Measure Information

This document contains the information submitted by measure developers/stewards, but is organized according to NQF's measure evaluation criteria and process. The item numbers refer to those in the submission form but may be in a slightly different order here. In general, the item numbers also reference the related criteria (e.g., item 1b.1 relates to sub criterion 1b).

Brief Measure Information

NQF #: 3501e
Corresponding Measures:
De.2. **Measure Title:** Hospital Harm – Opioid-Related Adverse Events
Co.1.1. **Measure Steward:** Centers for Medicare & Medicaid Services
De.3. **Brief Description of Measure:** This measure assesses the proportion of inpatient hospital encounters where patients ages 18 years of age or older have been administered an opioid medication, subsequently suffer the harm of an opioid-related adverse event, and are administered an opioid antagonist (naloxone) within 12 hours. This measure excludes opioid antagonist (naloxone) administration occurring in the operating room setting.This electronic clinical quality measure (eCQM) assesses the proportion of inpatient admissions for patients age 18 years and older who suffer the harm of receiving an excess of hospital-administered opioids, defined as receiving a narcotic antagonist (naloxone). In the first 24 hours of the hospitalization, a hospital-administered opioid must be documented prior to receiving naloxone to be considered part of the numerator.
1b.1. **Developer Rationale:** Opioids are often the foundation for sedation and pain relief. However, use of opioids can also lead to serious adverse events, including constipation, over sedation, delirium, and respiratory depression. Opioid-related adverse events have both patient-level and financial implications. Patients who experience this event have been noted to have 55% longer lengths of stay, 47% higher costs, 36% higher risk of 30-day readmission, and 3.4 times higher payments than patients without these adverse events (Kessler et al., 2013).

Most opioid-related adverse events are preventable. Of the adverse drug events reported to the Joint Commission´s Sentinel Event database, 47% were due to a wrong medication dose, 29% to improper monitoring, and 11% to other causes (e.g., medication interactions, drug reactions) (Joint Commission, 2012; Overdyk, 2009). Additionally, in a closed-claims analysis, 97% of adverse events were judged preventable with better monitoring and response (Lee et al., 2015) . Naloxone administration is often used as an indicator of a severe opioid-related adverse event, and implementation of this measure can advance safe use of opioids in hospitals and prevent these serious and potentially lethal adverse drug events.

Naloxone is an opioid reversal agent typically used for severe opioid-related adverse events. Naloxone administration has been used in a number of studies as an indicator of opioid-related adverse events (Nwulu et al., 2013; Eckstrand et al., 2009).

From Part 10 of the 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (Lavonas et al., 2015), the following recommendation is listed for use of Naloxone:

Naloxone is a potent opioid receptor antagonist in the brain, spinal cord, and gastrointestinal system. Naloxone has an excellent safety profile and can rapidly reverse central nervous system (CNS) and respiratory depression in a patient with an opioid-associated resuscitative emergency.

References:

Eckstrand, J. A., Habib, A. S., Williamson, A., Horvath, M. M., Gattis, K. G., Cozart, H., & Ferranti, J. Computerized surveillance of opioid-related adverse drug events in perioperative care: a cross-sectional study. Patient Saf Surg. 2009;3(1), 18.

Kessler ER, Shah M, Gruschkus SK, Raju A. Cost and quality implications of opioid-based postsurgical pain control using administrative claims data from a large health system: opioid-related adverse events and their impact on clinical and economic outcomes. Pharmacotherapy. 2013;33(4):383-391.

Lavonas EJ, Drennan IR, Gabrielli A, Heffner AC, Hoyte CO, Orkin AM, Sawyer KN, Donnino MW. Part 10: Special Circumstances of Resuscitation: 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation. 2015 Nov 3;132(18 Suppl 2):S501-18. doi: 10.1161/CIR.0000000000000264. Erratum in: Circulation. 2016 Aug 30;134(9):e122.

Lee, L. A., Caplan, R. A., Stephens, L. S., Posner, K. L., Terman, G. W., Voepel-Lewis, T., & Domino, K. B. Postoperative opioid-induced respiratory depression: a closed claims analysis. Anesthesiology. 2015:122(3), 659-665.

