

## Memo

#### November 17, 2020

- To: Consensus Standards Approval Committee (CSAC)
- From: Patient Safety Project Team
- Re: Patient Safety Spring 2020<sup>a</sup>

### **CSAC** Action Required

The CSAC will review recommendations from the Patient Safety project at its November 2020 meeting and vote on whether to uphold the recommendations from the Committee.

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

- Patient Safety Spring 2020 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.
- Comment Table. Staff has identified themes within the comments received. This <u>table</u> lists nine comments received during the post-meeting comment period and the NQF/Standing Committee responses.

## Background

The Patient Safety Portfolio Standing Committee oversees NQF's portfolio of safety measures. Measures in this portfolio address medication safety, healthcare-associated infection, falls, pressure ulcers, and other safety concerns. The Institute of Medicine (IOM) defined patient safety as "freedom from accidental injury due to medical care or medical errors." Patient safety problems cause hundreds of thousands of preventable deaths each year—a recent analysis estimated that up to 440,000 Americans die annually from medical errors in U.S. hospitals. A 2010 study by the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) estimated that over a quarter of hospitalized Medicare beneficiaries experience an adverse event during their hospital stay; subsequent studies in other care settings estimated that the adverse event rates among Medicare patients in Skilled Nursing Facilities (SNFs) and rehabilitation hospitals are 33 percent and 29 percent, respectively. Adverse events can take many forms, including healthcare-associated infections (HAIs), medication errors, falls, pressure ulcers, and other potentially avoidable occurrences. The costs of these events are high and are passed on in various ways—higher insurance premiums, taxes, lost work time and wages, and lower quality of life, to name a few. Proactively addressing patient safety will protect patients from harm and lead to

<sup>&</sup>lt;sup>a</sup> This memo is funded by the Centers for Medicare and Medicaid Services under contract HHSM-500-2017-00060I Task Order HHSM-500-T0001.

more affordable, effective, and equitable care.

## **Draft Report**

The Patient Safety Spring 2020 draft report presents the results of the evaluation of two measures considered under the Consensus Development Process (CDP). Both are recommended for endorsement.

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

	Maintenance	New	Total
Measures recommended for endorsement	1	1	2

## **CSAC** Action Required

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

#### Measures Recommended for Endorsement

• <u>NQF 3558</u> Initial Opioid Prescribing for Long Duration (IOP-LD) (Pharmacy Quality Alliance)

Overall Suitability for Endorsement: Yes-18; No-0

• <u>NQF 2723</u> Wrong-Patient Retract-and-Reorder (Wrong-Patient-RAR) Measure (New York-Presbyterian Hospital)

Overall Suitability for Endorsement: Yes-14; No-4

### **Comments and Their Disposition**

NQF received nine comments from eight organizations (including four NQF-member organizations) and several individuals, which pertained to the draft report and to the measures under endorsement consideration.

A table of comments submitted during the comment period, with the responses to each comment and the actions taken by the Standing Committee and measure developers, is posted to the <u>Patient Safety</u> <u>project webpage</u>.

#### **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 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

Please note that the following comments are abbreviated for the purposes of this memo. For full comment text, please refer to the <u>Patient Safety Spring 2020 Comment Table</u>.

#### Measure 3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

**Comment 1:** The American Geriatrics Society (AGS) has concerns about the appropriateness of this measure for older adults and for the clinicians who see a preponderance of older adults. Broadly

speaking, long-term opioid dependence is less of a concern among this population, particularly those nearing the end of life. The decision to exclude patients in hospice or with a cancer diagnosis is a good acknowledgment of instances where an opioid prescription is likely to be appropriate, but there are likely additional exclusions that could be made to ensure geriatricians aren't penalized for addressing chronic or acute pain among patients who are not at risk for long term addiction. Additionally, we would like to see more evidence on why >7-day supply was chosen. The measure seems to imply that prescribing more than a 7-day supply when initiating opioids is inappropriate, but we did not see any evidence supporting this being the case. The measure also doesn't seem to consider if the patient had recent procedures such as surgery or other injuries that may justify the opioid use.

#### Measure Steward/Developer Response:

PQA appreciates the AGS' feedback on the IOP-LD measure. PQA considers changes to PQAendorsed measures through a standardized, transparent, consensus-based process involving several multistakeholder panels composed of clinical and measurement science experts. As additional exclusions are identified to be potentially appropriate, they will be considered through this robust process.

The 7-day threshold was chosen based recommendations in the 2016 CDC Guidelines for Prescribing Opioids for Chronic Pain, noting that "When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed [Recommendation category A, evidence type 4]. This recommendation has been supported by a significant body of research that has emerged since the guideline was released, with strong empirical evidence regarding the extent to which additional days' supply increases risk of long-term opioid use, especially the work by Shah in the CDC MMR weekly reports (1), Brat (2), Zhang (3), among others. For more information, we recommend referring to the measure's evidence attachment.

Finally, we note that literature such as Zhang et al demonstrate that the risks associated with an initial prescription days' supply exceeding 7-days was present in a Medicare Advantage population, demonstrating that even older Americans face risks associated with initial opioid prescribing at long duration; furthermore, Brat et al demonstrated that these risks are also present in post-surgical patients.

1)Shah A, Hayes CJ, Martin BC. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015. MMWR Morb Mortal Wkly Rep 2017;66:265–269. DOI: http://dx.doi.org/10.15585/mmwr.mm6610a1external icon.

2)Brat GA, Agniel D, Beam A, et al. Postsurgical prescriptions for opioid naive patients and association with overdose and misuse: retrospective cohort study. BMJ. 2018;360:j5790. Published 2018 Jan 17. doi:10.1136/bmj.j5790

3) Zhang Y, Johnson P, Jeng PJ, et al. First Opioid Prescription and Subsequent High-Risk Opioid Use: a National Study of Privately Insured and Medicare Advantage Adults. J Gen Intern Med. 2018;33(12):2156-2162. doi:10.1007/s11606-018-4628-y

#### **Proposed Committee Response:**

Thank you for your comment. The Committee previously reviewed the evidence for this measure and agreed that the evidence provided supports the measure. The Committee also recommends to the developer that as additional exclusions are identified and are appropriate,

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they consider them in future updates of this measure.

#### **Action Item:**

The Committee should review the comments and the developer's response and be prepared to discuss any recommendations for the developer to consider.

**Comment 2:** While Magellan Health supports the measure, the note included in the proposed denominator of the algorithm, "[i]f 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," misses an opportunity to address one area of potential abuse. For example, where multiple prescriptions are written on the same day, the measure uses the longest. So, for instance, where three providers each prescribe three days' worth of opioids, the possibility exists of having a greater number of pills that could be used beyond seven days. While we recognize that adjudication systems may reject a prescription where one was filled the same day, the measure should be additive to avoid possibility of misuse. The IOP-LD measure fills a recognized need in opioid measurement and seeks to identify opportunities to reduce conversion to chronic opioid use and misuse before it occurs. Likewise, the IOP-LD measure identifies opportunities for early intervention, unlike other opioid measures that are more retrospective in nature. It is a feasible, actionable, and evidence-based measure that can improve patient safety.

#### Measure Steward/Developer Response:

PQA appreciates Magellan's support and feedback on the IOP-LD measure regarding interpretation of multiple opioid claims that occur on the same day. The IOP-LD measure's methodology in this case is aligned with other PQA opioid measures and accounts for the fact that multiple opioids may be prescribed to be taken concurrently. In such cases, adding days' supply of multiple opioid claims received on the same day may overestimate the true days' supply. However, the PQA team will take this under advisement for future consideration. PQA considers changes to PQA-endorsed measures through a standardized, transparent, consensusbased process involving several multistakeholder panels composed of clinical and measurement science experts.

#### **Proposed Committee Response:**

Thank you for your comment. The Committee previously reviewed the measure specifications and agreed with the developer's approach. However, the Committee recommends that the developer monitor for any unintended consequences and update the measure accordingly.

#### Action Item:

The Committee should review the comments and the developer's response and be prepared to discuss any recommendations for the developer to consider.

**Comment 3:** The American Society of Consultant Pharmacists (ASCP) cautions PQA and National Quality Forum (NQF) of the issues that this quality measure could pose to patients and clinicians in long-term care (LTC) settings. We agree that patients with cancer, sickle cell disease, or those who were in hospice at any point during the measurement year or the 90 days prior to the first day of the measurement year should be excluded to accurately capture the number of patients who were inappropriately prescribed more than a 7-days' supply of opioids. However, we believe that long-term care (LTC) settings should also be excluded from this measure because of the mitigation strategies in place to ensure accurate and safe prescribing of opioid medications and the type of admissions facilities commonly see today. Patients are frequently admitted to facilities for post-acute care following surgery or for therapy and rehabilitation. In many cases, an opioid-naïve patient may require acute pain management for slightly more extended time periods. Due to this robust framework of opioid management that exists in LTC settings, we ask that NQF adopt an exclusion for long-term care to help ensure patient access to pain management in these settings and not duplicate burdensome administrative systems.

#### Measure Steward/Developer Response:

PQA appreciates ASCP's support and feedback on the IOP-LD measure regarding a potential exclusion for individuals in long-term care. PQA considers changes to PQA-endorsed measures through a standardized, transparent, consensus-based process involving several multi-stakeholder panels composed of clinical and measurement science experts. The PQA team is currently evaluating the appropriateness and feasibility of adding an exclusion for individuals in long-term care and will consider this potential change through our standardized and robust maintenance process.

#### **Proposed Committee Response:**

Thank you for your comment. The Committee previously reviewed specifications of this measures and agreed to pass the measure. However, the Committee recommends to the developer that as additional exclusions are identified and are appropriate, they consider them in future updates of this measure.

#### **Action Item:**

The Committee should review the comments and the developer's response and be prepared to discuss any recommendations for the developer to consider.

**Comment 4:** The American Society of Health-System Pharmacists urges careful consideration of any potential impact on pain management or access to medications for opioid use disorder (OUD), namely methadone. We believe that the measure developer has constructed IOP-LD in a way that allows for a lookback period that carefully balances identification of a patient that is opioid naïve and a patient that may be experiencing a new, acute pain episode. We encourage careful evaluation of that balance as the measure is implemented. In addition, we believe the inclusion of methadone, identified through outpatient prescription claims, will accurately differentiate methadone that is indicated for pain from methadone prescribed for OUD, which is currently restricted to be dispensed from federally certified opioid treatment programs only. Of note, this is a specification that the Pharmacy Quality Alliance has used in all of their opioid measures, without any reports of unintentional access limitations to methadone for OUD. If measure implementation for IOP-LD reveals otherwise, we urge the measure developer to carefully evaluate the inclusion of methadone. We believe IOP-LD, as a retrospective population-level measure will provide valuable insight into initial opioid prescribing practices for the purpose of identifying areas of improvement while filling an important public health measure gap.

#### Measure Steward/Developer Response:

PQA appreciates ASHP's support of the IOP-LD measure and thoughtfulness on the inclusion of methadone. As ASHP notes, methadone identified through prescription claims can accurately differentiate methadone that is indicated used for medication-assisted treatment of opioid use disorder (OUD), which is restricted to be dispensed only from federally certified opioid treatment programs. This approach to inclusion of methadone is consistent with other PQA opioid measures implemented in several federal programs, and PQA has not received feedback or evidence of unintended consequences related to methadone inclusion in this manner. As IOP-LD is implemented, PQA will continue to monitor for feedback and will evaluate any appropriate changes through our standardized, transparent, consensus-based maintenance process.

#### **Proposed Committee Response:**

Thank you for your comment. The Committee previously reviewed specifications of this



measures and agreed to pass the measure. However, the Committee recommends that the developer monitor for any unintended consequences and update the measure accordingly.

#### **Action Item:**

The Committee should review the comments and the developer's response and be prepared to discuss any recommendations for the developer to consider.

**Comment 5:** Kaiser Permanente believes the Initial Opioid Prescribing – Long Duration measure fills a recognized need in opioid measurement and seeks to uncover opportunities to reduce conversion to chronic opioid use and misuse before it occurs. Likewise, the Initial Opioid Prescribing – Long Duration measure identifies opportunities for early intervention, unlike other opioid measures that are more retrospective in nature. It is a feasible, actionable, and evidence-based measure that can improve patient safety.

#### **Proposed Committee Response:**

Thank you for your comment.

#### Action Item:

No Committee action required.

**Comment 6:** The University of Mississippi-Center for Pharmaceutical Marketing and Management feels strongly about the value of this measure in monitoring the quality of opioid prescribing in the United States and would strongly encourage the committee to endorse this measure. A key component of the quality of opioid prescribing is the nature of the initial opioid prescription (IOP). I believe this measure goes a long way in preventing chronic use of opioids and decreasing high-risk prescriptions. Because the measure only includes an opioid-naïve population, it also ensures that it does not impact individuals with pre-existing chronic pain who have need for opioid prescriptions with a longer duration. Finally, by quantifying only the initial prescription alone, this measure encourages better patient-provider communication and coordination to transition from an acute pain episode to a long-term episode. This can help ensure that long-term prescribing of opioids is managed in a way that is safe and appropriately monitored by a healthcare provider. Overall, the measure is well supported by scientific evidence, is feasible, and covers a critical measure gap.

#### **Proposed Committee Response:**

Thank you for your comment.

#### Action Item:

No Committee action required.

**Comment 7:** Humana supports the continued development of quality measures to impact opioid utilization that may lead to higher likelihood for high-risk and long-term opioid use, misuse, overdose, and other negative outcomes. We fully support the evidence that long duration of initial opioid prescriptions may lead to and increase opportunities for harm. Currently the Centers for Medicare and Medicaid Services allow for the health plan to place point of sale edits for opioid naïve members at 7 days. We would like to request clarification if patient safety edits geared to impact this measure will be required to be submitted additionally in the annual opioid management templates submitted to CMS or if there will be specific rule making that will allow for patient safety edits that are aimed at curbing this quality measure through normal patient safety processes.

#### Measure Steward/Developer Response:

PQA appreciates Humana's comment in support of the IOP-LD measure. Although the IOP-LD measure is included in the CMS Part D Patient Safety Reports program, the PQA team is not able



to provide insight on future CMS implementations of related health plan patient safety edits and opioid management templates. PQA recommends that Humana bring this question to CMS for further clarification.

#### **Proposed Committee Response:**

Thank you for your comment. The Committee does not have oversight in the decision-making of future CMS implementations of related health plan patient safety edits and opioid management templates. The Committee recommends that the commenter bring this question to CMS for further clarification.

#### Action Item:

No Committee action required.

#### Measure 2723: Wrong-Patient Retract-and-Reorder (Wrong Patient-RAR) Measure

**Comment 1:** American Geriatrics Society believes the measure appears to have questionable face validity as it measures the occurrence of a mistake and nearly immediate correction of this mistake. We question why catching an error before any harm could be done would be a good signal for practices that could harm patient safety. More validation that the rate and retracted and replaced ordered was correlated with instances where medications are ordered for the wrong patient and not caught would be helpful in making this case. With respect to older adults, one concern is whether the rate of RARs was a function of the number of prescriptions being ordered (I.e., more prescriptions ordered equals a greater risk of making a mistake). If this is the case, it would be important not to risk adjust these measures for patient age or complexity, so that providers are held accountable for getting orders correct for more complex patients. It looks like this measure is not risk adjusted, but rather can be reported within age strata.

