of two or more existing opioids at discharge resulting in concurrent therapy is represented by QDM datatype and value set of Medication, Active: Schedule II and Schedule III Opioids (2.16.840.1.113762.1.4.1125.2).

To access the value sets for the measure, please visit the Value Set Authority Center (VSAC), sponsored by the National Library of Medicine, at https://vsac.nlm.nih.gov/.

Denominator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals >=18 years of age with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Individuals with cancer, sickle cell disease, or in hospice are excluded.

3316e: Safe Use of Opioids – Concurrent Prescribing

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.

Denominator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals 18 years and older by the first day of the measurement year with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Use Table COB-A: Opioids, below, to identify the opioid medications for the measure.

Complete the steps below to determine the denominator:

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Table COB-A: Opioids:

Benzhydrocodone, buprenorphine, butorphanol, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol

(note: includes combination products and prescription opioid cough medications. Excludes the following: injectable formulations; sublingual sufentanil (used in a supervised setting); and single-agent and combination buprenorphine products used to treat opioid use disorder (i.e., buprenorphine sublingual tablets, Probuphine® Implant kit subcutaneous implant, and all buprenorphine/naloxone combination products).

3316e: Safe Use of Opioids – Concurrent Prescribing

Inpatient Encounters are represented using the QDM datatype and value set of Encounter, Performed: Encounter Inpatient (OID: 2.16.840.1.113883.3.666.5.307). Length of stay is calculated within the measure based on encounter start and end dates. ED Encounters including observation stay are represented using the QDM datatype and value set of Encounter, Performed: Encounter ED and Observation Stay (OID: 2.16.840.1.113883.3.3157.1002.81).

Patients with an opioid or a benzodiazepine active on admission and continued at discharge are represented by the following QDM datatype and value sets:

- Medication, Active: Schedule II and Schedule III Opioids (OID: 2.16.840.1.113762.1.4.1125.2)
- Medication, Active: Benzodiazepines (OID: 2.16.840.1.113762.1.4.1125.1)

Patients who received a new opioid or benzodiazepine prescription at discharge from a qualifying encounter, not those patients who were given an opioid or benzodiazepine as part of their encounter treatment, are represented by the following QDM datatype and value sets:

- Medication, Discharge: Schedule II and Schedule III Opioids (OID: 2.16.840.1.113762.1.4.1125.2)
- Medication, Discharge: Benzodiazepines (OID: 2.16.840.1.113762.1.4.1125.1)

To access the value sets for the measure, please visit the Value Set Authority Center, sponsored by the National Library of Medicine, at https://vsac.nlm.nih.gov/. A list of value sets for the measure is attached in the Excel workbook provided for question S.2b.

Exclusions

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Individuals with cancer, sickle cell disease, or in hospice at any point during the measurement year are excluded from the denominator.

3316e: Safe Use of Opioids – Concurrent Prescribing

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.

Exclusion Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Hospice exclusion: Exclude any individual in hospice during the measurement year. To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

Cancer exclusion: Exclude any individuals with cancer during the measurement year. To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

Sickle Cell Disease exclusion: Exclude any individual with sickle cell disease during the measurement year.

- =1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

3316e: Safe Use of Opioids – Concurrent Prescribing

Active cancer diagnosis or palliative care order during the encounter are represented using the QDM datatype and following value sets:

- Diagnosis: Cancer (2.16.840.1.113883.3.526.3.1010)
- Intervention, Performed: Palliative care (2.16.840.1.113762.1.4.1125.3)
- Intervention, Order: Palliative care (2.16.840.1.113762.1.4.1125.3)

Risk Adjustment

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

No risk adjustment or risk stratification

3316e: Safe Use of Opioids – Concurrent Prescribing

No risk adjustment or risk stratification

Stratification

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

3316e: Safe Use of Opioids – Concurrent Prescribing

Not applicable; this measure is not stratified.

Type Score

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Rate/proportion better quality = lower score

3316e: Safe Use of Opioids – Concurrent Prescribing

Rate/proportion better quality = lower score

Algorithm

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

A. Target population (denominator):

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Step 5: Identify individuals with cancer, sickle cell disease or in hospice during the measurement year.

To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g., Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

To identify individuals with sickle cell disease:

- >=1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

Step 6: Exclude individuals with cancer, sickle cell disease, or in hospice (Step 5) from those identified in Step 4. This is the denominator.

B. Numerator Population:

Step 7: From the denominator population, identify individuals with >=2 prescriptions claims with different dates of service for any benzodiazepines (Table COB-B, below) during the measurement year.

Step 8: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days'

supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

Note: When identifying days' supply for opioids (or benzodiazepines):

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 9: Count the number of individuals with concurrent use of opioids and benzodiazepines for >=30 cumulative days. This is the numerator.

C. Measure Rate:

Step 10: Divide the number of individuals in the numerator (Step 9) by the denominator (Step 6) and multiply by 100. This is the measure rate reported as a percentage.

- Report the rates separately by line of business (e.g. Medicare, Medicaid, Commercial).

3316e: Safe Use of Opioids – Concurrent Prescribing

Please see the attached HQMF specifications for the complete measure logic. Additionally, a flow diagram of the denominator and numerator logic is attached to the NQF submission form as a supplemental document in response to question A.1, 'Opioids_LogicFlow_for S.14 response.pdf'.

Submission items

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

5.1 Identified measures: 2940 : Use of Opioids at High Dosage in Persons Without Cancer

2950 : Use of Opioids from Multiple Providers in Persons Without Cancer

2951 : Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

3316 : Safe Use of Opioids – Concurrent Prescribing

3541 : Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

3558 : Initial Opioid Prescribing for Long Duration (IOP-LD)

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: ---UPDATED FOR MAINTENANCE--- At time of maintenance, PQA has also identified the 3316e: Safe Use of Opioids – Concurrent Prescribing measure as related. Although the area of focus overlaps, 3316e is specified at the facility level as an eCQM, as opposed to 3389, which is specified at the health plan level and is claims-based. PQA identified the 3558: Initial Opioid Prescribing for Long Duration and 3541: Annual Monitoring for Persons on Long-Term Opioid Therapy) measures as related to opioid prescribing, although the areas of focus (initial opioid prescribing and annual monitoring) are different than 3389 (concurrent use of opioids and benzodiazepines).

5b.1 If competing, why superior or rationale for additive value: There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

---UPDATED FOR MAINTENANCE---

There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

3316e: Safe Use of Opioids – Concurrent Prescribing

5.1 Identified measures: 2940 : Use of Opioids at High Dosage in Persons Without Cancer

2950 : Use of Opioids from Multiple Providers in Persons Without Cancer

2951 : Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: This proposed measure is a new measure. The list of Schedule II and III opioids and denominator exclusions are harmonized, where feasible, with NQF-endorsed PQA measures 2940, 2950, and 2951. The measure specifications of the proposed measure are not completely harmonized with these PQA measures as they do not include benzodiazepines in the measure focus. Below we describe the differences between the proposed measure and NQF #2940, #2950, and #2951: The eligible population for the Concurrent Prescribing measure captures not only patients prescribed at least one opioid at discharge, but also patients prescribed at least one benzodiazepine at discharge per the measure focus. Experts stressed the importance of including both opioids and benzodiazepines in the denominator to ensure that the measure takes into consideration any iatrogenic risk from co-prescribing for both populations already on opioids or benzodiazepines; Only Schedule II and Schedule III opioids are in scope of the Concurrent Prescribing measure per expert consensus. The PQA measures also include Schedule IV opioids; The Concurrent Prescribing measure assesses patients across the hospital inpatients and outpatient settings (ED, including observation stays) per the programs in which the measure will be proposed for implementation. The PQA measure focuses on the prescription drug health plan level.

5b.1 If competing, why superior or rationale for additive value: Not applicable

Comparison of NQF #3389 and NQF #3541

3389: Concurrent Use of Opioids and Benzodiazepines (COB)
3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Steward

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

PQA, Inc.

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Pharmacy Quality Alliance

Description

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The percentage of individuals >=18 years of age with concurrent use of prescription opioids and benzodiazepines during the measurement year.

A lower rate indicates better performance.

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

The percentage of individuals 18 years of age and older who are on long-term opioid therapy and have not received a drug test at least once during the measurement year.

Type

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Process

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Process

Data Source

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Claims, Enrollment Data Administrative claims: prescription claims, medical claims, enrollment data

No data collection instrument provided Attachment pqa_meas_yr_2019_cob_value_sets_20200729_NQF.xlsx

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Claims, Enrollment Data There is no data collection instrument. Individual health plans produce administrative claims in the course of providing care to health plan members.

This measure is being considered for use in the Quality Rating System (QRS) for Qualified Health Plans (QHPs). QHPs operate in the Health Insurance Exchanges, established by the Patient Protection and Affordable Care Act. As a condition of participation, eligible QHPs are required to collect and submit quality measure data. CMS calculates quality ratings based on the data submitted, and Exchanges are required to display QHP overall quality ratings and three summary indicator ratings to assist in consumer selection of a QHP offered on an Exchange.

The following sources of data were used to calculate the measure:

1. QHP products: Claims data from issuers, consisting of hospital and office visits, pharmacy, and laboratory claims (when available); enrollment data; and members' demographic data OR
2. Medicare: Claims data from Medicare Parts A, B and D consisting of inpatient and outpatient claims and prescription drug events; enrollment data; and beneficiaries' demographic data.

Please note that Medicare data were used to supplement QHP data for measure testing because they offer a robust sample for calculation of measure performance reliability. Medicare PDPs are similar to QHPs in that they are offered by private insurance companies and are responsible for providing safe and effective medication management. Additionally, if variation in performance is similar among QHP products and Medicare PDPs, we could conclude this measure is generally applicable and reliable at the health plan level. At the time this form was completed, CMS does not have a plan to add this measure to quality reporting or value-based purchasing programs for Medicare enrollees but may consider this measure for the future.

No data collection instrument provided Attachment AMO_CompleteCoding_UPDATED-637002672397479085.xlsx

Level

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Health Plan

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Health Plan

Setting

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Outpatient Services

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Outpatient Services

Numerator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with concurrent use of opioids and benzodiazepines for >=30 cumulative days during the measurement year.

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Individuals in the denominator population who have not received a drug test during the measurement year.

Numerator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with:

- >=2 prescription claims for any benzodiazepine with different dates of service, AND
- Concurrent use of opioids and benzodiazepines for >=30 cumulative days.

Complete the steps below to identify individuals with concurrent use of opioids and benzodiazepines:

Step 1: From the denominator population, identify individuals with >=2 prescription claims with different dates of service for any benzodiazepine (Table COB-B, below) during the measurement year.

Step 2: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

NOTE:

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year

only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 3: Count the individuals with concurrent use for >=30 cumulative days. This is the numerator.

Table COB-B: Benzodiazepines:

Alprazolam, chlordiazepoxide, clobazam, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, triazolam

(Note: excludes injectable formulations, includes combination products)

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Individuals in the denominator who do not have at least one claim for a drug test during the measurement year will be counted in the numerator. The entire measurement year in which a member is continuously enrolled is used to calculate the measure.

A drug test is identified either through HCPCS drug test codes or through specified CPT or LOINC codes for presumptive or definitive drug screens/tests for at least one of the following targeted drug classes: amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, and opiates/opioids.

Qualifying CPT and HCPCS drug test codes, and suggested LOINC codes, are in the attached Excel file "AMO_CompleteCoding_UPDATED" in the following sheets: "Codes-2016 Data," "Codes-2017 Data," Codes-2018 Data," and "DrugScreen_LOINC_15,16,17."

Denominator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals >=18 years of age with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Individuals with cancer, sickle cell disease, or in hospice are excluded.

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

The target population for this measure is individuals 18 years of age and older and prescribed long-term opioid therapy during the measurement year. Individuals are excluded if they have had any claims indicating a cancer diagnosis or hospice care at any time during the measurement year.

Denominator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals 18 years and older by the first day of the measurement year with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Use Table COB-A: Opioids, below, to identify the opioid medications for the measure.

Complete the steps below to determine the denominator:

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Table COB-A: Opioids:

Benzhydrocodone, buprenorphine, butorphanol, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol

(note: includes combination products and prescription opioid cough medications. Excludes the following: injectable formulations; sublingual sufentanil (used in a supervised setting); and single-agent and combination buprenorphine products used to treat opioid use disorder (i.e., buprenorphine sublingual tablets, Probuphine® Implant kit subcutaneous implant, and all buprenorphine/naloxone combination products).

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

The measurement year is defined as 12 consecutive months. Continuous enrollment is defined as 11 out of 12 months enrollment in a health plan in the measurement year or enrolled with no gaps in enrollment until the month of death in the measurement year. Long-term opioid therapy is defined as at least 90 days of cumulative days' supply of any combination of opioid medications indicated for pain during the measurement period identified using prescription claims. Medications prescribed or provided as part of medication-assisted treatment for opioid use disorder are excluded from the calculation.

The target population is adults enrolled in a Qualified Health Plan (QHP) and on long-term opioid therapy.

Eligible members for this measure are those members who:

1) Are 18 years of age and older as of the first day of the measurement year.
2) Are continuously enrolled in a QHP which is defined as at least 11 out of 12 months during the measurement year or enrolled with no gaps until the date of death.
3) Have pharmacy claims indicating at least 90 days of cumulative supply of any combination of opioid medications indicated for pain during the measurement year.

Opioid medications are specified in the attached Excel file "AMO_CompleteCoding_UPDATED" in the following sheets "2016_OPIOIDFORPAINMEDICATION," "2017_OPIOIDFORPAINMEDICATION," and "2018_OPIOIDFORPAINMEDICATION."

Days' supply is calculated by summing the days' supply for every prescription during the measurement year for opioid medications indicated for pain from the above lists. Individuals qualify for the measure denominator if this sum is at least 90 days.

Note: The active ingredient of the opioid medications is limited to formulations indicated for pain and delivered through any route except intravenous (IV) or epidural (EP). These two routes are not included in this measure because they are not commonly prescribed as chronic pain medications. Medications prescribed or provided as part of medication-assisted treatment for opioid use disorder are excluded from the calculation.

Exclusions

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Individuals with cancer, sickle cell disease, or in hospice at any point during the measurement year are excluded from the denominator.

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

The measure excludes individuals with: 1) a diagnosis of cancer at any time during the measurement year; or 2) hospice care at any time during the year.

Exclusion Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Hospice exclusion: Exclude any individual in hospice during the measurement year. To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

Cancer exclusion: Exclude any individuals with cancer during the measurement year. To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

Sickle Cell Disease exclusion: Exclude any individual with sickle cell disease during the measurement year.

- =1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Members with a diagnosis of cancer are identified with the diagnosis codes listed below.

Cancer exclusion ICD-9 codes (for testing only):

Include 140 through 239

Omit 173.XX series

Cancer exclusion ICD-10 codes:

Include C00 through D49

Omit C44.XX series

Members with hospice care are identified with the codes listed below.

Hospice Codes 2015-2016:

Revenue Codes – 0115, 0125, 0135, 0145, 0155, 0235, 0650, 0651, 0652, 0655, 0656, 0657, 0658, 0659

CPT Codes – 99377, 99378

HCPCS Codes – G0182, G9473, G9474, G9475, G9476, G9477, G9478, G9479, Q5003, Q5004, Q50005, Q5006, Q5007, Q5008, Q5010, S9126, T2042, T043, T2044, T2045, T2046

Type of Bill (TOB) Codes – 0810, 0811, 0812, 0813, 0814, 0815, 0817, 0818, 0819, 0820, 0821, 0822, 0823, 0824, 0825, 0827, 0828, 0829, 081A, 081B, 081C, 081D, 081E, 081F, 081G, 081H, 081I, 081J, 081K, 081M, 081O, 081X, 081Y, 081Z, 082A, 082B, 082C, 082D, 082E, 082F, 082G, 082H, 082I, 082J, 082K, 082M, 082X, 082Y, 082Z

Note: A full list of codes is provided in the attached Excel file "AMO_CompleteCoding" in the sheet "Codes-2016 Data," "Codes-2017 Data," and "Codes-2018 Data."

Risk Adjustment

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

No risk adjustment or risk stratification

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

No risk adjustment or risk stratification

135614

Stratification

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Not applicable.

Type Score

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Rate/proportion better quality = lower score

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Rate/proportion better quality = lower score

Algorithm

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

A. Target population (denominator):

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.

- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Step 5: Identify individuals with cancer, sickle cell disease or in hospice during the measurement year.

To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g., Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

To identify individuals with sickle cell disease:

- >=1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

Step 6: Exclude individuals with cancer, sickle cell disease, or in hospice (Step 5) from those identified in Step 4. This is the denominator.

B. Numerator Population:

Step 7: From the denominator population, identify individuals with >=2 prescriptions claims with different dates of service for any benzodiazepines (Table COB-B, below) during the measurement year.

Step 8: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

Note: When identifying days' supply for opioids (or benzodiazepines):

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 9: Count the number of individuals with concurrent use of opioids and benzodiazepines for >=30 cumulative days. This is the numerator.

C. Measure Rate:

Step 10: Divide the number of individuals in the numerator (Step 9) by the denominator (Step 6) and multiply by 100. This is the measure rate reported as a percentage.

- Report the rates separately by line of business (e.g. Medicare, Medicaid, Commercial).

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Denominator: Individuals 18 years of age and older who are on long-term opioid therapy during the measurement year.

Create Denominator:

1. Include all individuals enrolled in a health plan for 11 of 12 months during the measurement year or enrolled with no gaps in enrollment until the month of death in the measurement year.
    a. For QHPs in the Health Insurance Marketplace, switching between QHP products is considered continuous enrollment if enrollment and claims/encounter data are available for 11 of 12 months. The measure score is attributed to the last enrolled QHP product, in accordance with technical guidance specific to the Health Insurance Marketplace Quality Rating System (QRS), available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/Revised_QRS-2018-Measure-Tech-Specs_20170929_508.pdf.
2. Include individuals from step 1 who were 18 years of age or older as of the first day of the measurement year.
3. Include individuals from step 2 with a total days' supply of opioids of 90 days or more identified in pharmacy claims (section S.7).
4. Exclude individuals with any institutional or non-institutional claims indicating a cancer diagnosis during the measurement year (section S.9)
5. Exclude individuals with any institutional or non-institutional claims indicating hospice care during the measurement year (section S.9)
6. Include only unique members from step 5 in the final denominator.

Numerator: Individuals in the denominator population with no claims for drug tests during the measurement year.

Create Numerator:

7. Include individuals from the denominator who do not have any claims for a drug test during the measurement year (section S.5)

Calculate Measure Score:

8. The measure score is calculated as the number of individuals in the numerator divided by the number of individuals in the denominator multiplied by 100 (to produce a percentage).

For the Health Insurance Marketplace, members are attributed to the last QHP enrolled product during the measurement year. 135614

Submission items

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

5.1 Identified measures: 2940 : Use of Opioids at High Dosage in Persons Without Cancer

2950 : Use of Opioids from Multiple Providers in Persons Without Cancer

2951 : Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

3316 : Safe Use of Opioids – Concurrent Prescribing

3541 : Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

3558 : Initial Opioid Prescribing for Long Duration (IOP-LD)

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: ---UPDATED FOR MAINTENANCE--- At time of maintenance, PQA has also identified the 3316e: Safe Use of Opioids – Concurrent Prescribing measure as related. Although the area of focus overlaps, 3316e is specified at the facility level as an eCQM, as opposed to 3389, which is specified at the health plan level and is claims-based. PQA identified the 3558: Initial Opioid Prescribing for Long Duration and 3541: Annual Monitoring for Persons on Long-Term Opioid Therapy) measures as related to opioid prescribing, although the areas of focus (initial opioid prescribing and annual monitoring) are different than 3389 (concurrent use of opioids and benzodiazepines).

5b.1 If competing, why superior or rationale for additive value: There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

---UPDATED FOR MAINTENANCE---

There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

5.1 Identified measures: 1617 : Patients Treated with an Opioid who are Given a Bowel Regimen

2940 : Use of Opioids at High Dosage in Persons Without Cancer

2950 : Use of Opioids from Multiple Providers in Persons Without Cancer

2951 : Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

3316 : Safe Use of Opioids – Concurrent Prescribing

3389 : Concurrent Use of Opioids and Benzodiazepines (COB)

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: An environmental scan revealed related measures listed above, which share similar populations of interest (patients receiving opioids). NQF 1617 targets vulnerable adults given a new prescription for an opioid, and therefore has a different target population than the AMO measure. NQF 3316e is an eCQM that targets patients discharged from a hospital-based encounter, a different setting of care than the AMO measure. Harmonization of value sets has been addressed to the extent possible with related outpatient health plan measures, NQF 2940, 2950, 2951, and 3389, including the cancer and hospice exclusions and targeted opioid medications. The AMO measure's area of focus (numerator) does not overlap with any existing measure, and its focus on drug tests for patients on long-term opioid therapy is unique. Therefore, while there are some related measures that evaluate similar target populations of patients receiving opioid therapy, the AMO measure is a new and evidence-based focus to empower health plans to address opioid misuse and opioid use disorder, and improve patient safety. Harmonization has been addressed to the extent possible, and PQA will continue to identify and address opportunities to harmonize with related measures over time.

5b.1 If competing, why superior or rationale for additive value: Not applicable.

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Steward

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

PQA, Inc.

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Pharmacy Quality Alliance

Description

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The percentage of individuals >=18 years of age with concurrent use of prescription opioids and benzodiazepines during the measurement year.

A lower rate indicates better performance.

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

The percentage of individuals 18 years of age and older who are on long-term opioid therapy and have not received a drug test at least once during the measurement year.

Type

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Process

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Process

Data Source

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Claims, Enrollment Data Administrative claims: prescription claims, medical claims, enrollment data

No data collection instrument provided Attachment pqa_meas_yr_2019_cob_value_sets_20200729_NQF.xlsx

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Claims, Enrollment Data There is no data collection instrument. Individual health plans produce administrative claims in the course of providing care to health plan members.

This measure is being considered for use in the Quality Rating System (QRS) for Qualified Health Plans (QHPs). QHPs operate in the Health Insurance Exchanges, established by the Patient Protection and Affordable Care Act. As a condition of participation, eligible QHPs are required to collect and submit quality measure data. CMS calculates quality ratings based on the data submitted, and Exchanges are required to display QHP overall quality ratings and three summary indicator ratings to assist in consumer selection of a QHP offered on an Exchange.

The following sources of data were used to calculate the measure:

1. QHP products: Claims data from issuers, consisting of hospital and office visits, pharmacy, and laboratory claims (when available); enrollment data; and members' demographic data OR
2. Medicare: Claims data from Medicare Parts A, B and D consisting of inpatient and outpatient claims and prescription drug events; enrollment data; and beneficiaries' demographic data.

Please note that Medicare data were used to supplement QHP data for measure testing because they offer a robust sample for calculation of measure performance reliability. Medicare PDPs are similar to QHPs in that they are offered by private insurance companies and are responsible for providing safe and effective medication management. Additionally, if variation in performance is similar among QHP products and Medicare PDPs, we could conclude this measure is generally applicable and reliable at the health plan level. At the time this form was completed, CMS does not have a plan to add this measure to quality reporting or value-based purchasing programs for Medicare enrollees but may consider this measure for the future.

No data collection instrument provided Attachment AMO_CompleteCoding_UPDATED-637002672397479085.xlsx

Level

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Health Plan

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Health Plan

Setting

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Outpatient Services

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Outpatient Services

Numerator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with concurrent use of opioids and benzodiazepines for >=30 cumulative days during the measurement year.

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Individuals in the denominator population who have not received a drug test during the measurement year.

Numerator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with:

- >=2 prescription claims for any benzodiazepine with different dates of service, AND
- Concurrent use of opioids and benzodiazepines for >=30 cumulative days.

Complete the steps below to identify individuals with concurrent use of opioids and benzodiazepines:

Step 1: From the denominator population, identify individuals with >=2 prescription claims with different dates of service for any benzodiazepine (Table COB-B, below) during the measurement year.

Step 2: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

NOTE:

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 3: Count the individuals with concurrent use for >=30 cumulative days. This is the numerator.

Table COB-B: Benzodiazepines:

Alprazolam, chlordiazepoxide, clobazam, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, triazolam

(Note: excludes injectable formulations, includes combination products)

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Individuals in the denominator who do not have at least one claim for a drug test during the measurement year will be counted in the numerator. The entire measurement year in which a member is continuously enrolled is used to calculate the measure.

A drug test is identified either through HCPCS drug test codes or through specified CPT or LOINC codes for presumptive or definitive drug screens/tests for at least one of the following targeted drug classes: amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, and opiates/opioids.

Qualifying CPT and HCPCS drug test codes, and suggested LOINC codes, are in the attached Excel file "AMO_CompleteCoding_UPDATED" in the following sheets: "Codes-2016 Data," "Codes-2017 Data," Codes-2018 Data," and "DrugScreen_LOINC_15,16,17."

Denominator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals >=18 years of age with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Individuals with cancer, sickle cell disease, or in hospice are excluded.

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

The target population for this measure is individuals 18 years of age and older and prescribed long-term opioid therapy during the measurement year. Individuals are

excluded if they have had any claims indicating a cancer diagnosis or hospice care at any time during the measurement year.

Denominator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals 18 years and older by the first day of the measurement year with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Use Table COB-A: Opioids, below, to identify the opioid medications for the measure.

Complete the steps below to determine the denominator:

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Table COB-A: Opioids:

Benzhydrocodone, buprenorphine, butorphanol, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol

(note: includes combination products and prescription opioid cough medications. Excludes the following: injectable formulations; sublingual sufentanil (used in a supervised setting); and single-agent and combination buprenorphine products used to treat opioid use disorder (i.e., buprenorphine sublingual tablets, Probuphine® Implant kit subcutaneous implant, and all buprenorphine/naloxone combination products).

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

The measurement year is defined as 12 consecutive months. Continuous enrollment is defined as 11 out of 12 months enrollment in a health plan in the measurement year or enrolled with no gaps in enrollment until the month of death in the measurement year. Long-term opioid therapy is defined as at least 90 days of cumulative days' supply of any combination of opioid medications indicated for pain during the measurement period

identified using prescription claims. Medications prescribed or provided as part of medication-assisted treatment for opioid use disorder are excluded from the calculation.

The target population is adults enrolled in a Qualified Health Plan (QHP) and on long-term opioid therapy.

Eligible members for this measure are those members who:

1) Are 18 years of age and older as of the first day of the measurement year.
2) Are continuously enrolled in a QHP which is defined as at least 11 out of 12 months during the measurement year or enrolled with no gaps until the date of death.
3) Have pharmacy claims indicating at least 90 days of cumulative supply of any combination of opioid medications indicated for pain during the measurement year.

Opioid medications are specified in the attached Excel file "AMO_CompleteCoding_UPDATED" in the following sheets "2016_OPIOIDFORPAINMEDICATION," "2017_OPIOIDFORPAINMEDICATION," and "2018_OPIOIDFORPAINMEDICATION."

