

Public Comment Summary Report

Potential Opioid Overuse

Project Title:

Electronic Clinical Quality Measures (eCQM) Development and Maintenance for Eligible Professionals (EP eCQM)

Dates:

- The Call for Public Comment ran from January 10, 2018 to February 9, 2018.
- The public comment summary was submitted to the Centers for Medicare & Medicaid Services (CMS) on February 26, 2018.

Project Overview:

CMS has contracted with Mathematica Policy Research to develop an eCQM that assesses potential opioid overuse. The contract name is Electronic Clinical Quality Measures Development and Maintenance for Eligible Professionals. The contract number is HHSM-500-2013-13011I/HHSM-500-T0001. As part of its measure development process, CMS requests that interested parties submit comments on the candidate or concept measures that are developed under this project.

Project Objectives:

The goal of this project is to develop eCQMs for use by eligible clinicians for CMS quality payment programs. We consulted with clinical experts and a multi-stakeholder technical expert panel to develop the measure of Potential Opioid Overuse. As part of the measure development process, we solicited comments from the public about the face validity, feasibility, usability, and potential use of the draft measure.

Information About the Comments Received:

The project team conducted outreach to notify key stakeholders and the general public about the comment period for the Potential Opioid Overuse measure. This outreach included:

- Posting a notification about the measure on the CMS public comment website and asking for comments
- Sending emails to the following stakeholders and stakeholder organizations:
 - Action to Address Opioid Epidemic (Missouri)

- Advocates for Opioid Recovery
- Advocates for the Reform of Prescription Opioids
- Agency for Healthcare Research and Quality (AHRQ)
- Alabama Opioid Overdose and Addiction Council
- Alaska Opioid Policy Task Force
- American Academy of Addiction Psychiatry
- American Academy of Emergency Medicine
- American Academy of Family Physicians
- American Academy of Orthopedic Surgeons
- American Academy of Pain Medicine*
- American Academy of Physical Medicine and Rehabilitation
- American Academy of Physician Assistants
- American Association for the Treatment of Opioid Dependence, Inc.
- American Association of Nurse Anesthetists
- American Association of Nurse Practitioners
- American Board of Addiction Medicine
- American Board of Internal Medicine
- American Board of Surgery
- American Chronic Pain Association
- American College of Emergency Physicians
- American College of Medical Toxicology
- American College of Occupational and Environmental Medicine
- American College of Physicians
- American College of Preventive Medicine
- American College of Rheumatology
- American Congress of Obstetricians and Gynecologists
- American Medical Association
- American Medical Association Task Force to Reduce Opioid Abuse
- American Medical Directors Association
- American Medical Group Association
- American Nurses Association*
- American Osteopathic Academy of Addiction Medicine

* The team conducted separate interviews with these organizations to obtain feedback on the Potential Opioid Overuse measure in advance of or during the public comment period.

- American Pain Society
- American Pharmacists Association
- American Psychiatric Association
- American Psychological Association
- American Public Health Association
- American Society of Addiction Medicine
- American Society of Anesthesiologists
- American Society of Health-System Pharmacists
- American Society of Interventional Pain Physicians
- American Society of Perianesthesia Nurses
- American Surgical Association
- Arizona Substance Abuse Task Force
- Association for Addiction Professionals
- Association for Medical Education and Research in Substance Abuse
- Association of Perioperative Registered Nurses
- Attorney General’s Prescription Drug Abuse Prevention Task Force (Indiana)
- Coalition to Stop Opioid Overdose
- Department of Veterans Affairs
- Electronic Health Record Association
- Facing Addiction Taskforce (New Jersey)
- Fed Up!
- Governor’s Opioid Addiction Working Group (Massachusetts)
- Governor’s Prescription Drug Abuse Prevention Task Force (Nevada)
- Governor’s Task Force on Drug Enforcement, Treatment, and Prevention (Indiana)
- Governor’s Task Force on Opioid Abuse (Wisconsin)
- Governor’s Task Force on Prescription Drug and Heroin Abuse (Virginia)
- Heroin and Opioid Coordinating Council (Maryland)
- Heroin Task Force (New York)
- Illinois Opioid Action Plan
- Institute for Clinical Systems Improvement
- Institute for Healthcare Improvement
- Institute for Healthcare Optimization
- Kentucky Office of Drug Control Policy
- Louisiana Commission on Preventing Opioid Abuse