Nwulu, U., Nirantharakumar, K., Odesanya, R., McDowell, S. E., & Coleman, J. J. Improvement in the detection of adverse drug events by the use of electronic health and prescription records: an evaluation of two trigger tools. Eur J Clin Pharmacol. 2013;69(2), 255-259.

Overdyk FJ: Postoperative respiratory depression and opioids. Initiatives in Safe Patient Care, Saxe Healthcare Communications, 2009

The Joint Commission. Safe use of opioids in hospitals. Sentinel Event Alert. 2012(49):1-5. https://www.jointcommission.org/-/media/deprecated-unorganized/imported-assets/tjc/system-folders/topics-library/sea_49_opioids_8_2_12_finalpdf.pdf?db=web&hash=0135F306FCB10D919CF7572ECCC65C84

S.4. **Numerator Statement:** Inpatient hospitalizations where an opioid antagonist (naloxone) was administered outside of the operating room and within 12 hours following administration of an opioid medication. Only one numerator event is counted per encounter.
S.6. **Denominator Statement:** Inpatient hospitalizations for patients 18 years or older during which at least one opioid medication was administered. An inpatient hospitalization includes time spent in the emergency department or in observation status when the patients are ultimately admitted to inpatient status.
S.8. **Denominator Exclusions:** N/A; there are no denominator exclusions

De.1. **Measure Type:** Outcome
S.17. **Data Source:** Electronic Health Records
S.20. **Level of Analysis:** Facility

IF Endorsement Maintenance – Original Endorsement Date: Most Recent Endorsement Date:

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. **IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results?** N/A

1. Evidence, Performance Gap, Priority – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. ***Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.***

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form
ORAE_Evidence_Form_Final.docx
1a.1 For Maintenance of Endorsement: Is there new evidence about the measure since the last update/submission?
Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

1b. Performance Gap
Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- Disparities in care across population groups.

1b.1. **Briefly explain the rationale for this measure** *(e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)*
If a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.
Opioids are often the foundation for sedation and pain relief. However, use of opioids can also lead to serious adverse events, including constipation, over sedation, delirium, and respiratory depression. Opioid-related adverse events have both patient-level and financial implications. Patients who experience this event have been noted to have 55% longer lengths of stay, 47% higher costs, 36% higher risk of 30-day readmission, and 3.4 times higher payments than patients without these adverse events (Kessler et al., 2013).

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References:

Eckstrand, J. A., Habib, A. S., Williamson, A., Horvath, M. M., Gattis, K. G., Cozart, H., & Ferranti, J. Computerized surveillance of opioid-related adverse drug events in perioperative care: a cross-sectional study. Patient Saf Surg. 2009;3(1), 18.

Kessler ER, Shah M, Gruschkus SK, Raju A. Cost and quality implications of opioid-based postsurgical pain control using administrative claims data from a large health system: opioid-related adverse events and their impact on clinical and economic outcomes. Pharmacotherapy. 2013;33(4):383-391.

Lavonas EJ, Drennan IR, Gabrielli A, Heffner AC, Hoyte CO, Orkin AM, Sawyer KN, Donnino MW. Part 10: Special Circumstances of Resuscitation: 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation. 2015 Nov 3;132(18 Suppl 2):S501-18. doi: 10.1161/CIR.0000000000000264. Erratum in: Circulation. 2016 Aug 30;134(9):e122.

Lee, L. A., Caplan, R. A., Stephens, L. S., Posner, K. L., Terman, G. W., Voepel-Lewis, T., & Domino, K. B. Postoperative opioid-induced respiratory depression: a closed claims analysis. Anesthesiology. 2015:122(3), 659-665.

Nwulu, U., Nirantharakumar, K., Odesanya, R., McDowell, S. E., & Coleman, J. J. Improvement in the detection of adverse drug events by the use of electronic health and prescription records: an evaluation of two trigger tools. Eur J Clin Pharmacol. 2013;69(2), 255-259.