Days' supply is calculated by summing the days' supply for every prescription during the measurement year for opioid medications indicated for pain from the above lists. Individuals qualify for the measure denominator if this sum is at least 90 days.

Note: The active ingredient of the opioid medications is limited to formulations indicated for pain and delivered through any route except intravenous (IV) or epidural (EP). These two routes are not included in this measure because they are not commonly prescribed as chronic pain medications. Medications prescribed or provided as part of medication-assisted treatment for opioid use disorder are excluded from the calculation.

Exclusions

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Individuals with cancer, sickle cell disease, or in hospice at any point during the measurement year are excluded from the denominator.

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

The measure excludes individuals with: 1) a diagnosis of cancer at any time during the measurement year; or 2) hospice care at any time during the year.

Exclusion Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Hospice exclusion: Exclude any individual in hospice during the measurement year. To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

Cancer exclusion: Exclude any individuals with cancer during the measurement year. To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

Sickle Cell Disease exclusion: Exclude any individual with sickle cell disease during the measurement year.

- =1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Members with a diagnosis of cancer are identified with the diagnosis codes listed below.

Cancer exclusion ICD-9 codes (for testing only):

Include 140 through 239

Omit 173.XX series

Cancer exclusion ICD-10 codes:

Include C00 through D49

Omit C44.XX series

Members with hospice care are identified with the codes listed below.

Hospice Codes 2015-2016:

Revenue Codes – 0115, 0125, 0135, 0145, 0155, 0235, 0650, 0651, 0652, 0655, 0656, 0657, 0658, 0659

CPT Codes – 99377, 99378

HCPCS Codes – G0182, G9473, G9474, G9475, G9476, G9477, G9478, G9479, Q5003, Q5004, Q50005, Q5006, Q5007, Q5008, Q5010, S9126, T2042, T043, T2044, T2045, T2046

Type of Bill (TOB) Codes – 0810, 0811, 0812, 0813, 0814, 0815, 0817, 0818, 0819, 0820, 0821, 0822, 0823, 0824, 0825, 0827, 0828, 0829, 081A, 081B, 081C, 081D, 081E, 081F, 081G, 081H, 081I, 081J, 081K, 081M, 081O, 081X, 081Y, 081Z, 082A, 082B, 082C, 082D, 082E, 082F, 082G, 082H, 082I, 082J, 082K, 082M, 082X, 082Y, 082Z

Note: A full list of codes is provided in the attached Excel file “AMO_CompleteCoding” in the sheet “Codes-2016 Data,” “Codes-2017 Data,” and “Codes-2018 Data.”

Risk Adjustment

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

No risk adjustment or risk stratification

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

No risk adjustment or risk stratification

135614

Stratification

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Not applicable.

Type Score

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Rate/proportion better quality = lower score

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Rate/proportion better quality = lower score

Algorithm

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

A. Target population (denominator):

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Step 5: Identify individuals with cancer, sickle cell disease or in hospice during the measurement year.

To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g., Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

To identify individuals with sickle cell disease:

- >=1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

Step 6: Exclude individuals with cancer, sickle cell disease, or in hospice (Step 5) from those identified in Step 4. This is the denominator.

B. Numerator Population:

Step 7: From the denominator population, identify individuals with >=2 prescriptions claims with different dates of service for any benzodiazepines (Table COB-B, below) during the measurement year.

Step 8: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

Note: When identifying days' supply for opioids (or benzodiazepines):

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 9: Count the number of individuals with concurrent use of opioids and benzodiazepines for >=30 cumulative days. This is the numerator.

C. Measure Rate:

Step 10: Divide the number of individuals in the numerator (Step 9) by the denominator (Step 6) and multiply by 100. This is the measure rate reported as a percentage.

- Report the rates separately by line of business (e.g. Medicare, Medicaid, Commercial).

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Denominator: Individuals 18 years of age and older who are on long-term opioid therapy during the measurement year.

Create Denominator:

1. Include all individuals enrolled in a health plan for 11 of 12 months during the measurement year or enrolled with no gaps in enrollment until the month of death in the measurement year.
    a. For QHPs in the Health Insurance Marketplace, switching between QHP products is considered continuous enrollment if enrollment and claims/encounter data are available for 11 of 12 months. The measure score is attributed to the last enrolled QHP product, in accordance with technical guidance specific to the Health Insurance Marketplace Quality Rating System (QRS), available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/Revised_QRS-2018-Measure-Tech-Specs_20170929_508.pdf.
2. Include individuals from step 1 who were 18 years of age or older as of the first day of the measurement year.
3. Include individuals from step 2 with a total days' supply of opioids of 90 days or more identified in pharmacy claims (section S.7).
4. Exclude individuals with any institutional or non-institutional claims indicating a cancer diagnosis during the measurement year (section S.9)
5. Exclude individuals with any institutional or non-institutional claims indicating hospice care during the measurement year (section S.9)

6. Include only unique members from step 5 in the final denominator.

Numerator: Individuals in the denominator population with no claims for drug tests during the measurement year.

Create Numerator:

7. Include individuals from the denominator who do not have any claims for a drug test during the measurement year (section S.5)

Calculate Measure Score:

8. The measure score is calculated as the number of individuals in the numerator divided by the number of individuals in the denominator multiplied by 100 (to produce a percentage).

For the Health Insurance Marketplace, members are attributed to the last QHP enrolled product during the measurement year. 135614

Submission items

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

5.1 Identified measures: 2940 : Use of Opioids at High Dosage in Persons Without Cancer

2950 : Use of Opioids from Multiple Providers in Persons Without Cancer

2951 : Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

3316 : Safe Use of Opioids – Concurrent Prescribing

3541 : Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

3558 : Initial Opioid Prescribing for Long Duration (IOP-LD)

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: ---UPDATED FOR MAINTENANCE--- At time of maintenance, PQA has also identified the 3316e: Safe Use of Opioids – Concurrent Prescribing measure as related. Although the area of focus overlaps, 3316e is specified at the facility level as an eCQM, as opposed to 3389, which is specified at the health plan level and is claims-based. PQA identified the 3558: Initial Opioid Prescribing for Long Duration and 3541: Annual Monitoring for Persons on Long-Term Opioid Therapy) measures as related to opioid prescribing, although the areas of focus (initial opioid prescribing and annual monitoring) are different than 3389 (concurrent use of opioids and benzodiazepines).

5b.1 If competing, why superior or rationale for additive value: There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

---UPDATED FOR MAINTENANCE---

There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

5.1 Identified measures: 1617 : Patients Treated with an Opioid who are Given a Bowel Regimen

2940 : Use of Opioids at High Dosage in Persons Without Cancer

2950 : Use of Opioids from Multiple Providers in Persons Without Cancer

2951 : Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

3316 : Safe Use of Opioids – Concurrent Prescribing

3389 : Concurrent Use of Opioids and Benzodiazepines (COB)

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: An environmental scan revealed related measures listed above, which share similar populations of interest (patients receiving opioids). NQF 1617 targets vulnerable adults given a new prescription for an opioid, and therefore has a different target population than the AMO measure. NQF 3316e is an eCQM that targets patients discharged from a hospital-based encounter, a different setting of care than the AMO measure. Harmonization of value sets has been addressed to the extent possible with related outpatient health plan measures, NQF 2940, 2950, 2951, and 3389, including the cancer and hospice exclusions and targeted opioid medications. The AMO measure's area of focus (numerator) does not overlap with any existing measure, and its focus on drug tests for patients on long-term opioid therapy is unique. Therefore, while there are some related measures that evaluate similar target populations of patients receiving opioid therapy, the AMO measure is a new and evidence-based focus to empower health plans to address opioid misuse and opioid use disorder, and improve patient safety. Harmonization has been addressed to the extent possible, and PQA will continue to identify and address opportunities to harmonize with related measures over time.

5b.1 If competing, why superior or rationale for additive value: Not applicable.

Comparison of NQF #3389 and NQF #3558

3389: Concurrent Use of Opioids and Benzodiazepines (COB)
3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

Steward

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

PQA, Inc.

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

Pharmacy Quality Alliance

Description

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The percentage of individuals >=18 years of age with concurrent use of prescription opioids and benzodiazepines during the measurement year.

A lower rate indicates better performance.

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

The percentage of individuals 18 years of age and older with one or more initial opioid prescriptions for >7 cumulative days' supply.

Type

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Process

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

Process

Data Source

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Claims, Enrollment Data Administrative claims: prescription claims, medical claims, enrollment data

No data collection instrument provided Attachment pqa_meas_yr_2019_cob_value_sets_20200729_NQF.xlsx

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

Claims, Enrollment Data Administrative claims: prescription claims, medical claims, Prescription Drug Hierarchical Condition Categories (RxHCCs); Enrollment data

No data collection instrument provided Attachment PQA_IOP_Value_Sets-637124369595574869.xlsx

Level

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Health Plan

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

Health Plan

Setting

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Outpatient Services

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

Outpatient Services

Numerator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with concurrent use of opioids and benzodiazepines for >=30 cumulative days during the measurement year.

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

The number of individuals from the denominator with >7 cumulative days' supply for all opioid prescription claims within any opioid initiation period.

The opioid initiation period is defined as the date of service of the initial opioid prescription plus two days, i.e., the 3-day time period when the numerator is assessed.

Numerator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with:

- >=2 prescription claims for any benzodiazepine with different dates of service, AND
- Concurrent use of opioids and benzodiazepines for >=30 cumulative days.

Complete the steps below to identify individuals with concurrent use of opioids and benzodiazepines:

Step 1: From the denominator population, identify individuals with >=2 prescription claims with different dates of service for any benzodiazepine (Table COB-B, below) during the measurement year.

Step 2: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

NOTE:

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 3: Count the individuals with concurrent use for >=30 cumulative days. This is the numerator.

Table COB-B: Benzodiazepines:

Alprazolam, chlordiazepoxide, clobazam, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, triazolam

(Note: excludes injectable formulations, includes combination products)

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

The number of individuals from the denominator with >7 cumulative days' supply for all opioid prescription claims within any opioid initiation period.

Use the steps below to identify the numerator population:

Step 1: For each individual in the denominator population, identify all initial opioid prescriptions and corresponding opioid initiation periods, defined as the date of service of the initial opioid prescription plus two days.

For example, if the date of service for an initial opioid prescription is March 15, identify all opioid prescription claims from March 15 through March 17.

Step 2: For each individual, starting with each initial opioid prescription, sum the days' supply of all opioid prescriptions within each opioid initiation period.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claim with the longest days' supply.

- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.
- If the opioid initiation period extends beyond the end of the measurement year, the opioid initiation period is truncated to the last day of the measurement year.

Step 3: Count the unique individuals with >7 cumulative days' supply for all opioid prescription claims during any opioid initiation period in the measurement year.

Denominator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals >=18 years of age with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Individuals with cancer, sickle cell disease, or in hospice are excluded.

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

The denominator includes individuals 18 years of age or older with one or more prescription claims for an opioid and a negative medication history for any opioid medication during the 90-day lookback period.

Denominator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals 18 years and older by the first day of the measurement year with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Use Table COB-A: Opioids, below, to identify the opioid medications for the measure.

Complete the steps below to determine the denominator:

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Table COB-A: Opioids:

Benzhydrocodone, buprenorphine, butorphanol, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol

(note: includes combination products and prescription opioid cough medications. Excludes the following: injectable formulations; sublingual sufentanil (used in a supervised setting); and single-agent and combination buprenorphine products used to treat opioid use disorder (i.e., buprenorphine sublingual tablets, Probuphine® Implant kit subcutaneous implant, and all buprenorphine/naloxone combination products).

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

The denominator includes individuals aged 18 years or older as of the first day of the measurement year with at least one prescription claim for an opioid medication during the measurement year, with continuous enrollment during the measurement year and 90 days prior to the index prescription start date (IPSD) and a negative medication history for any opioid medication during the 90-day lookback period.

Individuals in hospice at any time during the measurement year or 90 days prior to the first day of the measurement year, and those with a cancer or sickle cell disease diagnosis during the measurement year or 90 days prior to the first day of the measurement year are excluded from the measure.

Complete the steps below to determine the denominator population.

Step 1: Identify individuals 18 years or older as of the first day of the measurement year.

Step 2: Identify individuals with one or more prescription claims for an opioid (Medication Table OPIOIDS) during the measurement year.

Step 3: Identify individuals continuously enrolled during the measurement year and the 90 days prior to the IPSD.

Step 4: Identify unique individuals with a negative medication history for any opioid medication during the 90-day lookback period.

For example, an individual has opioid prescription claims on August 1, September 15 and December 20. For each of these dates of service, use the lookback period of 90 days to determine if the individual had no prescription claims for opioids (Medication Table OPIOIDS). For example, for August 1, determine whether the individual had no prescription claims for opioids from May 3 - July 31. Repeat for the September 15 and December 20 opioid prescription claims.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claim with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.
- Count the unique individuals (i.e., if an individual has multiple lookback periods, count the individual only once in the denominator).

Step 5: Exclude individuals with any of the following during the measurement year or the 90 days prior to the first day of the measurement year:

- Hospice
- Cancer

- Sickle Cell Disease

Medication Table OPIOIDS: Opioids

Benzhydrocodone, butorphanol, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol

(Note: Includes combination products. Excludes the following: injectable formulations; opioid cough and cold products; sublingual sufentanil [used in a supervised setting]; and all buprenorphine products, as buprenorphine, as a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.)

Exclusions

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Individuals with cancer, sickle cell disease, or in hospice at any point during the measurement year are excluded from the denominator.

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

Individuals with cancer, sickle cell disease, or in hospice at any point during the measurement year or the 90 days prior to the first day of the measurement year are excluded from the denominator.

Exclusion Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Hospice exclusion: Exclude any individual in hospice during the measurement year. To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

Cancer exclusion: Exclude any individuals with cancer during the measurement year. To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

Sickle Cell Disease exclusion: Exclude any individual with sickle cell disease during the measurement year.

- =1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

Hospice exclusion: Exclude any individuals in hospice during the measurement year or 90 days prior to the first day of the measurement year. To identify individuals in hospice:

- Hospice indicator from the enrollment database, if available (e.g. Medicare)
- One or more claims with place of service code 34 during the measurement year or 90 days prior to the first day of the measurement year, if hospice indicator is not available (e.g. Commercial, Medicaid)

Cancer exclusion: Exclude any individuals with cancer during the measurement year or 90 days prior to the first day of the measurement year.

- One or more claims with cancer in the primary diagnosis or any other diagnosis fields during the measurement year or 90 days prior to the first day of the measurement year. See PQA ICD Code Value Sets, Cancer tab.
- Pharmacy hierarchical condition category (RxHCC) 15, 16, 17, 18, 19 from the Medicare Part D risk adjustment model for payment year 2017 or 2018, if ICD codes are not available. [Available from https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors.html]

Sickle cell exclusion: Exclude any individuals having one or more claims with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year or 90 days prior to the first day of the measurement year. See PQA ICD Code Value Sets, SickleCellDisease tab.

Risk Adjustment

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

No risk adjustment or risk stratification

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

No risk adjustment or risk stratification

Stratification

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

The measure is stratified by the following lines of business for the health plan:

- Commercial
- Medicare
- Medicaid

Medicare plans are further stratified by Low Income Subsidy status.

Definition: Medicare Low Income Subsidy (LIS) - A subsidy paid by the Federal government to the drug plan for Medicare beneficiaries who need extra help with their prescription drug costs due to limited income and resources. Medicare beneficiaries apply for the LIS with the Social Security Administration or their State Medicaid agency.

The Medicare Master Beneficiary Summary file contains the Cost Share Group variable used to identify Low Income Subsidy status, which is subsidized Part D coverage. There are 12 monthly variables - where the 01 through 12 at the end of the variable name corresponds with the month (e.g., 01 is January and 12 is December). CMS identifies beneficiaries with fully subsidized Part D coverage by looking for individuals that have a 01, 02, or 03 for the month. Other beneficiaries who are eligible for the LIS but do not receive a full subsidy have a 04, 05, 06, 07, or 08. The remaining values indicate that the individual is not eligible for subsidized Part D coverage.

Type Score

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Rate/proportion better quality = lower score

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

Rate/proportion better quality = lower score

Algorithm

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

A. Target population (denominator):

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Step 5: Identify individuals with cancer, sickle cell disease or in hospice during the measurement year.

To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g., Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

To identify individuals with sickle cell disease:

- >=1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

Step 6: Exclude individuals with cancer, sickle cell disease, or in hospice (Step 5) from those identified in Step 4. This is the denominator.

B. Numerator Population:

Step 7: From the denominator population, identify individuals with >=2 prescriptions claims with different dates of service for any benzodiazepines (Table COB-B, below) during the measurement year.

Step 8: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

Note: When identifying days' supply for opioids (or benzodiazepines):

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 9: Count the number of individuals with concurrent use of opioids and benzodiazepines for >=30 cumulative days. This is the numerator.

C. Measure Rate:

Step 10: Divide the number of individuals in the numerator (Step 9) by the denominator (Step 6) and multiply by 100. This is the measure rate reported as a percentage.

- Report the rates separately by line of business (e.g. Medicare, Medicaid, Commercial).

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

A. Target population (denominator):

Step 1: Identify individuals 18 years or older as of the first day of the measurement year.

Step 2: Identify individuals with one or more prescription claims for an opioid (see Medication Table OPIOIDS, below) during the measurement year.

Step 3: Identify individuals continuously enrolled during the measurement year and the 90 days prior to the IPSD.

Step 4: Identify unique individuals with a negative medication history for any opioid medication during the 90-day lookback period.

For example, an individual has opioid prescription claims on August 1, September 15 and December 20. For each of these dates of service, use the lookback period of 90 days to determine if the individual had no prescription claims for opioids. For example, for August 1, determine whether the individual had no prescription claims for opioids from May 3 - July 31. Repeat for the September 15 and December 20 opioid prescription claims.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claim with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.
- Count the unique individuals (i.e., if an individual has multiple lookback periods, count the individual only once in the denominator).

Step 5: (Exclusions) Identify individuals with any of the following during the measurement year or the 90 days prior to the first day of the measurement year:

- Hospice: Individuals in hospice during the measurement year or 90 days prior to the first day of the measurement year. Identify individuals in hospice using:
  - Hospice indicator from the enrollment database, if available (e.g. Medicare); or
  - One or more claims with place of service code 34 during the measurement year or 90 days prior to the first day of the measurement year, if hospice indicator is not available (e.g. Commercial, Medicaid)
- Cancer: Identify individuals with cancer during the measurement year or 90 days prior to the first day of the measurement year. Identify individuals with cancer using:
  - One or more claims with cancer in the primary diagnosis or any other diagnosis fields during the measurement year or 90 days prior to the first day of the measurement year. See PQA ICD Code Value Sets, Cancer tab.
  - Pharmacy hierarchical condition category (RxHCC) 15, 16, 17, 18, 19 from the Medicare Part D risk adjustment model for payment year 2017 or 2018, if ICD codes are not available. [Available from https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors.html]
- Sickle Cell Disease: Identify individuals having one or more claims with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year or 90 days prior to the first day of the measurement year. See PQA ICD Code Value Sets, SickleCellDisease tab.

Table OPIOIDS: Opioids

Benzhydrocodone, butorphanol, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol

(Note: Includes combination products; Excludes the following: injectable formulations; opioid cough and cold products; sublingual sufentanil [used in a supervised setting]; and all buprenorphine products, as buprenorphine, as a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.)

Step 6: Subtract the individuals identified in Step 5 (exclusions) from the population identified through Steps 1-4. The remaining individuals represent the denominator.

B. Numerator Population:

Step 7: For each individual in the denominator population, identify all initial opioid prescriptions and corresponding opioid initiation periods.

Step 8: For each individual, starting with each initial opioid prescription, sum the days' supply of all opioid prescriptions within each opioid initiation period (i.e., the initial opioid prescription + 2 days).

For example, if the date of service for an initial opioid prescription is March 15, identify any opioid prescription claims from March 15 through March 17.

NOTE:

- The prescription can be for the same or different opioids.

- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claim with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.
- If the opioid initiation period extends beyond the end of the measurement year, the opioid initiation period is truncated to the last day of the measurement year.

Step 9: Count the unique individuals with >7 cumulative days' supply for all opioid prescription claims during any opioid initiation period in the measurement year. This is the numerator.

C. Measure Rate:

Step 10: Divide the number of individuals in the numerator (Step 9) by the denominator (Step 6) and multiply by 100. This is the measure rate reported as a percentage.

- Note: Report the rates separately by line of business (e.g. Medicare, Medicaid, Commercial). For Medicare, report rates for low-income subsidy (LIS) and non-LIS populations separately.

Submission items

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

5.1 Identified measures: 2940 : Use of Opioids at High Dosage in Persons Without Cancer

2950 : Use of Opioids from Multiple Providers in Persons Without Cancer

2951 : Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

3316 : Safe Use of Opioids – Concurrent Prescribing

3541 : Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

3558 : Initial Opioid Prescribing for Long Duration (IOP-LD)

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: ---UPDATED FOR MAINTENANCE--- At time of maintenance, PQA has also identified the 3316e: Safe Use of Opioids – Concurrent Prescribing measure as related. Although the area of focus overlaps, 3316e is specified at the facility level as an eCQM, as opposed to 3389, which is specified at the health plan level and is claims-based. PQA identified the 3558: Initial Opioid Prescribing for Long Duration and 3541: Annual Monitoring for Persons on Long-Term Opioid Therapy) measures as related to opioid prescribing, although the areas of focus (initial opioid prescribing and annual monitoring) are different than 3389 (concurrent use of opioids and benzodiazepines).

5b.1 If competing, why superior or rationale for additive value: There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

---UPDATED FOR MAINTENANCE---

There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

5.1 Identified measures: 2940 : Use of Opioids at High Dosage in Persons Without Cancer

2950 : Use of Opioids from Multiple Providers in Persons Without Cancer

2951 : Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

3389 : Concurrent Use of Opioids and Benzodiazepines (COB)

3541 : Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: Most of the PQA opioid measures (NQF # 2940, 2950, 2951, and 3389) use the same target population (denominator), and each have different areas of focus (numerator) related to opioid prescribing. The PQA AMO measure (NQF #3541, recommended for endorsement by the Behavioral Health and Substance Use Standing Committee and awaiting CSAC approval) shares a related denominator, but includes only individuals on long-term opioid therapy and has a different area of focus related to drug testing. The NCQA opioid measures were developed as an adaptation to existing PQA measures; the NCQA opioid measure denominators are similar to the PQA opioid measures but have a different area of focus than the IOP-LD measure.

5b.1 If competing, why superior or rationale for additive value: There are no competing measures (i.e., those that address both the same measure focus and the same target population).

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

Steward

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

PQA, Inc.

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

Pharmacy Quality Alliance

Description

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The percentage of individuals >=18 years of age with concurrent use of prescription opioids and benzodiazepines during the measurement year.

A lower rate indicates better performance.

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

The percentage of individuals 18 years of age and older with one or more initial opioid prescriptions for >7 cumulative days' supply.

Type

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Process

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

Process

Data Source

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Claims, Enrollment Data Administrative claims: prescription claims, medical claims, enrollment data

No data collection instrument provided Attachment pqa_meas_yr_2019_cob_value_sets_20200729_NQF.xlsx

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

Claims, Enrollment Data Administrative claims: prescription claims, medical claims, Prescription Drug Hierarchical Condition Categories (RxHCCs); Enrollment data

No data collection instrument provided Attachment PQA_IOP_Value_Sets-637124369595574869.xlsx

Level

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Health Plan

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

Health Plan

Setting

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Outpatient Services

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

Outpatient Services

Numerator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with concurrent use of opioids and benzodiazepines for >=30 cumulative days during the measurement year.

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

The number of individuals from the denominator with >7 cumulative days' supply for all opioid prescription claims within any opioid initiation period.

The opioid initiation period is defined as the date of service of the initial opioid prescription plus two days, i.e., the 3-day time period when the numerator is assessed.

Numerator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The number of individuals from the denominator with:

- >=2 prescription claims for any benzodiazepine with different dates of service, AND
- Concurrent use of opioids and benzodiazepines for >=30 cumulative days.

Complete the steps below to identify individuals with concurrent use of opioids and benzodiazepines:

Step 1: From the denominator population, identify individuals with >=2 prescription claims with different dates of service for any benzodiazepine (Table COB-B, below) during the measurement year.

Step 2: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

NOTE:

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 3: Count the individuals with concurrent use for >=30 cumulative days. This is the numerator.

Table COB-B: Benzodiazepines:

Alprazolam, chlordiazepoxide, clobazam, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, triazolam

(Note: excludes injectable formulations, includes combination products)

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

The number of individuals from the denominator with >7 cumulative days' supply for all opioid prescription claims within any opioid initiation period.

Use the steps below to identify the numerator population:

Step 1: For each individual in the denominator population, identify all initial opioid prescriptions and corresponding opioid initiation periods, defined as the date of service of the initial opioid prescription plus two days.

For example, if the date of service for an initial opioid prescription is March 15, identify all opioid prescription claims from March 15 through March 17.

Step 2: For each individual, starting with each initial opioid prescription, sum the days' supply of all opioid prescriptions within each opioid initiation period.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claim with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.
- If the opioid initiation period extends beyond the end of the measurement year, the opioid initiation period is truncated to the last day of the measurement year.

Step 3: Count the unique individuals with >7 cumulative days' supply for all opioid prescription claims during any opioid initiation period in the measurement year.

Denominator Statement

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals >=18 years of age with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Individuals with cancer, sickle cell disease, or in hospice are excluded.

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

The denominator includes individuals 18 years of age or older with one or more prescription claims for an opioid and a negative medication history for any opioid medication during the 90-day lookback period.

Denominator Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

The denominator includes individuals 18 years and older by the first day of the measurement year with >=2 prescription claims for opioid medications on different dates of service and with >=15 cumulative days' supply during the measurement year. Use Table COB-A: Opioids, below, to identify the opioid medications for the measure.

Complete the steps below to determine the denominator:

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Table COB-A: Opioids:

Benzhydrocodone, buprenorphine, butorphanol, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol

(note: includes combination products and prescription opioid cough medications. Excludes the following: injectable formulations; sublingual sufentanil (used in a supervised setting); and single-agent and combination buprenorphine products used to treat opioid use

disorder (i.e., buprenorphine sublingual tablets, Probuphine® Implant kit subcutaneous implant, and all buprenorphine/naloxone combination products).

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

The denominator includes individuals aged 18 years or older as of the first day of the measurement year with at least one prescription claim for an opioid medication during the measurement year, with continuous enrollment during the measurement year and 90 days prior to the index prescription start date (IPSD) and a negative medication history for any opioid medication during the 90-day lookback period.

Individuals in hospice at any time during the measurement year or 90 days prior to the first day of the measurement year, and those with a cancer or sickle cell disease diagnosis during the measurement year or 90 days prior to the first day of the measurement year are excluded from the measure.

Complete the steps below to determine the denominator population.

Step 1: Identify individuals 18 years or older as of the first day of the measurement year.

Step 2: Identify individuals with one or more prescription claims for an opioid (Medication Table OPIOIDS) during the measurement year.