#### Measure Steward/Developer Response:

Thank you for your comments. First, we agree that correlation between near-miss errors and errors that reach the patient is of interest. Nevertheless, the use of near-miss errors to test safety improvements in healthcare is endorsed by every major organization dedicated to improving patient safety, including the Agency for Healthcare Research and Quality, Institute of Medicine, World Health Organization, Institute for Healthcare Improvement, and The Joint Commission, because near-miss errors follow the same pathway as errors that cause harm.1 Near-miss errors are invaluable in quality improvement efforts and patient safety research, as they occur up to 100 times more frequently than errors that reach the patient and thus provide a sufficient number of outcome events to test the effectiveness of safety interventions.1

Second, the RAR rate is not risk adjusted, but can be stratified by location, provider, patient, or order characteristics.

1) Aspden P, Corrigan JM, Wolcott J, Erickson SM, eds. Patient Safety: Achieving a New Standard for Care. Washington (DC): National Academies Press (US); 2004. Patient Safety: Achieving a New Standard for Care.

#### **Proposed Committee Response:**

Thank you for your comments. The Committee previously reviewed the importance and validity of this measure and passed the measure on these criteria. Additionally, this measure is not risk adjusted, but can be stratified.

#### **Action Item:**

The Committee should review the comments and the developer's response and be prepared to discuss any recommendations for the developer to consider.

**Comment 2:** Baylor Scott & White Health believe that while WPRAR is a measure than can capture some errors, wouldn't a system that captured the "reason for order cancellation" be more direct? It could also be used dynamically to find problems rather than the single focus of WPRAR. Is this the best use of our resources? If the concept is to passively report WPRAR statistics by organization, that's interesting but it's unlikely to change behavior. How is implementation of this measurement going to improve quality? The document is inconsistent in its use of "provider" and "clinician", which are not the same thing. A "provider" can be a healthcare organization, a nurse, a therapist, a physician or many other people or even things.

#### Measure Steward/Developer Response:

Thank you for your comments and suggestions. First, we agree about the importance of understanding the reasons for order cancellations, which we have examined in validation studies of the measure and has been done in other studies of order errors (Adelman 2013, Hickman 2017, Abraham 2018). However, as the first and only fully automated measure of order errors in electronic health record (EHR) systems, the WPRAR measure serves to quantify the rate of wrong-patient orders for accountability, surveillance, and quality improvement activities.

Second, placing orders for the wrong patient occurs frequently and has the potential to cause serious harm. We agree that there are other types of errors that are important to measure, and we are in the process of developing and validating additional measures of medication order errors. These RAR measures use SQL queries that can be readily programmed into the EHR and other electronic data systems, without conducting labor-intensive chart review or relying on voluntary reporting of errors. Automated surveillance, in which electronic information systems are used to identify errors, has the potential to be a significantly more efficient and effective approach for identifying errors.

Third, this measure has been used to evaluate the effectiveness of several different interventions aimed at improving patient identification and preventing wrong-patient orders in varied clinical settings, including in the neonatal intensive care unit. Rates have been shown to be sensitive to change in response to intervention and to vary by clinical setting (inpatient vs emergency department vs outpatient). The measure is an indicator of where improvement is needed and, importantly, provides a systematic method of measuring improvement.

Finally, we recognize the inconsistent use of "provider" and "clinician". For future submissions, we will use the term "ordering clinician". We thank you again for your comments and suggestions.

#### **Proposed Committee Response:**

Thank you for your comments. The Committee previously reviewed the importance and validity of this measure and passed the measure on these criteria. The Committee recommends that the developer be more consistent with the term used to describe a clinician in future updates to the measure.

#### **Action Item:**

The Committee should review the comments and the developer's response and be prepared to discuss any recommendations for the developer to consider.

## **Member Expression of Support**

Throughout the 16-week continuous public commenting period, NQF members had the opportunity to express their support ('support' or 'do not support') for each measure submitted for endorsement consideration to inform the Committee's recommendations. Two NQF members provided their expression of 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	The developer of 3558: Initial Opioid Prescribing for Long Duration (IOP-LD) described similar and related opioid measures and that 3558 is harmonized to the extent possible. The Standing Committee did not raise any concerns or dissenting opinions.
Were any measurement gap areas addressed? If so, identify the areas.	Yes	The developer of 3558: Initial Opioid Prescribing for Long Duration (IOP-LD) described how this measure fills a gap in initial opioid prescribing for opioid naïve patients.
Are there additional concerns that require CSAC discussion? If so, briefly explain.	No	

## Appendix B: Measures Not Recommended for Endorsement

The Patient Safety Standing Committee recommends both spring 2020 candidate measures for endorsement.

## Appendix C: NQF Member Expression of Support Results

Two NQF members provided their expression of support or not support for one of the two measures under consideration. Results are provided in the table below.

#### Measure 3558: Initial Opioid Prescribing for Long Duration (IOP-LD) (Pharmacy Quality Alliance)

Member Council	Support	Do Not Support	Total
Health Professional	1	1	2

### **Appendix D: Details of Measure Evaluation**

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

#### Measures Recommended

#### 2723 Wrong-Patient Retract-and-Reorder (Wrong Patient-RAR) Measure

#### Submission

**Description**: A Wrong-Patient Retract-and-Reorder (Wrong Patient-RAR) event occurs when an order is placed on a patient within an EHR, is retracted within 10 minutes, and then the same clinician places the same order on a different patient within the next 10 minutes. A Wrong-Patient Retract-and-Reorder rate is calculated by dividing Wrong Patient-RAR events by total orders examined.

Numerator Statement: Total Wrong-Patient Retract-and-Reorder (Wrong-Patient RAR) events during a specified time period.

Denominator Statement: All electronic orders placed during a specified time period.

**Exclusions**: System-generated orders are excluded from the denominator. In some EHR systems, in addition to orders placed by clinicians, some orders are generated automatically by the EHR or other ancillary systems (e.g., the pharmacy system, the lab system, or other "interfaces"). Since these orders are not placed by an ordering clinician, they are not included in the denominator.

Adjustment/Stratification: No risk adjustment or stratification

Level of Analysis: Facility, Integrated Delivery System

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

Type of Measure: Process

Data Source: Electronic Health Data, Electronic Health Records, Other

Measure Steward: NewYork-Presbyterian Hospital

#### STANDING COMMITTEE MEETING 06/18/2020

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

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

1a. Evidence: **H-0; M-14; L-3; I-1**; 1b. Performance Gap: **H-0; M-17; L-1; I-0** Rationale:

• The developer noted that there are healthcare actions that may reduce the incidence of Wrong Patient RAR, such as better system design (e.g., putting a patient's picture in the electronic health record to ensure that the orders are written on the right patient).

• The developer cited studies conducted at different healthcare settings (e.g., NICU, emergency department) showing reductions in wrong patient order errors by displaying patient identification alerts when clinicians place orders in the electronic health record (EHR).

• The developer cited a 2013 validation study, conducted at Montefiore Medical Center, which found a Wrong Patient RAR rate of 58 wrong patient orders per 100,000 orders within a single year.

• The developer cited a 2015 study that was conducted at New York-Presbyterian Hospital in which a total of 3,457,342 electronic orders were recorded across five emergency departments and a total of 5,637 Wrong-Patient RAR events were identified; 163 per 100,000 orders (95% CI 159 to 167) within a 2.5 year study period (Dec 2010 – June 2013).

• The developer showed data from six hospitals and health systems resulting in a range of Wrong Patient RAR performance between 64 – 163 events per 100,000 patients.

Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u> (2a. Reliability precise specifications, testing; 2b. Validity testing, threats to validity
 Reliability: H-11; M-6; L-1; I-0; 2b. Validity: H-4; M-12; L-2; I-0

- Rationale:
  - The measure was tested for reliability in six health care systems. Test-retest and signal-to-noise reliability was assessed, across three different EHRs.

• The developer demonstrated that the data are highly reliable and repeatable, producing the exact same results when assessing the same population in the same time period. In >12m orders, there were 7,128 wrong patient RAR events, with an event rates of 58 per 100,000 orders. Across three attempts (i.e. data pulls), the kappa score for inter-rater reliability was 1.0 compared to the first pull.

#### 2723 Wrong-Patient Retract-and-Reorder (Wrong Patient-RAR) Measure

• The developer calculated a signal-to-noise ratio as a function of the variance <u>between</u> hospitals. Reliability was estimated using a beta-binomial model. In each of the six hospitals tested, the reliability score was 0.99 (near perfect). In addition, measure-level reliability was 0.99.

• One validation involved clinicians who triggered the measure were contacted within 6-12 hours of the occurrence to verify the event (in three health systems). The PPV range from 76.2% to 81.2% across published studies.

• Another validation approach involved the developer reporting studies evaluating different interventions aimed at preventing wrong patient errors using the Wrong Patient RAR measure as the primary outcome of the study. Two studies described showed a significant decrease in wrong patient RAR events when using an intervention aimed at preventing wrong patient errors. Another study was presented that demonstrated the impact on different EHR configurations allowing clinicians to open varying numbers of workspaces at a time.

#### 3. Feasibility: H-10; M-7; L-1; I-0

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

- The data used are electronic clinical data (i.e., EHR, Imaging/Diagnostic Study, Laboratory, Pharmacy, Registry) generated or collected by and used by healthcare personnel during the provision of care.
- All data alamanta ara in defined fields in EUDs
- All data elements are in defined fields in EHRs.

#### 4. Use and Usability

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

#### 4a. Use: **Pass-14; No Pass-4;** *4b. Usability:* **H-7; M-7; L-2; I-2** Rationale:

- The developer stated the measure is currently <u>not</u> being used within an accountability program. However, at present no regulatory body oversees or mandates public reporting or benchmarking of health IT safety measures.
- The measure is currently being evaluated for use as part of a "Leapfrog CPOE Evaluation Tool."
- The 21st Century Cures Act has established a new Electronic Health Record Reporting Program, which the measure is being discussed as a possible measure for this program.
- Several citations were provided on recommendations for the use by The Joint Commission, ECRI Institute, and the Office of the National Coordinator.

#### 5. Related and Competing Measures

• No related or competing measures noted.

#### 6. Standing Committee Recommendation for Endorsement: Yes-14; No-4

#### 7. Public and Member Comment

• NQF received two comments on measure 2723. One commenter expressed concern on validity and measure rate as a function of number of prescriptions ordered.

#### Measure Steward/Developer Response:

Thank you for your comments. First, we agree that correlation between near-miss errors and errors that reach the patient is of interest. Nevertheless, the use of near-miss errors to test safety improvements in healthcare is endorsed by every major organization dedicated to improving patient safety, including the Agency for Healthcare Research and Quality, Institute of Medicine, World Health Organization, Institute for Healthcare Improvement, and The Joint Commission, because near-miss errors follow the same pathway as errors that cause harm.(1) Near-miss errors are invaluable in quality improvement efforts and patient safety research, as they occur up to 100 times more frequently than errors that reach the patient and thus provide a sufficient number of outcome events to test the effectiveness of safety interventions.1 Second, the RAR rate is not risk adjusted, but can be stratified by location, provider, patient, or order characteristics.

	Aspden P, Corrigan JM, Wolcott J, Erickson SM, eds. Patient Safety: Achieving a New Standard for Care.
	Washington (DC): National Academies Press (US); 2004. Patient Safety: Achieving a New Standard for
	Care.
•	Another comment on the measure focused on the use of the term "provider" as compared to "clinician"
	and expanding the single focus of WPRAR to include "reason for order cancellation".
	Measure Steward/Developer Response:
	Thank you for your comments and suggestions. First, we agree about the importance of understanding
	the reasons for order cancellations, which we have examined in validation studies of the measure and ha
	been done in other studies of order errors (Adelman 2013, Hickman 2017, Abraham 2018). However, as
	the first and only fully automated measure of order errors in electronic health record (EHR) systems, the
	WPRAR measure serves to quantify the rate of wrong-patient orders for accountability, surveillance, and
	quality improvement activities.
	Second, placing orders for the wrong patient occurs frequently and has the potential to cause serious
	harm. We agree that there are other types of errors that are important to measure, and we are in the
	process of developing and validating additional measures of medication order errors. These RAR
	measures use SQL queries that can be readily programmed into the EHR and other electronic data
	systems, without conducting labor-intensive chart review or relying on voluntary reporting of errors.
	Automated surveillance, in which electronic information systems are used to identify errors, has the
	potential to be a significantly more efficient and effective approach for identifying errors.
	Third, this measure has been used to evaluate the effectiveness of several different interventions aimed
	at improving patient identification and preventing wrong-patient orders in varied clinical settings,
	including in the neonatal intensive care unit. Rates have been shown to be sensitive to change in
	response to intervention and to vary by clinical setting (inpatient vs emergency department vs
	outpatient). The measure is an indicator of where improvement is needed and, importantly, provides a
	systematic method of measuring improvement. Finally, we recognize the inconsistent use of "provider"
	and "clinician". For future submissions, we will use the term "ordering clinician". We thank you again for
	your comments and suggestions

#### 9. Appeals

### 3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

#### Submission

**Description**: The percentage of individuals 18 years of age and older with one or more initial opioid prescriptions for >7 cumulative days' supply.

**Numerator Statement**: 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.

**Denominator Statement**: 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.

**Exclusions**: 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.

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: Pharmacy Quality Alliance

#### STANDING COMMITTEE MEETING 06/18/2020

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

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

1a. Evidence: **H-7; M-13; L-0; I-0**; 1b. Performance Gap: **H-10; M-10; L-0; I-0** Rationale:

• This is new measure identifies individuals 18 years of age and older with one or more initial opioid prescriptions for >7 cumulative days' supply at the health plan level of analysis.

- The Standing Committee reviewed the evidence presented by the developer and sought clarification on the use of a 90-day lookback period for defining opioid naïve patients.
- The developer stated that they analyzed various lookback periods and presented the results to a technical expert panel, which determined that the 90-day lookback period was optimal. The Committee agreed with this approach.
- The Committee considered the range of performance for Medicaid, Medicare Advantage, and commercial health plans with means of 23.7%, 43.8%, and 25.1%, respectively.
- Committee members expressed concern with the higher rates found in Medicare. The developer stated that these rates are consistent with what is found in the primary literature.
- The Committee ultimately agreed that the evidence provided supported the measure and there is a gap in care that warrants a national performance measure.

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

(2a. Reliability precise specifications, testing; 2b. Validity testing, threats to validity 2a. Reliability: **H-13; M-6; L-0; I-0**; 2b. Validity: **H-0; M-18; L-2; I-0** 

Rationale:

- The Standing Committee reviewed the results for reliability and validity.
- There was some discussion regarding the limited variability in the commercial population. The developer mentioned that the commercial testing was limited to only three health plans, which is what is driving the limited variation seen.
- Based on the mean reliability scores of 0.939 for Medicare, 0.982 for Medicaid, and 0.935 for commercial, the Committee agreed that the measure is considered reliable.
- The Committee considered the that the developer conducted face validity only. The developer reported that a technical expert panel concluded in 100% agreement that the scores obtained from the measure as specified will provide an accurate reflection of quality and that the measure can be used to distinguish good and poor quality between health plans.
- The Committee reviewed other threats to validity, including exclusions and recommended that the developer consider excluding palliative care and certain social determinants in the future.
- While several considerations were noted on the reliability and validity of the measure, the Committee agreed to pass the measure on scientific acceptability.