Overdyk FJ: Postoperative respiratory depression and opioids. Initiatives in Safe Patient Care, Saxe Healthcare Communications, 2009

The Joint Commission. Safe use of opioids in hospitals. Sentinel Event Alert. 2012(49):1-5. https://www.jointcommission.org/-

/media/deprecated-unorganized/imported-assets/tjc/system-folders/topics-library/sea_49_opioids_8_2_12_finalpdf.pdf?db=web&hash=0135F306FCB10D919CF7572ECCC65C84

1b.2. **Provide performance scores on the measure as specified (current and over time) at the specified level of analysis**. *(This is required for maintenance of endorsement. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

The six implementation test sites vary by bed size (between 71 to over 500 beds), teaching and non-teaching status, are in five different states, and half of them are located in urban areas. Test sites 1 to 3 use Meditech and test sites 4 to 6 use Cerner. A detailed breakdown of the characteristics of the measured facilities and the patient population can be found in the attached Measure Testing Form section 1.7 (Beta Dataset – Implementation Testing).

The measure performance, including the denominator, numerator, and measure rate by hospital, are as follows:

Hospital Test Site 1 (Beta Dataset – Implementation Testing per Testing Form)
- Data collection period: 1/1/2019 - 12/31/2019
- Denominator(encounters): 1,839:
- Numerator: 2
- Performance rate: 0.11%
- Standard deviation: 3.30%
- 95% confidence interval: [0%, 0.26%]

Hospital Test Site 2 (Beta Dataset – Implementation Testing per Testing Form)
- Data collection period: 1/1/2019 - 12/31/2019
- Denominator (encounters): 2,089
- Numerator: 7
- Performance rate: 0.34%
- Standard deviation: 5.78%
- 95% confidence interval: [0.09%, 0.58%]

Hospital Test Site 3 (Beta Dataset – Implementation Testing per Testing Form)
- Data collection period: 1/1/2019-12/31/2019
- Denominator: 1,784
- Numerator: 8
- Performance Rate: 0.45%
- Standard deviation: 6.68%
- 95% confidence interval: [0.14%, 0.76%]

Hospital Test Site 4 (Beta Dataset – Implementation Testing per Testing Form)
- Data collection period: 1/1/2019-12/31/2019
- Denominator: 11,273
- Numerator: 50
- Performance Rate: 0.45%
- Standard deviation: 6.71%
- 95% confidence interval: [0.33%, 0.58%]

Hospital Test Site 5 (Beta Dataset – Implementation Testing per Testing Form)
- Data collection period: 1/1/2019-12/31/2019
- Denominator: 13,307
- Numerator: 44
- Performance Rate: 0.33%
- Standard deviation: 5.74%
- 95% confidence interval: [0.23%, 0.43%]

Hospital Test Site 6 (Beta Dataset – Implementation Testing per Testing Form)

- Data collection period: 1/1/2019-12/31/2019
- Denominator: 18,425
- Numerator: 64
- Performance Rate: 0.35%
- Standard deviation: 5.88%
- 95% confidence interval: [0.26%, 0.43%]

Overall Performance (calculated at the hospital level)
- Number of hospitals: 6
- Performance rate: 0.34%
- Standard deviation: 0.12%
- Range: 0.11%-0.45%

1b.3. **If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.**
The rate of ORAE estimated using the patient EHR data from calendar year 2019 were within the range of harm rates found in the literature, which was between 0.1% and 1.3% among studies using naloxone administration as a surrogate measure of respiratory depression (Cashman, 2004). The relatively wide variability in the rate of ORAE across the six sites demonstrates that there exists room for improvement in reducing the ORAE among at-risk patients.

ORAE measure performance rates ranged from 0.11% (for every 1,000 qualified hospital admissions there are 1.1 inpatient encounters where patients suffered ORAE) to 0.45% (for every 1,000 qualified hospital admissions there are 4.5 inpatient encounters where patients suffered ORAE), indicating ample room for quality improvement in hospital inpatient environment. Also, larger hospitals (e.g., test sites 4 to 6), though having more numerator admissions, do not necessarily have higher ORAE rates. This suggests that all hospitals, irrespective of size, need to follow best practices in patient care to prevent ORAE.