Step 3: Identify individuals continuously enrolled during the measurement year and the 90 days prior to the IPSD.

Step 4: Identify unique individuals with a negative medication history for any opioid medication during the 90-day lookback period.

For example, an individual has opioid prescription claims on August 1, September 15 and December 20. For each of these dates of service, use the lookback period of 90 days to determine if the individual had no prescription claims for opioids (Medication Table OPIOIDS). For example, for August 1, determine whether the individual had no prescription claims for opioids from May 3 - July 31. Repeat for the September 15 and December 20 opioid prescription claims.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claim with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.
- Count the unique individuals (i.e., if an individual has multiple lookback periods, count the individual only once in the denominator).

Step 5: Exclude individuals with any of the following during the measurement year or the 90 days prior to the first day of the measurement year:

- Hospice
- Cancer
- Sickle Cell Disease

Medication Table OPIOIDS: Opioids

Benzhydrocodone, butorphanol, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol

(Note: Includes combination products. Excludes the following: injectable formulations; opioid cough and cold products; sublingual sufentanil [used in a supervised setting]; and all buprenorphine products, as buprenorphine, as a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.)

Exclusions

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Individuals with cancer, sickle cell disease, or in hospice at any point during the measurement year are excluded from the denominator.

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

Individuals with cancer, sickle cell disease, or in hospice at any point during the measurement year or the 90 days prior to the first day of the measurement year are excluded from the denominator.

Exclusion Details

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Hospice exclusion: Exclude any individual in hospice during the measurement year. To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

Cancer exclusion: Exclude any individuals with cancer during the measurement year. To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

Sickle Cell Disease exclusion: Exclude any individual with sickle cell disease during the measurement year.

- =1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

Hospice exclusion: Exclude any individuals in hospice during the measurement year or 90 days prior to the first day of the measurement year. To identify individuals in hospice:

- Hospice indicator from the enrollment database, if available (e.g. Medicare)
- One or more claims with place of service code 34 during the measurement year or 90 days prior to the first day of the measurement year, if hospice indicator is not available (e.g. Commercial, Medicaid)

Cancer exclusion: Exclude any individuals with cancer during the measurement year or 90 days prior to the first day of the measurement year.

- One or more claims with cancer in the primary diagnosis or any other diagnosis fields during the measurement year or 90 days prior to the first day of the measurement year. See PQA ICD Code Value Sets, Cancer tab.
- Pharmacy hierarchical condition category (RxHCC) 15, 16, 17, 18, 19 from the Medicare Part D risk adjustment model for payment year 2017 or 2018, if ICD codes are not

available. [Available from https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors.html]

Sickle cell exclusion: Exclude any individuals having one or more claims with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year or 90 days prior to the first day of the measurement year. See PQA ICD Code Value Sets, SickleCellDisease tab.

Risk Adjustment

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

No risk adjustment or risk stratification

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

No risk adjustment or risk stratification

Stratification

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

The measure is stratified by the following lines of business for the health plan:

- Commercial
- Medicare
- Medicaid

Medicare plans are further stratified by Low Income Subsidy status.

Definition: Medicare Low Income Subsidy (LIS) - A subsidy paid by the Federal government to the drug plan for Medicare beneficiaries who need extra help with their prescription drug costs due to limited income and resources. Medicare beneficiaries apply for the LIS with the Social Security Administration or their State Medicaid agency.

The Medicare Master Beneficiary Summary file contains the Cost Share Group variable used to identify Low Income Subsidy status, which is subsidized Part D coverage. There are 12 monthly variables - where the 01 through 12 at the end of the variable name corresponds with the month (e.g., 01 is January and 12 is December). CMS identifies beneficiaries with fully subsidized Part D coverage by looking for individuals that have a 01, 02, or 03 for the month. Other beneficiaries who are eligible for the LIS but do not receive a full subsidy have a 04, 05, 06, 07, or 08. The remaining values indicate that the individual is not eligible for subsidized Part D coverage.

Type Score

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

Rate/proportion better quality = lower score

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

Rate/proportion better quality = lower score

Algorithm

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

A. Target population (denominator):

Step 1: Identify individuals >=18 years of age as of the first day of the measurement year.

Step 2: Identify individuals meeting the continuous enrollment criteria.

- To be continuously enrolled, an individual must be enrolled for the entire measurement year with no more than one gap in enrollment of up to 31 days during the measurement year. When enrollment is verified monthly, the individual may not have more than a 1-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Identify individuals with an Index Prescription Service Date (IPSD) that is >=30 days from the last day of the measurement year (January 1 through December 2). The IPSD is defined as the earliest date of service for an opioid during the measurement year.

Step 4: Identify individuals with >=2 prescription claims for opioids on different dates of service, and with >=15 cumulative days' supply during the measurement year. Exclude days' supply that occur after the end of the measurement year.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claims with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims, regardless of overlapping days' supply.

Step 5: Identify individuals with cancer, sickle cell disease or in hospice during the measurement year.

To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, where available (e.g., Medicare); or
- >=1 claim, encounter, or medical record during the measurement year. See Hospice Encounter Value Set and Hospice Intervention Value Set (e.g., Medicaid, commercial).

To identify individuals with cancer:

- >=1 claim with cancer in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Cancer.

To identify individuals with sickle cell disease:

- >=1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Sickle Cell Disease.

Step 6: Exclude individuals with cancer, sickle cell disease, or in hospice (Step 5) from those identified in Step 4. This is the denominator.

B. Numerator Population:

Step 7: From the denominator population, identify individuals with >=2 prescriptions claims with different dates of service for any benzodiazepines (Table COB-B, below) during the measurement year.

Step 8: Determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescription claims during the measurement year.

- Concurrent use is identified using the dates of service and days' supply of an individual's opioid and benzodiazepine prescription claims. The days of concurrent use is the count of days during the measurement year with overlapping days' supply for an opioid and a benzodiazepine. Exclude days' supply and overlap that occur after the end of the measurement year.

Note: When identifying days' supply for opioids (or benzodiazepines):

- If multiple prescriptions for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid (or benzodiazepine) using the prescription claims with the longest days' supply.
- If multiple prescription claims of opioids (or benzodiazepines) are dispensed on different days with overlapping days' supply, count each day in the measurement year only once toward the numerator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

Step 9: Count the number of individuals with concurrent use of opioids and benzodiazepines for >=30 cumulative days. This is the numerator.

C. Measure Rate:

Step 10: Divide the number of individuals in the numerator (Step 9) by the denominator (Step 6) and multiply by 100. This is the measure rate reported as a percentage.

- Report the rates separately by line of business (e.g. Medicare, Medicaid, Commercial).

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

A. Target population (denominator):

Step 1: Identify individuals 18 years or older as of the first day of the measurement year.

Step 2: Identify individuals with one or more prescription claims for an opioid (see Medication Table OPIOIDS, below) during the measurement year.

Step 3: Identify individuals continuously enrolled during the measurement year and the 90 days prior to the IPSD.

Step 4: Identify unique individuals with a negative medication history for any opioid medication during the 90-day lookback period.

For example, an individual has opioid prescription claims on August 1, September 15 and December 20. For each of these dates of service, use the lookback period of 90 days to determine if the individual had no prescription claims for opioids. For example, for August 1, determine whether the individual had no prescription claims for opioids from May 3 - July 31. Repeat for the September 15 and December 20 opioid prescription claims.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claim with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.
- Count the unique individuals (i.e., if an individual has multiple lookback periods, count the individual only once in the denominator).

Step 5: (Exclusions) Identify individuals with any of the following during the measurement year or the 90 days prior to the first day of the measurement year:

- Hospice: Individuals in hospice during the measurement year or 90 days prior to the first day of the measurement year. Identify individuals in hospice using:
  - Hospice indicator from the enrollment database, if available (e.g. Medicare); or

  - One or more claims with place of service code 34 during the measurement year or 90 days prior to the first day of the measurement year, if hospice indicator is not available (e.g. Commercial, Medicaid)
- Cancer: Identify individuals with cancer during the measurement year or 90 days prior to the first day of the measurement year. Identify individuals with cancer using:
  - One or more claims with cancer in the primary diagnosis or any other diagnosis fields during the measurement year or 90 days prior to the first day of the measurement year. See PQA ICD Code Value Sets, Cancer tab.
  - Pharmacy hierarchical condition category (RxHCC) 15, 16, 17, 18, 19 from the Medicare Part D risk adjustment model for payment year 2017 or 2018, if ICD codes are not available. [Available from https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors.html]
- Sickle Cell Disease: Identify individuals having one or more claims with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields during the measurement year or 90 days prior to the first day of the measurement year. See PQA ICD Code Value Sets, SickleCellDisease tab.

Table OPIOIDS: Opioids

Benzhydrocodone, butorphanol, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol

(Note: Includes combination products; Excludes the following: injectable formulations; opioid cough and cold products; sublingual sufentanil [used in a supervised setting]; and all buprenorphine products, as buprenorphine, as a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.)

Step 6: Subtract the individuals identified in Step 5 (exclusions) from the population identified through Steps 1-4. The remaining individuals represent the denominator.

B. Numerator Population:

Step 7: For each individual in the denominator population, identify all initial opioid prescriptions and corresponding opioid initiation periods.

Step 8: For each individual, starting with each initial opioid prescription, sum the days' supply of all opioid prescriptions within each opioid initiation period (i.e., the initial opioid prescription + 2 days).

For example, if the date of service for an initial opioid prescription is March 15, identify any opioid prescription claims from March 15 through March 17.

NOTE:

- The prescription can be for the same or different opioids.
- If multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claim with the longest days' supply.
- If multiple prescriptions for opioids are dispensed on different days, sum the days' supply for all the prescription claims regardless of overlapping days' supply.
- If the opioid initiation period extends beyond the end of the measurement year, the opioid initiation period is truncated to the last day of the measurement year.

Step 9: Count the unique individuals with >7 cumulative days' supply for all opioid prescription claims during any opioid initiation period in the measurement year. This is the numerator.

C. Measure Rate:

Step 10: Divide the number of individuals in the numerator (Step 9) by the denominator (Step 6) and multiply by 100. This is the measure rate reported as a percentage.

- Note: Report the rates separately by line of business (e.g. Medicare, Medicaid, Commercial). For Medicare, report rates for low-income subsidy (LIS) and non-LIS populations separately.

Submission items

3389: Concurrent Use of Opioids and Benzodiazepines (COB)

5.1 Identified measures: 2940 : Use of Opioids at High Dosage in Persons Without Cancer

2950 : Use of Opioids from Multiple Providers in Persons Without Cancer

2951 : Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

3316 : Safe Use of Opioids – Concurrent Prescribing

3541 : Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

3558 : Initial Opioid Prescribing for Long Duration (IOP-LD)

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: ---UPDATED FOR MAINTENANCE--- At time of maintenance, PQA has also identified the 3316e: Safe Use of Opioids – Concurrent Prescribing measure as related. Although the area of focus overlaps, 3316e is specified at the facility level as an eCQM, as opposed to 3389, which is specified at the health plan level and is claims-based. PQA identified the 3558: Initial Opioid Prescribing for Long Duration and 3541: Annual Monitoring for Persons on Long-Term Opioid Therapy) measures as related to opioid prescribing, although the areas of focus (initial opioid prescribing and annual monitoring) are different than 3389 (concurrent use of opioids and benzodiazepines).

5b.1 If competing, why superior or rationale for additive value: There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

---UPDATED FOR MAINTENANCE---

There are no competing measures (i.e., those that addresses both the same measure focus and the same target population).

3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

5.1 Identified measures: 2940 : Use of Opioids at High Dosage in Persons Without Cancer

2950 : Use of Opioids from Multiple Providers in Persons Without Cancer

2951 : Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

3389 : Concurrent Use of Opioids and Benzodiazepines (COB)

3541 : Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: Most of the PQA opioid measures (NQF # 2940, 2950, 2951, and 3389) use the same target population (denominator), and each have different areas of focus (numerator) related to opioid prescribing. The PQA AMO measure (NQF #3541, recommended for endorsement by the Behavioral Health and Substance Use Standing Committee and awaiting CSAC approval) shares a related denominator, but includes only individuals on long-term opioid therapy and has a different area of focus related to drug testing. The NCQA opioid measures were developed as an adaptation to existing PQA measures; the NCQA opioid measure denominators are similar to the PQA opioid measures but have a different area of focus than the IOP-LD measure.

5b.1 If competing, why superior or rationale for additive value: There are no competing measures (i.e., those that address both the same measure focus and the same target population).

Comparison of NQF #3621 and NQF #2820

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single
2820: Pediatric Computed Tomography (CT) Radiation Dose

Steward

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

American College of Radiology

2820: Pediatric Computed Tomography (CT) Radiation Dose

University of California, San Francisco

Description

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Measure title continued: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single phase scan and CT Head/Brain without contrast/single phase scan)

Description: Weighted average of 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single phase scan and CT Head/Brain without contrast/single phase scan)

2820: Pediatric Computed Tomography (CT) Radiation Dose

The measure requires hospitals and output facilities that conduct Computed Tomography (CT) examinations in children to: 1. Review their CT radiation dose metrics, 2. calculate the

distribution of the results, and 3.compare their results to benchmarks. This would then imply a fourth step to investigate instances where results exceed a trigger value for underlying cause, such as issues with protocol, tech, equipment, patient, etc.

It is important to review doses of radiation used for CT, as the doses are far higher than conventional radiographs (x-rays), the doses are in the same range known to be carcinogenic (Pearce, Lancet, 2012; Ozasa, Radiation Research, 2012), and the higher the doses, the greater the risk of subsequent cancer (Miglioretti, JAMA Pediatrics, 2013) Thus the goal of the measure is to provide a framework where facilities can easily assess their doses, compare them to benchmarks, and take corrective action to lower their doses if they exceed threshold values, as per specifications in benchmarks.

The measure calls for assessment of doses for the most frequently conducted CT examination types, and compare these doses to published benchmarks. The measure calls for the assessment of radiation doses within four anatomic areas (CT's of the head, chest, abdomen/pelvis and combined chest/abdomen/pelvis.) The measure provides a simple framework for how facilities can assess their dose, compare their doses to published benchmarks (Smith-Bindman, Radiology, 2015) and identify opportunities to improve if their doses are higher than the benchmarks. For example, If a hospital finds their doses are higher than published benchmarks, they can review the processes and procedures they use for performance of CT in children and take corrective action, and follow published guidelines for how to lower doses (such as "child sizing" the doses, reducing multiple phase scans, and reducing scan lengths).

Published benchmarks for radiation dose in children exist (Smith-Bindman, Radiology, 2015) and additional benchmarks are under development and will be published within the year by us. (Kumar, 2015) Other groups have also published benchmarks (Goeske) or in the process of doing so.

Our work and that of others have shown that institutional review of dose metrics as outlined in this measure results in a significant lowering of average and outlier doses. (Demb, 2015; Greenwood, RadioGraphics, 2015; Miglioretti, JAMA Pediatrics, 2013; Keegan, JACR, 2104; Wilson, ARRS, 2015).

This measure is being proposed for diagnostic CT in children, but can also be used for CT in adults, and CT used in conjunction with radiation therapy for cancer. Whenever context the doses are used, the doses should be compared with appropriate benchmarks.

A similar measure (#0739) was previously endorsed by the NQF in 2011. The NQF did not provide ongoing endorsement when the measure was up for renewal in 2015, primarily because there was no evidence that assessing doses as called for in the measure would result in an improvement in outcomes (i.e. patient dose). Since that time, there has been additional research that has shown that assessing doses using the format outlined in the measure does indeed result in lower doses, and thus we are re-submitting a similar although updated measure.

Of note, the surrogate measure we are using for outcomes is radiation dose. The true outcome of interest is the number of cancers that result from imaging. Because of the lag time between exposure to radiation and cancer development (years to decades) it is not feasible to use cancer cases as the outcome of a quality improvement effort. Thus while there is ample evidence that radiation causes cancer (sited below), and evidenced that cancer risk is proportional to dose, there are no direct data that suggest that lowering doses lowers cancer risk. However, we have used mathematical modeling to try to understand the relationship between lowering doses and cancers and estimated that if the top quartile of doses were reduced in children (i.e. the very high doses are brought down

the average doses), the number of cancer cases would be reduced by approximately 43%, the equivalent to preventing 4,350 cancer cases / year in the US among children (Miglioretti, JAMA Pediatrics 2013).

Cited in this section:

Demb J, manuscript under preparation. CT Radiation Dose Standardization Across the University of California Medical Centers Using Audits to Optimize Dose. 2015.

Following an in-person meeting regarding CT radiation dose, radiologists, technologists and medical physicists from University of California medical centers strategized how to best optimize dosing practices at their sites, which were then analyzed for effectiveness and success after implementation.

Greenwood T, Lopez-Costa R, Rhoades P, et al. CT Dose Optimization in Pediatric Radiology: A Multiyear Effort to Preserve the Benefits of Imaging While Reducing the Risks. RadioGraphics. Jan 2015;35(5):1539-1554

“This systematic approach involving education, streamlining access to magnetic resonance imaging and ultrasonography, auditing with comparison with benchmarks, applying modern CT technology, and revising CT protocols has led to a more than twofold reduction in CT radiation exposure between 2005 and 2012…” – Conclusion statement from Abstract

Keegan J, Miglioretti DL, Gould R, Donnelly LF, Wilson ND, Smith-Bindman R. Radiation Dose Metrics in CT: Assessing Dose Using the National Quality Forum CT Patient Safety Measure. Journal of the American College of Radiology: JACR; 11(3):309-315.

http://download.journals.elsevierhealth.com/pdfs/journals/1546-1440/PIIS1546144013006625.pdf. Mar 2014

Looking at dose metrics as per compliance with the previously endorsed #0739 NQF measure results in reasonably timed acquisition of CT doses, and seeing such doses resulted in 30-50% dose reduction.

Kumar K, manuscript under preparation. Radiation Dose Benchmarks in Children.

This paper will describe dose metrics among 29,000 children within age strata <1, 1-4 years, 5-9 years, 10-14 years, and 15-19 years. 2015.

Miglioretti D, Johnson E, Vanneman N, Smith-Bindman R, al e. Use of Computed Tomography and Associated Radiation Exposure and Leukemia Risk in Children and Young Adults across Seven Integrated Healthcare Systems from 1994 – 2010. JAMA Pediatrics Published online June 10, 2013 joli:101001/jamapediatrics2013311, 2013.

Radiation-induced cancers in children could be dramatically reduced if the highest quartile of CT radiation doses were lowered.

Miglioretti, YX Zhang, E Johnson, N Vanneman, R Smith-Bindman. Personalized Technologist Dose Audit Feedback for Reducing Patient Radiation Exposure from Computed Tomography. Journal of the American College of Radiology: JACR 2014.

“Personalized audit feedback and education can change technologists' attitudes about, and awareness of, radiation and can lower patient radiation exposure from CT imaging.” – Conclusion statement from Abstract

Ozasa K, Shimizu Y, Suyama A, et al. Studies of the mortality of atomic bomb survivors, Report 14, 1950-2003: an overview of cancer and noncancer diseases. Radiation Research; 177(3):229-243. Mar 2012

Fourteenth follow-up report on the lifetime health effects from radiation on atomic bomb survivor showing that: 58% of the 86,611 LSS cohort members with DS02 dose estimates

have died, 17% more cancer deaths especially among those under age 10 at exposure (58% more deaths).

Pearce MS, Salotti JA, Little MP, et al. Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study. Lancet;380(9840):499-505. Aug 4 2012

"Use of CT scans in children to deliver cumulative doses of about 50 mGy might almost triple the risk of leukaemia and doses of about 60 mGy might triple the risk of brain cancer… although clinical benefits should outweigh the small absolute risks, radiation doses from CT scans ought to be kept as low as possible" – Conclusion statement from Abstract

Smith-Bindman R, Moghadassi M, Wilson N, et al. Radiation Doses in Consecutive CT Examinations from Five University of California Centers. Radiology 2015:277: 134–141

"These summary dose data provide a starting point for institutional evaluation of CT radiation doses." – Conclusion statement from Abstract

Wilson N. CT Radiation Dose Standardization Across the Five University of California Medical Centers. ARRS: Annual Toronto Meeting presentation. April 19-24, 2015

Understanding the reasons for variation in commonly performed CT procedures, and figuring out how to standardize them.

Type

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Composite

2820: Pediatric Computed Tomography (CT) Radiation Dose

Outcome: Intermediate Clinical Outcome

Data Source

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Registry Data Clinical data registry (ACR National Radiology Data Registry - Dose Index Registry)

Available at measure-specific web page URL identified in S.1 Attachment ACRad_34_-_Multistrata_weighted_average_of_three_CT_exam_types.pdf

2820: Pediatric Computed Tomography (CT) Radiation Dose

Electronic Health Data, Electronic Health Records, Other, Registry Data The data sources will include electronic CT images [captured from the CT console at the time of scanning or harvested from the PACS (Picture Archiving Communication System) - the computerized systems for reviewing and storing imaging data], Radiology Information System, EPIC, printed CT images, or information stored in the medical record. Numerous other software products are now available for capturing these data (Bayer, GE, etc.) and several free ware programs are also available. Of note, the 2012 California law now requires the reporting of several of the dose metrics outlined in this measure in the patient medical record, and as a results, many software companies have provided techniques for collating these data.

No data collection instrument provided No data dictionary

Level

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Facility, Clinician : Group/Practice

2820: Pediatric Computed Tomography (CT) Radiation Dose

Facility, Integrated Delivery System

Setting

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Emergency Department and Services, Inpatient/Hospital, Other, Outpatient Services Dialysis Facility

2820: Pediatric Computed Tomography (CT) Radiation Dose

Inpatient/Hospital, Outpatient Services

Numerator Statement

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Number of CT Abdomen-Pelvis exams with contrast (single phase scan), CT Chest exams without contrast (single phase scan), and CT Head/Brain exams without contrast (single phase scan) for which Dose Length Product is at or below the size-specific exam-specific diagnostic reference level

2820: Pediatric Computed Tomography (CT) Radiation Dose

Radiation Dose metrics among consecutive patients, who have undergone CT of the head, chest, abdomen/pelvis, or chest/abdomen/pelvis. The metrics are 1) mean dose as measured using DLP, CTDIvol, and SSDE: within age strata. And 2) the proportion of exams with doses greater than the 75th percentile of the benchmark you are comparing with for the same anatomic area strata (Kumar, 2015; Smith-Bindman, Radiology, 2015; Goske, Radiology, 2013)

The CTDIvol and DLP are directly reported by the scanner using an “industry wide” standardized dose report (DICOM Radiation Dose Structured Report). The data should be assembled for the entire CT examination. If there are several series, the CTDIvol values should be averaged, and the DLP values should be added.

SSDE can be calculated using any dose monitoring software product, or using published multiplier coefficients which are highly valid.

These different metrics are highly correlated, but nonetheless reveal important differences regarding radiology practice and performance and are thus complimentary. However, if a practice only assesses data from a single metric, there is substantial opportunity for data-driven improvement.

CTDIvol reflects the average dose per small scan length. Modern CT scanners directly generate this.

DLP reflects the CTDIvol x scan length, and is directly generated by modern CT scanners.

SSDE is a modified measure of CTDIvol that takes into account the size of the patient scanned and is useful for scaling dose to patient size. Several current radiation tracking software tools directly report SSDE.

Cited in this section

Goske MJ, Strauss KJ, Coombs LP, et al. Diagnostic reference ranges for pediatric abdominal CT. Radiology. Jul 2013;268(1):208-218.

"Calculation of reference doses as a function of BW (body weight) for an individual practice provides a tool to help develop site-specific CT protocols that help manage pediatric patient radiation doses." – Conclusion statement from Abstract

Kumar K, manuscript under preparation. Radiation Dose Benchmarks in Children.

This paper will describe dose metrics among 29,000 children within age strata <1, 1-4 years, 5-9 years, 10-14 years, and 15-19 years. 2015.

Smith-Bindman R, Moghadassi M, Wilson N, et al. Radiation Doses in Consecutive CT Examinations from Five University of California Centers. Radiology 2015:277: 134–141

"These summary dose data provide a starting point for institutional evaluation of CT radiation doses." – Conclusion statement from Abstract

Smith-Bindman R, Miglioretti DL. CTDIvol, DLP, and Effective Dose are excellent measures for use in CT quality improvement. Radiology. Dec 2011;261(3):999; author reply 999-1000.

An explanation as to why these radiation dose metrics are useful in calculating a patient's absorbed doses.

Huda W, Ogden KM, Khorasani MR. Converting dose-length product to effective dose at CT. Radiology. Sep 2008;248(3):995-1003.

"This article describes a method of providing CT users with a practical and reliable estimate of adult patient EDs by using the DLP displayed on the CT console at the end of any given examination." – Conclusion statement from Abstract

Numerator Details

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Dose length product; CTDIw Phantom Type; Effective Diameter (calculated from localizer image); size specific exam-specific diagnostic reference level.

These components capture how well radiation exposure from the scanner is adjusted for patient size, using size-specific exam-level diagnostic reference levels and how well total radiation exposure to a patient from an exam is optimized based on the CT dose index dose-length product (DLP).

2820: Pediatric Computed Tomography (CT) Radiation Dose

Radiation dose distribution for the three metrics (CTDIvol, DLP, and SSDE) need to be recorded for a consecutive sample of CT examinations within anatomic area and age stratum. The mean, median, and the percent of examinations above the published 75% percentile needs to be generated.

These data can be extracted from the CT examinations in several ways. These numbers can written down directly from the CT scanner itself at the time of the examination; they can be written down from the PACS (computer terminal where images are reviewed and stored); or can be written down from the medical record if the facility stores these data as part of the medical record (all facilities in California due this based on statutory

requirements.) The CT manufacturers have agreed (through MITA, Medical Imaging and Technology Alliance, the professional trade association of imaging manufacturers) to make these data electronically available through export from the CT machines to a local server), and these data can also be collected electronically. A growing number of companies are leveraging the standardized data format to systematically collect dose metrics directly from a facilities imaging infrastructure. This not only improves the accuracy of the data but also markedly reduces the costs of data collection. From the PACS, Radiology Information System, EPIC program if the data are exported there, or using any number of dose monitoring software programs allowing the collection and reporting of these dose data. The easiest way to collect these data is through one of the 6 or so commercial software programs developed for dose tracking, and several free-ware programs that enable directly extracting CT dose information from the PACS. We have published (Keegan, JACR 2014) several examples of techniques for dose extraction that can be completed even by a small facility.

The strata for this measure include:

Anatomic area strata: head, chest, abdomen/pelvis, Chest/abdomen/pelvis

Age strata: infant (<1); small child (1-5); medium child (>5 - 10); large child (>10-15) and adult (>15)

NOTE: The SSDE was developed as a metric for adjusting for size. However, it does not completely adjust for size and analysis within age strata are still needed among children to account for the different doses that are used and should be used for infants to obese children.