#### 3. Feasibility: H-11; M-7; L-0; I-0

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

• The Standing Committee agreed that the measure uses claims data that can be generated or collected during the provision of care and that there are no fees, licensing, or requirements to use the measure.

- The Committee did express concerns regarding the measure licensing.
- The Committee considered the developer's response that the licensing fee is charged for commercial use, and that government entities are not charged a fee, and ultimately 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: Pass-19; No Pass-0 4b. Usability: H-8; M-10; L-0; I-1 Rationale:

• The Standing Committee acknowledged that this measure is planned for use as part of CMS's Five Star Rating System for Part D.

• The Committee noted that this is a new measure and there is no information available on performance improvement. This measure is not currently used in a program, but a primary goal of the measure is to provide information necessary to implement focused quality improvement efforts. Once the measure is implemented, the developer plans to examine trends in improvements over time.

#### 5. Related and Competing Measures

- This measure is related with the following measures:
  - NQF 2940: Use of Opioids at High Dosage in Persons Without Cancer
  - o NQF 2950: Use of Opioids from Multiple Providers in Persons Without Cancer

• NQF 2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

- NQF 3389: Concurrent Use of Opioids and Benzodiazepines (COB)
- NQF 3541: Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)
- The Committee did not raise any concerns as the measures are harmonized and that there are no competing measures.

#### 6. Standing Committee Recommendation for Endorsement: Yes-18; No-0

#### 7. Public and Member Comment

- NQF received two pre-evaluation comments and seven post-evaluation comments on measure 3558. Three post-evaluation comments were in support of the measure. Comments received expressed:
- Concerns about the evidence criterion; unintended negative consequences and the definition of "opioid naïve".

#### Measure Steward/Developer Response:

PQA appreciates the FAH's comments regarding the IOP-LD measure. Regarding the use of a 90-day lookback period, "lookback periods" are variably defined in the current literature, with some studies using 60-days and others up to twelve months. Considering Part D opioid naïve edits, CMS recommends that Part D sponsors use a lookback of at least 60 days, with most sponsors using lookback periods between 60 and 120 days (4). PQA tested numerous lookback period options, including: 30, 45, 90, and 120 days and discussed this question extensively with subject matter experts and technical expert panels. Ultimately, the technical expert panel found the 30-day interval to be oversensitive in identifying prescriptions as initial, and there were inherently tradeoffs for between sensitivity and specificity at each of the other lookback periods. Per testing, the overall impact of using different lookback periods were generally minor. As such, the technical expert panel came to consensus that the 90-day lookback period is most appropriate.

PQA appreciates the AMA's comments on the IOP-LD measure. Regarding the evidence to support the 7day threshold, the 7-day threshold was chosen based on recommendations in the 2016 CDC Guidelines for Prescribing Opioids for Chronic Pain, noting that "When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed [Recommendation category A, evidence type 4].

As the AMA notes, this recommendation is based on expert consensus. This recommendation is also supported by a significant body of research that has emerged since the guideline was released, with strong empirical evidence regarding the extent to which additional days' supply increases risk of long-term opioid use, especially the work by Shah et al in the CDC MMR weekly reports (1), Brat et al (2), Zhang et al (3), among others. For more information, we recommend referring to the measure's evidence attachment.

Regarding the use of a 90-day lookback period, "lookback periods" are variably defined in the current

literature, with some studies using 60-days and others up to twelve months. Considering Part D opioid naïve edits, CMS recommends that Part D sponsors use a lookback period of at least 60 days, with most sponsors using lookback periods between 60 and 120 days (4,5). PQA tested numerous lookback period options, including: 30, 45, 90, and 120 days and discussed this question extensively with subject matter experts and technical expert panels. Ultimately, the technical expert panel found the 30-day interval to be oversensitive in identifying prescriptions as initial, and there were inherently tradeoffs for between sensitivity and specificity at each of the other lookback periods. Per testing, the overall impact of using different lookback periods were generally minor. As such, the technical expert panel came to consensus that the 90-day lookback period is most appropriate.

Regarding the measure's use of methadone, methadone identified through prescription claims is accurately differentiated from methadone that is indicated used for medication-assisted treatment of opioid use disorder (OUD), which is restricted to be dispensed only from federally certified opioid treatment programs. As a result, an exclusion for individuals receiving OUD is not required, as the measure only captures methadone prescribed for pain management, and drugs indicated for medication assisted treatment of OUD (e.g., buprenorphine) are not included in the measure. This approach to inclusion of methadone is consistent with other PQA opioid measures implemented in federal programs, and PQA has not received feedback or evidence of unintended consequences related to methadone inclusion in this manner. As IOP-LD is implemented, PQA will continue to monitor for feedback and will evaluate any appropriate changes through our standardized, transparent, consensus-based maintenance process.

Regarding the AMA's concerns about this measure's use and potential for unintended consequences, PQA would like to emphasize that as a retrospective population-level measure, the measure is not intended to serve as a guide for individual patient care decisions. Although a lower rate indicates better performance, the rate is not expected to be zero, and there are rare situations in which providers may choose to initially prescribe for a greater days' supply for individual patients due to patient individualization considerations. This performance measure is not intended to preclude such situations, but is intended to give a population-level metric for quality, and to establish benchmarks and identify opportunities to decrease initial opioid prescriptions for long duration that may place patients at increased risk for long-term opioid use, misuse, overdose, and other negative outcomes.

1) Shah A, Hayes CJ, Martin BC. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015. MMWR Morb Mortal Wkly Rep 2017;66:265–269. DOI: http://dx.doi.org/10.15585/mmwr.mm6610a1external icon.

2) Brat GA, Agniel D, Beam A, et al. Postsurgical prescriptions for opioid naive patients and association with overdose and misuse: retrospective cohort study. BMJ. 2018;360:j5790. Published 2018 Jan 17. doi:10.1136/bmj.j5790

Zhang Y, Johnson P, Jeng PJ, et al. First Opioid Prescription and Subsequent High-Risk Opioid
 Use: a National Study of Privately Insured and Medicare Advantage Adults. J Gen Intern Med.
 2018;33(12):2156-2162. doi:10.1007/s11606-018-4628-y

4) Centers for Medicare and Medicaid Services. Contract Year (CY) 2020 Opioid Safety Edit Reminders and Recommendations. Available from https://www.cms.gov/files/document/cy-2020-opioidsafety-edits-reminders-and-recommendations.pdf.

5) Centers for Medicare and Medicaid Services. Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available from https://www.cms.gov/MEDICARE/HEALTH-PLANS/MEDICAREADVTGSPECRATESTATS/DOWNLOADS/ANNOUNCEMENT2019.PDF.

• Concerns about the inclusion of methadone.

Measure Steward/Developer Response: PQA appreciates ASHP's support of the IOP-LD measure and thoughtfulness on the inclusion of

methadone. As ASHP notes, methadone identified through prescription claims can accurately differentiate methadone that is indicated used for medication-assisted treatment of opioid use disorder (OUD), which is restricted to be dispensed only from federally certified opioid treatment programs. This approach to inclusion of methadone is consistent with other PQA opioid measures implemented in several federal programs, and PQA has not received feedback or evidence of unintended consequences related to methadone inclusion in this manner. As IOP-LD is implemented, PQA will continue to monitor for feedback and will evaluate any appropriate changes through our standardized, transparent, consensus-based maintenance process.

• Support with concerns about inclusion of long-term care (LTC) settings.

#### Measure Steward/Developer Response:

PQA appreciates ASCP's support and feedback on the IOP-LD measure regarding a potential exclusion for individuals in long-term care. PQA considers changes to PQA-endorsed measures through a standardized, transparent, consensus-based process involving several multi-stakeholder panels composed of clinical and measurement science experts. The PQA team is currently evaluating the appropriateness and feasibility of adding an exclusion for individuals in long-term care and will consider this potential change through our standardized and robust maintenance process.

• Support with concern for potential abuse.

#### Measure Steward/Developer Response:

PQA appreciates Magellan's support and feedback on the IOP-LD measure regarding interpretation of multiple opioid claims that occur on the same day. The IOP-LD measure's methodology in this case is aligned with other PQA opioid measures and accounts for the fact that multiple opioids may be prescribed to be taken concurrently. In such cases, adding days' supply of multiple opioid claims received on the same day may overestimate the true days' supply. However, the PQA team will take this under advisement for future consideration. PQA considers changes to PQA-endorsed measures through a standardized, transparent, consensus-based process involving several multistakeholder panels composed of clinical and measurement science experts.

• Concerns about the appropriateness of the measure and evidence criterion being met.

#### Measure Steward/Developer Response:

PQA appreciates the AGS' feedback on the IOP-LD measure. PQA considers changes to PQA-endorsed measures through a standardized, transparent, consensus-based process involving several multistakeholder panels composed of clinical and measurement science experts. As additional exclusions are identified to be potentially appropriate, they will be considered through this robust process.

The 7-day threshold was chosen based recommendations in the 2016 CDC Guidelines for Prescribing Opioids for Chronic Pain, noting that "When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed [Recommendation category A, evidence type 4]. This recommendation has been supported by a significant body of research that has emerged since the guideline was released, with strong empirical evidence regarding the extent to which additional days' supply increases risk of long-term opioid use, especially the work by Shah in the CDC MMR weekly reports (1), Brat (2), Zhang (3), among others. For more information, we recommend referring to the measure's evidence attachment.

Finally, we note that literature such as Zhang et al demonstrate that the risks associated with an initial prescription days' supply exceeding 7-days was present in a Medicare Advantage population, demonstrating that even older Americans face risks associated with initial opioid prescribing at long duration; furthermore, Brat et al demonstrated that these risks are also present in post-surgical patients.

558 Initia	al Opioid Prescribing for Long Duration (IOP-LD)
	Shah A, Hayes CJ, Martin BC. Characteristics of Initial Prescription Episodes and Likelihood of ng-Term Opioid Use — United States, 2006–2015. MMWR Morb Mortal Wkly Rep 2017;66:265–269. DI: http://dx.doi.org/10.15585/mmwr.mm6610a1external icon.
	Brat GA, Agniel D, Beam A, et al. Postsurgical prescriptions for opioid naive patients and sociation with overdose and misuse: retrospective cohort study. BMJ. 2018;360:j5790. Published 2018 n 17. doi:10.1136/bmj.j5790
	Zhang Y, Johnson P, Jeng PJ, et al. First Opioid Prescription and Subsequent High-Risk Opioid e: a National Study of Privately Insured and Medicare Advantage Adults. J Gen Intern Med. 18;33(12):2156-2162. doi:10.1007/s11606-018-4628-y
	quiry on future CMS implementations of related health plan patient safety edits and opioid anagement templates.
Me	easure Steward/Developer Response:
inc on	A appreciates Humana's comment in support of the IOP-LD measure. Although the IOP-LD measure is cluded in the CMS Part D Patient Safety Reports program, the PQA team is not able to provide insight future CMS implementations of related health plan patient safety edits and opioid management mplates. PQA recommends that Humana bring this question to CMS for further clarification.
	us Standards Approval Committee (CSAC) Vote: Y-X; N-X



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# Patient Safety Spring 2020 Review Cycle

**CSAC** Review and Endorsement

November 17, 2020

Funded by the Centers for Medicare and Medicaid Services under contract HHSM-500-2017-00060I Task Order HHSM-500-T0001.



## **Standing Committee Recommendations**

- Two measures reviewed for Spring 2020
- Both measures recommended for endorsement
  - NQF 2723 Wrong-Patient Retract-and-Reorder (Wrong-Patient-RAR) Measure (Maintenance Measure)
  - NQF 3558 Initial Opioid Prescribing for Long Duration (IOP-LD) (New Measure)



## **Overarching Issues**

- Developing Measures that Can Be Designed to Work within Electronic Health Records (EHRs)
  - With increased use of EHRs across healthcare facilities, it will be increasingly important to embed quality measures into EHRs systems.
  - The Wrong-Patient-RAR measure was viewed by the Committee as the type of measure that could be built into the EHRs, and inferences from its study could be used for the general design of EHRs (i.e., not allowing for multiple patient records to be open at the same time to reduce the incidence of wrong-patient orders).
- Reduce Barriers to Measure Use
  - The Committee discussed the importance of ensuring that measures are available to a wide variety of stakeholders and there are no barriers to feasibility, such as high licensing fees that would limit the use of measures.



## Public and Member Comment and Member Expressions of Support

- Nine total comments received
- One NQF member provided expression of support and another NQF member provided expression of non-support for the same measure



## **Questions?**

- Project team:
  - Matthew Pickering, PharmD, Senior Director
  - Chris Dawson, MHA, Manager
  - Yemsrach Kidane, PMP, Project Manager
  - Isaac Sakyi, MSGH, Analyst
  - Jesse Pines, MD, MBA, MSCE, Consultant
- Project webpage: <u>http://www.qualityforum.org/Patient\_Safety.aspx</u>
- Project email address: <u>patientsafety@qualityforum.org</u>

# THANK YOU.

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## Patient Safety Spring 2020 Cycle: CDP Report

DRAFT REPORT FOR CSAC REVIEW NOVEMBER 17, 2020

This report is funded by the Centers for Medicare and Medicaid Services under contract HHSM-500-2017-00060I – 75FCMC19F0007.

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NATIONAL QUALITY FORUM NQF REVIEW DRAFT

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## **Executive Summary**

Medical errors and adverse events are major threats to patient safety in healthcare and are linked to more than 100,000 preventable deaths per year in the United States. Patient-safety related events occur across all settings including hospitals and outpatient clinics, as well as nursing homes, rehabilitation facilities, and others. Patient-safety related events include a variety of preventable outcomes, including healthcare-associated infections, falls, and pressure ulcers.

The National Quality Forum's (NQF) portfolio of safety measures spans a variety of topical areas and includes such outcomes, as well as important, measurable processes in healthcare that are associated with patient safety. Public accountability and quality improvement programs use many measures from the NQF portfolio. Nevertheless, significant gaps in patient safety persist. Over more than a decade, NQF's portfolio has expanded to address current and evolving public health issues such as the opioid crisis. As electronic health records (EHRs) have become increasingly prevalent in healthcare, it is important to develop measures that monitor and improve safety events that may be caused by the technology itself.

The Patient Safety Standing Committee oversees the NQF patient safety measure portfolio. The Committee evaluates newly submitted and previously endorsed measures against NQF's measure evaluation criteria, identifies portfolio gaps, provides feedback on gaps in measurement, and conducts ad hoc reviews. On June 18 and 19, 2020, the Patient Safety Standing Committee evaluated two measures against NQF's standard evaluation criteria.

Critical issues discussed during the meeting included that measures are integrated into the design of EHRs, and measures should be feasibly adopted without barriers such as high licensing fees.

For this cycle, the Standing Committee evaluated one newly submitted measure and one measure undergoing maintenance review against NQF's standard evaluation criteria. The Standing Committee recommended both measures for endorsement. The measures are:

- NQF 2723 Wrong-Patient Retract-and-Reorder (Wrong-Patient-RAR) Measure (New York-Presbyterian Hospital)
- NQF 3558 Initial Opioid Prescribing for Long Duration (IOP-LD) (Pharmacy Quality Alliance)

Brief summaries of the measures currently under review are included in the body of the report; detailed summaries of the Committee's discussion and ratings of the criteria for each measure are in <u>Appendix A</u>.