Reference:
Cashman, J. N., and S. J. Dolin. "Respiratory and haemodynamic effects of acute postoperative pain management: evidence from published data." British Journal of Anaesthesia 93, no. 2 (2004): 212-223.

1b.4. **Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability.** *(This is required for maintenance of endorsement. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*
We examined the measure performance rate in various subgroups of population. Of note, these summary statistics are calculated at the encounter-level and derived from a sample of six hospitals and may not be generalizable to the entire population. Data below are from initial development testing; this eCQM is not yet implemented. The measure performance was stratified for disparities by age, sex, race, ethnicity, and payer source for each of the six Beta Implementation Test Sites as presented in Tables 15-16 in the testing attachment. In addition, summary statistics that including the mean performance rate and standard deviation for each demographic characteristic across all six Beta Implementation Test Sites are provided below.

Demographic Characteristic//Mean Rate//Std.Dev//95%CI
Across all denominator patient-encounters//0.36%//6.00%//[0.31%, 0.41%]
Sub-groups
Age bins
18-35//0.07%//2.60%//[0.02%, 0.11%]
36-64//0.41%//6.40%//[0.32%, 0.50%]
65+//0.51%//7.11%//[0.40%, 0.62%]
Sex
Male//0.42%//5.63%//[0.33%, 0.51%]
Female//0.32%//6.50%//[0.25%, 0.38%]
Race

Black or African American//0.24%//4.94%//[0.08%, 0.40%]
White//0.37%//6.04%//[0.30%, 0.43%]
Other//0.48%//6.91%//[0.29%, 0.67%]
Unknown//0.25%//4.97%//[0.08%, 0.42%]
Ethnicity
Hispanic or Latino//0.32%//5.65%//[0.21%, 0.43%]
Non-Hispanic//0.40%//6.28%//[0.33%, 0.46%]
Unknown//0.25%//5.01%//[0.12%, 0.38%]
(Primary) Payer
Medicare//0.52%//7.21%//[0.41%, 0.63%]
Medicaid//0.29%//5.36%//[0.21%, 0.37%]
Private Insurance//0.26%//5.09%//[0.15%, 0.37%]
Self-pay or Uninsured//0.24%//4.85%//[0.07%, 0.40%]
Other//0.40%//6.35%//[0.08%, 0.73%]
Unknown//0.00%//0.00%//N/A

1b.5. **If no or limited data on disparities from the measure as specified is reported in 1b.4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in 1b.4**
N/A

2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. ***Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.***

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. **Subject/Topic Area** *(check all the areas that apply):*

De.6. **Non-Condition Specific***(check all the areas that apply):*

De.7. **Target Population Category** *(Check all the populations for which the measure is specified and tested if any):*

S.1. **Measure-specific Web Page** *(Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)*
Final measure specifications for implementation will be made publicly available on CMS' appropriate quality reporting website, once finalized through the NQF endorsement and CMS rulemaking processes.

S.2a. **If this is an eMeasure**, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)
This is an eMeasure **Attachment:** Opioid_v6_02_Artifacts.zip,ORAE-_Bonnie_v4.2.0__Measure_View_-_CMS819v0.pdf

S.2b. **Data Dictionary, Code Table, or Value Sets** *(and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)*
Attachment **Attachment:** Opioid_Value_Set_Directory.xlsx

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.
No, this is not an instrument-based measure **Attachment:**

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.
Not an instrument-based measure

S.3.1. **For maintenance of endorsement:** Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

S.3.2. **For maintenance of endorsement,** please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.
N/A

S.4. **Numerator Statement** *(Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome) DO NOT include the rationale for the measure.*
IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).
Inpatient hospitalizations where an opioid antagonist (naloxone) was administered outside of the operating room and within 12 hours following administration of an opioid medication. Only one numerator event is counted per encounter.

S.5. **Numerator Details** *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*
IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).
This is an eCQM, and therefore uses electronic health record data to calculate the measure score. The time period for data collection is during an inpatient hospitalization, beginning at hospital arrival (whether through emergency department, observation stay, or directly admitted as inpatient).