- National Alliance of Advocates for Buprenorphine Treatment
- National Association for Alcoholism and Drug Abuse Counselors (NAADAC)
- National Association of Addiction Treatment Providers
- National Association of Boards of Pharmacy
- National Association of State Alcohol and Drug Abuse Directors
- National Coalition Against Prescription Drug Abuse
- National Institute on Drug Abuse: Prescription Opioid and Pain Workgroup
- National Physicians Alliance
- North Carolina's Opioid Action Plan
- Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services (HHS/ASPE)
- Opioid and Heroin Study Task Force (Mississippi)
- Opioid Prescribing Guidelines for Oklahoma Workgroup
- Opioid Prescribing Work Group (Minnesota)
- Opioid Task Force (Massachusetts)
- Oregon Opioid Prescribing Guidelines Task Force
- Overdose Lifeline, Inc.
- Overdose Prevention and Intervention Task Force (Rhode Island)
- Pacific Business Group on Health
- Pain News Network
- Patient-Centered Primary Care Collaborative
- Pennsylvania Department of Health: Prescription Drug Monitoring Program; Prescribing Guidelines for Physicians and Prescribers
- Pharmacy Quality Alliance
- Physicians for Responsible Opioid Prescribing
- Prescription Drug Action Committee (Delaware)
- Prescription Drug and Opioid Task Force (Michigan)
- Prescription Opioid Abuse Advisory Committee (South Dakota)
- President's Commission on Combating Drug Addiction and the Opioid Crisis
- Prevention Alliance of Tennessee
- Shatterproof
- Society for Preventive Research
- Society of Critical Care Medicine
- Statewide Prescription Opioid Misuse and Overdose Prevention Workgroup (California)

- Statewide Task Force on Prescription Drug Abuse & Newborns (Florida)
- Steve Rummeler Hope Network
- Substance Abuse and Mental Health Services Administration
- Substance Abuse and Suicide Prevention Program
- Substance Abuse Research Alliance (Georgia)
- Task Force on Substance Abuse Treatment Services
- Task Force to Address the Opioid Crisis in the State (Maine)
- The Connecticut Opioid Response Initiative
- The Governor's Cabinet Opiate Action Team (Ohio)
- The Governor's Initiative on Substance Abuse (West Virginia)
- The New Hampshire Governor's Commission on Alcohol and Other Drug Abuse Prevention, Treatment and Recovery
- The Police Assisted Addiction and Recovery Initiative
- U.S. Food and Drug Administration
- U.S. Pain Foundation
- Washington State Agency Medical Directors' Group
- Washington State Interagency Opioid Working Plan

The project team also notified facilitators in the following groups and asked them to announce the public comment period at their meetings:

- Battelle's MIDS C3 meeting
- Weekly governance call for measure developers

The project team received 22 comments about the Potential Opioid Overuse measure from 21 unique commenters. The following individuals and organizations submitted responses during the public comment period:

- Two health systems (Memorial Hermann Health System; Cleveland Clinic)
- Two electronic health record (EHR) vendors (NextGen Healthcare; Foothold Technology)
- One full service family medicine practice (Door to Door Doctors)
- One patient advocate for chronic pain reform
- One patient safety advocacy group (Alliance for the Treatment of Intractable Pain)
- One health insurance company (Anthem, Inc.)
- Ten professional societies (American Nurses Association; American College of Osteopathic Family Physicians; American Society of Anesthesiologists; American Academy of Hospice and Palliative Medicine; American Medical Association; American Society of Addiction Medicine; American College of Obstetricians and Gynecologists; Society for Post-Acute and Long-Term Care)

Medicine; American Academy of Pain Medicine; American College of Emergency Physicians)

- Two federal or state government agencies (North Carolina Department of Health and Human Services, Division of Public Health; Veterans Health Administration, National Center for Ethics in Health Care)
- A group of three researchers affiliated with the U.S. Department of Veterans Affairs

Stakeholder Comments—General and Measure Specific:

Below, we summarize general and measure-specific stakeholder comments, along with the project team’s responses to them. The comments are organized by their subject matter. In this summary, we paraphrase many of the comments; original comments and the responses to them can be found in this document’s *Public Comment Verbatim Report*, which begins on page 17.

Overall, 2 commenters supported the measure, 8 did not support the measure, and 11 had mixed feedback, saying the measure was useful but they had a number of concerns about it. In addition to these 22 submitted comments, the project team received 7 comments in a comment thread on the measure’s usability. That is, we received 7 comments in response to an earlier comment in which concern about the measure was expressed.

Support

Two commenters expressed their support for the measure intent and rationale, saying the measure would provide useful information for clinicians and improve quality of care.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. We appreciate your support of the measure’s intent and usability.

General comments

One commenter recommended adding a disclaimer to the measure that would acknowledge it is a screening tool only and should not be used as a basis for any provider sanctions. The commenter suggested the measure should be a starting point for exploring several factors that, taken together, more accurately portray the practitioner’s quality of patient care in terms of prescribing opioids and monitoring their use.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. We view this measure as one of several potential tools to reduce the harms of the opioid crisis. Other measure developers, agencies, and organizations are undertaking efforts to evaluate alternative approaches to pain management, medication reconciliation, and other instruments intended to decrease unnecessary use of opioids.

Two commenters noted that there is no language in the measure description on how the measure is expected to be used or how its implementation would lead to improvements in processes or outcomes. One commenter asked for clarification on the intended care setting(s) for this measure.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. This measure aims to reduce risks of adverse drug events by creating incentives for providers to review the patient’s individual needs and consider all potential alternatives for managing pain. CMS has not yet made a determination on the program in which the measure will be implemented.