Cited in this section:

Keegan J, Miglioretti DL, Gould R, Donnelly LF, Wilson ND, Smith-Bindman R. Radiation Dose Metrics in CT: Assessing Dose Using the National Quality Forum CT Patient Safety Measure. Journal of the American College of Radiology: JACR; 11(3):309-315.

http://download.journals.elsevierhealth.com/pdfs/journals/1546-1440/PIIS1546144013006625.pdf. Mar 2014

Looking at dose metrics as per compliance with the previously endorsed #0739 NQF measure results in reasonably timed acquisition of CT doses, and seeing such doses resulted in 30-50% dose reduction.

Denominator Statement

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Number of CT Abdomen-pelvis exams with contrast (single phase scans), CT Chest exams without contrast (single phase scans), and CT Head/Brain (single phase scans)

Target population: all patients regardless of age.

2820: Pediatric Computed Tomography (CT) Radiation Dose

Consecutive sample of CTs conducted in the head, chest, abdomen/pelvis and chest/abdomen/pelvis. No examinations should be excluded

Denominator Details

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Study description; Exam date; Acquisition protocol

Target population: all patients who require either a CT Abdomen-pelvis exam with contrast (single phase scans), a CT Chest exam without contrast (single phase scans), and/or a CT Head/Brain (single phase scans) exam regardless of age.

2820: Pediatric Computed Tomography (CT) Radiation Dose

Consecutive sample of CTs conducted in the head, chest, abdomen/pelvis, chest/abdomen/pelvis

Exclusions

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

No denominator exclusions

2820: Pediatric Computed Tomography (CT) Radiation Dose

CT examinations conducted in anatomic areas not included above (such as CTs of the extremities or lumbar spine) or that combine several areas (head and chest) should not be included. In children, these four included categories will reflect approximately 80% of CT scans.

Examinations performed as part of diagnostic procedures – such as biopsy procedures – should not be included. CT examinations performed as part of surgical planning or radiation therapy should not be included.

Examinations that are considered "limited abdomen" or "limited pelvis" studies should be included in the abdomen and pelvis category. Any examinations that include any parts of the abdomen and or pelvis should count in the abdomen/pelvis category.

Exclusion Details

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

No denominator exclusions

2820: Pediatric Computed Tomography (CT) Radiation Dose

Most abdominal/pelvis CT scans in adult patients include scanning of the abdomen and pelvis as one contiguous area. If examinations are conducted limited to one region, these should also be included, as it is difficult/impossible to define what areas would be considered limited.

Risk Adjustment

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Stratification by risk category/subgroup

2820: Pediatric Computed Tomography (CT) Radiation Dose

No risk adjustment or risk stratification

141072| 109921

Stratification

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

The measure calculation is stratified by patient size. The results are not reported separately by the stratification variable.

2820: Pediatric Computed Tomography (CT) Radiation Dose

Anatomic area strata: head, chest, abdomen/pelvis, chest/abdomen/pelvis

These were chosen based on being the most common CT examination types conducted in the US, comprising >80% of all CT scans, and because dose varies by these groups.

Age strata: infant (<1); small child (1-5); medium child (>5 - 10); large child (>10-15) and adult (>15)

These patient age groups were chosen based on the variation of CT settings and resulting radiation dose based on patient size (and age is frequently used as a surrogate for size.) The ICRU (International Commission on Radiation Units and Measurements) uses these child size categories, they correspond to available phantoms, and they are the ones found to be most reliable

Geographic location where studies were done (zip code or state), to facilitate using the data to create geographically specific benchmarks

Type Score

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Rate/proportion better quality = higher score

2820: Pediatric Computed Tomography (CT) Radiation Dose

Algorithm

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Target population is all patients regardless of age.

To calculate the denominator for each of the measures we include all exams that are mapped to a standardized exam name/study description that corresponds to one of the three exam types used for measures, has a localizer image to permit size assessment, and has non-zero values for dose indices.

To calculate the numerator:

Head exams are categorized using lateral thickness (size) from scout images submitted by facilities. Body exams (chest and abdomen/pelvis) are categorized using the effective diameter (size) that ACR calculates from scout images. The numerator consists of the total number of exams among the denominator that are at or below the size specific DRL.

To calculate the performance rate, the numerator (Total number of exams among the denominator that are at or below the size specific DRL) is divided by the denominator (submitted eligible records) and multiplied by 100 to indicate the percentage. Physician groups/facilities may compare their performance to other facilities using aggregate registry level benchmarks.

Step 1: Denominator: Total number of exams that were mapped to one of the 3 exam names, had a non-zero DLP and a non-zero CTDIvol, CTDIvol<DLP, age was not missing, and patient size is available

Step 2: Numerator: Total number of exams among the denominator that are at or below the size specific DRL

Step 3: Percentage at or below size-specific DRL for each body part: (Numerator/Denominator)*100

Step 4: Percentage of all exams at or below size-specific DRL. Alternately, calculate weighted average of component measures, where weight is number of records for each body part.

Composite score:

Each component measure percentile score is weighted by the denominator count. The weighted scores are summed then divided by the sum of weights of all 3. Alternatively, the numerator and denominator counts for each measure can be totaled then averaged by 3.

Example:

	Numerator	Denominator	Rate
Head	3000	8000	38%
Abdomen/Pelvis	5000	10000	50%
Chest	2000	5000	40%
All	10000	23000	43%
Weighted average			43%

Weighted average = (Weight Head x Rate Head) + (Weight Abdomen/Pelvis x Rate Abdomen/Pelvis) + (Weight Chest x Rate Chest)))/Sum of weights of all 3

2820: Pediatric Computed Tomography (CT) Radiation Dose

N/A 141072| 109921

Submission items

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

5.1 Identified measures: 2820 : Pediatric Computed Tomography (CT) Radiation Dose

5a.1 Are specs completely harmonized?

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value: NQF #3621 is a competing measure to NQF #2820 because our measure addresses the same measure focus and target population. The target population in NQF #2820 is a subset population of NQF #3621. Additionally, while NQF #2820 primarily targets pediatric patients, the measure description states that the measure can also be used for CT in adults.

In NQF #3621 performance for facilities and groups is calculated comparing dose indices to published benchmarks.

NQF #2820, “provides a simple framework for how facilities can assess their dose, compare their doses to published benchmarks (Smith-Bindman, Radiology, 2015) and identify opportunities to improve if their doses are higher than the benchmarks”. Measure users thus are self-calculating results against one of three published benchmarks themselves using one of three benchmarks published benchmarks for both levels of measurement (group and facility).

NQF #3621 uses data published in the ACR 2017 study, U.S. Diagnostic Reference Levels and Achievable Doses for 10 Adult CT Examinations, identifying DRLs and Achievable Doses (ADs) for the 10 most common CT adult examinations performed in the United States. It represents the first time that national adult DRLs and ADs have been developed as a function of patient size, a milestone in optimizing radiation dose to patients. NQF #3621 has eight years of performance data for each measure component, as well as four years of data for the composite. Using electronic data sources, NQF #3621 has high feasibility and low collection burden, which minimizes missing data bias. NQF #3621 provides greater consistency and level of comparison across facilities and groups, providing more validity and reliability for use in quality improvement and specifically for accountability programs.

Reference: Kanal KM, Butler PF, Sengupta D, Bhargavan-Chatfield M, Coombs LP, Morin RL. U.S. Diagnostic Reference Levels and Achievable Doses for 10 Adult CT Examinations. Radiology. 2017 Jul;284(1):120-133. doi: 10.1148/radiol.2017161911. Epub 2017 Feb 21. PMID: 28221093.

2820: Pediatric Computed Tomography (CT) Radiation Dose

5.1 Identified measures:

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value: N/A

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

2820: Pediatric Computed Tomography (CT) Radiation Dose

2820: Pediatric Computed Tomography (CT) Radiation Dose

Steward

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

American College of Radiology

2820: Pediatric Computed Tomography (CT) Radiation Dose

University of California, San Francisco

Description

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Measure title continued: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single phase scan and CT Head/Brain without contrast/single phase scan)

Description: Weighted average of 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single phase scan and CT Head/Brain without contrast/single phase scan)

2820: Pediatric Computed Tomography (CT) Radiation Dose

The measure requires hospitals and output facilities that conduct Computed Tomography (CT) examinations in children to: 1. Review their CT radiation dose metrics, 2. calculate the distribution of the results, and 3.compare their results to benchmarks. This would then imply a fourth step to investigate instances where results exceed a trigger value for underlying cause, such as issues with protocol, tech, equipment, patient, etc.

It is important to review doses of radiation used for CT, as the doses are far higher than conventional radiographs (x-rays), the doses are in the same range known to be carcinogenic (Pearce, Lancet, 2012; Ozasa, Radiation Research, 2012), and the higher the doses, the greater the risk of subsequent cancer (Miglioretti, JAMA Pediatrics, 2013) Thus the goal of the measure is to provide a framework where facilities can easily assess their doses, compare them to benchmarks, and take corrective action to lower their doses if they exceed threshold values, as per specifications in benchmarks.

The measure calls for assessment of doses for the most frequently conducted CT examination types, and compare these doses to published benchmarks. The measure calls for the assessment of radiation doses within four anatomic areas (CT's of the head, chest, abdomen/pelvis and combined chest/abdomen/pelvis.) The measure provides a simple framework for how facilities can assess their dose, compare their doses to published benchmarks (Smith-Bindman, Radiology, 2015) and identify opportunities to improve if their doses are higher than the benchmarks. For example, If a hospital finds their doses are higher than published benchmarks, they can review the processes and procedures they use for performance of CT in children and take corrective action, and follow published guidelines for how to lower doses (such as "child sizing" the doses, reducing multiple phase scans, and reducing scan lengths).

Published benchmarks for radiation dose in children exist (Smith-Bindman, Radiology, 2015) and additional benchmarks are under development and will be published within the year by us. (Kumar, 2015) Other groups have also published benchmarks (Goeske) or in the process of doing so.

Our work and that of others have shown that institutional review of dose metrics as outlined in this measure results in a significant lowering of average and outlier doses. (Demb, 2015; Greenwood, RadioGraphics, 2015; Miglioretti, JAMA Pediatrics, 2013; Keegan, JACR, 2104; Wilson, ARRS, 2015).

This measure is being proposed for diagnostic CT in children, but can also be used for CT in adults, and CT used in conjunction with radiation therapy for cancer. Whenever context the doses are used, the doses should be compared with appropriate benchmarks.

A similar measure (#0739) was previously endorsed by the NQF in 2011. The NQF did not provide ongoing endorsement when the measure was up for renewal in 2015, primarily because there was no evidence that assessing doses as called for in the measure would result in an improvement in outcomes (i.e. patient dose). Since that time, there has been additional research that has shown that assessing doses using the format outlined in the measure does indeed result in lower doses, and thus we are re-submitting a similar although updated measure.

Of note, the surrogate measure we are using for outcomes is radiation dose. The true outcome of interest is the number of cancers that result from imaging. Because of the lag time between exposure to radiation and cancer development (years to decades) it is not feasible to use cancer cases as the outcome of a quality improvement effort. Thus while there is ample evidence that radiation causes cancer (sited below), and evidenced that cancer risk is proportional to dose, there are no direct data that suggest that lowering doses lowers cancer risk. However, we have used mathematical modeling to try to understand the relationship between lowering doses and cancers and estimated that if the top quartile of doses were reduced in children (i.e. the very high doses are brought down the average doses), the number of cancer cases would be reduced by approximately 43%, the equivalent to preventing 4,350 cancer cases / year in the US among children (Miglioretti, JAMA Pediatrics 2013).

Cited in this section:

Demb J, manuscript under preparation. CT Radiation Dose Standardization Across the University of California Medical Centers Using Audits to Optimize Dose. 2015.

Following an in-person meeting regarding CT radiation dose, radiologists, technologists and medical physicists from University of California medical centers strategized how to best optimize dosing practices at their sites, which were then analyzed for effectiveness and success after implementation.

Greenwood T, Lopez-Costa R, Rhoades P, et al. CT Dose Optimization in Pediatric Radiology: A Multiyear Effort to Preserve the Benefits of Imaging While Reducing the Risks. RadioGraphics. Jan 2015;35(5):1539-1554

“This systematic approach involving education, streamlining access to magnetic resonance imaging and ultrasonography, auditing with comparison with benchmarks, applying modern CT technology, and revising CT protocols has led to a more than twofold reduction in CT radiation exposure between 2005 and 2012…” – Conclusion statement from Abstract

Keegan J, Miglioretti DL, Gould R, Donnelly LF, Wilson ND, Smith-Bindman R. Radiation Dose Metrics in CT: Assessing Dose Using the National Quality Forum CT Patient Safety Measure. Journal of the American College of Radiology: JACR; 11(3):309-315.

http://download.journals.elsevierhealth.com/pdfs/journals/1546-1440/PIIS1546144013006625.pdf. Mar 2014

Looking at dose metrics as per compliance with the previously endorsed #0739 NQF measure results in reasonably timed acquisition of CT doses, and seeing such doses resulted in 30-50% dose reduction.

Kumar K, manuscript under preparation. Radiation Dose Benchmarks in Children.

This paper will describe dose metrics among 29,000 children within age strata <1, 1-4 years, 5-9 years, 10-14 years, and 15-19 years. 2015.

Miglioretti D, Johnson E, Vanneman N, Smith-Bindman R, al e. Use of Computed Tomography and Associated Radiation Exposure and Leukemia Risk in Children and Young Adults across Seven Integrated Healthcare Systems from 1994 – 2010. JAMA Pediatrics Published online June 10, 2013 joli:101001/jamapediatrics2013311, 2013.

Radiation-induced cancers in children could be dramatically reduced if the highest quartile of CT radiation doses were lowered.

Miglioretti, YX Zhang, E Johnson, N Vanneman, R Smith-Bindman. Personalized Technologist Dose Audit Feedback for Reducing Patient Radiation Exposure from Computed Tomography. Journal of the American College of Radiology: JACR 2014.

“Personalized audit feedback and education can change technologists' attitudes about, and awareness of, radiation and can lower patient radiation exposure from CT imaging.” – Conclusion statement from Abstract

Ozasa K, Shimizu Y, Suyama A, et al. Studies of the mortality of atomic bomb survivors, Report 14, 1950-2003: an overview of cancer and noncancer diseases. Radiation Research; 177(3):229-243. Mar 2012

Fourteenth follow-up report on the lifetime health effects from radiation on atomic bomb survivor showing that: 58% of the 86,611 LSS cohort members with DS02 dose estimates have died, 17% more cancer deaths especially among those under age 10 at exposure (58% more deaths).

Pearce MS, Salotti JA, Little MP, et al. Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study. Lancet;380(9840):499-505. Aug 4 2012

“Use of CT scans in children to deliver cumulative doses of about 50 mGy might almost triple the risk of leukaemia and doses of about 60 mGy might triple the risk of brain cancer… although clinical benefits should outweigh the small absolute risks, radiation doses from CT scans ought to be kept as low as possible” – Conclusion statement from Abstract

Smith-Bindman R, Moghadassi M, Wilson N, et al. Radiation Doses in Consecutive CT Examinations from Five University of California Centers. Radiology 2015:277: 134–141

“These summary dose data provide a starting point for institutional evaluation of CT radiation doses.” – Conclusion statement from Abstract

Wilson N. CT Radiation Dose Standardization Across the Five University of California Medical Centers. ARRS: Annual Toronto Meeting presentation. April 19-24, 2015

Understanding the reasons for variation in commonly performed CT procedures, and figuring out how to standardize them.

Type

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Composite

2820: Pediatric Computed Tomography (CT) Radiation Dose

Outcome: Intermediate Clinical Outcome

Data Source

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Registry Data Clinical data registry (ACR National Radiology Data Registry - Dose Index Registry)

Available at measure-specific web page URL identified in S.1 Attachment ACRad_34_-_Multistrata_weighted_average_of_three_CT_exam_types.pdf

2820: Pediatric Computed Tomography (CT) Radiation Dose

Electronic Health Data, Electronic Health Records, Other, Registry Data The data sources will include electronic CT images [captured from the CT console at the time of scanning or harvested from the PACS (Picture Archiving Communication System) - the computerized systems for reviewing and storing imaging data], Radiology Information System, EPIC, printed CT images, or information stored in the medical record. Numerous other software products are now available for capturing these data (Bayer, GE, etc.) and several free ware programs are also available. Of note, the 2012 California law now requires the reporting of several of the dose metrics outlined in this measure in the patient medical record, and as a results, many software companies have provided techniques for collating these data.

No data collection instrument provided No data dictionary

Level

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Facility, Clinician : Group/Practice

2820: Pediatric Computed Tomography (CT) Radiation Dose

Facility, Integrated Delivery System

Setting

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Emergency Department and Services, Inpatient/Hospital, Other, Outpatient Services Dialysis Facility

2820: Pediatric Computed Tomography (CT) Radiation Dose

Inpatient/Hospital, Outpatient Services

Numerator Statement

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Number of CT Abdomen-Pelvis exams with contrast (single phase scan), CT Chest exams without contrast (single phase scan), and CT Head/Brain exams without contrast (single phase scan) for which Dose Length Product is at or below the size-specific exam-specific diagnostic reference level

2820: Pediatric Computed Tomography (CT) Radiation Dose

Radiation Dose metrics among consecutive patients, who have undergone CT of the head, chest, abdomen/pelvis, or chest/abdomen/pelvis. The metrics are 1) mean dose as measured using DLP, CTDIvol, and SSDE: within age strata. And 2) the proportion of exams with doses greater than the 75th percentile of the benchmark you are comparing with for the same anatomic area strata (Kumar, 2015; Smith-Bindman, Radiology, 2015; Goske, Radiology, 2013)

The CTDIvol and DLP are directly reported by the scanner using an "industry wide" standardized dose report (DICOM Radiation Dose Structured Report). The data should be assembled for the entire CT examination. If there are several series, the CTDIvol values should be averaged, and the DLP values should be added.

SSDE can be calculated using any dose monitoring software product, or using published multiplier coefficients which are highly valid.

These different metrics are highly correlated, but nonetheless reveal important differences regarding radiology practice and performance and are thus complimentary. However, if a practice only assesses data from a single metric, there is substantial opportunity for data-driven improvement.

CTDIvol reflects the average dose per small scan length. Modern CT scanners directly generate this.

DLP reflects the CTDIvol x scan length, and is directly generated by modern CT scanners.

SSDE is a modified measure of CTDIvol that takes into account the size of the patient scanned and is useful for scaling dose to patient size. Several current radiation tracking software tools directly report SSDE.

Cited in this section

Goske MJ, Strauss KJ, Coombs LP, et al. Diagnostic reference ranges for pediatric abdominal CT. Radiology. Jul 2013;268(1):208-218.

"Calculation of reference doses as a function of BW (body weight) for an individual practice provides a tool to help develop site-specific CT protocols that help manage pediatric patient radiation doses." – Conclusion statement from Abstract

Kumar K, manuscript under preparation. Radiation Dose Benchmarks in Children.

This paper will describe dose metrics among 29,000 children within age strata <1, 1-4 years, 5-9 years, 10-14 years, and 15-19 years. 2015.

Smith-Bindman R, Moghadassi M, Wilson N, et al. Radiation Doses in Consecutive CT Examinations from Five University of California Centers. Radiology 2015:277: 134–141

"These summary dose data provide a starting point for institutional evaluation of CT radiation doses." – Conclusion statement from Abstract

Smith-Bindman R, Miglioretti DL. CTDIvol, DLP, and Effective Dose are excellent measures for use in CT quality improvement. Radiology. Dec 2011;261(3):999; author reply 999-1000.

An explanation as to why these radiation dose metrics are useful in calculating a patient's absorbed doses.

Huda W, Ogden KM, Khorasani MR. Converting dose-length product to effective dose at CT. Radiology. Sep 2008;248(3):995-1003.

"This article describes a method of providing CT users with a practical and reliable estimate of adult patient EDs by using the DLP displayed on the CT console at the end of any given examination." – Conclusion statement from Abstract

Numerator Details

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Dose length product; CTDIw Phantom Type; Effective Diameter (calculated from localizer image); size specific exam-specific diagnostic reference level.

These components capture how well radiation exposure from the scanner is adjusted for patient size, using size-specific exam-level diagnostic reference levels and how well total radiation exposure to a patient from an exam is optimized based on the CT dose index dose-length product (DLP).

2820: Pediatric Computed Tomography (CT) Radiation Dose

Radiation dose distribution for the three metrics (CTDIvol, DLP, and SSDE) need to be recorded for a consecutive sample of CT examinations within anatomic area and age stratum. The mean, median, and the percent of examinations above the published 75% percentile needs to be generated.

These data can be extracted from the CT examinations in several ways. These numbers can written down directly from the CT scanner itself at the time of the examination; they can be written down from the PACS (computer terminal where images are reviewed and stored); or can be written down from the medical record if the facility stores these data as part of the medical record (all facilities in California due this based on statutory requirements.) The CT manufacturers have agreed (through MITA, Medical Imaging and Technology Alliance, the professional trade association of imaging manufacturers) to make these data electronically available through export from the CT machines to a local server), and these data can also be collected electronically. A growing number of companies are leveraging the standardized data format to systematically collect dose metrics directly from a facilities imaging infrastructure. This not only improves the accuracy of the data but also markedly reduces the costs of data collection. From the PACS, Radiology Information System, EPIC program if the data are exported there, or using any number of dose monitoring software programs allowing the collection and reporting of these dose data. The easiest way to collect these data is through one of the 6 or so commercial software programs developed for dose tracking, and several free-ware programs that enable directly extracting CT dose information from the PACS. We have published (Keegan, JACR 2014) several examples of techniques for dose extraction that can be completed even by a small facility.

The strata for this measure include:

Anatomic area strata: head, chest, abdomen/pelvis, Chest/abdomen/pelvis

Age strata: infant (<1); small child (1-5); medium child (>5 - 10); large child (>10-15) and adult (>15)

NOTE: The SSDE was developed as a metric for adjusting for size. However, it does not completely adjust for size and analysis within age strata are still needed among children to account for the different doses that are used and should be used for infants to obese children.

Cited in this section:

Keegan J, Miglioretti DL, Gould R, Donnelly LF, Wilson ND, Smith-Bindman R. Radiation Dose Metrics in CT: Assessing Dose Using the National Quality Forum CT Patient Safety Measure. Journal of the American College of Radiology: JACR; 11(3):309-315.

http://download.journals.elsevierhealth.com/pdfs/journals/1546-1440/PIIS1546144013006625.pdf. Mar 2014

Looking at dose metrics as per compliance with the previously endorsed #0739 NQF measure results in reasonably timed acquisition of CT doses, and seeing such doses resulted in 30-50% dose reduction.

Denominator Statement

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Number of CT Abdomen-pelvis exams with contrast (single phase scans), CT Chest exams without contrast (single phase scans), and CT Head/Brain (single phase scans)

Target population: all patients regardless of age.

2820: Pediatric Computed Tomography (CT) Radiation Dose

Consecutive sample of CTs conducted in the head, chest, abdomen/pelvis and chest/abdomen/pelvis. No examinations should be excluded

Denominator Details

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Study description; Exam date; Acquisition protocol

Target population: all patients who require either a CT Abdomen-pelvis exam with contrast (single phase scans), a CT Chest exam without contrast (single phase scans), and/or a CT Head/Brain (single phase scans) exam regardless of age.

2820: Pediatric Computed Tomography (CT) Radiation Dose

Consecutive sample of CTs conducted in the head, chest, abdomen/pelvis, chest/abdomen/pelvis

Exclusions

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

No denominator exclusions

2820: Pediatric Computed Tomography (CT) Radiation Dose

CT examinations conducted in anatomic areas not included above (such as CTs of the extremities or lumbar spine) or that combine several areas (head and chest) should not be included. In children, these four included categories will reflect approximately 80% of CT scans.

Examinations performed as part of diagnostic procedures – such as biopsy procedures – should not be included. CT examinations performed as part of surgical planning or radiation therapy should not be included.

Examinations that are considered "limited abdomen" or "limited pelvis" studies should be included in the abdomen and pelvis category. Any examinations that include any parts of the abdomen and or pelvis should count in the abdomen/pelvis category.

Exclusion Details

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

No denominator exclusions

2820: Pediatric Computed Tomography (CT) Radiation Dose

Most abdominal/pelvis CT scans in adult patients include scanning of the abdomen and pelvis as one contiguous area. If examinations are conducted limited to one region, these should also be included, as it is difficult/impossible to define what areas would be considered limited.

Risk Adjustment

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Stratification by risk category/subgroup

2820: Pediatric Computed Tomography (CT) Radiation Dose

No risk adjustment or risk stratification

141072| 109921

Stratification

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

The measure calculation is stratified by patient size. The results are not reported separately by the stratification variable.

2820: Pediatric Computed Tomography (CT) Radiation Dose

Anatomic area strata: head, chest, abdomen/pelvis, chest/abdomen/pelvis

These were chosen based on being the most common CT examination types conducted in the US, comprising >80% of all CT scans, and because dose varies by these groups.

Age strata: infant (<1); small child (1-5); medium child (>5 - 10); large child (>10-15) and adult (>15)

These patient age groups were chosen based on the variation of CT settings and resulting radiation dose based on patient size (and age is frequently used as a surrogate for size.) The ICRU (International Commission on Radiation Units and Measurements) uses these child size categories, they correspond to available phantoms, and they are the ones found to be most reliable

Geographic location where studies were done (zip code or state), to facilitate using the data to create geographically specific benchmarks

Type Score

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Rate/proportion better quality = higher score

2820: Pediatric Computed Tomography (CT) Radiation Dose

Algorithm

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Target population is all patients regardless of age.

To calculate the denominator for each of the measures we include all exams that are mapped to a standardized exam name/study description that corresponds to one of the three exam types used for measures, has a localizer image to permit size assessment, and has non-zero values for dose indices.

To calculate the numerator:

Head exams are categorized using lateral thickness (size) from scout images submitted by facilities. Body exams (chest and abdomen/pelvis) are categorized using the effective diameter (size) that ACR calculates from scout images. The numerator consists of the total number of exams among the denominator that are at or below the size specific DRL.

To calculate the performance rate, the numerator (Total number of exams among the denominator that are at or below the size specific DRL) is divided by the denominator (submitted eligible records) and multiplied by 100 to indicate the percentage. Physician groups/facilities may compare their performance to other facilities using aggregate registry level benchmarks.

Step 1: Denominator: Total number of exams that were mapped to one of the 3 exam names, had a non-zero DLP and a non-zero CTDIvol, CTDIvol<DLP, age was not missing, and patient size is available

Step 2: Numerator: Total number of exams among the denominator that are at or below the size specific DRL

Step 3: Percentage at or below size-specific DRL for each body part: (Numerator/Denominator)*100

Step 4: Percentage of all exams at or below size-specific DRL. Alternately, calculate weighted average of component measures, where weight is number of records for each body part.

Composite score:

Each component measure percentile score is weighted by the denominator count. The weighted scores are summed then divided by the sum of weights of all 3. Alternatively, the numerator and denominator counts for each measure can be totaled then averaged by 3.