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

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

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

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

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

S.6. **Denominator Statement** *(Brief, narrative description of the target population being measured)*
Inpatient hospitalizations for patients 18 years or older during which at least one opioid medication was administered. An inpatient hospitalization includes time spent in the emergency department or in observation status when the patients are ultimately admitted to inpatient status.

S.7. **Denominator Details** *(All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*
IF an OUTCOME MEASURE, describe how the target population is identified. Calculation of the risk-adjusted outcome should be

described in the calculation algorithm (S.14).
This measure includes all patients aged 18 years and older at the time of admission, and all payers. Measurement period is one year. This measure is at the hospital admission level; only one numerator event is counted per encounter.

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

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

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

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

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

S.8. **Denominator Exclusions** *(Brief narrative description of exclusions from the target population)*
N/A; there are no denominator exclusions

S.9. **Denominator Exclusion Details** *(All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*
N/A

S.10. **Stratification Information** *(Provide all information required to stratify the measure results, if necessary, including the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b.)*
N/A; this measure is not stratified.

S.11. **Risk Adjustment Type** (Select type. Provide specifications for risk stratification in measure testing attachment)
No risk adjustment or risk stratification
If other:

S.12. **Type of score:**
Rate/proportion
If other:

S.13. **Interpretation of Score** *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*
Better quality = Lower score

S.14. **Calculation Algorithm/Measure Logic** (*Diagram or describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period for data, aggregating data; risk adjustment; etc.)*
This measure defines the indication of a harm for an opioid-related adverse event by assessing administration of an opioid antagonist (naloxone).

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

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

To create the numerator:

1. First, start with those encounters meeting denominator criteria

2. Next, remove all events where an opioid antagonist (naloxone) was only administered in the operating room.

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

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

This eCQM is an episode-based measure.

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

S.15. **Sampling** *(If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)*
IF an instrument-based performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.
N/A; this measure does not use a sample.

S.16. **Survey/Patient-reported data** *(If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.)*
Specify calculation of response rates to be reported with performance measure results.
N/A; this measure does not use a survey.

S.17. **Data Source** *(Check ONLY the sources for which the measure is SPECIFIED AND TESTED).*
If other, please describe in S.18.
Electronic Health Records

S.18. **Data Source or Collection Instrument** *(Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.)*
IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.
Hospitals collect EHR data using certified electronic health record technology (CEHRT). The MAT output, which includes the human readable and XML artifacts of the clinical quality language (CQL) for the measure are contained in the eCQM specifications attached. No additional tools are used for data collection for eCQMs.

S.19. **Data Source or Collection Instrument** *(available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*
No data collection instrument provided

S.20. **Level of Analysis** *(Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)*
Facility

S.21. **Care Setting** *(Check ONLY the settings for which the measure is SPECIFIED AND TESTED)*
Inpatient/Hospital
If other:

S.22. **COMPOSITE Performance Measure** - Additional Specifications *(Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)*
N/A

2. Validity – See attached Measure Testing Submission Form

ORAE_NQF_Testing_Attachment_v3.docx

2.1 For maintenance of endorsement

Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

2.2 For maintenance of endorsement

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

2.3 For maintenance of endorsement

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. **Data Elements Generated as Byproduct of Care Processes.**

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)

If other:

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. **To what extent are the specified data elements available electronically in defined fields** (*i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields*) Update this field for **maintenance of endorsement**.

ALL data elements are in defined fields in electronic health records (EHRs)

3b.2. **If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources.** For **maintenance of endorsement**, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

This is an eCQM that uses all data elements from defined fields in the EHR. Of all sites used for the measure feasibility assessment, some reported that their anesthesiologists document their activities on paper-based anesthesia records inside of the OR rather than via the electronic medication administration record (eMAR). This suggests that, at this time, for these sites, opioid and naloxone administration inside of the OR will not be available for structured electronic extraction or appear in patient EHRs. For opioid and naloxone administration outside of OR suite, however, all test sites confirmed that they are documented in the eMARs, and available for electronic extraction. Test sites' decisions to document opioid administration inside of the OR on paper can be driven by many

factors, one of which is a workflow preference. Since all hospital-based EHR vendor systems offer anesthesia modules, there should be no technical limitation in transitioning paper-based documentation to electronic documentation. Given that non-anesthesia-related opioid administrations are already captured electronically, we are optimistic that measure implementation is still feasible. Moreover, measure implementation will drive workflow changes toward electronic capture within the OR.