## Introduction

The Institute of Medicine (IOM) report "To Err Is Human: Building a Safer Health System," published in 2000, created a movement by individuals and institutions to closely examine the avoidable harms in healthcare. These included hospital-based medical errors, adverse drug events (ADE), injuries from surgery, falls, pressure ulcers, and other causes of preventable morbidity and mortality.

Despite 20 years of progress since the publication of that report, medical errors and other patient-safety events remain common across all settings of care. There has been demonstrated improvement in specific areas, including the reduction of hospital-acquired infections. Yet, the scale of improvements in patient safety have been limited. Many interventions to improve patient safety have been effective, but many others have proven ineffective, and the effectiveness of many interventions is unclear. Nevertheless, the U.S. healthcare system is not a high reliability system. Today, patients commonly experience potentially preventable harm. It is estimated that medical errors are the third leading cause of deaths in the US with more than 250,000 deaths per year.<sup>1</sup>

Healthcare providers are increasingly being held accountable for improving patient safety and the quality of care delivery through the use of quality measurement and public reporting. Measurement and quality improvement activities can incentivize the healthcare system to reduce potentially preventable patient safety events, develop effective processes to remediate issues that occur, and build a culture of organizational safety. NQF has a nearly 20-year history of focusing on patient safety and measurement. NQF's Patient Safety Standing Committee is a longstanding group that convenes regularly to assess patient safety measures, identify measure gaps, and operate as a thought leader in the next generation of approaches to improve safety across all settings. Additionally, NQF has endorsed 34 safe practices in the 2010 update of the <u>Safe Practices for Better Healthcare</u> and 29 Serious Reportable Events (SRE). The Safe Practices, SREs, and NQF-endorsed patient safety measures are important tools for tracking and improving patient safety performance in American healthcare.

## NQF Portfolio of Performance Measures for Patient Safety Conditions

The Patient Safety Standing Committee (<u>Appendix C</u>) oversees NQF's portfolio of Patient Safety measures (<u>Appendix B</u>). This portfolio contains 60 measures: 16 process measures, 37 outcome measures, one intermediate outcome measure, three structure measures, and three composite measures (see Table 1 below).

	Process	Outcome	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	5	0	0	0	6
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
Other	5	6	0	0	2	13
Total	16	37	1	3	3	60

#### Table 1. NQF Patient Safety Portfolio of Measures

Additional measures related to patient safety are assigned to other projects. These include various diabetes assessment and screening measures (Prevention and Population Health/Behavioral Health and Substance Use), primary care and chronic illness measures (Primary Care and Chronic Illness), ACEI/ARB medication measures (Cardiovascular), complications measures (Prevention and Population Health/Surgery), and cost and efficiency measures (Cost and Efficiency).

## **Patient Safety Measure Evaluation**

On June 18 and 19, 2020, the Patient Safety Standing Committee evaluated one new measure and one measure undergoing maintenance review against NQF's <u>standard measure evaluation criteria</u> (Table 2).

Table 2. Patient Safety Measure Evaluation Summary

	Maintenance	New	Total
Measures under consideration	1	1	2
Measures recommended for endorsement	1	1	2

## **Comments Received Prior to Committee Evaluation**

NQF solicits comments on endorsed measures on an ongoing basis through the <u>Quality Positioning</u> <u>System (QPS)</u>. In addition, NQF solicits comments for a continuous 16-week period during each

NATIONAL QUALITY FORUM NQF REVIEW DRAFT evaluation cycle via an online tool located on the project webpage. For this evaluation cycle, the commenting period opened on April 3, 2020 and closed on August 25, 2020. As of June 5, 2020, two comments were submitted and shared with the Committee prior to the measure evaluation meeting(s) (Appendix F).

All submitted comments were provided to the Committee prior to its initial deliberations during the Measure Evaluation web meeting.

## **Comments Received After Committee Evaluation**

The continuous 16-week public commenting period with NQF member support closed on August 25, 2020. Following the Committee's evaluation of the measures under consideration, NQF received nine comments from four member organizations and individuals pertaining to the draft report and to the measures under consideration. All comments for each measure under consideration have been summarized in <u>Appendix A</u>.

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. Two NQF members provided their expression of support or not support for one of the two measures under consideration. Results are provided below.

#### Measure 3558: Initial Opioid Prescribing for Long Duration (IOP-LD) (Pharmacy Quality Alliance)

Member Council	Support	Do Not Support	Total
Health Professional	1	1	2

#### **Overarching Issues**

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

#### Designing Measures that Can Be Designed to Work within EHRs

With increased use of EHRs and their near ubiquity across healthcare facilities, it will be increasingly important to embed quality measures into EHRs systems. In particular, the *Wrong-Patient Retract-and-Reorder* (Wrong-Patient-RAR) measure was seen as the type of measure that could be built into the EHRs, and inferences from its study could be used for the general design of EHRs (i.e., not allowing for multiple patient records to be open at the same time to reduce the incidence of wrong-patient orders).

#### Reduce Barriers to Measure Use

The Committee discussed the importance of ensuring that measures are available to a wide variety of stakeholders and there are no barriers to feasibility, such as high licensing fees that would limit the use of measures.

### Summary of Measure Evaluation

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

## 2723 Wrong-Patient Retract-and-Reorder (Wrong-Patient-RAR) Measure (New York-Presbyterian Hospital): Recommended

**Description**: A Wrong-Patient-RAR event occurs when an order is placed on a patient within an EHR is retracted within 10 minutes, and then the same clinician places the same order on a different patient within the next 10 minutes. A wrong-patient retract-and-reorder Rate is calculated by dividing wrong patient-RAR events by total orders examined. **Measure Type**: Process; **Level of Analysis**: Facility, Integrated Delivery System; **Setting of Care**: Emergency Department and Services, Inpatient/Hospital, Outpatient Services; **Data Source**: Electronic Health Data, Electronic Health Records, Other

The Standing Committee recommended the measure for continued endorsement. Originally endorsed in 2015, the focus of the measure is to identify when providers place an order on the wrong-patient, retract it within 10 minutes, and then the same provider places the same order on a different patient within the next 10 minutes. Committee members asked for clarity regarding the intent of the measure, specifically if the measure is capturing human error or information technology error. The developer responded stating that the measure currently captures whether a provider catches the error. The Committee agreed that this is an important focus area of measurement. However, they would recommend that this measure, or a future version, focus more on the design features of the electronic health record (EHR) systems, such that there would be an incentive to change these systems to prevent these errors. The developer agreed and stated that as more and more interventions are developed by health systems, #2723 could become a measure of the optimization and success of the EHR. One Committee member asked why the measure uses 10 minutes. The developer stated that 10 minutes optimized the sensitivity and specificity of the measure.

Concerning the evidence criterion, some Committee members questioned the potential for avoiding a serious event or unintended consequences with this measure. Specifically, since the measure captures "near misses," the Committee questioned whether there has been evidence showing the impact of this measure on errors that cause significant harm. The developer stated that they are currently attempting to explore the associations of this measure and the impact of errors that reach the patient. The Committee agreed that this is an important metric, which can lead to further EHR design optimization rather than provider vigilance. The Committee observed that there is an appropriate measure performance gap and did not express any concerns. Regarding reliability, a Committee member questioned if there was specific code that is needed for implementation and recommended that those instructions, along with specifying the reporting period, be incorporated into the measure specifications. The developer confirmed that code would be needed for certain EHR systems and agreed to add these changes to the measure specifications in future versions of the measure.

Moving to validity, the Committee raised some concern over the accuracy of self-report to confirm the retract and reorder event. The developer mentioned that the validity testing found sufficient accuracy in provider self-report of retract and reorders, but it may be higher since some providers may not confirm

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that they placed a wrong order. The developer also reiterated that they are looking into evaluating the association of this measure to errors that reach the patient. The measure was regarded as feasible by the Committee with no concerns.

In their discussions related to usability and use, the Committee noted that the measure is currently not in use. However, the developer provided a rationale on the recommendations for its potential use, including the use of the measure by Leapfrog. The Committee did question whether the measure was intended for quality improvement or public reporting. There was discussion on if the measures could be submitted for endorsement as a quality improvement metric. The NQF staff clarified that, currently, there is no designation of "quality improvement." However, the Committee recognized that the measures can and has been used as such. The Committee observed that there are no related measures for this metric and voted to recommend the measure for continued endorsement.

Comments received during the public commenting period focused on validity and measure rate as a function of number of prescriptions ordered and the use of the term "provider" as compared to "clinician". The developer mentioned on the call that the measure captures self-caught miss errors, which has been endorsed by several different groups including NQF. The developer also described the theoretical model that associated near-misses with actual wrong patient safety orders had not been fully linked; yet, conceptually near-misses captured in this measure are designed as a proxy for actual error. The Committee further stated that the measure may be an indirect measure of electronic health record usability and compliance for best practices at the system measure rather than holding individuals accountable for personal failures, which is the intent of the measure. However, the Committee was reminded by NQF staff that they previously reviewed these issues and passed the measure on importance and validity during the June 2020 meeting. The Committee also recommended that the developer be more consistent with the term used to describe a clinician in future updates to the measure.

#### 3558 Initial Opioid Prescribing for Long Duration (IOP-LD) (Pharmacy Quality Alliance): Recommended

**Description**: The percentage of individuals 18 years of age and older with one or more initial opioid prescriptions for greater than seven cumulative days' supply. **Measure Type**: Process; **Level of Analysis**: Health Plan; **Setting of Care**: Outpatient Services; **Data Source**: Claims, Enrollment Data

The Standing Committee recommended the measure for initial endorsement.

The focus of the measure is to identify individuals 18 years of age and older with one or more initial opioid prescriptions for greater than seven cumulative days' supply. Concerning the evidence criterion, Committee members were concerned with the higher measure rate found in Medicare population and if the measure excludes individuals in hospice, palliative care, or those with certain social determinants. The developer stated that higher rates of opioid use have been reported among hospice patients in the primary literature and that, currently, the measure does exclude hospice patients. The measure does not exclude patients in palliative care nor those with certain social determinants, but the developer is looking to explore these exclusions in the future. The Committee also questioned why the developer chose a 90-day lookback period for defining opioid naïve patients. The developer stated that this varies within the literature. The developer also noted that they analyzed various lookback periods in the data

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and engaged a technical expert panel that identified that a 90-day lookback period was the optimal timeframe. They further noted that going beyond 90- to 120-days did not impact the measure rates and that smaller windows of time were too conservative. The Committee observed that there is an appropriate measure performance gap in care and did not express any concerns.

Regarding reliability, a Committee member questioned if the measure is intended to have a mixed dataset of commercial, Medicare, and Medicaid. The developer clarified the measure would be implemented at different lines of business, rather than having multiple lines being mixed into one measure rate (i.e., mixing commercial, Medicare, and Medicaid). One Committee member questioned whether the measure is sensitive to claims restrictions that a health plan may place on opioid medications. The developer stated that if there are any health plan point of sale edits or restrictions, the pharmacy would not be able to fill the claim and this would not be captured. For validity, a Committee member questioned why there was limited variability in the commercial population. The developer mentioned that the commercial testing was limited to only three health plans, which is what is driving the limited variation seen. There was some discussion on what the outcome or outcome measure would be to assess empirical validity, as the developer conducted face validity only. The developer stated that they could consider the prescription drug monitoring program to capture potential misuse as an outcome or if the measure is predictive for overdose.

The measure was regarded as feasible by the Committee. However, there were concerns with respect to the licensing and how that may impact measure adoption. The developer stated that the licensing fee is charged for commercial use and government entities are not charged a fee. Additionally, there is not any reporting or feedback captured through the licensing.

In their discussions related to usability and use, the Committee noted that the measure is planned to be used in the Centers for Medicare & Medicaid Services (CMS) Five Star Rating System for Medicare Part D. One Committee member did ask for more clarity on its current use. The developer mentioned that the measure is currently implemented in a pilot program for the Enhanced Medication Therapy Management model through the CMS Center for Medicare & Medicaid Innovation. The results of this implementation are not published to the public yet as the model is still ongoing. The Committee observed that there are several related measures, all of which are measures stewarded by the developer. However, the Committee did not raise any concerns with respect to harmonization and voted to recommend the measure for endorsement.

Comments received during the public commenting period addressed the evidence criterion not being met, potential for multiple opioid prescriptions being dispensed the same day for a single patient, inclusion of patients in Long Term Care (LTC) settings, inclusion of methadone, CMS reporting requirements, and overall support of the Committee's recommendation. During the post-comment deliberations, the Committee reviewed the comments and proposed responses and recommended to the developer that they continue to monitor for potential exclusions, such as LTC settings and methadone, and for unintended consequences that are identified and if appropriate, to consider them in future updates of this measure.

## References

1 Makary MA, Daniel M. Medical error—the third leading cause of death in the US. *BMJ*. 2016;353. https://www.bmj.com/content/353/bmj.i2139. Last accessed July 2020.
# **Appendix A: Details of Measure Evaluation**

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

## Measures Recommended

## 2723 Wrong-Patient Retract-and-Reorder (Wrong-Patient-RAR) Measure

#### Submission | Specifications

**Description**: A Wrong-Patient-RAR event occurs when an order is placed on a patient within an EHR, is retracted within 10 minutes, and then the same clinician places the same order on a different patient within the next 10 minutes. Its rate is calculated by dividing Wrong-Patient-RAR events by total orders examined.

Numerator Statement: Wrong-Patient RAR events during a specified time period.

Denominator Statement: All electronic orders placed during a specified time period.

**Exclusions**: System-generated orders are excluded from the denominator. In some EHR systems, in addition to orders placed by clinicians, some orders are generated automatically by the EHR or other ancillary systems (e.g., the pharmacy system, the lab system, or other "interfaces"). Since these orders are not placed by an ordering clinician, they are not included in the denominator.

Adjustment/Stratification: No risk adjustment or stratification

Level of Analysis: Facility, Integrated Delivery System

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

Type of Measure: Process

Data Source: Electronic Health Data, Electronic Health Records, Other

Measure Steward: NewYork-Presbyterian Hospital

STANDING COMMITTEE MEETING 06/18/2020

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

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

1a. Evidence: H-0; M-14; L-3; I-1; 1b. Performance Gap: H-0; M-17; L-1; I-0 Patienale:

Rationale:

- The developer noted that there are healthcare actions that may reduce the incidence of Wrong-Patient-RAR, such as better system design (e.g., putting a patient's picture in the electronic health record to ensure that the orders are written on the right patient).
- The developer cited studies conducted at different healthcare settings (e.g., NICU, emergency department) showing reductions in wrong-patient order errors by displaying patient identification alerts when clinicians place orders in the electronic health record (EHR).
- The developer cited a 2013 validation study, conducted at Montefiore Medical Center, which found a Wrong-Patient-RAR Rate of 58 wrong-patient orders per 100,000 orders within a single year.
- The developer cited a 2015 study that was conducted at New York-Presbyterian Hospital in which a total of 3,457,342 electronic orders were recorded across five emergency departments and a total of 5,637 Wrong-Patient RAR events were identified; 163 per 100,000 orders (95% Cl 159 167) within a 2.5 year study period (Dec 2010-June 2013).
- The developer showed data from six hospitals and health systems resulting in a range of Wrong-Patient RAR performance between 64-163 events per 100,000 patients.