Example:

	Numerator	Denominator	Rate
Head	3000	8000	38%
Abdomen/Pelvis	5000	10000	50%
Chest	2000	5000	40%
All	10000	23000	43%
Weighted average			43%

Weighted average = (Weight Head x Rate Head) + (Weight Abdomen/Pelvis x Rate Abdomen/Pelvis) + (Weight Chest x Rate Chest)))/Sum of weights of all 3

2820: Pediatric Computed Tomography (CT) Radiation Dose

N/A 141072| 109921

Submission items

3621: Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

5.1 Identified measures: 2820 : Pediatric Computed Tomography (CT) Radiation Dose

5a.1 Are specs completely harmonized?

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value: NQF #3621 is a competing measure to NQF #2820 because our measure addresses the same measure focus and target population. The target population in NQF #2820 is a subset population of NQF #3621. Additionally, while NQF #2820 primarily targets pediatric patients, the measure description states that the measure can also be used for CT in adults.

In NQF #3621 performance for facilities and groups is calculated comparing dose indices to published benchmarks.

NQF #2820, “provides a simple framework for how facilities can assess their dose, compare their doses to published benchmarks (Smith-Bindman, Radiology, 2015) and identify opportunities to improve if their doses are higher than the benchmarks”. Measure users thus are self-calculating results against one of three published benchmarks themselves using one of three benchmarks published benchmarks for both levels of measurement (group and facility).

NQF #3621 uses data published in the ACR 2017 study, U.S. Diagnostic Reference Levels and Achievable Doses for 10 Adult CT Examinations, identifying DRLs and Achievable Doses (ADs) for the 10 most common CT adult examinations performed in the United States. It represents the first time that national adult DRLs and ADs have been developed as a function of patient size, a milestone in optimizing radiation dose to patients. NQF #3621 has eight years of performance data for each measure component, as well as four years of data for the composite. Using electronic data sources, NQF #3621 has high feasibility and low collection burden, which minimizes missing data bias. NQF #3621 provides greater consistency and level of comparison across facilities and groups, providing more validity and reliability for use in quality improvement and specifically for accountability programs.

Reference: Kanal KM, Butler PF, Sengupta D, Bhargavan-Chatfield M, Coombs LP, Morin RL. U.S. Diagnostic Reference Levels and Achievable Doses for 10 Adult CT Examinations. Radiology. 2017 Jul;284(1):120-133. doi: 10.1148/radiol.2017161911. Epub 2017 Feb 21. PMID: 28221093.

2820: Pediatric Computed Tomography (CT) Radiation Dose

5.1 Identified measures:

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value: N/A

Appendix F: Pre-Evaluation Comments

Comments received as of June 3, 2021.

#0500 Severe Sepsis and Septic Shock: Management Bundle

Submitted by the American Medical Association

The American Medical Association (AMA) supports the intent of #500, Severe Sepsis and Septic Shock: Management Bundle and believes that a measure on this topic that is evidence-based and precisely specified has great potential to improve the quality of care provided to patients and save lives. Regrettably, we do not agree that this composite measure meets this need and therefore, we urge this committee to recommend removal of endorsement due to ongoing concerns over the lack of alignment with current evidence and the potential for negative unintended consequences such as incentivizing antibiotic overuse. Specifically, the AMA strongly urges the Standing Committee to consider the concerns and recommended revisions outlined in recent position paper by the Infectious Diseases Society of America (IDSA) and endorsed by five medical specialty societies (Rhee, 2021).

Concerns on the measure as specified have been repeatedly raised regarding the potential for patient harm, including the recent position paper by IDSA, as well as the article by Pronovost and colleagues published in the American Journal of Medical Quality (Pronovost 2017) and researchers continue to examine the potential influence of this measure on patient care. For example, an analysis on the impact that this measure had on antibiotic utilization rates demonstrated that its implementation likely contributed to increases in broad-spectrum antibiotic use (Pakyz, 2021) and in comments that the AMA provided during the last endorsement review, we also identified a scenario where a physician may determine that treating a patient severe systolic dysfunction (LVSD) with the amount of fluids required under this composite would be harmful to the patient, possibly causing fluid overload. Research shows that this can be harmful to patients with septic shock and increase mortality and more than 60 percent of patients who present with septic shock have LVSD (Baciak 2015, Pulido 2012, Boyd 2011). If a physician provides the appropriate care to the patient in this circumstance (limiting the fluids), it would impact their ability to comply with the measure. This need to allow physicians to tailor treatment based on individual patient needs and clinical judgment continues to be reaffirmed (Pepper, 2019).

The developers and implementers such as the Centers for Medicare & Medicaid Services (CMS) must ensure that the specifications are flexible enough to allow for individual patient differences to be factored, while also enabling hospitals to demonstrate the quality of care provided.

During the 2017 review, we also questioned whether the measure was based on strong evidence. Specifically, Kalil and colleagues examined more than thirty-five observational studies and randomized clinical trials to determine why results in more recent studies were not supportive of the original trials from 2001. On review, they found that patient survival rates were primarily driven by prompt and appropriate antibiotic administration rather than early goal-directed therapy (EGDT). In addition, EGDT was associated with higher mortality rates in patients that had higher disease severity (Kalil, 2017). A similar analysis by the PRISM investigators found no differences in outcomes for patients who received EGDT versus usual care and those same patients had higher costs associated with the hospitalization

(PRISM, 2017). The IDSA position paper (Rhee, 2021) also raised concerns with the evidence used to support the inclusion of suspected sepsis without shock, yet the measure continues to include these individuals. We do not believe that the developer has provided any new evidence in this latest submission to address these discrepancies.

The AMA strongly urges the Standing Committee to not recommend the measure for continued endorsement in light of the lack of alignment with clinical evidence and known potential for negative unintended consequences.

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#0500 Severe Sepsis and Septic Shock: Management Bundle

Submitted by the Society of Critical Care Medicine

To whom it may concern,

On behalf of the Society of Critical Care Medicine (SCCM), I write in support of continued endorsement of NQF #0500. The NQF #0500 Severe Sepsis and Septic Shock Management Bundle began with the work of Dr. Emanuel Rivers' seminal trial in 2001 and exponentially grew based on the important contributions of the Surviving Sepsis Campaign (SSC), a joint international effort sponsored by SCCM and the European Society of Intensive Care Medicine. Between 2008 and 2014, the measures were comprehensively reviewed and vetted by multiple expert stakeholder groups leading to incorporation of NQF #0500 into the CMS Hospital IQR program in 2015.

Sepsis has been documented to be a major public health issue with an estimated 1.7 million adult cases annually in the United States and approximately 270,000 related deaths. Furthermore, the disability resulting from sepsis can have a profound and lasting impact on patients and their families. It is for these reasons that SCCM collaborates with dedicated experts from emergency medicine, infectious diseases, and intensive care medicine across multidisciplinary professions to publish continually updated guidance with an aim to refresh with the most recent, reliable scientific evidence. This evidence can then inform changes to the measures intended to have a meaningful impact on patient outcomes. These efforts reflect the ongoing evaluation of the measures and recognition by NQF of the important role that #0500 plays in improving care for patients with sepsis and septic shock .

Hospitals across the United States respond to Federal and now growing State mandates. Many have engaged in strategic innovations to support early detection and intervention models across care settings. A diverse and growing number of States have engaged involuntary state-wide initiatives funded by CMS to support implementation of the #0500 management bundle to improve care and facilitate compliance with the SEP-1 core measures. This ground-swell movement toward deeper adoption of the #0500 sepsis measures is stimulated in part by SEP-1 incorporation into the IQR program and as is the case with any initiative time, resources, and regular affirmation of accuracy is vital.

Therefore, SCCM endorses the ongoing process of NQF #0500 maintenance to bring measures into alignment with the latest published evidence as a stimulant to implement evidence-based practice. It is in this spirit of pursuing clinical excellence that SCCM supports NQF #0500 as the nation's first, and evolving, sepsis quality measures.

Sincerely,

Greg S. Martin, MD, MSc, FCCM

President, Society of Critical Care Medicine

500 Midway Drive

Mount Prospect, IL 60056

president@sccm.org

#0500 Severe Sepsis and Septic Shock: Management Bundle

Submitted by the Sepsis Alliance

To whom it may concern,

On behalf of Sepsis Alliance, the nation's first and leading sepsis organization, and on behalf of the many millions of sepsis patients and survivors we represent, I write to express strong support of the continued measure of hospitals' compliance with the Severe Sepsis and Septic Shock Management Bundle (NQF # 0500, or SEP-1), with modifications as research continues to advance in the field.

Sepsis Alliance's mission is simple: to save lives and reduce the suffering caused by sepsis. Sepsis is the leading cause of death in U.S. hospitals[i] and claims over 270,000 American lives each year[ii]. Another 1.4 million American survive sepsis every year[iii], many of them with lingering costs and complications—including approximately 14,000 amputations annually[iv].

SEP-1 focuses on timely recognition of sepsis and early intervention with life-saving therapies. We know that saving lives and limbs from sepsis is about time: 12% of septic emergency department patients develop shock within 48 hours of presentation[v] and each hour of delay until initial antimicrobials are administered is associated with an 8.0% increase in progression to septic shock[vi]. By emphasizing the screening of every patient in an effort to catch sepsis early, SEP-1 helps prevent the progression of sepsis to septic shock and ultimately saves lives.

Moreover, studies have shown the association between performance metrics and patient outcomes[vii] and that decreased risk-adjusted sepsis mortality is associated with increased hospital-level compliance with mandated public reporting[viii]. The mandate that hospitals gather and report sepsis-relevant performance data is part of what makes SEP-1 a life-saving measure.

The effectiveness and widespread approval of the SEP-1 measure led to its incorporation into the CMS Hospital IQR program in 2015. Today, there are sepsis screening programs at every hospital in the U.S., which has brought every community hospital in America up to the level of an academic facility on diagnosing and treating this challenging syndrome.

We respectfully disagree with those who urge removal of this measure. We understand that care is nuanced and that no single test can (yet) accurately or reliably establish a diagnosis of sepsis. In fact, this lack of a precise test is exactly why we should maintain a measure meant to focus on improving the quality of care for the sepsis patient. Based on continued insights from analysis of the SEP-1 measure and associated outcomes, we support its continued improvement—there are, in fact, ongoing efforts to modify the measure in response to updated evidence and provider feedback.

Furthermore, we understand and wholeheartedly agree with the widespread concern about the immense problem of antimicrobial resistance (AMR). In fact, because AMR is a growing threat to sepsis

prevention and treatment, and because sepsis patients are at the greatest risk if we lose access to a wide range of antimicrobials, we believe efforts to combat AMR are crucial,

Sepsis Alliance embraces the dual responsibility to diagnose and treat sepsis patients in a timely way, and to manage our antimicrobial medicine chest. At this time, the SEP-1 measure's stewards have proposed modifications meant to promote both decreased time to sepsis treatment and appropriate antibiotic usage; we also recognize the judicious use of IV fluids in the resuscitation of the sepsis patient and continue to encourage better multidisciplinary clinician engagement in the care of septic patients throughout their illness and recovery. Importantly, that standard of care includes stewardship considerations.

Continuing the SEP-1 measure would assure that hospitals maintain their focus on the number one cause of death in U.S. hospitals: sepsis. With modification, the SEP-1 measure will support the continued necessary education, screening, early recognition, and management of sepsis that improves care and saves lives in every community. Sepsis Alliance joins its organizational voice with the many leaders in the field who strongly support the maintenance and continued development of the SEP-1 measure.

Sincerely,

Thomas Heymann

President & CEO

Sepsis Alliance

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#0500 Severe Sepsis and Septic Shock: Management Bundle

Submitted by Bruce Quinn

While the opportunity to comment is appreciated, the NQF review must be driven by systematic review of the published evidence for SEP-1 as a real Quality Measure, which is fundamentally different than its performance as an RCT intervention.

It is no longer necessary to make decisions based only on the original RCTs. Rather, we have a direct volume of evidence of how well this measure's performance is correlated with real-world patient outcomes. The answer is that the correlation is not very strong.

Some of the best hospitals perform dismally on SEP-1. Henry Ford Hospital, the measure holder, currently has a 41% performance today at CMS Hospital Compare. Other top hospitals fall below that: 39% at Yale, 30% at Emery, 13% at Vanderbilt. Either these top hospitals have an avalanche of iatrogenic sepsis deaths, or, the measure – in the real world – isn't what what it was in RCTs.

We should welcome this finding (for more detail, see Faust (2021) Ann Emerg Med, Epub, PMID 33962816). What we are seeing in these publications and reports is simple. It is the difference between efficacy in clinical trials, and effectiveness in the real-world. It is the generalizability or external validity of a controlled scientific intervention into real life. In most of healthcare, we have to guess how externally valid an intervention is, but with SEP-1, there is voluminous data and a steady output of academic articles, more each year. This empirical question has now been studied in 3000 hospitals for 5 years. SEP-1 performance does not correlate very well with real-world outcomes (Barbash, Ann Int Med, epub, PMID 33872042.)

While SEP-1 outcomes (such propensity-adjusted mortality or ICU length of stay) appear to be patient-centered outcomes, the intervention is something of a different nature, the impact on physician behavior. A small cohort of physicians were subjects in closely orchestrated, monitored, protocol-driven RCTs, conducted with funding, focus, and education. This is very different than the transformation of SEP-1 from an RCT intervention into a quality measure, meaning that an auditor is paid to review records of the previous quarter or year against a SEP-1 rulebook.

Let me emphasize: the RCT with all its steps and controls and protocols, IRBs, and nurse monitors and logbooks is one thing. An administrative regulation to calculate SEP-1 measurement rules, carried out by staff in the records room, is a wholly different thing, like an apple is different from the picture of an

apple. Active SEP-1 RCTs justified the registration of SEP-1 as a hospital measure, the way a Phase 2 trial justifies a Phase 3 trial. But a hospital measure is far different in its nature than an RCT intervention. The brand new empirical question is whether the living RCT intervention, after being transformed into a required medical records exercise, remains similarly impactful on outcomes. It might, it might not, and data is the answer. Debates in 2012-2017 focused on the validity or design of SEP-1 RCTs (e.g. debates between Townsend and Pepper), but our focus should shift fully to SEP-1 measure outcomes in 2018-2021. This means: Whether or not the originally trials were correctly designed, if CMS SEP-1 has large and favorable outcomes, we would keep it. And regardless of whether or why the original trials were favorable, if the transformation into CMS SEP-1 were now found to make no difference or be harmful, we shouldn't be using it.

The question for NQF isn't about the importance of sepsis, the importance of timely interventions, or the importance of the right interventions for which confusing, multiple symptomatic, and ill patients. It is whether SEP-1 improved hospital-based health outcomes correlated with its scores.

#0500 Severe Sepsis and Septic Shock: Management Bundle

Submitted by the New Jersey Hospital Association

On behalf of the New Jersey Hospital Association's more than 400 members, we are writing to express strong support of the Severe Sepsis and Septic Shock Management Bundle (NQF # 0500, or SEP-1). NJHA appreciates the opportunity to offer context for our support of this measure.

The SEP-1 measure is grounded in the clinical judgment and expertise of the nation's foremost experts in sepsis prevention and care, including two from New Jersey -- R. Philip Dellinger, MD, FCCM, FCCP, Director, Cooper Research Institute, Cooper University Health Care and David V. Condoluci, DO, immediate-past Chief Patient Safety & Quality Officer, Jefferson Health in New Jersey. In addition, NJHA's multi-year track record of working with hospitals, physicians and nursing homes in sepsis prevention, identification and care, have also informed our position. Below is a summary of additional key components that have informed our position.

- In a letter to the editor of JAMA (July 26, 2016 Volume 316, Number 4), CMS voiced its rationale to continue with the existing sepsis definition. CMS' view was "The existing sepsis definition, including the use of SIRS criteria, have been instrumental in training clinicians and nurses on how best to identify the earliest stages of sepsis. The widespread teaching of these sepsis criteria and the adoption of screening and protocolized care processes have resulted in an unprecedented reduction in sepsis mortality. As such, the existing sepsis definitions have helped clinicians to identify, diagnose, and treat sepsis early, before a patient's condition worsens. As opposed to early identification, the proposed task force definitions may delay the diagnosis of sepsis until patients are much sicker. Although the task force's definition structure may identify patients with the highest likelihood of poor outcomes, it does not clearly identify patient in the early stages of sepsis when rapid resuscitation provides the greatest patient benefit and improves survival. A change to the existing definition could disrupt the 15-year trend toward further reduction in sepsis mortality."
- The Sepsis 1 definition, in partnership with the standard bundle of care, has reduced mortality and hospital readmissions for all sepsis cases. The effectiveness and widespread approval of SEP-1 led to its incorporation into the CMS Hospital IQR program in 2015, which has brought every community

hospital to the same level as academic facilities. This is based on many years of data, study and evaluation. In the absence of agreement by CMS and other national leadership groups such as the American College of Emergency Physicians, American College of Chest Physicians, American Thoracic Society, Infectious Disease Society of America, Society of Critical Care Medicine and ICD-10-CM, a new measure that uses other definitions opens the door for conflicting protocols and confusion.

- Early recognition, diagnosis and immediate medical treatment are critical to saving lives of people like Rory Staunton, a young and healthy boy who died from sepsis in April 2012. The Rory Staunton Foundation continues to champion the cause of early identification of sepsis by healthcare practitioners in all settings.
- Our entire health care system is shifting toward value-based care and population health. Both of these concepts center on keeping people healthy and intervening before a medical issue requires intensive resources.
- Hospitals' clinical quality improvement teams have focused on recognizing symptoms and acting appropriately in a patient-centric manner before sepsis leads to severe complications or even death. This is complicated by the fact that sepsis can rapidly develop from an issue as innocuous as a scratch. Health care providers studied and implemented bundled interventions to standardize response every time sepsis is suspected. Time is of the utmost importance when identifying and treating sepsis, so much so that the Sepsis Alliance promotes the acronym TIME (Temperature, Infection, Mental Decline, Extremely Ill) to educate the public on early symptoms of sepsis. Health care professionals prioritize the needs of their patients in alignment with compelling clinical evidence that clearly support early reaction to warning signs. The risk of not taking potential sepsis cases seriously is death.
- Disruption in data capture that would be caused by the elimination of the SEP-1 measure will significantly impact the healthcare community's ability to understand the severity of sepsis and whether quality interventions work because our data will not be as specific or complete.
- Efforts to modify the SEP-1 measure in response to updated evidence and provider feedback are ongoing. The elimination of the SEP-1 measure would mean that many institutions, including those serving the most underserved populations, may divert their attention away from the number one cause of death in U.S. hospitals, and may no longer push the education, screening, early recognition, and management of sepsis that improves care and saves lives. This is not a prudent approach.
- Significant decisions about quality measurement could have the unintended effect of delaying what is most beneficial for patients and that put their lives at risk. This contradicts best practices and a culture of health and would be a step in the wrong direction. Promoting good preventive strategies and public education is beneficial to patients, providers and payers in achieving the common goal of saving lives.

It is true that clinical evidence will continue to evolve, but until CMS and the leading clinical organizations dedicated to the science of sepsis come to agreement on what best practice is, NJHA believes SEP-1 should remain in place. In the meantime, the collective health care community should focus on the public health issue sepsis presents to all. By coming together in a collaborative manner, we can find solutions that encourage the most effective care – from a cost and quality perspective -- without sacrificing value to all of the stakeholders.

Thank you again for the opportunity to provide the context and basis for our position. Please feel free to contact me at 609-275-4241 or cbennett@njha.com with any questions you may have.

Sincerely,

Cathleen D. Bennett

President & CEO

#0500 Severe Sepsis and Septic Shock: Management Bundle

Submitted by Society to Improve Diagnosis in Medicine

On behalf of the Society to Improve Diagnosis in Medicine (SIDM), we support the continued endorsement of Measure 0500. Inaccurate or delayed diagnosis is the most common, the most catastrophic and the most costly of all medical errors leading to the premature deaths of 300,000 per year and costing the US economy in excess of $100 billion annually. When considering high-severity harm (NAIC 6 to 9), 34% of all such malpractice claims involved diagnostic error (#1) and of those, 74% were concentrated in three categories, vascular events, infection, and cancer. In the area of infection, Sepsis was number one (Newman-Toker, 2019).

We recognize that the current sepsis measure, 0500, is imperfect and needs to be updated based on the improving evidence base. We strongly urge that the measure steward and NQF work aggressively to update this measure based on the latest evidence. We also urge consideration by hospital administrators and others for the limitations of the current measure amid competing priorities so clearly visible during the COVID pandemic.

However, despite its limitations, we believe that abandoning this measure at this time would be the wrong decision. Morbidity and mortality of sepsis will only improve with more timely diagnosis leading to earlier administration of antibiotics and fluids (Rhea, 2019). While measures alone cannot guarantee improved diagnostic outcomes, they do bring attention and increased awareness to the diagnostic process in general and, in this case, to the potential diagnosis of sepsis, in particular. To abandon the current measure would invite a lessening of attention to and consideration of this important diagnosis at the very moment when increased attention and data gathering is needed.

#0500 Severe Sepsis and Septic Shock: Management Bundle

Submitted by the American College of Emergency Physicians

Dear Members of the NQF Patient Safety Committee,

Since 2015, NQF measure #500 "Severe Sepsis and Septic Shock: Management Bundle" serves as the basis for the Centers for Medicare and Medicaid Services Core Quality Measure, "SEP-1" which is currently a part of Hospital Compare.

We write to express and offer our expert insight, representing over 50,000 physicians delivering care to acutely ill patients with sepsis and with other conditions in the key early phases of care. We believe the measure should be markedly revised if it is to be continued, and we support a sepsis measure that embraces evidence-based expert clinical input. Our view is shared by other expert groups including the infectious Diseases Society of America (IDSA).

NQF #500 and CMS SEP-1 sought to improve sepsis care; something needed at the original endorsement time and still needed today despite improvements. Currently, however, we believe that neither the NQF #500 measure nor the CMS SEP-1 quality measure reflect the best available evidence. Specifically, current evidence published in high impact scientific journals show that NQF #500 and CMS SEP-1 are neither necessary nor sufficient in achieving better outcomes, especially when appropriate risk-adjustment is performed (JAMA Internal Medicine, Critical Care Medicine). 1,2 In addition to not creating a better care path as measured by outcomes, they do not save the healthcare system money. In the current form, both measures impose a high burden to healthcare systems and clinicians (Critical Care Medicine, Journal of Infectious Diseases). 3,4 This constellation of results was clearly not intended but nevertheless realized and run against the stated intent of using quality measures to improve care and decrease cost in the United States healthcare sector.

ACEP supports the recommended revisions to NQF #500/CMS SEP-1 proposed by the IDSA, as outlined earlier this year by Rhee et al (Clinical Infectious Diseases).5 Specifically, we support the removal of all sepsis without shock from NQF #500/CMS SEP-1 (as currently defined by the CMS SEP-1 Data Dictionary). As Rhee et al state:

"Removing sepsis without shock from SEP-1 will mitigate the risk of unnecessary antibiotic prescribing for noninfectious syndromes, simplify data abstraction, increase measure reliability, and focus attention on the population most likely to benefit from immediate empiric broad-spectrum antibiotics."

ACEP believes that this change would make NQF #500/CMS SEP-1 more targeted and aligned with the data supporting key aspects of the measure; the evidence supporting the bundle largely arose from this subset of septic patients, yet the measure is applied more broadly. This risks harm and wastes effort, and our clinicians and experts agree that harm exists now with the current measures.

We are aware some believe change of this measure is thwarted because NQF #500 and CMS SEP-1 are process measures. However, even process measures require ongoing evaluation and honing based on evidence and feedback. One challenge was that the specific aspects of these measures were not directly tested prior to approval, noted by the Joint Commission public comment prior to rule's enacting in 2015 and by the measure stewards themselves in public comments at that time. Since enactment by CMS, the resulting measures' lack of evidence-basis and testing has been highlighted by others, including researchers at the National Institutes of Health (Annals of Internal Medicine). 6 In addition, the measure stewards have routinely altered the CMS SEP-1 in response to public comments made each year. While many of the changes have been welcome improvements (for example, excluding patients with ventricular assist devices form the fluid requirements of the bundle), none of them were tested and core concerns remain, especially surrounding the target populations.

Accordingly, we believe that the working standards for making substantial changes to NQF #500/CMS SEP-1 allow for the changes that the IDSA recommends and that we support. The current stewards of the measure may suggest that absent evidence of harm or no tangible benefits, the measure should continue. If failure to adapt and revise occurs because lack of evidence refuting impact, we believe this would become a capricious standard for ongoing changes in federal regulation. This would expose NQF #500/CMS SEP-1 to substantial legal vulnerability.

ACEP also has a new, multidisciplinary, and multi-organizational consensus paper being published in the coming days that outlines this and other opportunities to improve sepsis care starting at the earliest phases. We think this and input form other expert stakeholders can truly elevate the measures and ultimately improve outcomes for those with septic shock.

We thank the NQF for the opportunity to comment. The three-year cycle that NQF adheres to is wise in creating these natural reassessment and revision or removal opportunities. We hope to join you and others to achieve our mutual goals.

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#0500 Severe Sepsis and Septic Shock: Management Bundle

Submitted by The Leapfrog Group

Sepsis causes terrible suffering for an estimated 1.7 million adult cases annually, with approximately 270,000 related deaths. Sepsis should be a top priority public health concern and a core part of the nation’s measurement strategy. On behalf of employers and other purchasers who founded the nonprofit Leapfrog Group, we strongly support continuation of SEP-1 even as modifications are made. All measures should modify as evidence evolves, but a measure that is largely validated, tested, and established in practice, with its dramatic public health implications, should not be removed under any circumstances. The measure as it stands, even without modifications, serves a vital purpose that emphasizes education, screening, early recognition, and management of sepsis to prevent disability and suffering, and save lives. We also find that the use of the measure in public reporting and quality improvement has contributed to meaningful enhancements in adherence to recommended guidelines.

As measurement science evolves, we need to move forward with progress, not backward by removing a well-tested measure shown to positively impact one of the great public health challenges of our time.

#3621 Composite weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT Abdomen-pelvis with contrast/single phase scan, CT Chest without contrast/single

Submitted by the University of California, San Francisco

The American College of Radiology (ACR) has proposed measure #3621 titled "Multi-strata weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level" for the purpose of measuring the radiation doses used for computed tomography (CT). A quality measure that can inform clinicians about how they can safely lower radiation doses used for diagnostic CT scanning while maintaining the quality of images needed for diagnosis can greatly improve the health and safety of patients. However, the ACR's proposed measure is inadequate for this purpose and, if adopted, could undermine the broad application of more effective ways of using quality measures to achieve this goal. I therefore strongly recommend that National Quality Forum not endorse the proposed measure as it will not reduce the unintended harm of radiation in diagnostic imaging.