3b.3. **If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.**
Attachment: ORAE_NQF_feasibility_scorecard_vFinal_External.xlsx

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. **Required for maintenance of endorsement. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.**
IF instrument-based, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.
This measure is not instrument-based. Feasibility assessment of this eCQM across twenty-three hospitals with four different EHR vendors (Epic, Cerner, Meditech, and Allscripts) found that the critical data elements used for measure calculation were, for the most part, reliably available in a structured format within the EHR, captured as part of the course of care, accurately recorded information, and coded using nationally accepted terminology.

However, some sites reported that their anesthesiologists document activities on paper-based anesthesia records inside of the OR rather than via the electronic medication administration record (eMAR). Since all hospital-based EHR vendor systems offer anesthesia modules, there should be no technical limitation in transitioning paper-based documentation to electronic documentation. Given that non-anesthesia-related opioid administrations are already captured electronically, we are optimistic that measure implementation is still feasible. Moreover, measure implementation will drive workflow changes toward electronic capture within the OR. Of all the test sites, 21 confirmed that their EHR systems are capable of collecting such information and documenting the events either directly in patient EHRs using encounter location or via proxy information, such as the location associated with nurse administration of medication or time into and out of the OR.

3c.2. **Describe any fees, licensing, or other requirements to use any aspect of the measure as specified** *(e.g., value/code set, risk model, programming code, algorithm)*.
There are no fees associated with the use of this eCQM. Value sets are housed in the Value Set Authority Center (VSAC), which is provided by the National Library of Medicine (NLM), in coordination with the Office of the National Coordinator for Health Information Technology and the Centers for Medicare & Medicaid Services (CMS). Viewing or downloading value sets requires a free Unified Medical Language System® (UMLS) Metathesaurus License, due to usage restrictions on some of the codes included in the value sets. Individuals interested in accessing value set content can request a UMLS license at (https://uts.nlm.nih.gov/license.html).

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. **Current and Planned Use**
NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported

within 6 years of initial endorsement in addition to performance improvement.

Specific Plan for Use	Current Use (for current use provide URL)
Not in use	

4a1.1 **For each CURRENT use, checked above (update for maintenance of endorsement), provide:**

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

N/A; this eCQM is under initial endorsement review and is not currently used in any accountability program.

4a1.2. **If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons?** (*e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?*)

This eCQM is under initial endorsement review and is not currently used in any accountability program. In December 2017 this measure was presented to the Measure Applications Partnership (MAP), who recommended this measure be revised and resubmitted prior to rulemaking. The MAP asked the measure developers to demonstrate reliability and validity in their completed testing, and submit the finalized eCQM to NQF for review and endorsement; this had been completed and submitted to NQF in the Spring 2019 cycle. Based on feedback received from NQF during the 2019 Spring cycle, CMS has subsequently made substantive updates and re-tested the measure. CMS intends to submit this eCQM for the 2021-2022 pre-rulemaking process including the Measures Under Consideration list and the Measures Application Partnership (MAP). Following MAP 2021-2022 review, we envision that this measure will be considered for accountability programs via future rulemaking. Thus, CMS is seeking endorsement by NQF.

4a1.3. **If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement.** (*Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.*)

Following MAP 2021-2022 review, we envision that this measure will be considered for accountability programs via future rulemaking.

4a2.1.1. **Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.**
How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.

N/A; this measure is being submitted as de novo as has not yet been implemented. Implementation is planned pending finalization of the NQF endorsement and CMS rulemaking processes.

4a2.1.2. **Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.**

N/A; this measure is being submitted as de novo as has not yet been implemented. Implementation is planned pending finalization of the NQF endorsement and CMS rulemaking processes.

4a2.2.1. **Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.**
Describe how feedback was obtained.

N/A; this measure is being submitted as de novo as has not yet been implemented. Implementation is planned pending finalization of the NQF endorsement and CMS rulemaking processes.