**2. Scientific Acceptability of Measure Properties:** <u>The measure meets the scientific acceptability criteria</u> (2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity

2a. Reliability: H-11; M-6; L-1; I-0; 2b. Validity: H-4; M-12; L-2; I-0 Rationale:

## 2723 Wrong-Patient Retract-and-Reorder (Wrong-Patient-RAR) Measure

- The measure was tested for reliability in six health care systems. Test-retest and signal-to-noise reliability was assessed, across three different EHRs.
- The developer demonstrated that the data are highly reliable and repeatable, producing the exact same results when assessing the same population in the same time period. In >12 million orders, there were 7,128 Wrong-Patient-RAR events, with an event rate of 58 per 100,000 orders. Across three attempts (i.e. data pulls), the kappa score for inter-rater reliability was 1.0 compared to the first pull.
- The developer calculated a signal-to-noise ratio as a function of the variance <u>between</u> hospitals. Reliability was estimated using a beta-binomial model. In each of the six hospitals tested, the reliability score was 0.99 (near perfect). In addition, measure-level reliability was 0.99.
- One validation involved clinicians who triggered the measure. They were contacted within six to 12 hours of the occurrence to verify the event (in three health systems). The PPV range from 76.2% to 81.2% across published studies.
- Another validation approach involved the developer reporting studies evaluating different interventions aimed at preventing wrong-patient errors using the Wrong-Patient-RAR measure as the primary outcome of the study. Two studies described showed a significant decrease in Wrong-Patient-RAR events when using an intervention aimed at preventing wrong-patient errors. Another study demonstrated the impact on different EHR configurations allowing clinicians to open varying numbers of workspaces at a time.

## 3. Feasibility: H-10; M-7; L-1; I-0

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

- The data used are electronic clinical data (i.e., EHR, imaging/diagnostic study, laboratory, pharmacy, registry) generated or collected by and used by healthcare personnel during the provision of care.
- All data elements are in defined fields in EHRs.

#### 4. Use and Usability

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

## 4a. Use: Pass-14; No Pass-4; 4b. Usability: H-7; M-7; L-2; I-2

Rationale:

- The developer stated the measure is currently <u>not</u> being used within an accountability program. However, at present, no regulatory body oversees or mandates public reporting or benchmarking of health IT safety measures.
- The measure is currently being evaluated for use as part of a "Leapfrog CPOE Evaluation Tool."
- The 21st Century Cures Act has established a new Electronic Health Record Reporting Program, which the measure is being discussed as a possible measure for this program.
- Several citations were provided on recommendations for the use by The Joint Commission, ECRI Institute, and the Office of the National Coordinator.

#### 5. Related and Competing Measures

• No related or competing measures noted.

## 2723 Wrong-Patient Retract-and-Reorder (Wrong-Patient-RAR) Measure

#### 6. Standing Committee Recommendation for Endorsement: Yes-14; No-4

#### 7. Public and Member Comment

• NQF received two comments on measure 2723. One commenter expressed concern on validity and measure rate as a function of number of prescriptions ordered.

#### Measure Steward/Developer Response:

Thank you for your comments. First, we agree that correlation between near-miss errors and errors that reach the patient is of interest. Nevertheless, the use of near-miss errors to test safety improvements in healthcare is endorsed by every major organization dedicated to improving patient safety, including the Agency for Healthcare Research and Quality, Institute of Medicine, World Health Organization, Institute for Healthcare Improvement, and The Joint Commission, because near-miss errors follow the same pathway as errors that cause harm.(1) Near-miss errors are invaluable in quality improvement efforts and patient safety research, as they occur up to 100 times more frequently than errors that reach the patient and thus provide a sufficient number of outcome events to test the effectiveness of safety interventions.1

Second, the RAR rate is not risk adjusted, but can be stratified by location, provider, patient, or order characteristics.

- Aspden P, Corrigan JM, Wolcott J, Erickson SM, eds. Patient Safety: Achieving a New Standard for Care. Washington (DC): National Academies Press (US); 2004. Patient Safety: Achieving a New Standard for Care.
- Another comment on the measure focused on the use of the term "provider" as compared to "clinician" and expanding the single focus of WPRAR to include "reason for order cancellation".

Measure Steward/Developer Response:

Thank you for your comments and suggestions. First, we agree about the importance of understanding the reasons for order cancellations, which we have examined in validation studies of the measure and has been done in other studies of order errors (Adelman 2013, Hickman 2017, Abraham 2018). However, as the first and only fully automated measure of order errors in electronic health record (EHR) systems, the WPRAR measure serves to quantify the rate of wrong-patient orders for accountability, surveillance, and quality improvement activities.

Second, placing orders for the wrong patient occurs frequently and has the potential to cause serious harm. We agree that there are other types of errors that are important to measure, and we are in the process of developing and validating additional measures of medication order errors. These RAR measures use SQL queries that can be readily programmed into the EHR and other electronic data systems, without conducting labor-intensive chart review or relying on voluntary reporting of errors. Automated surveillance, in which electronic information systems are used to identify errors, has the potential to be a significantly more efficient and effective approach for identifying errors. Third, this measure has been used to evaluate the effectiveness of several different interventions aimed at improving patient identification and preventing wrong-patient orders in varied clinical settings, including in the neonatal intensive care unit. Rates have been shown to be sensitive to change in response to intervention and to vary by clinical setting (inpatient vs emergency department vs outpatient). The measure is an indicator of where improvement is needed and, importantly, provides a systematic method of measuring improvement. Finally, we recognize the inconsistent use of "provider" and "clinician". For future submissions, we will use the term "ordering clinician". We thank you again for your comments and suggestions.

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

9. Appeals

#### Submission | Specifications

**Description**: The percentage of individuals 18 years of age and older with one or more initial opioid prescriptions for greater than seven greater than seven cumulative days' supply.

**Numerator Statement**: The number of individuals from the denominator with greater than seven greater than sevencumulative 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 three-day time period when the numerator is assessed.

**Denominator Statement**: 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.

**Exclusions**: Individuals with cancer, sickle cell disease (SCD), 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.

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: Pharmacy Quality Alliance

#### STANDING COMMITTEE MEETING 06/18/2020

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

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

#### 1a. Evidence: H-7; M-13; L-0; I-0; 1b. Performance Gap: H-10; M-10; L-0; I-0

Rationale:

- This is new measure identifies individuals 18 years of age and older with one or more initial opioid prescriptions for greater than seven greater than seven cumulative days' supply at the health plan level of analysis.
- The Standing Committee reviewed the evidence presented by the developer and sought clarification on the use of a 90-day lookback period for defining opioid naïve patients.
- The developer stated that they analyzed various lookback periods and presented the results to a technical expert panel, which determined that the 90-day lookback period was optimal. The Committee agreed with this approach.
- The Committee considered the range of performance for Medicaid, Medicare Advantage, and commercial health plans with means of 23.7%, 43.8%, and 25.1%, respectively.
- Committee members expressed concern with the higher rates found in Medicare. The developer stated that these rates are consistent with what is found in the primary literature.
- The Committee ultimately agreed that the evidence provided supported the measure and there is a gap in care that warrants a national performance measure.

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

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

2a. Reliability: H-13; M-6; L-0; I-0; 2b. Validity: H-0; M-18; L-2; I-0

Rationale:

- The Standing Committee reviewed the results for reliability and validity.
- There was some discussion regarding the limited variability in the commercial population. The developer mentioned that the commercial testing was limited to only three health plans, which is what is driving the limited variation seen.

- Based on the mean reliability scores of 0.939 for Medicare, 0.982 for Medicaid, and 0.935 for commercial, the Committee agreed that the measure is considered reliable.
- The Committee considered that the developer conducted face validity only. The developer reported that a technical expert panel concluded in 100% agreement that the scores obtained from the measure as specified will provide an accurate reflection of quality and that the measure can be used to distinguish good and poor quality between health plans.
- The Committee reviewed other threats to validity, including exclusions and recommended that the developer consider excluding palliative care and certain social determinants in the future.
- While several considerations were noted on the reliability and validity of the measure, the Committee agreed to pass the measure on scientific acceptability.

## 3. Feasibility: H-11; M-7; L-0; I-0

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

- The Standing Committee agreed that the measure uses claims data that can be generated or collected during the provision of care and that there are no fees, licensing, or requirements to use the measure.
- The Committee did express concerns regarding the measure licensing.
- The Committee considered the developer's response that the licensing fee is charged for commercial use, and that government entities are not charged a fee, and ultimately 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: Pass-19; No Pass-0 4b. Usability: H-8; M-10; L-0; I-1

Rationale:

- The Standing Committee acknowledged that this measure is planned for use as part of CMS's Five Star Rating System for Part D.
- The Committee noted that this is a new measure and there is no information available on performance improvement. This measure is not currently used in a program, but a primary goal of the measure is to provide information necessary to implement focused quality improvement efforts. Once the measure is implemented, the developer plans to examine trends in improvements over time.

#### 5. Related and Competing Measures

- This measure is related with the following measures:
  - NQF #2940 Use of Opioids at High Dosage in Persons Without Cancer
  - NQF #2950 Use of Opioids from Multiple Providers in Persons Without Cancer
  - NQF #2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer
  - NQF #3389 Concurrent Use of Opioids and Benzodiazepines (COB)
  - NQF #3541 Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)
- The Committee did not raise any concerns as the measures are harmonized and that there are no competing measures.

#### 6. Standing Committee Recommendation for Endorsement: Yes-18; No-0

7. Public and Member Comment

• NQF received two pre-evaluation comments and seven post-evaluation comments on measure 3558. Three post-evaluation comments were in support of the measure.

Comments received expressed:

 Concerns about the evidence criterion; unintended negative consequences and the definition of "opioid naïve".

#### Measure Steward/Developer Response:

PQA appreciates the FAH's comments regarding the IOP-LD measure. Regarding the use of a 90-day lookback period, "lookback periods" are variably defined in the current literature, with some studies using 60-days and others up to twelve months. Considering Part D opioid naïve edits, CMS recommends that Part D sponsors use a lookback of at least 60 days, with most sponsors using lookback periods between 60 and 120 days (4). PQA tested numerous lookback period options, including: 30, 45, 90, and 120 days and discussed this question extensively with subject matter experts and technical expert panels. Ultimately, the technical expert panel found the 30-day interval to be oversensitive in identifying prescriptions as initial, and there were inherently tradeoffs for between sensitivity and specificity at each of the other lookback periods. Per testing, the overall impact of using different lookback periods were generally minor. As such, the technical expert panel came to consensus that the 90-day lookback period is most appropriate.

PQA appreciates the AMA's comments on the IOP-LD measure. Regarding the evidence to support the 7-day threshold, the 7-day threshold was chosen based on recommendations in the 2016 CDC Guidelines for Prescribing Opioids for Chronic Pain, noting that "When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed [Recommendation category A, evidence type 4].

As the AMA notes, this recommendation is based on expert consensus. This recommendation is also supported by a significant body of research that has emerged since the guideline was released, with strong empirical evidence regarding the extent to which additional days' supply increases risk of long-term opioid use, especially the work by Shah et al in the CDC MMR weekly reports (1), Brat et al (2), Zhang et al (3), among others. For more information, we recommend referring to the measure's evidence attachment.

Regarding the use of a 90-day lookback period, "lookback periods" are variably defined in the current literature, with some studies using 60-days and others up to twelve months. Considering Part D opioid naïve edits, CMS recommends that Part D sponsors use a lookback period of at least 60 days, with most sponsors using lookback periods between 60 and 120 days (4,5). PQA tested numerous lookback period options, including: 30, 45, 90, and 120 days and discussed this question extensively with subject matter experts and technical expert panels. Ultimately, the technical expert panel found the 30-day interval to be oversensitive in identifying prescriptions as initial, and there were inherently tradeoffs for between sensitivity and specificity at each of the other lookback periods. Per testing, the overall impact of using different lookback periods were generally minor. As such, the technical expert panel came to consensus that the 90-day lookback period is most appropriate.

Regarding the measure's use of methadone, methadone identified through prescription claims is accurately differentiated from methadone that is indicated used for medication-assisted treatment of opioid use disorder (OUD), which is restricted to be dispensed only from federally certified opioid treatment programs. As a result, an exclusion for individuals receiving OUD is not required, as the measure only captures methadone prescribed for pain management, and drugs indicated for

medication assisted treatment of OUD (e.g., buprenorphine) are not included in the measure. This approach to inclusion of methadone is consistent with other PQA opioid measures implemented in federal programs, and PQA has not received feedback or evidence of unintended consequences related to methadone inclusion in this manner. As IOP-LD is implemented, PQA will continue to monitor for feedback and will evaluate any appropriate changes through our standardized, transparent, consensus-based maintenance process.

Regarding the AMA's concerns about this measure's use and potential for unintended consequences, PQA would like to emphasize that as a retrospective population-level measure, the measure is not intended to serve as a guide for individual patient care decisions. Although a lower rate indicates better performance, the rate is not expected to be zero, and there are rare situations in which providers may choose to initially prescribe for a greater days' supply for individual patients due to patient individualization considerations. This performance measure is not intended to preclude such situations, but is intended to give a population-level metric for quality, and to establish benchmarks and identify opportunities to decrease initial opioid prescriptions for long duration that may place patients at increased risk for long-term opioid use, misuse, overdose, and other negative outcomes.

1) Shah A, Hayes CJ, Martin BC. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015. MMWR Morb Mortal Wkly Rep 2017;66:265–269. DOI: http://dx.doi.org/10.15585/mmwr.mm6610a1external icon.

2) Brat GA, Agniel D, Beam A, et al. Postsurgical prescriptions for opioid naive patients and association with overdose and misuse: retrospective cohort study. BMJ. 2018;360:j5790. Published 2018 Jan 17. doi:10.1136/bmj.j5790

3) Zhang Y, Johnson P, Jeng PJ, et al. First Opioid Prescription and Subsequent High-Risk Opioid Use: a National Study of Privately Insured and Medicare Advantage Adults. J Gen Intern Med. 2018;33(12):2156-2162. doi:10.1007/s11606-018-4628-y

4) Centers for Medicare and Medicaid Services. Contract Year (CY) 2020 Opioid Safety Edit Reminders and Recommendations. Available from https://www.cms.gov/files/document/cy-2020opioid-safety-edits-reminders-and-recommendations.pdf.

5) Centers for Medicare and Medicaid Services. Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available from https://www.cms.gov/MEDICARE/HEALTH-PLANS/MEDICAREADVTGSPECRATESTATS/DOWNLOADS/ANNOUNCEMENT2019.PDF.

• Concerns about the inclusion of methadone.

Measure Steward/Developer Response:

PQA appreciates ASHP's support of the IOP-LD measure and thoughtfulness on the inclusion of methadone. As ASHP notes, methadone identified through prescription claims can accurately differentiate methadone that is indicated used for medication-assisted treatment of opioid use disorder (OUD), which is restricted to be dispensed only from federally certified opioid treatment programs. This approach to inclusion of methadone is consistent with other PQA opioid measures implemented in several federal programs, and PQA has not received feedback or evidence of unintended consequences related to methadone inclusion in this manner. As IOP-LD is implemented, PQA will continue to monitor for feedback and will evaluate any appropriate changes through our standardized, transparent, consensus-based maintenance process.

• Support with concerns about inclusion of long-term care (LTC) settings.