The radiation doses used for CT examinations are highly variable across hospitals and imaging facilities for patients imaged for the same indications, are frequently far higher than needed for diagnosis, and are in the range known to be carcinogenic. More than patient or machine characteristics, the most important predictor of radiation dose is the choice the radiologist makes as to what protocol to use (e.g., single-phase scan or double-phase scan). Protocols with more phases deliver proportionally more radiation, yet for most indications, there is no evidence suggesting the higher phase protocol provides better diagnostic utility.

The measure that the ACR has proposed will evaluate radiation doses that are used for three specific protocols: a single-phase head, single-phase chest, and single-phase abdomen. The measure will assess doses in these three groups against benchmarks only after the primary decision of protocol selection is made. This limited assessment of dose within these stratified groups ignores the primary factor determining the patient's dose (i.e., which protocol to use), which is almost entirely at the discretion of the imaging physician. The measure will assess only the relatively smaller variation in technical parameters within single-phase head, chest, or abdomen protocols, but will leave unassessed the variation that occurs due to the choice of protocol. The unnecessary variation in protocol selection is the critical factor, but the ACR measure over-adjusts for this factor by stratifying based on the protocol. The ACR defines the target population for the measure as "all patients who require either a CT Abdomen-pelvis exam with contrast (single-phase scans), a CT Chest exam without contrast (single-phase scans), and/or a CT Head/Brain (single-phase scans) exam." However, the measure fails to identify patients who require these exams based on their clinical need, but who instead received much higher doses through multi-phase exams, when the single-phase study would have been appropriate. In the University of California, San Francisco International CT Dose Registry, which includes over 8 million CT scans from 162 hospitals and image facilities, these three CT exam types together make up 39% of exams overall across the registry. However, they account for 1% to 83% of exams across the different hospitals and imaging

facilities, suggesting the denominator for this measure does not reflect a patient population who require these exams, but rather reflects the varying decisions of radiologists to assign patients to different protocols.

The only way to accurately judge physicians in their use of radiation for CT is to evaluate how they use radiation in a population of patients where their selection of imaging protocol is included in the assessment. Radiation doses need to be assessed based on the intent and clinical question of the provider ordering the scan, not on the radiologist's subjective choice of protocol, which is too often driven more by preference than clinical need. The measurement of the dose within the ACR's narrowly defined groups will only camouflage the large variation in practice that exists and will not serve to improve practice.

The University of California, San Francisco was contracted by CMS to develop a quality measure for CT for use in the MIPS payment program. The measure was submitted to the CMS MUC list in May 2021 and will be submitted to NQF in August. This measure assesses radiation doses among adult patients who undergo diagnostic CT based on the diagnoses and clinical questions generated at the time of the test order, and therefore is not undermined by the concern raised in the ACR measure.

Rebecca Smith-Bindman, MD

University of California, San Francisco

#3389 Concurrent Use of Opioids and Benzodiazepines (COB)

Submitted by the American Medical Association

The American Medical Association (AMA) appreciates the opportunity to comment on Measure #3389, Concurrent Use of Opioids and Benzodiazepines. While we appreciate the updates made to the measure including the addition of an exclusion for sickle cell disease, we continue to believe that the measure lacks the precision needed to ensure that only those patients for whom concurrent prescribing of two or more opioids or an opioid and benzodiazepine are included in the denominator. The patient population could likely include patients for whom concurrent prescribing of these medications may be appropriate, particularly those with chronic pain.

In addition and more importantly, the National Quality Forum (NQF) and the measure developer must consider the potential for unintended consequences and complete robust evaluations to minimize these risks. In fact, we believe that the narrow and reactionary response to the drug overdose epidemic has exacerbated the stigma around opioid use and made it more difficult for patients with pain or opioid use disorder to receive treatment. Research continues to demonstrate that individuals may or may not have access to pain management therapies based on their race/ethnicity and measures that may further exacerbate this problem should be avoided (Goshal, 2020). In addition to stigmatization of those with substance use disorder, patients with other complex pain management conditions (such as sickle cell disease) are often viewed as opioid-seeking when presenting in the emergency department. Therefore, we urge NQF to consider whether this and other measures that are focused on areas such as opioid dose and duration continue to be appropriate.

As a result, the AMA believes that there is a significant risk for performance to be inaccurately represented. More importantly, there is a substantial risk that patients for whom these medications may be warranted will not receive appropriate therapies, leading to potential adverse outcomes, including depression, loss of function and other negative unintended consequences.

The AMA believes that quality measurement needs to focus on how well patients' pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain. If pain can be well controlled and function improved without the need of these concurrent medications, then that is an indication of good patient care, but the measure must precisely define the patients for which it is appropriate and be tested to ensure that negative unintended consequences are not experienced by patients. We do not believe that this measure as specified is an appropriate goal as it may leave patients without access to needed therapies.

The AMA supports addressing the opioid crisis through quality measurement in addition to other avenues but strongly believes that any measure endorsed by NQF must also demonstrate that it does not compromise patient care. As a result, the AMA does not support continued endorsement of measure #3389.

Reference:

Goshal M, Shapiro H, Todd, K, Schatman ME. Chronic noncancer pain management and systemic racism: Time to move toward equal care standards. J Pain Res. 2020;13:2825-2836.

Appendix G: Post-Evaluation Comments

Following the Committee's evaluation of the measures under review, NQF received 15 comments from six organizations (including six member organizations) and individuals pertaining to the draft report and to the measures under review (Appendix G) as of September 7, 2021.

Measure-Specific Comments on Patient Safety Spring 2021 Submissions

NQF #0500, Comment #7759

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7759

Commenter: Kevin Brennan, Coalition for Improving Sepsis and Antibiotic Practices; Submitted by Bruce Quinn

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/7/21

Developer Response Required? Yes

Level of Support: Level of Support

Theme: target population

Comment

To Whom It May Concern:

We comment as the Coalition for Improving Sepsis and Antibiotic Practices (CISAP), which includes medical diagnostics companies Thermo Fisher Scientific, Roche Diagnostics, bioMérieux, Abbott, and Siemens. CISAP was formed several years ago to advance policy to improve sepsis care, promote antibiotic stewardship, and enhance patient health outcomes. We write to provide public comment on the National Quality Forum's (NQF) review of the Severe Sepsis and Septic Shock (SEP-1) quality metric.

Our member companies seek to advance knowledge among clinicians, policymakers, and payers of the benefits of using innovative, biomarker-assisted sepsis treatment and antibiotic use to improve critical public health outcomes. As stakeholders work to develop improved sepsis management measures -- including the Medicare SEP-1 quality metric -- CISAP encourages policymakers to consider evidence-based and biomarker-assisted sepsis management in both new and improved sepsis measures.

Sepsis is one of the most devastating and lethal health conditions, yet when recognized early, it is often treatable. Since 2015, Medicare has used a quality measure – SEP-1 – to rate hospitals with regard to their performance with potentially septic patients.

Sepsis always has an infectious cause – whether bacterial, viral, or fungal – but many patients with similar symptoms are not septic. SEP-1 requires that all patients meeting certain general symptom criteria be administered broad-spectrum antibiotics immediately and hospitals are penalized for not doing so. The Infectious Disease Society of America (IDSA) and other organizations have adopted policy positions that SEP-1 needs to be substantially reformed beyond the minor changes which have been made since 2015, such as not applying SEP-1 to patients on ventricular assist devices or to certain patients participating in clinical trials.

The Coalition takes the position that high-quality management and care pathways must be available to all patients who potentially have sepsis, regardless of emergency room or in-hospital settings. However, an increasing body of peer-reviewed publications suggest that SEP-1 may not be the optimal way to do this. We need to use appropriate biomarker-based diagnostic tests to inform the management of sepsis, and we should focus on measures that have been proven to impact outcomes in real-world healthcare settings, not only in the initial randomized clinical trials with elaborate educational procedures and other controls. The full range of knowledge and expertise in the healthcare community, along with the laboratory community, needs to be brought to bear on sepsis management. Now is the right time to encourage new thinking, through forums, town-halls, and other means, to ensure a national dialog on sepsis measures is both innovative and effective.

We thank the advisors and staff of the NQF for your continuing efforts to improve sepsis care and look forward to working with interested stakeholders in improving the diagnosis and treatment of individuals with sepsis.

Sincerely,

The Coalition for Improving Sepsis and Antibiotic Practices

Kevin Brennan

Bluebird Strategies

Advisor to CISAP

kbrennan@bluebird-strategies.com

Developer Response

We appreciate CISAP's reference to the Infectious Disease Society of America (IDSA) Position Paper on SEP-1 and encourage readers to review our remarks on this document elsewhere in our replies to public commentary.

In summary, we support CISAP's call for better diagnostics for sepsis and bacterial infection and, as this early science matures, we look forward to the opportunity to incorporate such approaches to sepsis quality of care measures.

NQF Response

N/A

NQF Committee Response

Thank you for your comment. The Standing Committee reviewed and considered this information during the post-comment meeting and agrees that some of the concerns raised in this comment may require further examination in the future, but the Committee maintains that this measure is suitable for endorsement at the current time.

NQF #0500, Comment #7771

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7771

Commenter: Mary Hayden, Society for Healthcare Epidemiology of America; Submitted by Geeta Sood

Council / Public: Health Professional

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/9/21

Developer Response Required? Yes

Level of Support: Member Does not support

Theme: Lack of evidence, unintended consequences, target population

Comment

The Society for Healthcare Epidemiology of America (SHEA) appreciates the opportunity to provide comments on the proposed NQF 0500 sepsis metric. SHEA supports measurement and interventions that reduce harm to patients. We do not believe NQF 0500 meets this standard.

Performance metrics raise awareness of conditions that cause harm and incentivize hospitals to prioritize and add resources to prevent those harms. Poorly designed metrics may be ineffective in creating structural and process changes that reduce harm, may divert resources from evidence-based interventions known to work or worse, may cause more harm through unintended consequences.

The National Quality Forum's robust scientific endorsement process is an important mechanism to ensure that not only are important patient safety conditions being addressed, but that the specifications of the proposed metrics are effective, feasible, cost-effective, maximize safety, and minimize harm.

One million seven hundred thousand patients develop sepsis annually and sepsis accounts for 270,000 deaths in the United States annually. ^1Undoubtedly, sepsis is a serious and lethal public health risk.

We have reviewed the Infectious Disease Society of America comments and agree with the concerns raised regarding the 1) lack of good-quality evidence that using the SEP-1 sepsis bundle reduces mortality, and 2) lack of evidence that measuring lactate levels reduces mortality, 3) lack of specificity in the target population by conflating sepsis with septic shock, 4) unintended consequences of increased inappropriate antibiotic use, and 5) need for an objective time-zero definition in the SEP-1 metric that is more specific and simpler to abstract than the current definition based on systemic inflammatory

response syndrome criteria, documentation of suspected infection, and organ dysfunction or refractory hypotension.

We would like to offer some additional comments to the well-described discussion by IDSA.

1. **Heterogeneity of the target population**
   Sepsis and septic shock are not clinical diagnoses per se but a constellation of symptoms. Just like it would be difficult to equate all patients with "fever", it is difficult to consider patients with fever and vital sign dysfunction as having the same underlying diagnosis. In many cases, this label may not reflect infection at all. Thirty – forty percent of patients coded as sepsis have a non-infectious cause for their sepsis symptoms [2,3].
2. **Unintended consequences – antibiotics and resources**
   In addition to the unintended consequences of unnecessary antibiotic administration, with consequential adverse effects (e.g. renal insufficiency, C. difficile infection, MDRO colonization and infection) noted in the IDSA statement, there is also the unintended consequence of diverting critical patient safety resources into data collection for this metric. The IDSA statement notes that chart abstraction is very time-consuming. There are several pages of data elements required for data collection for this metric. We would add that at present, hospitals employ FTEs whose sole responsibility is collection of data for the SEP-1 measure. The time and effort of those individuals would be better served by spearheading evidence-based initiatives known to improve sepsis care.
3. **Alternative measures**
   While we agree that sepsis is an important area of focus and that measures targeting this condition are valuable, we suggest that NQF and value-based purchasing programs evaluate alternative metrics to the SEP-1 metric that have demonstrated greater evidence of impact with greater specificity of the target population. A more precise target population would identify patients that are most likely benefit from these interventions and would reduce the unintended consequences from broad implementation.
   If the goal is to encourage rapid recognition of clinical deterioration events related to hospital-acquired infections, a more global measure such as hospital-onset bacteremia (HOB) or rate of admissions to the ICU >48 hours after hospitalization should be considered.
   Another alternative to the SEP-1 metric could be the ACEP-48 metric which focuses on sepsis in the emergency room. Ninety percent of cases of sepsis start outside of the hospital [1,2]. Thirty five percent were associated with previous hospitalization at an acute or long-term facility in the 30 days prior to index admission and 42% of cases occurred in the community with no healthcare exposure [3]. Ninety percent of cases of sepsis start outside of the hospital [1,2]. Thus interventions early in the hospital course are likely to be most impactful.
   Other researchers are also evaluating the CDC's hospital-onset Adult Sepsis Event metric that uses objective clinical criteria to identify sepsis, differentiates community and hospital-onset sepsis, and could be imbedded in the electronic medical record [4].

We appreciate the investment by NQF, other professional and community organizations and the public to improve the quality of care for patients with this highly prevalent and highly lethal condition, however we would like to ensure that metrics that are used to improve processes for sepsis care do improve clinical outcomes for patients without causing harm. While the SEP-1 metric targets an

important condition, it does so without enough specificity for the patients that would benefit and without enough evidence of improvement in clinical outcomes.

We ask NQF to not endorse SEP-1 and to continue to evaluate other metrics that better impact sepsis outcomes.

Thank you,

Mary Hayden MD

President, Society for Healthcare Epidemiology of America

1. Sepsis: What is Sepsis. 8/17/2021. [1]https://www.cdc.gov/sepsis/what-is-sepsis.html (accessed 9/1/2021 2021).
2. Fay K, Sapiano MRP, Gokhale R, et al. Assessment of Health Care Exposures and Outcomes in Adult Patients With Sepsis and Septic Shock. JAMA Netw Open 2020; 3(7): e206004.
3. Novosad SA, Sapiano MR, Grigg C, et al. Vital Signs: Epidemiology of Sepsis: Prevalence of Health Care Factors and Opportunities for Prevention. MMWR Morb Mortal Wkly Rep 2016; 65(33): 864-9.
4. Page B, Klompas M, Chan C, et al. Surveillance for Healthcare-Associated Infections: Hospital-Onset Adult Sepsis Events versus Current Reportable Conditions. Clin Infect Dis 2021.

Developer Response

We appreciate the opportunity to address the concerns of The Society for Healthcare Epidemiology of America (SHEA) regarding SEP-1. We note that the balance of the remarks by SHEA are based upon the analysis and conclusions drawn in the Infectious Diseases Society of America (IDSA) position paper on SEP-1. We would politely request that SHEA and readers of these remarks kindly review our response to IDSA and colleagues elsewhere in these commentaries.

Please also see our formal published response to IDSA and their society partners in Clinical Infectious Diseases, and the recent publication by the CMS measure stewards regarding SEP-1 and mortality changes among Medicare beneficiaries, if they have not already been reviewed:

Townsend SR, Rivers EP, Duseja R. Centers for Medicare and Medicaid Services Measure Stewards' Assessment of the Infectious Diseases Society of America's Position Paper on SEP-1. Clin Infect Dis. 2021 Feb 16;72(4):553-555. doi: 10.1093/cid/ciaa458. PMID: 32374387.

Townsend SR, Phillips GS, Duseja R, Tefera L, Cruikshank D, Dickerson R, Nguyen HB, Schorr CA, Levy MM, Dellinger RP, Conway WA, Browner WS, Rivers EP. Effects of Compliance with the Early Management Bundle (SEP-1) on Mortality Changes among Medicare Beneficiaries with Sepsis: A Propensity Score Matched Cohort Study. Chest. 2021 Aug 5:S0012-3692(21)03623-0. doi: 10.1016/j.chest.2021.07.2167. Epub ahead of print. PMID: 34364867.

A position paper's conclusions are only valid if it firmly establishes the assumptions the paper's conclusions and suggestions rest upon. Here, the position paper falls short in establishing:

- that SEP-1 has increased antibiotic usage in the United States (the Centers for Disease Control reports that including years after SEP-1's inception, inpatient antibiotic usage has remained stable, see Baggs J, Kazakova S, Hatfield KM et al. 2891.Trends in Inpatient Antibiotic Use in US Hospitals, 2012–2017, Open Forum Infectious Diseases, Volume 6, Issue Supplement_2, October 2019, Page S79.);
- that the hypothesized increase in antibiotic usage due to SEP-1 has resulted in harm in the form of increasing antibiotic resistance and promoted increases in C. difficile infections (see well-done studies by investigators at the Centers for Disease Control finding the opposite during the years SEP-1 has been in effect including Guh AY, Mu Y, Winston LG, et al. Trends in U.S. Burden of Clostridioides difficile Infection and Outcomes. N Engl J Med. 2020;382(14):1320-1330, and Jernigan JA, Hatfield KM, Wolford H, et al. Multidrug-Resistant Bacterial Infections in U.S. Hospitalized Patients, 2012-2017. N Engl J Med. 2020;382(14):1309-1319.)

In short, it would be a rush to judgment to accept the IDSA position paper as having established the necessary assumptions with proper evidence to advance the claims they wish to make without consideration of these other publications which substantially refute these assumptions.

As regards other concerns raised by SHEA, we welcome the opportunity to describe our understanding of these matters:

1. **Heterogeneity of the target population**

    - SHEA notes that sepsis and septic shock are a constellation of symptoms that may not have the same underlying diagnosis and that coded patients with sepsis may not have infections.
    - While we appreciate the sense and meaning of the statement that sepsis is a constellation of symptoms, most conventional definitions of sepsis (sepsis-3) or severe sepsis (sepsis-2, the entity treated by SEP-1 along with septic shock) would run counter to this remark by going beyond symptoms and requiring documentation of a suspected infection and actual organ dysfunction.
    - SEP-1 carefully specifies criteria for making a diagnosis of sepsis and does not rely on coding to verify those criteria. While the population may be drawn from coded cases, clinicians at hospitals review each case for the presence of 1) physician documented suspicion of infection; 2) the presence of 2 or more systemic inflammatory response criteria; 3) specific quantifiable organ dysfunction. If any of these criteria are not met, the case is not included in the measure sample. Therefore, the comment that "forty percent of patients coded as sepsis have a non-infectious cause for their symptoms" would not apply to the SEP-1 population because SEP-1 does not rely on coding to establish the diagnosis of sepsis and because clinician documented suspicion of infection is required.
    - More generally, the concept that sepsis is a constellation of symptoms has not stopped substantial literature from developing about this entity or that it must be defined and treated somehow, since 270,000 patients die from this constellation of symptoms each year.

2. **Unintended consequences – antibiotics and resources**

    - SHEA is concerned about the unintended consequences of antibiotic administration, which we have addressed carefully in these commentaries elsewhere, and about diverting critical patient safety resources into data collection for SEP-1.
    - As regards the burdens of chart abstraction, we note SHEA is relying upon the

characterization by IDSA regarding chart abstraction being overly burdensome. This characterization is unfortunately shorn from context.

- Studying all Medicare beneficiaries from 2012 to 2018, Buchman et al. found one-week mortality ranged from 16.4%–20.5% in severe sepsis and 41.1%–42.4% in septic shock (Buchman TG, Simpson SQ, Sciarretta KL, et al. Sepsis Among Medicare Beneficiaries: 1. The Burdens of Sepsis, 2012-2018. Crit Care Med. 2020;48(3):276-288). This study found Medicare's costs for sepsis admissions and skilled nursing care exceeded $41.5 billion annually. This highly lethal condition represents the single most costly healthcare condition in the United States. Given this estimate and the severity of the disease, the burden of SEP-1 abstraction is contextually appropriate.
- To quantify that burden realistically, SEP-1 permits hospitals to submit 20% of their cases each quarter (Department of Health and Human Services [Internet]. Baltimore: CMS.gov, QualityNet [cited 2020 May 28]. Hospital Inpatient Specifications Manuals; Version 5.8 - Specifications Manual for discharges 07/01/20 - 12/31/20 (Updated 04/2020) [about 2 screens]. Available from: https://www.qualitynet.org/inpatient/specifications-manuals).
- Abstractors spend 30–120 minutes abstracting each chart citing the same evidence IDSA references (which other studies suggest decreases with experience). In the unusual circumstance that a hospital accrued 300 sepsis cases per quarter, abstraction would require less than one-quarter full-time employee (assuming 300 cases in 3 months, 20% sample, 120 minutes of abstraction time per case, 40-hour work week).
- We would respectfully ask the question: is it a tenable position that hospitals should not dedicate a quarter of a full-time employee to measure sepsis improvement activities, the costliest healthcare condition in the United States, with a mortality rate that is equally as concerning?

3. Alternative measures

- SHEA has suggested several alternative measures. We appreciate any advancements in the field and recognize that other measures may have value. We also recognize that the devil is in the detail of any measure once scrutiny is applied and there are published critiques of each of the measures SHEA has noted in the literature.
- Under NQF rules, any of the alternative measures suggested by SHEA could be brought before NQF for evaluation if the developers so choose. We encourage innovation in the field and welcome the opportunity to evaluate new approaches.

NQF Response

N/A

NQF Committee Response

Thank you for your comment. The Standing Committee reviewed and considered this information during the post-comment meeting in conjunction with the developer's response. The Committee agrees that some of the concerns raised in this comment may require further examination in the future but the Committee maintains that this measure is suitable for endorsement at the current time.

NQF #0500, Comment #7770

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7770

Commenter: Thomas Kim, Infectious Diseases Society of America; Submitted by Thomas Kim

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/9/21

Developer Response Required? Yes

Level of Support: N/A

Theme: Lack of evidence, unintended consequences, target population

Comment

Patient Safety Post-Comment Web Meeting (Spring 2021 Cycle)

Comments on Severe Sepsis and Septic Shock: Early Management Bundle (SEP-1)

Submitted by the Infectious Diseases Society of America with endorsement from the American College of Emergency Physicians, American Hospital Association, Pediatric Infectious Disease Society, Society for Healthcare Epidemiology of America, Society of Hospital Medicine, and Society of Infectious Disease Pharmacists

September 9, 2021

NQF, CMS, and the SEP-1 measure stewards deserve due credit for creating SEP-1, which has helped raise awareness of sepsis and improved the standard of care for this deadly disease. However, data have emerged over the past 6 years that have identified problems that, if rectified, would significantly strengthen SEP-1 and reduce unintended measure consequences.

The Infectious Diseases Society of America is joined by the following five organizations in strongly urging that SEP-1 not be re-endorsed unless and until the bundle is revised: American College of Emergency Physicians, American Hospital Association, Pediatric Infectious Disease Society, Society for Healthcare Epidemiology of America, Society of Hospital Medicine, and Society of Infectious Disease Pharmacists.

The goals for the major revisions we request are:

- Focus the bundle on the subset of patients most likely to benefit from rapid and aggressive interventions, i.e., those with septic shock, not those without shock
- Minimize antibiotic overuse and adverse effects by eliminating patients with sepsis without shock from the bundle, and redefining the goals for time to antibiotic delivery

- Eliminate bundle elements that do not contribute to improved patient outcomes, such as measuring serial lactates
- Streamline the reporting process to focus on clinical outcomes
- Make reporting electronic with data that is easily extractable from the electronic health record
- Get input and support for intended changes from all the professional organizations that are most affected by the measure

Below, we summarize our major concerns that were addressed in an IDSA position paper published in 2020 and endorsed by five major professional societies (Rhee 2021). For the purposes of this letter, "sepsis" and "severe sepsis" are used interchangeably hereafter and are distinguished from "septic shock."

1. Despite massive investments by US hospitals to implement, assess compliance with, and report data on the SEP-1 core measure, our analysis of published literature indicates that these SEP-1 activities have not improved outcomes for patients.

- Much of the evidence used to support the SEP-1 measure comes from before-after studies or studies of association that reported lower mortality rates in sepsis patients who received bundle compliant care versus those who did not. These studies are at high risk for confounding due to failure to adequately adjust for factors that influenced bundle compliance and outcomes leading to misleading claims of lower mortality (Rhee, 2021).
- More rigorous analyses using interrupted time series models and detailed clinical data for risk adjustment demonstrate that SEP-1 did lead to changes in the processes of care (50% increase in lactate checks, 10% increase in broad spectrum antibiotics, and a 30% increase in infusion of 30mL/kg fluids within 3 hours of culture orders) but no improvement in sepsis-associated mortality (Barbash, 2021). These data support the concern that SEP-1 forces clinicians and hospitals to focus on a low yield set of processes and interventions. These processes and interventions constrain practice but have not clearly led to better outcomes for patients.

2. SEP-1's requirement to immediately administer antibiotic therapy to all patients with possible sepsis risks increasing excessive and unwarranted antibiotic administration.

- The signs and symptoms of sepsis are non-specific and mimicked by many non-infectious conditions. At least one third of patients treated with antibiotics for possible sepsis turn out to have non-infectious conditions. A forced rush to treatment therefore exposes many patients to the risk of antibiotics without benefit. This in turn exacerbates the public health crisis of antibiotic resistance (Weinberger 2020, Klouwenberg 2015, Shappell 2021).

3. SEP-1 conflates the urgency of antibiotic administration for sepsis and septic shock.

- SEP-1 stipulates the same time-to-antibiotic goals for sepsis and septic shock, but the association between time-to-antibiotics and mortality is much stronger for septic shock than for sepsis.
- The perception that any delays in antibiotic therapy led to worse outcomes for patients with sepsis, regardless of severity-of-illness, contributes to inappropriate antibiotic prescribing and is the wrong message for providers Weinberger, 2020).

4. The current SEP-1 time-zero is complex, subjective, and not evidence based.

- The SEP-1 time zero definition requires documentation of suspected infection, SIRS criteria, and one of more than 8 potential organ dysfunction criteria within a limited time window. The complexity of the current time zero definition contributes to variability in abstraction and therein undermines the validity of the measure (Bauer, 2019)..
- The original early-goal directed therapy trial that served as the inspiration for SEP-1 focused on patients with septic shock, as defined by refractory hypotension or lactate levels ≥4 mmol/L (Rivers, 2001). The sepsis bundle has since been extrapolated to a much broader set of patients, but there are no high-quality studies demonstrating the benefit of immediate antibiotics in patients whose only signs of organ dysfunction are abnormal creatinine, bilirubin, coagulopathy, or mildly elevated lactate levels at the thresholds specified in the time zero definition.

5. Serial lactate measurements have not been shown to consistently improve clinical outcomes in patients with sepsis (Pepper, 2018).

- The lack of benefit of this bundle component is further supported by a recent randomized controlled trial of patients with septic shock that showed no difference in mortality between fluid resuscitation based on physical exam (capillary refill time) versus serial lactate measurements (Hernández, 2019).