4a2.2.2. **Summarize the feedback obtained from those being measured.**

N/A; this measure is being submitted as de novo as has not yet been implemented. Implementation is planned pending finalization of the NQF endorsement and CMS rulemaking processes.

4a2.2.3. Summarize the feedback obtained from other users

While this measure does not have usability information from measured entities, as it is being developed de novo and has not been implemented yet, our team sought input from multiple stakeholder groups throughout the measure development process. We believe in a transparent measure development process, and highly value the feedback received on the measure. During development, a technical expert panel composed of a variety of stakeholders was engaged at various stages of development to obtain balanced, expert input. We also solicited and received feedback on the measure through an MMS Blueprint 44-day Public Input Period during development.

We also received feedback from various stakeholders in 2019 including the NQF Patient Safety Standing Committee during the Spring 2019 cycle as well as a 60-day comment period for Federal rulemaking. Concerns raised by commenters included how the measure was specified as a proportion of all hospitalized patients, the use of naloxone as an indicator for quality, potential unintended consequences, and a potential lack of a performance gap. All of these concerns have been addressed by the revisions to the measure specifications described in the following section (4a2.3).

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

As noted above, input received from TEP members was instrumental to the development and specification of this measure. Feedback received during the NQF 2019 Spring cycle and public comment during Federal rulemaking was also incorporated into the measure refinement and re-testing process. Specifically:

- We updated the measure value sets to ensure that the most current codes hospital administered opioids and naloxone are used and that the codes harmonize across other eCQMs in current CMS quality reporting programs;
- We limited the measure denominator to encounters where patients received at least one opioid during the hospitalization;
- We added a 12-hour time window such that the opioid administration must precede the subsequent naloxone administration to ensure that a hospital administered opioid was the cause for the naloxone administration;
- We subsequently re-tested the refined measure for feasibility at 23 hospital test sites using four EHR vendors (Epic, Cerner, Meditech; and Allscripts);
- We also re-tested for the scientific acceptability of the measure's properties including reliability and validity at six beta implementation test sites.

Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b1. Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included.)

If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

This is a new eCQM and there is no time trend information available regarding facility performance improvement. This eCQM is not currently used in any quality improvement program, but a primary goal of the eCQM is to provide hospitals with performance information necessary to implement focused quality improvement efforts.

4b2. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.

We did not identify any unintended consequences during eCQM development or testing. However, CMS is committed to monitoring this eCQM's use and assessing potential unintended consequences over time, such as the inappropriate shifting of care and other negative unintended consequences for patients. However, it is important that the eCQM, as currently specified, does not detect false positives. To verify this, we conducted empirical tests to examine whether numerator cases identified by the measure are true

positives. In the chart review (or parallel-form comparison) process, we instructed clinical abstractors to extract both indications for and patient subsequent responses to the naloxone administration. We found that the predominant rationale for subsequent naloxone administration was that patients were somnolent or unresponsive, with the second mostly cited reason being opiate reversal. In terms of patient responses to naloxone administration, we found that the most frequently documented was: patient showed clear signs of response to naloxone administration. This qualitative evidence solidifies the evaluation of measure logic and suggests that the measure can correctly predict a true positive.

4b2.2. **Please explain any unexpected benefits from implementation of this measure.**
No unexpected benefits were noted during eCQM development or testing.

5. Comparison to Related or Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

5. Relation to Other NQF-endorsed Measures
Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.
Yes

5.1a. **List of related or competing measures (selected from NQF-endorsed measures)**

5.1b. **If related or competing measures are not NQF endorsed please indicate measure title and steward.**

5a. Harmonization of Related Measures
The measure specifications are harmonized with related measures;
OR
The differences in specifications are justified

5a.1. **If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):**
Are the measure specifications harmonized to the extent possible?
Yes