Measure Steward/Developer Response:

PQA appreciates ASCP's support and feedback on the IOP-LD measure regarding a potential exclusion for individuals in long-term care. PQA considers changes to PQA-endorsed measures through a standardized, transparent, consensus-based process involving several multi-stakeholder panels composed of clinical and measurement science experts. The PQA team is currently evaluating the appropriateness and feasibility of adding an exclusion for individuals in long-term care and will consider this potential change through our standardized and robust maintenance process.

• Support with concern for potential abuse.

#### Measure Steward/Developer Response:

PQA appreciates Magellan's support and feedback on the IOP-LD measure regarding interpretation of multiple opioid claims that occur on the same day. The IOP-LD measure's methodology in this case is aligned with other PQA opioid measures and accounts for the fact that multiple opioids may be prescribed to be taken concurrently. In such cases, adding days' supply of multiple opioid claims received on the same day may overestimate the true days' supply. However, the PQA team will take this under advisement for future consideration. PQA considers changes to PQA-endorsed measures through a standardized, transparent, consensus-based process involving several multistakeholder panels composed of clinical and measurement science experts.

Concerns about the appropriateness of the measure and evidence criterion being met.

#### Measure Steward/Developer Response:

PQA appreciates the AGS' feedback on the IOP-LD measure. PQA considers changes to PQA-endorsed measures through a standardized, transparent, consensus-based process involving several multistakeholder panels composed of clinical and measurement science experts. As additional exclusions are identified to be potentially appropriate, they will be considered through this robust process.

The 7-day threshold was chosen based recommendations in the 2016 CDC Guidelines for Prescribing Opioids for Chronic Pain, noting that "When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed [Recommendation category A, evidence type 4]. This recommendation has been supported by a significant body of research that has emerged since the guideline was released, with strong empirical evidence regarding the extent to which additional days' supply increases risk of long-term opioid use, especially the work by Shah in the CDC MMR weekly reports (1), Brat (2), Zhang (3), among others. For more information, we recommend referring to the measure's evidence attachment.

Finally, we note that literature such as Zhang et al demonstrate that the risks associated with an initial prescription days' supply exceeding 7-days was present in a Medicare Advantage population, demonstrating that even older Americans face risks associated with initial opioid prescribing at long duration; furthermore, Brat et al demonstrated that these risks are also present in post-surgical patients.

1) Shah A, Hayes CJ, Martin BC. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015. MMWR Morb Mortal Wkly Rep 2017;66:265–269. DOI: http://dx.doi.org/10.15585/mmwr.mm6610a1external icon.

2) Brat GA, Agniel D, Beam A, et al. Postsurgical prescriptions for opioid naive patients and association with overdose and misuse: retrospective cohort study. BMJ. 2018;360:j5790. Published 2018 Jan 17. doi:10.1136/bmj.j5790

3) Zhang Y, Johnson P, Jeng PJ, et al. First Opioid Prescription and Subsequent High-Risk Opioid Use: a National Study of Privately Insured and Medicare Advantage Adults. J Gen Intern Med. 2018;33(12):2156-2162. doi:10.1007/s11606-018-4628-y

• Inquiry on future CMS implementations of related health plan patient safety edits and opioid management templates.

#### Measure Steward/Developer Response:

PQA appreciates Humana's comment in support of the IOP-LD measure. Although the IOP-LD measure is included in the CMS Part D Patient Safety Reports program, the PQA team is not able to provide insight on future CMS implementations of related health plan patient safety edits and opioid management templates. PQA recommends that Humana bring this question to CMS for further clarification.

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

9. Appeals

NQF#	Title	Federal Programs: Finalized or Implemented
0022	Use of High-Risk Medications in the Elderly (DAE)	Merit-Based Incentive Payment System (MIPS) Program (Implemented)
0097	Medication Reconciliation Post-Discharge	Medicare Part C Star Rating (Implemented) Physician Compare (Implemented) MIPS Program (Implemented)
0101	Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls	Medicare Shared Savings Program (MSSP) (Implemented) MIPS Program (Implemented)
0138	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	Hospital Acquired Condition Reduction Program (HACRP) (Implemented) Hospital Compare (HC) (Implemented) Hospital Inpatient Quality Reporting (Implemented) Inpatient Rehabilitation Facility (IRF) Quality Reporting (Implemented) Long-Term Care Hospital (LTCH) Quality Reporting (Implemented)
0139	National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure	<ul> <li>HACRP (Implemented)</li> <li>HC (Implemented)</li> <li>Hospital IQR (Implemented)</li> <li>LTCH Quality Reporting (Implemented)</li> <li>Long-Term Care Hospital (LTCH)</li> <li>Compare (Implemented)</li> </ul>
0141	Patient Fall Rate	None
0202	Falls with injury	None
0204	Skill mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], unlicensed assistive personnel [UAP], and contract)	None
0205	Nursing Hours per Patient Day	None
0206	Practice Environment Scale - Nursing Work Index (PES-NWI) (composite and five subscales)	None

# Appendix B: Patient Safety Portfolio—Use in Federal Programs<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> Per CMS Measures Inventory Tool as of 02/25/2020

NQF#	Title	Federal Programs: Finalized or Implemented
0231	Pneumonia Mortality Rate (IQI #20)	None
0337	Pressure Ulcer Rate (PDI 2)	None
0344	Accidental Puncture or Laceration Rate (PDI #1)	None
0345	Unrecognized Abdominopelvic Accidental Puncture or Laceration Rate (PSI15)	HC (Implemented)
0346	latrogenic Pneumothorax Rate (PSI 6)	None
0347	Death Rate in Low-Mortality Diagnosis Related Groups (PSI02)	None
0348	latrogenic Pneumothorax Rate (PDI 5)	None
0349	Transfusion Reaction Count (PSI 16)	None
0350	Transfusion Reaction Count (PDI 13)	None
0352	Failure to Rescue In-Hospital Mortality (risk adjusted)	None
0353	Failure to Rescue 30-Day Mortality (risk adjusted)	None
0362	Retained Surgical Item or Unretrieved Device Fragment Count (PDI 03)	None
0363	Retained Surgical Item or Unretrieved Device Fragment Count (PSI 05)	None
0419	Documentation of Current Medications in the Medical Record	MIPS Program (Implemented)
0419e	Documentation of Current Medications in the Medical Record	MIPS Program (Implemented) Medicaid Promoting Interoperability Program for Eligible Professionals (Implemented)
0450	Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate (PSI 12)	HC (Implemented)
0468	Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following pneumonia hospitalization	None
0500	Severe Sepsis and Septic Shock: Management Bundle	HC (Implemented) Hospital IQR (Implemented)
0530	Mortality for Selected Conditions	None
0531	Patient Safety and Adverse Events Composite	HC (Implemented)
0553	Care for Older Adults (COA) – Medication Review	Medicare Part C Star Rating (Implemented)
0555	INR Monitoring for Individuals on Warfarin	None

NQF#	Title	Federal Programs: Finalized or Implemented
0674	Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)	Home Health Compare (Implemented) Nursing Home Compare (Implemented) Nursing Home Quality Initiative (NHQI) (Implemented)
0679	Percent of High Risk Residents with Pressure Ulcers (Long Stay)	NHQI (Implemented)
0684	Percent of Residents with a Urinary Tract Infection (Long-Stay)	Nursing Home Compare (Implemented) NHQI (Implemented)
0686	Percent of Residents Who Have/Had a Catheter Inserted and Left in Their Bladder (long stay)	Nursing Home Compare (Implemented) NHQI (Implemented)
0687	Percent of Residents Who Were Physically Restrained (Long Stay)	Nursing Home Compare (Implemented) NHQI (Implemented)
0689	Percent of Residents Who Lose Too Much Weight (Long-Stay)	Nursing Home Compare (Implemented) NHQI (Implemented)
0753	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	HC (Implemented) Hospital Value-Based Purchasing (VBP) (Implemented)
1716	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure	HACRP (Implemented) HC(Implemented) Hospital IQR (Implemented) Hospital (VBP) (Implemented) Prospective Payment System (PPS)- Exempt Cancer Hospital Quality Reporting (Implemented) Inpatient Rehabilitation Facility Compare (Implemented) Long-Term Care Hospital (LTCH) Compare (Implemented)
1717	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure	HACRP (Implemented) HC (Implemented) Hospital IQR (Implemented) Hospital (VBP) (Implemented) IRF Quality Reporting (Implemented) LTCH Quality Reporting (Implemented) PPS-Exempt Cancer Hospital Quality Reporting (Implemented) Inpatient Rehabilitation Facility Compare (Implemented)

NQF#	Title	Federal Programs: Finalized or Implemented
		LTCH Compare (Implemented)
1893	Hospital 30-Day, all-cause, risk-standardized mortality rate (RSMR) following chronic obstructive pulmonary disease (COPD) hospitalization	HC (Implemented) Hospital IQR (Implemented) Hospital (VBP) (Finalized)
2065	Gastrointestinal Hemorrhage Mortality Rate (IQI #18)	None
2456	Medication Reconciliation: Number of Unintentional Medication Discrepancies per Patient	None
2720	National Healthcare Safety Network (NHSN) Antimicrobial Use Measure	None
2723	Wrong-Patient Retract-and-Reorder (Wrong Patient-RAR) Measure	None
2726	Prevention of Central Venous Catheter (CVC)-Related Bloodstream Infections	MIPS Program (Implemented)
2732e	INR Monitoring for Individuals on Warfarin after Hospital Discharge	None
2820	Pediatric Computed Tomography (CT) Radiation Dose	None
2909	Perioperative Hemorrhage or Hematoma Rate (PSI 09)	None
2940	Use of Opioids at High Dosage in Persons Without Cancer	Medicaid (Implemented)
2950	Use of Opioids from Multiple Providers in Persons Without Cancer	None
2951	Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer	None
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities	End-Stage Renal Disease Quality Incentive Program (Finalized)
2993	Potentially Harmful Drug-Disease Interactions in the Elderly	None
3000	PACE-Acquired Pressure Ulcer/Injury Prevalence Rate	None
3001	PACE Participant Fall Rate	None
3003	PACE Participant Falls With Injury Rate	None
3025	Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome Measure	None

NQF#	Title	Federal Programs: Finalized or Implemented
3136	GAPPS: Rate of preventable adverse events per 1,000 patient-days among pediatric inpatients	None
3215	Adult Inpatient Risk Adjusted Sepsis Mortality	None

# **Appendix C: Patient Safety Standing Committee and NQF Staff**

## STANDING COMMITTEE

## Ed Septimus, MD (Co-Chair)

Professor of Internal Medicine Texas A&M Health Science Center College of Medicine, Houston, Texas, and Senior Lecturer Department of Population Medicine, Harvard Medical School Boston, MA

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## Theresa Edelstein, MPH, LNHA

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## **Appendix D: Measure Specifications**

## 2723 Wrong-Patient Retract-and-Reorder (Wrong Patient-RAR) Measure

#### STEWARD

NewYork-Presbyterian Hospital

#### DESCRIPTION

A Wrong-Patient-RAR event occurs when an order is placed on a patient within an EHR, is retracted within 10 minutes, and then the same clinician places the same order on a different patient within the next 10 minutes. A Wrong-Patient-RAR rate is calculated by dividing Wrong-Patient-RAR events by total orders examined.

#### ТҮРЕ

Process

#### DATA SOURCE

Electronic Health Data, Electronic Health Records, Other

The data source for the Wrong-Patient RAR measure is a replicate EHR or data warehouse. The *Wrong-Patient-RAR* measure uses an electronic query to retrospectively extract information on all electronic orders placed during a specified time period.

#### LEVEL

Facility, Integrated Delivery System

#### SETTING

Emergency Department and Services, Inpatient/Hospital, Outpatient Services

#### NUMERATOR STATEMENT

Total Wrong-Patient RAR events during a specified time period.

#### NUMERATOR DETAILS

A (Wrong-Patient RAR event occurs when an electronic order, including medications, lab tests, imaging, procedures and general care orders, is placed on a patient, is retracted within 10 minutes by the same provider, and then the same clinician places the same order on a different patient within the next 10 minutes.

Note 1: Definition of a Retracted Order –an order that is discontinued and never acted upon. For EMRs that do not support the "retraction" function, retracted orders can be defined as orders that are "discontinued" or "cancelled," excluding those in which an action has been charted prior to being discontinued or cancelled.

Note 2: Definition of an Ordering Clinician – for this measure, the ordering clinician is the person who enters the order into the computer. Example 1: if a nurse takes a verbal order from a physician and enters the order into the computer, it is the nurse who may select the wrong patient and is considered the ordering clinician. Example 2: if a medical student enters an order

for a patient that is co-signed by a supervising resident, it is the medical student who may select the wrong patient and is considered the ordering clinician.

Note 3: A "retract-and-reorder" event only qualifies for this measure if it is the very next order entry activity by that clinician after he/she retracts the initial order. In other words, if a clinician places an order for patient A, retracts it within 10 minutes, and before reordering it for patient B, he or she places one or more orders for patient C, this would not qualify as a retract-and-reorder event.

#### DENOMINATOR STATEMENT

All electronic orders placed during a specified time period.

#### DENOMINATOR DETAILS

All electronic orders, including medications, lab tests, imaging, procedures and general care orders placed by ordering clinicians during a specified time period.

#### EXCLUSIONS

System-generated orders are excluded from the denominator. In some EHR systems, in addition to orders placed by clinicians, some orders are generated automatically by the EHR or other ancillary systems (e.g., the pharmacy system, the lab system, or other "interfaces"). Since these orders are not placed by an ordering clinician, they are not included in the denominator.

#### EXCLUSION DETAILS

None

#### **RISK ADJUSTMENT**

Stratification by risk category/subgroup

#### STRATIFICATION

Results may be stratified by provider type (e.g. MD, RN, PA, pharmacist, etc.), patient type (e.g. age group, gender, race, ethnicity, etc.), order type (e.g. medications, lab tests, imaging, etc.), or location (e.g. ED, inpatient, outpatient, etc.).

#### TYPE SCORE

Rate/proportion better quality = lower score

#### ALGORITHM

Measure Logic for Wrong-Patient Retract-and-Reorder (Wrong-Patient-RAR) Events.

#### Numerator

1. Obtain all orders and retraction of orders for a specified time period. For each order and retraction of an order, capture patient and provider demographic characteristics of interest, as well as order information including date and time of order or retraction, and type of order with order details (e.g. Tylenol 325 mg orally three times per day for seven days).

2. Identify the First Order of a potential Wrong-Patient-RAR event (orders that are retracted within 10 minutes of being placed by the same clinician).

3. Identify the Second Order of a potential Wrong-Patient-RAR event. Get the next nonretracted order that was placed within 10 minutes of the above, the similar retracted order by the same clinician on a different patient. The order should be the same general order, but the underlying details do not need to be an exact match (e.g. dose can change as computer may adjust dose based on patient weight).

4. Any order that meets the above criteria is a Wrong-Patient-RAR event. Each RAR event involves a single ordering clinician and two different patients.

#### Denominator

1. Obtain all orders examined in the specified time period. For each order, capture patient and provider demographic characteristics of interest, as well as order information including date and time of order and type of order with order details.

Rate Calculation (per 100,000 orders)

1. For a specified time period, the Wrong-Patient-RAR Rate is calculated as tota Wrong-Patient RAR Events divided by total orders multiplied by 100,000.