Concrete suggestions to revise SEP-1 are as follows:

1. Sepsis without shock should be removed from SEP-1.

- Limiting SEP-1 to septic shock will focus the measure on the patients in whom the evidence best supports the potential benefit of immediate antibiotics.
- This will also reduce the risk of harm from unnecessary antibiotics (or unnecessarily broad antibiotics) by allowing clinicians more time and discretion in relatively stable patients to determine if infection is present versus one of the many conditions that can mimic infection.
- We note that this view is further emphasized in a separate statement by the American College of Emergency Medicine (Yealy, 2021).

2. SEP-1 should include a clear and reproducible definition of time-zero.

- The current SEP-1 time-zero definition is complex and subjective. SEP-1 should have an evidence-based time-zero that can be easily recorded from an electronic health record such as the time when vasopressors were initiated, sustained measures of hypotension, or the time of antibiotic order. This will increase reliability of time zero identification and reduce the burden of abstraction.

3. Serial lactate measurements should be removed from SEP-1.

- Requiring repeat lactate measurements in all patients with initial mildly elevated lactate levels is not evidence-based and a poor use of resources.

Over the long term, we believe that sepsis quality measurement should transition to an electronic measure focusing on outcomes rather than processes. We appreciate the opportunity to work with CMS and the IMPAQ group on developing an objective risk-adjusted electronic outcome measure that can help drive further innovations and improvements in sepsis care.

Until a validated outcome measure is established, however, we strongly recommend updating SEP-1 with the suggestions outlined above and believe that a decision by NQF against re-endorsing this measure will encourage the measure stewards to make these important updates to the measure. The impact of a CMS measure is substantially enhanced if stakeholders have confidence that the measure truly improves outcomes, does not lead to unintended consequences, and has minimal reporting burden.

It should be noted that the American Medical Association has also issued formal comments (May 27, 2021) to NQF recommending removal of endorsement due to ongoing concerns over the lack of alignment with current evidence and the potential for negative unintended consequences such as incentivizing antibiotic overuse. **The fact that multiple professional societies are calling for change now suggests many well informed and thoughtful clinicians support the need for a substantial update of this high-stakes measure.**

Thank you for your consideration.

Developer Response

We genuinely appreciate the commentary submitted by the Infectious Diseases Society of America, the American College of Emergency Physicians, American Hospital Association, Pediatric Infectious Disease Society, Society for Healthcare Epidemiology of America, Society of Hospital Medicine, and Society of Infectious Disease Pharmacists. These remarks have been published elsewhere in a position paper by IDSA and their partner societies. This position paper was fully responded to by the CMS measure stewards. Please see:

- Townsend SR, Rivers EP, Duseja R. Centers for Medicare and Medicaid Services Measure Stewards' Assessment of the Infectious Diseases Society of America's Position Paper on SEP-1. *Clin Infect Dis.* 2021 Feb 16;72(4):553-555. doi: 10.1093/cid/ciaa458. PMID: 32374387.

We will summarize some of the most important fallacies and evidentiary deficiencies in the remarks above (and in the position paper) here for the sake of accessibility to the public.

In brief, the remarks above and the position paper assume that antibiotic resistance and other harms have been increasing after SEP-1 was launched. There is also an assumption that SEP-1 has directly caused increased antibiotic usage. These assumptions amount to rhetorical flourish because there is no credible evidence supporting the first assumption, and very low-quality evidence that the latter assumption is factual. Readers should not dismiss the significance of this absence of evidence: ungrounded arguments cannot drive policy-making considerations.

As to the first issue, IDSA and colleagues assume that resistant infections of all types have increased due to SEP-1's promotion of indiscriminate antibiotic usage across the United States since SEP-1 went into effect. In fact, as documented in two papers published by investigators from the Centers for Disease Control in the New England Journal of Medicine last year, most resistant infections of concern and rates of *Clostridium difficile* infections have decreased, including during the years since SEP-1 went into effect. Please see:

- Guh AY, Mu Y, Winston LG, et al. Trends in U.S. Burden of *Clostridioides difficile* Infection and Outcomes. *N Engl J Med*. 2020;382(14):1320-1330.

- Jernigan JA, Hatfield KM, Wolford H, et al. Multidrug-Resistant Bacterial Infections in U.S. Hospitalized Patients, 2012-2017. *N Engl J Med*. 2020;382(14):1309-1319.

As to the second issue, at the time of the publication of IDSA and colleagues' position paper, there were no published studies directly linking SEP-1 to increased antibiotic usage in the literature. The position paper referenced several low-quality studies with serious methodological flaws that were not studies of SEP-1 in an effort to indirectly establish this point. The table in the article by Townsend, Duseja and Rivers in *Clinical Infectious Diseases* cited above highlights the methodological flaws, confounding issues, and indirect nature of these studies.

Since that time, a single paper has been published in the literature that indicates that after SEP-1 was launched, *one hospital* experienced an increase in overly broad antibiotic therapy for urinary tract infections (no other infections had increased usage observed). That paper was a retrospective review, did not control for changing resistance patterns, did not account for patient characteristics or comorbidities beyond that the patients had sepsis and were similar in age and gender, and established no harm from the observed changes, among other serious deficiencies:

- Miller J, Hall B, Wilson K, Cobian J. Impact of SEP-1 on broad-spectrum combination antibiotic therapy in the emergency department. *Am J Emerg Med*. 2020 Dec;38(12):2570-2573. doi: 10.1016/j.ajem.2019.12.045. Epub 2020 Jan 7. PMID: 31932126.

IDSA and its society partners express concerns about the reliability of time zero in SEP-1, but they do not fairly represent the details of the only two studies in the literature to consider this question. The first study by Rhee et al. provided just one hour of training for non-professional abstractors, including bedside clinicians, and compared their results to professionally trained abstractors before assessing inter-rater reliability. Such an approach sets up an unfair comparison wherein poor agreement should be expected rather than a surprise. It should be noted that Medicare, through its Clinical Data Abstraction Center, audits hospital abstractors for clinical competency in abstraction of its measures including SEP-1 and does not permit hospitals that do not attain passing scores to submit data to Medicare. A second study by Bauer et al., which IDSA and colleagues cite here, found fair agreement among trained abstractors in the first few months after SEP-1 was first launched but attained *perfect reliability and concordance between abstractors* after improvement efforts. Bauer et al. conclude that, "[a]bstraction by a dedicated team for SEP-1 can reduce variability and improve efficiency."

- Rhee C, Brown SR, Jones TM, et al. Variability in determining sepsis time zero and bundle compliance rates for the Centers for Medicare and Medicaid services SEP-1 measure. *Infect Control Hosp Epidemiol*. 2018;39(8):994-996.
- Department of Health and Human Services [Internet]. Baltimore: CMS.gov, QualityNet [cited 2019 Nov 8]. Chart-Abstracted Data Validation [about 2 screens]. Available from: https://qualitynet.org/inpatient/data-management/chart-abstracted-data-validation.
- Bauer SR, Gonet JA, Rosario RF, Griffiths LA, Kingery T, Reddy AJ. Inter-rater Agreement for Abstraction of the Early Management Bundle, Severe Sepsis/Septic Shock (SEP-1) Quality Measure in a Multi-Hospital Health System. *Jt Comm J Qual Patient Saf*. 2019;45(2):108-111.

IDSA and colleagues point to a recent time-series analysis by Barbash et al. that found changes in processes of care but no changes in mortality among sepsis patients after SEP-1's inception. Barbash et al. studied patients that do not meet published definitions of sepsis, specifically studying patients with an order for a blood, urine, respiratory or other culture who exhibited a change in SOFA score of ≥ 2 in

the first 6 hours of care in the emergency department. This definition does not conform to sepsis-2, sepsis-3, or the CDC's Adult Sepsis Events definitions and appears to be novel.

Average in-hospital mortality was low in Barbash et al. at 4.5% in Q3 2015, before SEP-1, and 4% in Q4 2017, after SEP-1's inception, despite median ages compatible with a Medicare population (72 and 71 years, respectively).This low mortality population stands in contrast to the CMS measure stewards and colleagues' study of actual SEP-1 cases cited immediately above with average 30-day mortality at 26.7%. Studying all Medicare beneficiaries from 2012 to 2018, Buchman et al. found one-week mortality ranged from 16.4%–20.5% in severe sepsis and 41.1%–42.4% in septic shock (Buchman TG, Simpson SQ, Sciarretta KL, et al. Sepsis Among Medicare Beneficiaries: 1. The Burdens of Sepsis, 2012-2018. *Crit Care Med*. 2020;48(3):276-288).

The low mortality rates observed in Barbash et al. limit the generalizability of their findings and raise concerns that these patients may not have had sepsis by conventional definitions. In support of this belief, the mortality rate in Barbash et al. is similar to that of undifferentiated hospitalized patients (Shahian DM, Wolf RE, Iezzoni LI, Kirle L, Normand SL. Variability in the measurement of hospital-wide mortality rates [published correction appears in *N Engl J Med*. 2011 Apr 7;364(14):1382]. *N Engl J Med*. 2010;363(26):2530-2539).

The issues above as well as other concerns raised in IDSA and colleagues' remarks are substantively answered in the CMS measure stewards and colleagues' analysis of 333,770 verified SEP-1 patients from 3,241 U.S. hospitals. This study, carefully adjusted for possible confounding, found that compliance with SEP-1 is associated with substantial benefits including a reduction in 30-day mortality: 21.81% compliant care versus 27.48% non-compliant care, yielding an absolute risk reduction of 5.67% (95% confidence interval [CI]: 5.33–6.00; $P < 0.001$).

- Townsend SR, Phillips GS, Duseja R, Tefera L, Cruikshank D, Dickerson R, Nguyen HB, Schorr CA, Levy MM, Dellinger RP, Conway WA, Browner WS, Rivers EP. Effects of Compliance with the Early Management Bundle (SEP-1) on Mortality Changes among Medicare Beneficiaries with Sepsis: A Propensity Score Matched Cohort Study. *Chest*. 2021 Aug 5:S0012-3692(21)03623-0. doi: 10.1016/j.chest.2021.07.2167. Epub ahead of print. PMID: 34364867.

In conclusion, the thrust of IDSA and colleagues' concerns results in their call for not requiring early antibiotic therapy for patients with severe sepsis and reserving these antibiotics for septic shock patients. We note that the study by Townsend, Phillips, Duseja et al. includes a super-majority of severe sepsis patients who appear to derive a notable benefit from early antibiotic therapy. We therefore believe IDSA and colleagues' request to not endorse SEP-1 is poorly grounded and insufficiently evidence-based.

NQF Response

N/A

NQF Committee Response

Thank you for your comment. The Standing Committee reviewed and considered this information during the post-comment meeting in conjunction with the developer's response. The Committee agrees that some of the concerns raised in this comment may require further examination and discussion in the future and may require modifications to the measure, but the Committee maintains that this measure is suitable for endorsement at the current time.

NQF #0500, Comment #7745

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7745

Commenter: Submitted by Sean Townsend

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 8/20/21

Developer Response Required? No

Level of Support: N/A

Theme: N/A

Comment

As SEP-1 measure stewards, Dr. Rivers and I are pleased to present published national performance data on SEP-1, which not fully availalble at the time of consideration by the Patient Safety Committee. Similar data was presented in the re-endorsement package, however these peer reviewed results confirm reductions in mortality with compliance with SEP-1 and decreased length of stay carefully adjusted for relevant confounding factors.

[1]https://pubmed.ncbi.nlm.nih.gov/34364867/

The citation is:

Townsend SR, Phillips GS, Duseja R, Tefera L, Cruikshank D, Dickerson R, Nguyen HB, Schorr CA, Levy MM, Dellinger RP, Conway WA, Browner WS, Rivers EP. Effects of Compliance with the Early Management Bundle (SEP-1) on Mortality Changes among Medicare Beneficiaries with Sepsis: A Propensity Score Matched Cohort Study. Chest. 2021 Aug 5:S0012-3692(21)03623-0. doi: 10.1016/j.chest.2021.07.2167. Epub ahead of print. PMID: 34364867.

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Developer Response

N/A

NQF Response

Thank you for your comment. The Standing Committee reviewed and considered this information during the post-comment meeting and determined the measure is suitable for endorsement at the current time.

NQF Committee Response

N/A

NQF #0500, Comment #7760

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7760

Commenter: Submitted by Thomas Heymann

Council / Public: Consumer

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/8/21

Developer Response Required? No

Level of Support: N/A

Theme: N/A

Comment

We, the undersigned patient safety and advocacy organizations, on behalf of the many millions of patients, families, and survivors we represent, write to express strong support of and gratitude for the Patient Safety Standing Committee's re-endorsement of the continued measure of hospitals' compliance with the Severe Sepsis and Septic Shock Management Bundle (NQF # 0500, or SEP-1). We are grateful that the Standing Committee took what we believe to be a lifesaving step in re-endorsing this quality measure, and we urge the Consensus Standards Approval Committee (CSAC) and other decisionmakers within NQF to do the same.

Sepsis is the leading cause of death in U.S. hospitals[1][i] and claims over 270,000 American lives each year[2][ii]. Another 1.4 million American survive sepsis every year[3][iii], many of them with lingering costs and complications—including approximately 14,000 amputations[4][iv] annually.

SEP-1 focuses on timely recognition of sepsis and early intervention with life-saving therapies. Saving lives and limbs from sepsis is about time: 12% of septic emergency department patients develop shock within 48 hours of presentation[5][v] and each hour of delay until initial antimicrobials are administered is associated with an 8.0% increase in progression to septic shock[6][vi]. By emphasizing the screening of every patient in an effort to catch sepsis early, SEP-1 helps prevent the progression of sepsis to septic shock and ultimately saves lives. A new study of patient-level data reported to Medicare by 3,241 hospitals between 2015 and 2017 shows that SEP-1 compliance is associated with lower 30-day mortality[7][vii].

Moreover, studies have shown the association between performance metrics and patient outcomes[8][viii] and that decreased risk-adjusted sepsis mortality is associated with increased hospital-level compliance with mandated public reporting[9][ix]. The mandate that hospitals gather and report sepsis-relevant performance data is part of what makes SEP-1 a life-saving measure.

The effectiveness and widespread approval of the SEP-1 measure led to its incorporation into the CMS Hospital IQR program in 2015. Today, there are sepsis screening programs at every hospital in the U.S., which has brought every community hospital in America up to the level of an academic facility on diagnosing and treating this challenging syndrome.

We respectfully disagree with those who continue to urge removal of this measure. We understand that care is nuanced and that no single test can (yet) accurately or reliably establish a diagnosis of sepsis. In fact, this lack of a precise test is exactly why we should maintain a measure meant to focus on improving the quality of care for the sepsis patient. Based on continued insights from analysis of the SEP-1 measure and associated outcomes, we support its continued improvement—there are, in fact, ongoing efforts to modify the measure in response to updated evidence and provider feedback. These include efforts to combat the growing threat of antimicrobial resistance and to encourage better multidisciplinary clinician engagement in the care of septic patients throughout their illness and recovery.

By re-endorsing the SEP-1 measure, the Patient Safety Standing Committee has taken a critical step toward assuring that focus is maintained on the number one cause of death in U.S. hospitals: sepsis. With modifications as appropriate, the SEP-1 measure will support the continued necessary education, screening, early recognition, and management of sepsis that improves care and saves lives in every community.

With this letter of support, our groups join with the many leaders in the field who strongly support the maintenance and continued development of the SEP-1 measure. We thank the Patient Safety Standing Committee for its lifesaving decision, and we urge the CSAC and other decisionmakers within NQF to follow suit.

Sincerely,

Tom Heymann

President & CEO, Sepsis Alliance

The Alliance for Aging Research

Americare CSS and Americare Inc

Home Care Association of New York State

The Leapfrog Group

MoMMA's Voices Coalition

NTM Info & Research

Peggy Lillis Foundation

Society to Improve Diagnosis in Medicine

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Developer Response

N/A

NQF Response

Thank you for your comment. The Standing Committee reviewed and considered this information during the post-comment meeting and determined the measure is suitable for endorsement at the current time.

NQF Committee Response

N/A

NQF #3621, Comment #7744

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7744

Commenter: Rebecca Smith-Bindman, University of California, San Francisco; Submitted by Carly Stewart

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 444208/12/21

Developer Response Required? Yes

Level of Support: N/A

Theme: N/A

Comment

I write in response to the NQF Patient Safety, Spring 2021 Cycle, draft CDP Report issued August 11, 2021.

The NQF standing committee has endorsed measure 3621, proposed by the American College of Radiology (ACR), titled “Composite weighted average for 3 CT exam types: overall percent of CT exams for which dose length product is at or below the size-specific diagnostic reference level.” There is ample need for quality measurement to inform clinicians and imaging facilities of how they can safely lower radiation doses in diagnostic CT while maintaining the quality of images needed for diagnosis. While measure 3621 has strengths, including encouraging radiologists to reduce the average doses for three common protocols, ultimately, measure 3621 is inadequate because it does not account for the strongest driver of excessive radiation dose, as I lay out below. I therefore remain against the

endorsement of the proposed measure as it will not reduce the unintended harm of radiation in diagnostic imaging.

The evidence for measure 3621 highlights a critical patient safety imperative: extensive epidemiological and biological research suggests that exposure to radiation in the same range as that routinely delivered by CT increases a person's risk of developing cancer, and exposure to CT is estimated to cause over 2% of cancers diagnosed annually in the United States. Not only are CT radiation doses frequently much higher than needed for diagnosis, they are highly variable across imaging facilities for patients imaged for the same clinical indication. Yet, more so than patient or machine characteristics, the single most important predictor of radiation dose is the choice the radiologist makes as to what protocol to use for any given exam (e.g. a single-phase scan or double-phase scan). Protocols with more phases deliver proportionally more radiation, yet for most indications, there is no evidence suggesting the higher phase protocol provides better diagnostic utility. Also, in most high

radiation dose exams, the dose is frequently driven by multiple phases, not by upping technical parameters, such as the kilovoltage peak or milliampere-seconds. The fact that measure 3621 assesses only single-phase CT scans completely excludes most excessively dosed exams from scrutiny.

Measure 3621 will evaluate radiation doses used for three specific CT protocols: a single-phase head, single-phase chest, and single-phase abdomen. The measure will assess doses in these three groups against benchmarks only after the primary decision of protocol selection is made. In other words, the measure does not consider the underlying clinical reason for imaging, nor assess whether the right protocol was selected. This limited assessment of dose within protocol groups ignores the primary factor determining dose, i.e. protocol selection, which is almost entirely at the discretion of the imaging physician. In effect, the measure will assess only the relatively smaller variation in technical parameters within single-phase head, chest, or abdomen protocols, but will leave unassessed the variation that occurs due to the choice of protocol.

Further, the denominator for measure 3621 is not stable. The ACR defines the target population for the measure as “all patients who require either a CT abdomen-pelvis exam with contrast (single-phase scans), a CT chest exam without contrast (single-phase scans), and/or a CT head/brain (single-phase scans) exam.” But since the measure does not account for underlying indication, it fails to identify those patients who required these exams, but who instead received much higher doses through unnecessary multi-phase exams. In the University of California, San Francisco International CT Dose Registry, which includes over 8 million CT scans from 162 hospitals and image facilities, these three CT exam types together make up 39% of exams overall across the registry. However, they account for 1% to 83% of exams across the different imaging facilities, suggesting the denominator for this measure does not reflect a patient population who require these exams, but rather reflects the varying decisions of radiologists to assign patients to different protocols.

Radiation doses must be assessed based on the intent and clinical question of the provider ordering the scan, not on the radiologist’s subjective choice of protocol, which is too often driven more by preference than clinical need. The measurement of dose within the ACR’s narrowly defined groups will only camouflage the large existing variation in practice and will not improve practice.

The University of California, San Francisco was contracted by CMS to develop a quality measure for CT, which was submitted to NQF for the Fall 2021 cycle review. This measure assesses radiation doses among adult patients who undergo diagnostic CT based on the diagnoses and clinical questions generated at the time of the test order, and therefore is not undermined by the concern raised in measure 3621.

Rebecca Smith-Bindman, MD

University of California, San Francisco

Developer Response

The ACR appreciates the concerns raised by Dr. Smith-Bindman on the endorsement of our measure, NQF #3621.

We agree that protocol selection that is appropriate for a clinical indication is an important component of radiation dose management, along with radiation dose optimization. Our measure addresses optimization but not whether the exam performed was appropriate for the clinical indication or any of the other aspects of protocol selection.

We believe that the protocol selection issue needs to be addressed as a different quality action because the level of standardization and availability of national benchmarks on that is much less further along than dose optimization. Dose optimization results in a quality action for facilities to adjust their protocols and is a responsibility of the team as a whole – physicists, technologists, and physicians who oversee the team at the facility. Protocol selection addresses the appropriateness of the exam for the clinical indication and other factors such as patient time on the scanner and optimal radiation dose.

The measure UCSF and Dr. Smith-Bindman have submitted to NQF for the Fall 2021 cycle conflates appropriateness of protocol for the clinical indication and radiation dose optimization, and disregards applicability.

A facility's protocol selection process may result in more multi-phase studies than needed, resulting in increased radiation exposure. The most accurate way to address that is to measure both the appropriateness of an exam and the radiation dose output (dose indices per exam) and look at the two separately or together. However, the UCSF measure combines the effect of dose optimization and appropriateness; from that, a facility may not be able to determine if its performance could be improved by adjusting protocols or by focusing on appropriateness of the ordered exam, and therefore improvement may be limited.

There are challenges with the implementation of an indications-based measure. Indications for exams do not have standardized language that could be used to track them. Most health and IT systems have just enough ICD-10 coding for reimbursement, but not enough to characterize the patient's condition and the resulting rationale for performing an imaging exam. Electronic Health Records (EHRs) are notoriously incomplete with this type of information and interoperability issues exist with other software systems that might contain such information. In pursuit of an indication-based measure, how would correct characterization of exam appropriateness be determined? A validated method for determining classification of studies using high-dose vs routine protocols appropriate to the indication

must be incorporated into such a measure. As benchmarks or guides to drive process improvement, indication-based benchmarks are ideal. We believe that the ACR measure is the first step in that process.

Furthermore, the claim that our measure amounts to as low as 1% exams is invalid. Head-Chest-Abdomen-Pelvis (HCAP) procedures account for nearly 75% of all CT exams, of which only 11% to 13% may be multiple-phase scans. 1

The ACR will continue to work on a measure that looks at dose indices by indication, but that measure needs to be tested and gather consensus on groupings before it is usable for accountability.

1. National Council on Radiation Protection and Measurements (Ed.). (2019). Medical radiation exposure of patients in the United States: Recommendations of the National Council on Radiation Protection and Measurements. National Council on Radiation Protection and Measurements.

NQF Response

N/A

NQF Committee Response

Thank you for your comment. The Standing Committee reviewed and considered this information and the developer's response during the post-comment meeting and determined that the measure is suitable for endorsement at the current time

NQF #3501e, Comment #7763

Standing Committee Recommendation: Consensus Not Reached

Comment ID#: 7763

Commenter: Submitted by Anna Legreid Dopp

Council / Public: Health Professional

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/9/21

Developer Response Required? Yes

Level of Support: Member Does not support

1030 15th Street NW, Suite 800

Washington, DC 20005

Re: NQF #3501e Hospital Harm – Opioid-Related Adverse Events

ASHP is pleased to submit comments on the National Quality Forum (NQF) Patient Safety Spring 2021 Cycle Draft Report for Comment (hereinafter, the "Draft Report"). ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's more than 58,000 members include pharmacists, student pharmacists, and pharmacy technicians. For over 79 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

ASHP commends NQF for its commitment to patient safety and honors the contributions from the Patient Safety Standing Committee members. ASHP thanks NQF for the opportunity to comment on the medication-related measure in the proposed Draft Report, NQF 3501e Hospital Harm – Opioid-Related Adverse Events from Centers for Medicare & Medicaid Services. We support the Standing Committee's decision to delay consensus on NQF 3501e. Importantly this measure addresses an important medication safety gap related to opioid related overdose; however, it is important to carefully balance the public health impact of these measures with unintended consequences on patient care.

Our comments are designed to assist NQF in closing the gap between measuring and improving patient safety around medication use and opioid safety. There are a growing number of opioid-related process measures in the marketplace that are aimed at placing safeguards around prescribing practices. We recognize the value in having a suite of these type of measures, or a measure set, that enables a comprehensive and balanced evaluation of opioid prescribing for the purpose of minimizing opioid misuse and overdose.

NQF 3501e Hospital Harm – Opioid-Related Adverse Events

Overall, we understand how the committee was unable to reach consensus on this measure. In the past, this measure was brought forth and not endorsed due to a lack of evidence and several comments discussing concerns about its applicability in real world settings. Some revisions made to NQF 3501e address past concerns such as expansion of the events considered beyond respiratory related to any opioid-related adverse outcome, removal of the exclusion of utilization of naloxone "within 2 hours of a procedure" (still only including events outside of the operating room), focus on naloxone alone and removal of doxapram/respiratory stimulants, and adjustments of the description/numerator/denominator utilized for the measure. While the NQF committee passed the measure in regards to evidence, consensus wasn't reached regarding the performance gap of the measure. This was due to discussions regarding the appropriateness of naloxone administration as an outcome, concerns about the disparity between states' event report rates (some with four-fold differences), and an overall low absolute rate reported from the measure's studies. Overall, we support the existence of a measure aimed at addressing opioid-related adverse events for the purpose of reducing hospital harm; however, we urge care in the development and endorsement of such a measure in meeting a performance gap while minimizing unintended consequences.

In summary, ASHP applauds the NQF Patient Safety Standing Committee for delaying its decision on NQF 3501e. We believe it is important to create measures related to hospital harm and related to the opioid epidemic; however feel more consideration is needed in NQF 3501e.

ASHP appreciates this opportunity to provide comments. Please contact me if you have any questions on ASHP's comments on the proposed draft report. I can be reached by telephone at 301-664-8889 or by email at [1]adopp@ashp.org.

Sincerely,

Anna Legreid Dopp, Pharm.D., CPHQ

Director, Clinical Guidelines and Quality Improvement

American Society of Health-System Pharmacists

Developer Response

IMPAQ would like to thank the American Society of Health-System Pharmacists (ASHP) for their support of a measure that addresses an important medication safety gap related to opioid related overdose. Unfortunately, their comments do not appear to be relevant to the measure 3501e which was initially submitted to NQF for the Spring 2019 cycle and subsequently revised and resubmitted for the Spring 2021 cycle. Since IMPAQ acquired this measure under contract with CMS in 2019, there have been no exclusions for the use of naloxone within 2 hours of a procedure, nor did this measure address the use of doxapram or any other respiratory stimulant.

Based on feedback received from NQF during the 2019 Spring cycle, we made several substantive updates and re-tested the measure for the 2021 Spring cycle submission. Specifically, we:

- Updated the measure value sets to ensure that the most current codes for hospital administered opioids and naloxone are used and that the codes harmonize across other eCQMs in current CMS quality reporting programs;
- Limited the measure denominator to encounters where patients received at least one opioid during the hospitalization;
- Added a time constraint such that the opioid administration not only precedes the subsequent naloxone administration but also the time gap in between is no larger than 12 hours;
- Re-tested the refined measure for feasibility at 23 hospitals with four different EHR systems (Epic, Cerner, Meditech; and Allscripts); and
- Re-tested for the scientific acceptability of the measure's properties including reliability and validity at six implementation test sites.