5a.2. **If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.**
The Hospital Harm – Opioid Related Adverse Events eCQM, the Safe Use of Opioids – Concurrent Prescribing Measure (NQF #3316e), and the Concurrent Use of Opioids and Benzodiazepines (NQF #3389) all have the same general target population, which are adult patients who receive opioids. However, the focus of each measure is very different. The Hospital Harm – Opioid Related Adverse Events eCQM focuses on patients who receive excessive doses of opioids during their hospitalization and, subsequently, require naloxone to prevent further patient harm. In contrast, NQF #3316e focuses on patients who receive concurrent opioid or opioid and benzodiazepine prescriptions at discharge, putting them at-risk of adverse drug events after hospital discharge, and NQF #3389 tracks concurrent opioid and benzodiazepine outpatient prescriptions. As a result of the varying measure focuses, the Hospital Harm – Opioid Related Adverse Events eCQM has a broad denominator of all inpatient adults >=18 years who received a hospital administered opioid, while NQF #3316e has a more narrow denominator of adults >=18 years prescribed an opioid or benzodiazepine at discharge from a hospital-based encounter. NQF #3316e also excludes patients with an active cancer diagnoses, palliative care order, or length of stay >120 days. NQF #3389 addresses outpatient prescription claims and excludes patients in hospice, or with a cancer or sickle cell disease diagnosis.

5b. Competing Measures
The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);
OR
Multiple measures are justified.

5b.1. **If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):**
Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)
N/A

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.
No appendix **Attachment:**

Contact Information

Co.1 **Measure Steward (Intellectual Property Owner):** Centers for Medicare & Medicaid Services
Co.2 **Point of Contact:** Annese, Abdullah-Mclaughlin, Annese Abdullah-Mclaughlin@cms.hhs.gov, 410-786-2995-
Co.3 **Measure Developer if different from Measure Steward:** IMPAQ International, LLC
Co.4 **Point of Contact:** Katie, Magoulick, nqf@impaqint.com, 443-259-5449-

Additional Information

Ad.1 **Workgroup/Expert Panel involved in measure development**
Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.
TEP Members:

David Baker, MD, MPH; The Joint Commission
Cynthia Barnard, PhD, MBA, MSJS; Northwestern Memorial HealthCare
Lisa Freeman, Connecticut Center for Patient Safety
Christine Norton, MA; Consumer/Patient Caregiver
David Hopkins, MS, PhD; Stanford University
Kevin Kavanagh, MD, MS; Health Watch USA
Joseph Kunisch, PhD, RN-BC, CPHQ, Memorial Hermann Hospital System
Timothy Lowe, PhD; Premier, Inc.
Amita Rastogi, MD, MHA, CHE, MS; Remedy Partners
Karen Zimmer, MD, MPH; Jefferson School of Population Health and Jefferson University College of Medicine
Steven Jarrett, Pharm.D., Atrium Health

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.2 **Year the measure was first released:**
Ad.3 **Month and Year of most recent revision:**
Ad.4 **What is your frequency for review/update of this measure?** As a de novo measure submission, we anticipate annual updates and potentially triennial endorsement
Ad.5 **When is the next scheduled review/update for this measure?**

Ad.6 **Copyright statement:** Limited proprietary coding is contained in the Measure specifications for user convenience. Users of proprietary code sets should obtain all necessary licenses from the owners of the code sets. IMPAQ disclaims all liability for use or accuracy of any third party codes contained in the specifications. CPT(R) contained in the Measure specifications is copyright 2004-2020 American Medical Association. LOINC(R) copyright 2004-2020 Regenstrief Institute, Inc. This material contains SNOMED Clinical Terms(R) (SNOMED CT[R]) copyright 2004-2020 International Health Terminology Standards Development Organisation. ICD-10 copyright 2020 World Health Organization. All Rights Reserved.
Ad.7 **Disclaimers:** This measure and specifications are subject to further revisions. This performance measure is not a clinical guideline and does not establish a standard of medical care, and has not been tested for all potential applications. THE MEASURES

AND SPECIFICATIONS ARE PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND. Due to technical limitations, registered trademarks are indicated by (R) or [R] and unregistered trademarks are indicated by (TM) or [TM].

Ad.8 **Additional Information/Comments:** This measure was originally developed, specified, and tested by Yale New Haven Health Service Corporation Center for Outcomes Research and Evaluation, and by Mathematica Policy Research on behalf of the Centers for Medicare and Medicaid Services (CMS). IMPAQ International, LLC assumed developer responsibility for this measure in March 2019.