(Total Wrong-Patient RAR Events/Total Orders) ? 100,000

2. The Wrong-Patient RAR Rate can be stratified by subgroups of interest. 123738 150991 | 147926 | 141015 | 150289

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None

#### 3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

#### STEWARD

Pharmacy Quality Alliance

#### DESCRIPTION

The percentage of individuals 18 years of age and older with one or more initial opioid prescriptions for greater than sevengreater than seven cumulative days' supply.

#### түре

Process

#### DATA SOURCE

Claims, Enrollment Data Administrative claims: prescription claims, medical claims, Prescription Drug Hierarchical Condition Categories (RxHCCs); enrollment data

## LEVEL

Health Plan

#### SETTING

**Outpatient Services** 

#### NUMERATOR STATEMENT

The number of individuals from the denominator with greater than seven greater than sevencumulative 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 three-day time period when the numerator is assessed.

#### NUMERATOR DETAILS

The number of individuals from the denominator with greater than sevengreater than seven 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.

Step 3: Count the unique individuals with greater than sevengreater than seven cumulative days' supply for all opioid prescription claims during any opioid initiation period in the measurement year.

#### DENOMINATOR STATEMENT

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

The denominator includes individuals aged18 years or older as of the first day of the measurement year with at least one prescription claim for an opioid medication and continuous enrollment during that time 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**

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**

Hospice exclusion: Exclude any individuals in hospice during the measurement year or 90 days prior to the first day of the measurement year. Use the following 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)

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 Pharmayc Quality Alliance 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).

Exclude any individuals having one or more claims with sickle cell disease 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**

No risk adjustment or risk stratification

#### STRATIFICATION

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 government to the drug plan for Medicae 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 variable 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

Rate/proportion better quality = lower score

## ALGORITHM

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:

• Individuals in hospice during the measurement year or 90 days prior to the first day of the measurement year. Identify individuals in hospice using:

o Hospice indicator from the enrollment database, if available (e.g. Medicare); or

o 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)

• 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:

o 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.

o 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).

• Identify individuals having one or more claims with 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.

Step 9: Count the unique individuals with greater than seven greater than seven 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 LIS and non-LIS populations separately. 135614

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## **Appendix E: Related and Competing Measures**

## Comparison of NQF #3558 and NQF #2940

#3558 Initial Opioid Prescribing for Long Duration (IOP-LD) #2940 Use of Opioids at High Dosage in Persons Without Cancer

#### Steward

#### #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Pharmacy Quality Alliance

## **#2940** Use of Opioids at High Dosage in Persons Without Cancer

Pharmacy Quality Alliance

## Description

#### 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 greater than seven cumulative days' supply.

## 2940: Use of Opioids at High Dosage in Persons Without Cancer

The percentage of individuals greater than or equal to 18 years of age who received prescriptions for opioids with an average daily dosage of greater than or equal to 90 morphine milligram equivalents (MME) over a period of greater than or equal to 90 days. A lower rate indicates better performance.

## Туре

#### 3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

Process

## 2940: Use of Opioids at High Dosage in Persons Without Cancer

Process

#### Data Source

#### #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

## #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

#### #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Health Plan

#### #2940 Use of Opioids at High Dosage in Persons Without Cancer

Health Plan, Other, Population : Regional and State

#### Setting

## #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

**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

#### **#3558 Initial Opioid Prescribing for Long Duration (IOP-LD)**

The number of individuals from the denominator with greater than seven 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.

#### #2940 Use of Opioids at High Dosage in Persons Without Cancer

The numerator includes individuals from the denominator with an average daily dosage greater than or equal to 90 MME during the opioid episode.

#### Numerator Details

#### #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

The number of individuals from the denominator with greater than seven 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.

Step 3: Count the unique individuals with greater than seven cumulative days' supply for all opioid prescription claims during any opioid initiation period in 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 greater than or equal to 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

 $25 \mu g/hr$  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 greater than or equal to 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**

#### #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.

#### #2940 Use of Opioids at High Dosage in Persons Without Cancer

Individuals 18 years and older with greater than or equal to two prescription claims for opioid medications on different dates of service and with a cumulative days' supply greater than or equal to 15 during the measurement year. Individuals with cancer or in hospice are excluded.

#### **Denominator Details**

#### #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.

# NATIONAL QUALITY FORUM

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.)

#### #2940 Use of Opioids at High Dosage in Persons Without Cancer

Individuals 18 years and older with greater than or equal to two prescription claims for opioid medications on different dates of service and with a cumulative days' supply greater than or equal to 15 during the measurement year. Individuals with cancer or in hospice are excluded.

1. Identify individuals aged greater than or equal to 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 two months [60 days] is not considered continuously enrolled).

3. Identify individuals with greater than or equal to two prescription claims for opioid medications on different dates of service and with a cumulative days' supply greater than or equal to 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 greater than or equal to 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**

## #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.

## #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**

## #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Exclude any individuals in hospice during the measurement year or 90 days prior to the first day of the measurement yea, using the following to identify them:

•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)

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).

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.

#### #2940 Use of Opioids at High Dosage in Persons Without Cancer

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

## #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

No risk adjustment or risk stratification

#### #2940 Use of Opioids at High Dosage in Persons Without Cancer

No risk adjustment or risk stratification

## Stratification

#### #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.

#### #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

#### #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Rate/proportion better quality = lower score

#### #2940 Use of Opioids at High Dosage in Persons Without Cancer

Rate/proportion better quality = lower score

## Algorithm

#### #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:

• Individuals in hospice during the measurement year or 90 days prior to the first day of the measurement year. Identify individuals in hospice using:

- o Hospice indicator from the enrollment database, if available (e.g. Medicare); or
- o 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)

• 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:

o 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.

o 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).
• 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 + two 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.

Step 9: Count the unique individuals with greater than seven 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 LIS and non-LIS populations separately.

#### #2940 Use of Opioids at High Dosage in Persons Without Cancer

DENOMINATOR

1. Identify individuals aged greater than or equal to 18 years as of the first day of the measurement year.

2. Identify individuals meeting the continuous enrollment criteria.

3. Identify individuals with greater than or equal to two prescription claims for opioid medications on different dates of service and with a cumulative days' supply greater than or equal to 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 greater than or equal to 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

 $25 \mu g/hr$  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 greater than or equal to 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

# #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 (#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).

#### #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 #3558 and NQF #2950

#3558 Initial Opioid Prescribing for Long Duration (IOP-LD) #2950 Use of Opioids from Multiple Providers in Persons Without Cancer

#### Steward

#### #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Pharmacy Quality Alliance

#### #2950 Use of Opioids from Multiple Providers in Persons Without Cancer

Pharmacy Quality Alliance

#### Description

#### #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 greater than seven cumulative days' supply.

### #2950 Use of Opioids from Multiple Providers in Persons Without Cancer

The percentage of individuals greater than or equal to 18 years of age who received prescriptions for opioids from greater than or equal to four prescribers AND greater than or equal to four pharmacies within less than or equal to 180 days.

A lower rate indicates better performance.

# Туре

#### #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Process

#### #2950 Use of Opioids from Multiple Providers in Persons Without Cancer

Process

### Data Source

### #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

### #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

# #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Health Plan

# #2950 Use of Opioids from Multiple Providers in Persons Without Cancer

Health Plan, Other, Population : Regional and State

# Setting

### #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

**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

### #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

The number of individuals from the denominator with greater than seven 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 three-day time period when the numerator is assessed.

#### #2950: Use of Opioids from Multiple Providers in Persons Without Cancer

Individuals from the denominator with opioid prescription claims from greater than or equal to four prescribers AND greater than or equal to four pharmacies within less than or equal to 180 days during the opioid episode.

# Numerator Details

# #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

The number of individuals from the denominator with greater than seven 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.

Step 3: Count the unique individuals with greater than seven cumulative days' supply for all opioid prescription claims during any opioid initiation period in the measurement year.

#### #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 greater than or equal to 1 opioid prescription claims represents the beginning of a numerator evaluation period of less than or equal to 180 days during the opioid episode.

2. For each individual, starting with each unique date of service (for greater than or equal to 1 opioid prescriptions), identify the number of unique prescribers by NPI occurring within less than or equal to 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 greater than or equal to one opioid prescriptions), identify the number of unique pharmacies by NPI occurring within less than or equal to 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 greater than or equal to four prescribers AND greater than or equal to four pharmacies during the opioid episode.

Table Opioid-A: Opioid Medications butorphanol codeine dihydrocodeine fentanyl hydrocodone hydromorphone levorphanol meperidine methadone morphine opium oxycodone oxymorphone pentazocine

NATIONAL QUALITY FORUM NQF REVIEW DRAFT

#### 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**

#### #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.

#### #2950 Use of Opioids from Multiple Providers in Persons Without Cancer

Individuals 18 years and older with greater than or equal to two prescription claims for opioid medications on different dates of service and with a cumulative days' supply greater than or equal to 15 during the measurement year. Individuals with cancer or in hospice are excluded.

### **Denominator Details**

#### #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.)

# #2950 Use of Opioids from Multiple Providers in Persons Without Cancer

1. Identify individuals aged greater than or equal to 18 years as of the first day of the measurement year.

2. Identify individuals meeting the continuous enrollment criteria.

3. Identify individuals with greater than or equal to 2 prescription claims for opioid medications on different dates of service and with a cumulative days' supply greater than or equal to 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 greater than or equal to 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**

### #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.

#### #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**

# #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Exclude any individuals in hospice during the measurement year or 90 days prior to the first day of the measurement year, using the following to identify them:

•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)

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).

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.

### #2950 Use of Opioids from Multiple Providers in Persons Without Cancer

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). 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

### #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

No risk adjustment or risk stratification

#### #2950 Use of Opioids from Multiple Providers in Persons Without Cancer

No risk adjustment or risk stratification

# **Stratification**

#### #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.

#### #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

### #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Rate/proportion better quality = lower score

# #2950 Use of Opioids from Multiple Providers in Persons Without Cancer

Rate/proportion better quality = lower score

# Algorithm

# #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:

• Individuals in hospice during the measurement year or 90 days prior to the first day of the measurement year. Identify individuals in hospice using:

- o Hospice indicator from the enrollment database, if available (e.g. Medicare); or
- o 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)

• 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:

o 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.

o 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).

• 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 + two 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.

Step 9: Count the unique individuals with greater than seven 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.

#### #2950 Use of Opioids from Multiple Providers in Persons Without Cancer

DENOMINATOR

- 1. Identify individuals aged greater than or equal to 18 years as of the first day of the measurement year.
- 2. Identify individuals meeting the continuous enrollment criteria.

3. Identify individuals with greater than or equal to two prescription claims for opioid medications on different dates of service and with a cumulative days' supply greater than or equal to 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 greater than or equal to 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 greater than or equal to one opioid prescription claims represents the beginning of a numerator evaluation period of less than or equal to 180 days during the opioid episode.

8. For each individual, starting with each unique date of service (for greater than or equal to one opioid prescriptions), identify the number of unique prescribers by NPI occurring within less than or equal to 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 greater than or equal to one opioid prescriptions), identify the number of unique pharmacies by NPI occurring within less than or equal to 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 greater than or equal to four prescribers AND greater than or equal to four 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

### #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 (#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).

#### #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 #3558 and NQF #2951

#3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

#2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

# Steward

# #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Pharmacy Quality Alliance

# #2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Pharmacy Quality Alliance

# Description

# #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 greater than seven cumulative days' supply.

#### #2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

The percentage of individuals greater than or equal to 18 years of age who received prescriptions for opioids with an average daily dosage of greater than or equal to 90 morphine milligram equivalents (MME) AND who received prescriptions for opioids from greater than or equal to four prescribers AND greater than or equal to four pharmacies.

A lower rate indicates better performance.

### Туре

#### #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Process

#### #2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Process

### Data Source

#### #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

#### #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

#### #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

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

#### #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

**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

# #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

The number of individuals from the denominator with greater than seven 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 three-day time period when the numerator is assessed.

# #2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Individuals from the denominator with an average daily dosage greater than or equal to 90 MME during the opioid episode AND with opioid prescription claims from greater than or equal to four prescribers AND greater than or equal to four pharmacies within less than or equal to 180 days during the opioid episode.

# Numerator Details

# #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

The number of individuals from the denominator with greater than seven 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.

Step 3: Count the unique individuals with greater than seven cumulative days' supply for all opioid prescription claims during any opioid initiation period in the measurement year.

# #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

 $25 \,\mu$ g/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 greater than or equal to 90.00 MME during the opioid episode.

7. For each individual identified in step 6, starting with each unique date of service (for greater than or equal to 1 opioid prescriptions) within the opioid episode, identify the number of unique prescribers by NPI occurring within less than or equal to 180 days or through the end of the opioid episode, whichever is shorter.

Each date of service for greater than or equal to 1 opioid prescription claims represents the beginning of a numerator evaluation period of less than or equal to 180 days during the opioid episode.

8. For each individual in step 7, starting with each unique date of service (for greater than or equal to one opioid prescriptions) within the opioid episode, identify the number of unique pharmacies by NPI occurring within less than or equal to 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 greater than or equal to four prescribers AND greater than or equal to four 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**

### #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.

#### #2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Individuals 18 years and older with greater than or equal to two prescription claims for opioid medications on different dates of service and with a cumulative days' supply greater than or equal to 15 during the measurement year. Individuals with cancer or in hospice are excluded.

# **Denominator Details**

# #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.)

# #2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Individuals 18 years and older with greater than or equal to two prescription claims for opioid medications on different dates of service and with a cumulative days' supply greater than or equal to 15 during the measurement year. Individuals with cancer or in hospice are excluded.

1. Identify individuals aged greater than or equal to 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 one-month gap in coverage (i.e., an individual whose coverage lapses for twomonths [60 days] is not considered continuously enrolled).

3. Identify individuals with greater than or equal to two prescription claims for opioid medications on different dates of service and with a cumulative days' supply greater than or equal to 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 greater than or equal to 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

NATIONAL QUALITY FORUM NQF REVIEW DRAFT

#### 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**

### #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.

### #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**

# #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Exclude any individuals in hospice during the measurement year or 90 days prior to the first day of the measurement year, using the following to identify them:

•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)

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).

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.

#### #2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

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). 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

### #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

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

#### #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.

#### #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

#### #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

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

#### #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:

• Individuals in hospice during the measurement year or 90 days prior to the first day of the measurement year. Identify individuals in hospice using:

- o Hospice indicator from the enrollment database, if available (e.g. Medicare); or
- o 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)

• 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:

o 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.

o 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).

• 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 + two 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.

Step 9: Count the unique individuals with greater than seven 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.

# 2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

DENOMINATOR

- 1. Identify individuals aged greater than or equal to 18 years as of the first day of the measurement year.
- 2. Identify individuals meeting the continuous enrollment criteria.

3. Identify individuals with greater than or equal to two prescription claims for opioid medications on different dates of service and with a cumulative days' supply greater than or equal to 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 greater than or equal to 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 greater than or equal to 90.00 MME during the opioid episode.

13. For each individual identified in step 12, starting with each unique date of service (for greater than or equal to one opioid prescriptions) within the opioid episode, identify the number of unique prescribers by NPI occurring within less than or equal to 180 days or through the end of the opioid episode, whichever is shorter.

Each date of service for greater than or equal to 1 opioid prescription claims represents the beginning of a numerator evaluation period of less than or equal to 180 days during the opioid episode.