We would like to clarify that measure testing used de-identified EHR data from six hospitals with two different EHR systems (Cerner and Meditech). At no point did measure testing utilize state-based data.

We would also like to clarify that the NQF Standing Committee voted in favor of the appropriateness of naloxone as an opioid reversal agent typically used for severe opioid-related adverse events as they reached consensus in passing 3501e on the Evidence criterion. Empirically, we investigated the extent

to which the measure as currently specified may suffer false positives and false negatives and found little evidence of the two. We refer the commenter to measure testing form of 3501e for details.

Lastly, we would like to remind the ASHP, the Patient Safety Standing Committee, and other readers to the substantial performance gap and variations in care which we identified. In addition to testing at six hospitals for reliability and validity, we collected frequency counts on the measure's numerators and denominators from 13 additional hospitals in CY 2019. The rate of ORAE, with the addition of 13 hospitals, ranges from 1.1 to 6.1 per 1,000 qualified inpatient encounters. Using the weighted average measure rate of 0.37%, we estimate that approximately 62,000 adult inpatients suffer ORAEs across the nation annually. While the absolute harm rate can appear small, these measures are of great value to the community both because there is so much room for quality improvement and because of the qualityadjusted life years that could be gained. We also identified variability in performance by age, sex, race, ethnicity, and payer source, which following national implementation of the measure may uncover additional performance gaps among vulnerable populations. The literature also verifies that thousands of Americans experience severe adverse events related to hospital administered opioids each year (Herzig et al., 2014). Finally, we note that several NQF-endorsed "harm" measures are in the same frequency range as this eCQM (3501e). Based on these results, which have been confirmed in the literature, and the precedent for endorsement of other harm measures at this frequency, we strongly believe that measure 3501e meets the NQF criteria for performance gap.

1. Herzig SJ, Rothberg MB, Cheung M, Ngo LH, Marcantonio ER. Opioid utilization and opioid- related adverse events in nonsurgical patients in US hospitals. J Hosp Med. 2014;9(2):73–81. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3976956/

NQF Response

N/A

NQF Committee Response

Thank you for your comment. The Standing Committee reviewed and discussed the comments presented and the developer's response during the post-comment meeting and determined that the measure is suitable for endorsement at the current time.

NQF #3501e, Comment #7751

Standing Committee Recommendation: Consensus Not Reached

Comment ID#: 7751

Commenter: Measure Developer, IMPAQ International; Submitted by Stacie Schilling

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 444409/1/21

Developer Response Required? No

Level of Support: N/A

Theme: N/A

Comment

Opioids are often the foundation for acute pain control in the inpatient setting, but excessive administration of opioids can lead to serious adverse events, including over-sedation, respiratory depression and death. Opioid-related adverse events (ORAE) have both clinical and financial implications. Previous studies have shown that patients who experience ORAE have 55% longer lengths of hospital stay, 47% higher health care costs, 36% higher risk of 30-day readmission, and 3.4 times higher payments than those who do not suffer this adverse event (Kessler et al., 2013; Sahfi et al., 2018).

IMPAQ was tasked by CMS to develop the ORAE electronic clinical quality measure (eCQM) (NQF #3501e), using data solely from the electronic health record (EHR). This facility-level eCQM assesses the proportion of inpatient hospital encounters in which patients aged 18 or older are administered an opioid medication and are then administered an opioid antagonist (naloxone) within 12 hours, suggesting an ORAE. The eCQM excludes opioid antagonist (naloxone) administration occurring in the operating room setting, acknowledging that the use of opioid antagonist within the operating room setting may be part of the sedation plan.

The intent of the measure is not to reduce clinically appropriate use of naloxone, nor to reduce naloxone use to zero, but to identify hospitals that have particularly high rates of naloxone use, suggesting excessive dosing of opioids in the inpatient setting. Use of this measure will incentivize improved clinical practices, such as avoiding over-sedation and closely monitoring patients on opioids to prevent serious and potentially lethal adverse drug events.

As required by the evaluation rubrics set by the National Quality Forum (NQF), we assessed the measure's scientific properties by partnering with a large healthcare system and a quality measure reporting service provider with access to various hospitals, including rural and small hospitals. To evaluate measure feasibility, in particular, the extent to which critical data elements needed for measure implementation are readily available and electronically retrievable in the EHRs, we recruited 23 sites from our measure testing partners. These 23 sites cover major EHR systems in the mainstream market (Epic, Cerner, Meditech, and Allscripts). Testing results showed high feasibility of the measure's critical data elements.

To then quantify the measure performance rate, i.e., the rate of hospital-level ORAE, we selected six sites from the alpha testing participants to participate in measure implementation testing. These six sites vary along the following dimensions: EHR vendor (Meditech and Cerner), bed size (25-99 to 500+), geographic location (Midwest and West), teaching and non-teaching status, as well as rural vs. urban. Using EHR data from calendar year (CY) 2019, measure implementation testing identified a total of 1,839, 2,089, 1,784, 11,273, 13,307, and 18,425 denominator encounters from each of the six sites, with the hospital-level harm rate ranging from 1.1 to 4.5 per 1,000 qualified inpatient encounters. The four-fold variation indicates ample room for quality improvement and a sufficient performance gap. Furthermore, while not an NQF requirement for new measures, we examined the measure performance

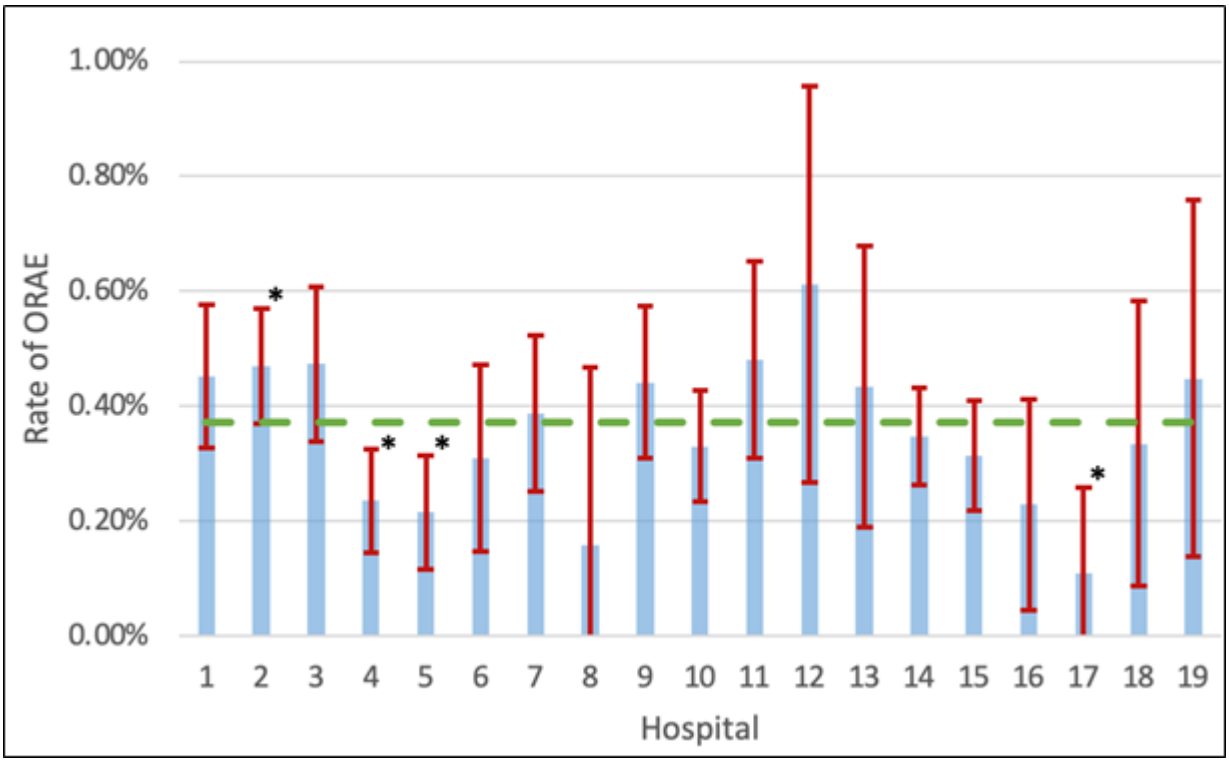
rate in various subgroups of population to identify potential disparities. We found variability by age, sex, race, ethnicity, and payer source that may not be generalizable to the entire population but suggests a need to monitor these populations during measure implementation to gather evidence on possible performance gaps.

To better understand measure performance gaps, we worked with the large healthcare system (one of the two test partners) and collected frequency counts on the measure's numerators and denominators from 13 additional hospitals in CY 2019. These 13 hospitals vary in bed size, geographic location, teaching vs. non-teaching status, but all use Cerner. Table 1 shows the hospital-level performance rate by site and offers clear evidence that the measure performance gap exists. The rate of ORAE, with the addition of 13 sites, ranges from 1.1 to 6.1 per 1,000 qualified inpatient encounters. Given an overall system-wide rate of 0.37%, several hospitals' rates are significantly higher or lower than the system-wide rate (based on their 95% confidence intervals, shown in Figure 1). For example, Hospital 17's rate of 0.11% is significantly below the system-wide rate, and Hospital 2's rate of 0.47% is significantly above the system-wide rate.

Table 1. Measure Numerator and Denominator Counts and Measure Performance Rate; Data from CY 2019

Test Site	Numerator Ct.	Denominator Ct.	Measure Performance Rate
1	51	11,273	0.45%
2	84	17,903	0.47%
3	47	9,936	0.47%
4	26	11,029	0.24%
5	18	8,369	0.22%
6	14	4,523	0.31%
7	31	8,003	0.39%
8	1	632	0.16%
9	43	9,737	0.44%
10	44	13,307	0.33%
11	30	6,248	0.48%
12	12	1,961	0.61%
13	12	2,767	0.43%
14	64	18,425	0.35%
15	41	13,091	0.31%
16	6	2,615	0.23%
17	2	1,839	0.11%
18	7	2,089	0.34%
19	8	1,784	0.45%

Figure 1: Measure Performance Rate by Site; Data from CY 2019



Note: 95% confidence intervals are shown in capped red bars. Horizontal dashed line indicates system-wide average. * $p < 0.05$

Developer Response

N/A

NQF Response

Thank you for your comment. The Standing Committee reviewed and considered this information during the post-comment meeting.

NQF Committee Response

Thank you for your comment. The Standing Committee reviewed and discussed this additional information during the post-comment meeting and determined the measure is suitable for endorsement at the current time.

NQF #3501e, Comment #7774

Standing Committee Recommendation: Consensus Not Reached

Comment ID#: 7774

Commenter: Melissa Danforth, The Leapfrog Group; Submitted by Melissa Danforth

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/9/21

Developer Response Required? No

Level of Support: Member supports

Theme: N/A

Comment

The Leapfrog Group and its members are aware of the debate regarding the performance gap for measure 3501e: Hospital Harm - Opioid-Related Adverse Events and welcomes the opportunity to submit comments.

Based on our review of the measure and the measure developer's detailed testing results regarding performance gap, we believe the measure unequivocally demonstrates clinically and statistically significant variation among hospitals that more than meets NQF's performance gap requirement. The stated intent of the measure is to identify hospitals with high rates of naloxone use, which might indicate excessive dosing of opioids in inpatients. The measure, as specified, accomplishes this intent. The measure developers have identified a hospital-level harm rate ranging from 1.1 to 4.5 per 1,000 inpatient encounters. This four-fold variation equates to 60,000 patients harmed annually - a very meaningful performance gap. Additionally, the measure developers identified variability in performance by age, sex, race, ethnicity, and payer source, which following national implementation of the measure may uncover additional performance gaps among vulnerable populations.

We strongly support the endorsement of 3501e and strongly believe the performance gap demonstrated by the measure developers meets NQF's criteria.

Developer Response

N/A

NQF Response

Thank you for your comment. The Standing Committee reviewed and considered this information during the post-comment meeting.

NQF Committee Response

Thank you for your comment.

NQF #3501e, Comment #7749

Standing Committee Recommendation: Consensus Not Reached

Comment ID#: 7749

Commenter: Submitted by Steven Tremain

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 444409/1/21

Developer Response Required? No

Level of Support: N/A

Theme: N/A

Comment

I am in support of this effort, although frankly I don't think it goes far enough. I would not exclude naloxone use in the operating theater, because the American Society of Anesthesiologists no longer supports the routine use of naloxone as a tool to assist patients in their emergence from anesthesia. Part of it may be because naloxone in some patients has a shorter half-life than certain opioids, even fentanyl.

Much of the variation we see in naloxone use in our hospitals is due to the outdated use of naloxone routinely by anesthesia at the end of surgeries.

In addition, I strongly encourage you to maintain the inclusion of procedural areas (i.e. gastroenterology labs, cardiovascular labs, interventional radiology labs) where too often throughput pressure encourages overuse of sedation followed by routine naloxone reversal. The patient safety risks are underappreciated while capacity is enhamced.

Overall, I strongly support this measure as a step in the right direction of responsible and safe opioid use.

Steven Tremain, MD FACPE

National ADE Advisor,

Convergence-Cynosure HQIC

Developer Response

N/A

NQF Response

Thank you for your comment. The Standing Committee reviewed and considered this information during the post-comment meeting.

NQF Committee Response

Thank you for your comment.

NQF #3389, Comment #7765

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7765

Commenter: Lilian Ndehi, Humana Inc; Submitted by Lilian Ndehi

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/9/21

Developer Response Required? No

Level of Support: N/A

Theme: N/A

Comment

September 9, 2021

National Quality Forum

1030 15th Street NW, Suite 800

Washington, DC 20005

Re: NQF #3389 Concurrent Use of Opioids and Benzodiazepines (COB)

Humana is pleased to submit comments on the National Quality Forum (NQF) measure #3389: Concurrent Use of Opioids and Benzodiazepines.

Opioid-related safety continues to be a major concern for both patients and their health plans. Recent data highlighting opioid utilization during the pandemic are especially troubling, with overdose rates spiking over the course of the last year, and studies suggesting more than a 25% increase in total overdose deaths, driven primarily by opioids. Opioid safety is as important and urgent now as ever, and it's critical that health plans have appropriate quality measures that address high-risk opioid prescribing associated with overdose at the population level.

One well established risk for overdose and other adverse events is concurrent use of opioids and benzodiazepines (COB). The 2016 Centers for Disease Control and Prevention Guidelines issued a class A recommendation that concurrent use of these medications should be avoided whenever possible, and the FDA issued a black box warning highlighting the danger of using these medications together. A broad body of evidence has continued to demonstrate the starkly higher overdose risk for patients receiving these drugs concurrently, while demonstrating that co-prescribing continues to occur at substantial levels [1,2].

The COB measure addresses a high priority area with identified performance gaps and is based on strong guideline recommendations and a broad body of clinical evidence. It is a feasible, actionable, and evidence-based measure that is improving patient safety in Humana's beneficiaries.

We remain concerned with both the high prevalence of concurrent opioids and benzodiazepines therapy, as well as instances of high MME accumulations and long durations. Humana continues to support and implement programs that further educate our providers to evaluate risk versus benefit when prescribing the combination or continuing the therapies along with counselling the beneficiaries who concomitantly take opioids and benzodiazepines on their risks of harm along with possible alternative therapies.

Best Regards,

Lilian Ndehi, PharmD, MBA, BCPS

Associate Vice President, Clinical Pharmacy

Humana Inc.

References

1. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep. 2016;65. doi:10.15585/mmwr.rr6501e1er.

2. Hernandez I, He M, Brooks MM, Zhang Y. Exposure-Response Association Between Concurrent Opioid and Benzodiazepine Use and Risk of Opioid-Related Overdose in Medicare Part D Beneficiaries. JAMA Netw Open. 2018;1(2):e180919

Developer Response

N/A

NQF Response

Thank you for your comment.

NQF #3389, Comment #7762

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7762

Commenter: Submitted by Anna Legreid Dopp

Council / Public: Health Professional

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/9/21

Developer Response Required? No

Level of Support: Member Supports

Theme: N/A

Comment

September 9, 2021

National Quality Forum

1030 15th Street NW, Suite 800

Washington, DC 20005

Re: NQF #3389 Concurrent Use of Opioids and Benzodiazepines (COB)

Humana is pleased to submit comments on the National Quality Forum (NQF) measure #3389: Concurrent Use of Opioids and Benzodiazepines.

Opioid-related safety continues to be a major concern for both patients and their health plans. Recent data highlighting opioid utilization during the pandemic are especially troubling, with overdose rates spiking over the course of the last year, and studies suggesting more than a 25% increase in total overdose deaths, driven primarily by opioids. Opioid safety is as important and urgent now as ever, and it's critical that health plans have appropriate quality measures that address high-risk opioid prescribing associated with overdose at the population level.

One well established risk for overdose and other adverse events is concurrent use of opioids and benzodiazepines (COB). The 2016 Centers for Disease Control and Prevention Guidelines issued a class A recommendation that concurrent use of these medications should be avoided whenever possible, and the FDA issued a black box warning highlighting the danger of using these medications together. A broad body of evidence has continued to demonstrate the starkly higher overdose risk for patients receiving these drugs concurrently, while demonstrating that co-prescribing continues to occur at substantial levels [1,2].

The COB measure addresses a high priority area with identified performance gaps and is based on strong guideline recommendations and a broad body of clinical evidence. It is a feasible, actionable, and evidence-based measure that is improving patient safety in Humana's beneficiaries.

We remain concerned with both the high prevalence of concurrent opioids and benzodiazepines therapy, as well as instances of high MME accumulations and long durations. Humana continues to support and implement programs that further educate our providers to evaluate risk versus benefit when prescribing the combination or continuing the therapies along with counselling the beneficiaries who concomitantly take opioids and benzodiazepines on their risks of harm along with possible alternative therapies.

Best Regards,

Lilian Ndehi, PharmD, MBA, BCPS

Associate Vice President, Clinical Pharmacy

Humana Inc.

References

1. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep. 2016;65. doi:10.15585/mmwr.rr6501e1er.

2. Hernandez I, He M, Brooks MM, Zhang Y. Exposure-Response Association Between Concurrent Opioid and Benzodiazepine Use and Risk of Opioid-Related Overdose in Medicare Part D Beneficiaries. JAMA Netw Open. 2018;1(2):e180919

Developer Response

N/A

NQF Response

Thank you for your comment.

NQF #3389, Comment #7773

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7773

Commenter: Submitted by Elizabeth Bentley

Council / Public: Health Plan

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/9/21

Developer Response Required? No

Level of Support: N/A

Theme: N/A

Comment

The opioid epidemic continues to plague health care systems and society, with data from the past year suggesting a sharp increase in opioid-related adverse events during the pandemic. This context makes measures such as Concurrent Use of Opioids and Benzodiazepines (COB) critical, as health plans search for opportunities to mitigate the risk to patients at a population health level. There is a generous body of evidence to demonstrate that benzodiazepines, when used concomitantly with opioids, increase the

risk of emergency department and/or hospital visits as well as both fatal and non-fatal overdose (see References). Both the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (Boxed Warning) caution against concurrent use of opioids and benzodiazepines due to the level of currently available evidence.

COB measures the percent of individuals 18 and older with concurrent use of opioids and benzodiazepines with at least 30 days of overlap during the measurement year. Individuals with cancer, sickle cell, or enrolled in hospice are excluded. The data available through the Medicare Part D Patient Safety Reports as well as data provided by Pharmacy Quality Alliance in the NQF Review Draft suggest variability in performance across health systems and opportunity for improvement.

In summary, COB addresses a gap in the performance measurement space related to safe use of opioids, and there is ample evidence to suggest opportunity for improvement along with a low risk of unintended consequences in the healthcare system. This evidence-based measure improves overall quality of care, particularly in its potential to reduce opioid-related adverse events.

Elizabeth Bentley, Kaiser Permanente, Clinical Pharmacy Services

References:

1. CDC. Overdose Deaths Accelerating during COVID-19. [1] https://www.cdc.gov/media/releases/2020/p1218-overdose-deaths-covid-19.html. December 17, 2020.

2. Dasgupta N, Funk MJ, Proescholdbell S, Hirsch A, Ribisl KM, Marshall S. Cohort Study of the Impact of High-Dose Opioid Analgesics on Overdose Mortality. Pain Med. 2016 Jan;17(1):85-98.

3. Garg RK, Fulton-Kehoe D, Franklin GM. Patterns of Opioid Use and Risk of Opioid Overdose Death Among Medicaid Patients. Med Care. 2017 Jul;55(7):661-668.

4. Hernandez I, He M, Brooks MM, Zhang Y. Exposure-Response Association Between Concurrent Opioid and Benzodiazepine Use and Risk of Opioid-Related Overdose in Medicare Part D Beneficiaries. JAMA Netw Open. 2018 Jun 1;1(2):e180919.

5. Park TW, Saitz R, Ganoczy D, Ilgen MA, Bohnert AS. Benzodiazepine prescribing patterns and deaths from drug overdose among US veterans receiving opioid analgesics: case-cohort study. BMJ. 2015 Jun 10;350:h2698.

6. Sun EC, Dixit A, Humphreys K, Darnall BD, Baker LC, Mackey S. Association between concurrent use of prescription opioids and benzodiazepines and overdose: retrospective analysis. BMJ. 2017 Mar 14;356:j760.

Developer Response

N/A

NQF Response

Thank you for your comment.

NQF #3389, Comment #7775

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7775

Commenter: Submitted by Sujith Ramachandran

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/9/21

Developer Response Required? No

Level of Support: N/A

Theme: N/A

Comment

There has been a robust response to the opioid overdose crisis over the course of the past several years from governmental payers, private insurance agencies, quality developers and healthcare providers. This response has effectively reduced the number of opioid prescriptions back to levels similar to those in 2002, but the rates of death and overdose in the United States have not shown a parallel decrease. However, this change in prescribing practice has resulted in substitution and addition of opioid medications with other psychotropic medications such as benzodiazepines, which may lead to an even greater risk of adverse reactions. In addition, the increasing risk of mental health illnesses among patients with chronic pain have also led to an increase in co-prescribing of opioids with psychotropic substances such as benzodiazepines.

Among overdose deaths in the US today, a majority of cases involve multiple substances and not opioids alone. Given these changes, it is important for the quality measurement frameworks to adapt to the dynamic trends in opioid prescribing, and continue to strive toward high quality care among patients with pain. There is a large amount of evidence demonstrating the risks of interaction of opioids with benzodiazepines, as this is a synergistic interaction that can cause an increase in opioid plasma concentrations, potentiation of respiratory depressive effects, and risk of other adverse reactions.

Therefore, I believe this measure is a critical part of monitoring changes in opioid prescribing practices and evaluating safety among individuals receiving treatment for pain.

Developer Response

N/A

NQF Response

Thank you for your comment.

NQF #3389, Comment #7761

Standing Committee Recommendation: Measure Recommended for Endorsement

Comment ID#: 7761

Commenter: Vikki Ahern, Magellan; Submitted by Kristina Arnoux

Council / Public: Public

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/9/21

Developer Response Required? No

Level of Support: N/A

Theme: N/A

Comment

September 9, 2021

Dana Gelb Safran

President and CEO

National Quality Forum

1099 14th Street NW

Suite 500

Washington, DC 20005

Attention: Patient Safety Portfolio Standing Committee

Re: Concurrent Use of Opioids and Benzodiazepines (NQF #3389)

Dear Dr. Safran:

Magellan Health, Inc. (Magellan) welcomes the opportunity to comment on NQF Measure #3389: Concurrent Use of Opioids and Benzodiazepines. Magellan supports the measure as proposed. The measure will help to reduce overdoses and other adverse events.

Magellan is a leader in managing the fastest growing, most complex areas of healthcare, including individuals with special healthcare needs, complete pharmacy benefits, and other specialty areas of healthcare. Through Magellan Rx Management, the full-service pharmacy benefit management division of Magellan, we specialize in solving complex pharmacy challenges for Medicare, Medicaid and other

state programs, health plans and managed care organizations, and employers. We connect behavioral, physical, pharmacy, and social needs with high-impact, evidence-based clinical and community support programs to ensure the care and services provided to our members are individualized, coordinated, fully integrated, and cost effective.

Opioid misuse is a health crisis affecting communities all over the nation across a wide spectrum of social, racial and class boundaries. This is a situation deserving immediate and decisive action. At Magellan, we have an unyielding commitment to helping those impacted by the opioid crisis. As a pioneer in offering integrated, comprehensive opioid risk and substance use management programs, we are uniquely positioned to bring together behavioral, medical and pharmaceutical programs to positively impact overall population health and cost.

Magellan is a national leader in serving individuals with OUD and other SUDs. Our experience includes a wide variety of activities, programs and tools for health plans, Medicare and Medicaid managed care organizations, employers, labor unions, state Medicaid programs, and military and government agencies designed to support long-term recovery and resiliency.

As a result, Magellan is familiar with the magnitude of the opioid crisis and has first-hand experience with its impact on individuals, families and communities. We have consistently taken a leadership role in promoting screening, assessment and evidence-based treatment for individuals with OUD and other SUDs.

Below, we are pleased to provide comments to NQF in support of the proposed NQF Measure #3389: Concurrent Use of Opioids and Benzodiazepines (COB).

Magellan's Comments

As the United States continues to grapple with the opioid epidemic, prescription opioids for pain management remain a major contributor to the crisis, with evidence suggesting that 21-29% of patients prescribed opioids for chronic pain will ultimately misuse them. The 2016 Centers for Disease Control and Prevention Guidelines issued a class A recommendation that concurrent use of these medications should be avoided whenever possible, and the FDA issued a black box warning highlighting the danger of using these medications together.

Subsequently, evidence continues to build and demonstrate the significant increase in overdose risk for patients receiving these drugs concurrently. Despite this clear data, co-prescribing continues to occur at considerable levels. The measure was developed in conjunction with a technical expert panel that provided input throughout the development process and unanimously found the measure to have face validity. This measure fills a recognized need and seeks to identify opportunities to reduce overdose deaths and adverse events. It is a feasible, actionable, and evidence-based measure that can improve patient safety.

Conclusion

Thank you for the opportunity to comment on NQF Measure #3389: Concurrent Use of Opioids and Benzodiazepines. We appreciate the Patient Safety Portfolio Standing Committee's leadership on these important issues. We look forward to engagement on these and other issues.

As NQF considers our comments, Magellan would be glad to answer questions. Please contact Brian Coyne, vice president of federal affairs, at (804) 548-0248 or bcoyne@magellanhealth.com; or, Kristina Arnoux, vice president of government affairs and public policy, at (401) 480-8034 or arnouxk@magellanhealth.com.

Thank you for the opportunity to share our perspective on this important issue.

Sincerely,

Vikki Ahern

SVP, Plan President, Medicare Part D

Magellan Rx Management

Developer Response

N/A

NQF Response

Thank you for your comment.

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