14. For each individual in step 13, starting with each unique date of service (for greater than or equal to one opioid prescriptions) within the opioid episode, identify the number of unique pharmacies by NPI occurring within less than or equal to180 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 greater than or equal to four prescribers AND greater than or equal to four 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

### #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 (#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 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).

#### #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 #3558 and NQF #3389

#3558 Initial Opioid Prescribing for Long Duration (IOP-LD) #3389 Concurrent Use of Opioids and Benzodiazepines (COB)

# Steward

# #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Pharmacy Quality Alliance

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

PQA, Inc.

# Description

# #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 greater than seven cumulative days' supply.

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

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

A lower rate indicates better performance.

# Туре

#3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Process

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

Process

### Data Source

#### #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

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

Claims Administrative claims: prescription claims, medical claims, Prescription Drug Hierarchical Condition Categories (RxHCCs) No data collection instrument provided Attachment PQA\_ICD\_Code\_Cancer\_Value\_Set\_Feb\_2018.xlsx

#### Level

#3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Health Plan

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

Health Plan

# Setting

#3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

**Outpatient Services** 

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

Other

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

#### #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

The number of individuals from the denominator with greater than seven 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 three-day time period when the numerator is assessed.
## #3389 Concurrent Use of Opioids and Benzodiazepines (COB)

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

## Numerator Details

## #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

The number of individuals from the denominator with greater than seven 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.

Step 3: Count the unique individuals with greater than seven cumulative days' supply for all opioid prescription claims during any opioid initiation period in the measurement year.

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

The number of individuals from the denominator with:

- Two or more prescription claims for any benzodiazepine with unique dates of service, AND
- Concurrent use of opioids and benzodiazepines for 30 or more 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 two or more prescriptions claims on unique dates of service for any benzodiazepine (Table COB-B, below) during the measurement year.

Step 2: Of the population identified in Step 1, determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescriptions during the measurement year.

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

Step 3: Count the number of individuals with concurrent use of opioids and benzodiazepines for 30 or more cumulative days. This is the numerator.

Note: When identifying days' supply for opioids (or benzodiazepines), do the following:

- Exclude any days' supply that occur after the end of the measurement year.
- If multiple prescription claims for opioids (or benzodiazepines) are dispensed on the same day, calculate the number of days covered by an opioid using the prescriptions with the longest days' supply.

Table COB-B: Benzodiazepines:

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

(note: excludes injectable formulations)

## **Denominator Statement**

## #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.

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

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

## **Denominator Details**

## #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.)

## #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 two or more prescription claims for opioids with unique dates of service, for which the sum of the days' supply is 15 or more days. 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 aged 18 years and older as of the first day of the measurement year

Step 2: Of those identified in step 1, 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 one-month gap in coverage (i.e., an individual whose coverage lapses for two months [60 days] is not considered continuously enrolled).

Step 3: Of those identified in step 2, identify individuals with 2 or more prescription claims for opioids on unique dates of service, for which the sum of the days' supply is 15 or more days' supply during the measurement year.

Step 4: Of those identified in step 3, identify individuals where the earliest prescription for an opioid (i.e. Index Prescription Start Date [IPSD]) is 30 or more days from the last day of the measurement year (January 1 through December 2)

Note: When identifying days' supply for opioids, do the following,

- Exclude any days' supply that occur after the end of the measurement year.
- : If multiple prescription claims 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.

Table COB-A: Opioids:

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

(note: excludes injectable formulations; includes prescription opioid cough medications; excludes single-agent and combination buprenorphine products used to treat opioid use disorder (i.e., buprenorphine sublingual tablets, Probuphine<sup>®</sup> Implant kit subcutaneous implant, and all buprenorphine/naloxone combination products).

## Exclusions

## #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.

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

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

## **Exclusion Details**

## #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Exclude any individuals in hospice during the measurement year or 90 days prior to the first day of the measurement year, using the following to identify them:

•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)

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).

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.

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

Exclude any individual in hospice during the measurement year, using the following to identify them:

- Use the hospice indicator from the enrollment database, where available (e.g. Medicare); or
- Use place of service code 34 where a hospice indicator is not available (e.g. commercial, Medicaid)

Exclude any individuals with cancer during the measurement year. Use the following to identify individuals with cancer:

• Using ICD codes, refer to those listed in the file titled, PQA ICD Code Cancer Value Set Feb 2018 and attached in S.2b. The list is based on the American Medical Association-convened Physician Consortium for Performance Improvement Cancer value set (OID: 2.16.840.1.113883.3.526.3.1010). 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.

• For Medicare Data, if ICD codes are not available, use Prescription Drug Hierarchical Condition Categories (RxHCCs) 15, 16, 17, 18, 19 for Payment Year 2016 or 2017 to identify cancer exclusions. RxHCCs are available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors.html

## Risk Adjustment

## #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

No risk adjustment or risk stratification

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

No risk adjustment or risk stratification

## Stratification

## #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 ffederal 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.

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

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 (LIS) status.

LIS is 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 LIS 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

## #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Rate/proportion better quality = lower score

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

Rate/proportion better quality = lower score

## Algorithm

## #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:

- o Hospice indicator from the enrollment database, if available (e.g. Medicare); or
- o 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:

o 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.

o 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).

• 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 + two 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.

Step 9: Count the unique individuals with greater than seven 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.

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

A. Target population (denominator):

Step 1: Identify individuals aged 18 years and older as of the first day of the measurement year

Step 2: Of those identified in step 1, 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 one-month gap in coverage (i.e., an individual whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).

Step 3: Of those identified in step 2, identify individuals with two or more prescription claims for opioids on unique dates of service, for which the sum of the days' supply is 15 or more days' supply during the measurement year.

Step 4: Of those identified in step 3, identify individuals where the earliest prescription for an opioid (i.e. Index Prescription Start Date [IPSD]) is 30 or more days from the last day of the measurement year (January 1 through December 2)

Note: When identifying days' supply for opioids, do the following:

- Exclude any days' supply that occur after the end of the measurement year.
- If multiple prescription claims 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.

Step 5: Use the following to identify individuals with cancer or 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 where a hospice indicator is not available (e.g. Commercial, Medicaid)

Use the following to identify individuals with cancer:

• Using ICD codes, refer to those listed in the file titled, PQA ICD Code Cancer Value Set Feb 2018 and attached in S.2b. The list is based on the American Medical Association-convened Physician Consortium for Performance Improvement Cancer value set (OID: 2.16.840.1.113883.3.526.3.1010). 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.

• For Medicare Data, if ICD codes are not available, use Prescription Drug Hierarchical Condition Categories (RxHCCs) 15, 16, 17, 18, 19 for Payment Year 2016 or 2017 to identify cancer exclusions. RxHCCs are available at:

https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors.html

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

B. Numerator Population:

Step 7: From the denominator population (from Step 6), identify individuals with two or more prescriptions claims on unique dates of service for any benzodiazepine during the measurement year.

Step 8: Of the population identified in Step 7, determine the total days of overlap (concurrent use) between the opioid and benzodiazepine prescriptions during the measurement year.

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

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

Note: When identifying days' supply for opioids (or benzodiazepines), do the following:

• Exclude any days' supply that occur after the end of the measurement year.

• For multiple prescription claims for opioids (or benzodiazepines) with overlapping days' supply, count each day in the measurement year only once toward the denominator. There is no adjustment for early fills or overlapping days' supply for opioids (or benzodiazepines).

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). For Medicare, report rates for LIS and non-LIS populations separately.

## Submission items

## #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 (#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)

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: The PQA opioid measures (#2940, #2950, and #2951) use the same target population (denominator), and each have different areas of focus (numerator) related to opioid prescribing. The NCQA opioid measures were developed as an adaptation to existing PQA measures. The NCQA opioid measure denominators are similar to the PQA opioid measures, but have a different area of focus than the concurrent use of opioids and benzodiazepines measure.

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).

## Comparison of NQF #3558 and NQF #3541

#3558 Initial Opioid Prescribing for Long Duration (IOP-LD) #3541 Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

## Steward

#3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Pharmacy Quality Alliance

## #3541 Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Pharmacy Quality Alliance

## Description

#### #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 greater than seven cumulative days' supply.

#### #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.

## Туре

#### #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Process

#### #3541 Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Process

## Data Source

#### #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

#### #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

## #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Health Plan

## #3541 Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Health Plan

## Setting

## #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

**Outpatient Services** 

## #3541 Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

**Outpatient Services** 

## Numerator Statement

## #3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

The number of individuals from the denominator with greater than seven cumulative days' supply for all opioid prescription claims within any opioid initiation period.

## NATIONAL QUALITY FORUM NQF REVIEW DRAFT

The opioid initiation period is defined as the date of service of the initial opioid prescription plus two days, i.e., the three-day time period when the numerator is assessed.

## #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

## #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

The number of individuals from the denominator with greater than seven 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 dayyear.

Step 3: Count the unique individuals with greater than seven cumulative days' supply for all opioid prescription claims during any opioid initiation period in the measurement year.

## #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**

## #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.

## #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**

## #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.)

## #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 must fit the following qualifications:

1) 18 years of age and older as of the first day of the measurement year.

2) Cntinuously 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**

## #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.

## #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**

## #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Exclude any individuals in hospice during the measurement year or 90 days prior to the first day of the measurement year, using the following to identify them:

•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)

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).

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.

## #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

## #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

No risk adjustment or risk stratification

## #3541 Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

No risk adjustment or risk stratification

## Stratification

## #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.

## #3541 Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Not applicable.

## Type Score

## #3558 Initial Opioid Prescribing for Long Duration (IOP-LD)

Rate/proportion better quality = lower score

## #3541 Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Rate/proportion better quality = lower score

## Algorithm

## #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:

• Individuals in hospice during the measurement year or 90 days prior to the first day of the measurement year. Identify individuals in hospice using:

o Hospice indicator from the enrollment database, if available (e.g. Medicare); or

o 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)

• 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:

o 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.

o 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).

• 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 + two 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 .

Step 9: Count the unique individuals with greater than seven 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 LIS and non-LIS populations separately.

## #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.

## Submission items

#### #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 (#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 set an adaptation 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).

## #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.

## **Appendix F: Pre-Evaluation Comments**

Comments received as of June 5, 2020.

Торіс	Commenter	Comment
3558: Initial Opioid	The American Medical	The American Medical Association (AMA) strongly opposes the endorsement of NOF #3558: Initial Opioid
Opioid Prescribing for Long Duration (IOP-LD)	Medical Association (AMA)	the endorsement of NQF #3558: Initial Opioid Prescribing for Long Duration (IOP-LD) as we believe that the measure is not aligned with the evidence as specified and there are significant unintended negative consequences that could be experienced with the use of this measure. The AMA believes that all care provided to patients must be individualized and quality measurement should not focus on preventing and/or reducing opioid use. Rather measurement should address the larger clinical issue—how well patients' pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain while also lowering the risk of addiction
		and developing an opioid use disorder (OUD). The ongoing singular focus on the dose and duration of
		opioid prescriptions disregards the important steps that the administration has taken to address
		the national epidemic of opioid-related overdose deaths, which the AMA strongly supports. The final report of the Department of Health and
		Human Services (HHS) Interagency Pain Management Best Practices Task Force, for example, made a
		compelling case for the need to focus on patients experiencing pain as individuals and to develop treatment plans that meet their individual needs and not employ one-
		size-fits-all approaches that assume prescriptions of long duration are indications of overuse (HHS, 2019). Likewise, a Centers for Disease Control
		and Prevention (CDC) publication in the New England Journal of Medicine (Dowell, 2019) expressed concern
		that its opioid prescribing guidelines have been misapplied and wrongly used to discontinue or reduce
		prescriptions for patients with pain with some actions likely to result in patient harm.
		The CDC stated that its guideline should not be used to create hard and fast policy; yet, it is the primary evidence provided to

Торіс	Commenter	Comment
		support this measure for accountability uses.
		Specifically, the AMA does not believe that the evidence
		cited in support of the measure is
		sufficient since the CDC guidelines used the arbitrary seven-
		day threshold as a voluntary recommendation
		rather than a hard threshold. As the AMA warned in 2016,
		the CDC voluntary recommendation was taken
		beyond its context and used by state legislatures, pharmacy chains, pharmacy benefit managers, and health
		plans as authoritative to impose a hard, seven-day cap on opioid analgesic prescriptions and now we see it being
		used to hold a health plan accountable. Sole reliance on one guideline where the authors have explicitly
		voiced concerns with the inappropriate application of the recommendations should be avoided and we
		believe that the evidence subcriterion has not been met.
		The AMA is further concerned that the measure uses a 90-
		day lookback period to define individuals
		who are "opioid naïve." The CDC guideline does not define this population and the multiple studies cited
		throughout the measure submission form use varying timeframes (e.g., 60 days, 12 months). As a result, we
		believe that the use of a 90-day lookback period could drive inappropriate treatment decisions and the lack
		of an agreed upon definition for "opioid naïve" should
		prohibit this committee from determining that the
		measure as specified is evidence-based.
		The AMA also believes that the numerator will incorrectly include those individuals who receive
		methadone for OUD treatment. Currently, the measure specifications consider methadone to be one of the
		opioid medications that should be included but because it
		does not exclude those patients with a diagnosis
		of OUD, anyone who receives one or more prescriptions for methadone for greater than seven days will be
		considered to meet the numerator. We believe that the
		measure must address this error since it will lead to
		misrepresentations of performance and could lead to
		inappropriate treatment decisions in an effort to
		improve performance scores.

Торіс	Commenter	Comment
		Lastly, the AMA is concerned with the usability of the measure and believes that there is significant potential for unintended negative consequences. While this measure is currently focused on health plan performance, there is great risk that it will lead to denials of medication in all instances even when an opioid is appropriately prescribed. Given these significant concerns, the AMA does not support this measure and urges the Standing Committee not to recommend its endorsement. References: Dowell D, Haegerich T, Chou R. No shortcuts to safer opioid prescribing. N Engl J Med. 2019;380:2285–7. https://doi.org/10.1056/NEJMp1904190. U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices InterAgency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Retrieved from U. S. Department of Health and Human Services website: https://www.hhs.gov/ash/advisory- committees/pain/reports/index.html.
3558: Initial Opioid Prescribing for Long Duration (IOP-LD)	The Federation of American Hospitals (FAH)	The Federation of American Hospitals (FAH) appreciates the opportunity to comment on this measure prior to the Standing Committee's evaluation. The FAH recognizes the need to address inappropriate opioid use given the ongoing concerns around this important public health issue, but we believe that measure must be aligned with evidence, provide useful information to accurately represent performance, and allow patients to make informed decisions. The FAH requests that the committee consider whether the definition of "opioid naïve" used in this measure is aligned with current evidence and would not lead to inappropriate treatment decisions in an effort to improve performance scores. Specifically, the Centers for Disease Control and Prevention (CDC) guideline on which this measure is based does not explicitly define "opioid naïve" and the timeframes used in the other studies cited in the evidence form and throughout the submission vary from six months up to

Торіс	Commenter	Comment
		12 months. As a result, it is not clear how the measure developers determined that a 90-day lookback period was the correct definition for "opioid naïve".
		The FAH does not believe that measures used for accountability purposes should include
		specifications on which timeframes are selected in the absence of any consistent evidence and the resulting
		potential unintended negative consequences must be considered. The FAH requests that the committee
		discuss the lack of any evidence to support this lookback period and determine whether the measure as
		specified meets the NQF measure evaluation criteria.

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