Potential unintended consequences of measure implementation

Nineteen commenters expressed concern about the potential unintended consequences of publically reporting this measure, including that it could discourage providers from writing opioid prescriptions when appropriate, leading to undertreatment of pain.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. We are committed to limiting the potential harms and unintended consequences of any measure relating to pain management and opioid use. Based on the strong relationship between high-dose, long-term opioid use and patient harms (including addiction and death), however, we believe that implementation of this measure will help improve public health and reduce opioid-associated deaths. This measure is not intended to limit access to opioids more broadly and does not prohibit physician discretion in making patient-level treatment decisions. We know that the treatment selected for pain management can vary widely based on the individual needs of the patient. We also expect that providers may encounter some patients who have limited alternatives to long-term, high-dose opioid therapy. For this reason, we do not expect provider scores for this measure to reach zero percent consistently.

Eight commenters mentioned that implementation of the measure may prompt patients to seek alternative methods of pain management (for example, heroin or fentanyl). Four commenters said that providers may inappropriately stop or taper existing opioid regimens, leading to withdrawal and increased rates of depression and/or suicide. One commenter suggested that patients will forgo regular visits to primary care physicians if they think they cannot get the treatment they need.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. We are sensitive to the fact that unintended consequences could stem from implementation of this measure, such as provider reluctance to prescribe opioids, increased numbers of patient referral to pain specialists, or undertreatment of pain while patients transition to other therapies. It is well documented, however, that long-term, high-dose opioid therapy is associated with significant risks of addiction and adverse events, including death. We believe that reductions in long-term, high-dose opioid use—which we aim to assess using this eCQM—should be paired with concurrent policies to encourage optimal patient care. We will continue to balance recommendations to reduce unsafe opioid use, while promoting an increased focus on safer alternatives, including non-opioid therapies and lower doses of opioids.

Recommendations intended to minimize potential unintended consequences

Three commenters suggested identifying an approach to assess and minimize the potential unintended consequences of implementing the measure. The first commenter recommended creating a post-implementation process to identify whether the measure had caused patient harm. The second commenter noted that the clinical recommendation statement in the measure specifications should include language on informed consent to ensure that decisions on pain management are made within a framework of shared decision making and that the framework promotes communication between the provider and the patient. The third commenter recommended creating a measure that rewards physicians for secondary follow-up and use of alternatives to opioids.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. We will consider the changes you suggest to the measure's specifications to improve its usability and uptake within the clinical community, for patients, and as a public health tool. We will discuss the updates you propose in your comment about restructuring the measure specifications to evaluate appropriate opioid use and the recommendation statements used to describe the measure's rationale and intent.

Seven comments on this subject were submitted in a comment thread on the usability of the measure. In particular, commenters noted the potential harms associated with the measure, such as undertreatment of pain and increased rates of depression and/or suicide, and suggested that the measure consider individual differences in patients who are prescribed opioids.

Response: We appreciate these additional comments and reiterate that a patient-centered approach to pain management must complement the use of this eCQM; we view the potential implementation of this measure as but one tool available in the management of the opioid crisis, including alternative forms of pain management and other resources put in place by federal and state agencies (such as prescription drug monitoring programs).

Feasibility challenges

Six commenters expressed concern about ensuring the accuracy and completeness of data elements that would have to be extracted from the EHR in order to calculate the measure. Two of these commenters mentioned that the data elements may have to be collected from multiple fields in the EHR or from multiple EHRs with limited information exchange. Two commenters expressed concern about the accuracy of EHR data on hospice or palliative care, and one commenter was concerned about the completeness of the list of patient problems, the documentation of treatment of end-of-life care, and the documentation of addiction and previously ineffective pain treatment.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. We recognize that some providers currently use EHRs or other record-keeping practices that do not align with the minimum standards set forth to support reporting of this clinical quality measure; we encourage eligible clinicians interested in reporting this measure to evaluate the feasibility of doing so at their site(s).

Four commenters mentioned that MME is not typically a structured field in the EHR, making it difficult to track across different EHR systems. *Three commenters* suggested that the measure consider vocabularies other than RxNorm, such as providing Value Set Authority Center (VSAC) organizational IDs (OIDs) for MME data, and asked for the specific RxNorm codes included in the measure.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. Our intention is to build calculation of MME into the measure logic. If the measure is implemented, we will release value sets for each opioid included in the measure specifications that will include RxNorm codes, which can be mapped to the medication's units and dose. Providing these tools for calculating MME will decrease provider burden and improve transparency into the populations eligible for inclusion in the measure's numerator.

One commenter recommended that the measure developer work with EHR vendors and pharmaceutical companies to eliminate gaps in the currently available data and thereby achieve a more accurate representation of patient populations at risk of opioid overuse.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. Unfortunately, it is not practical at this time to develop an eCQM that incorporates data from sources external to the EHR (such as pharmacy data).

One commenter pointed out that opioid dosing and prescribing patterns may differ based on the specific cancer diagnosis, and recommended the measure include SNOMED/ICD codes for cancers to be excluded from the denominator population. The commenter also asked for the specific value sets used for sickle cell disease and palliative care.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. To your questions about the definitions of cancer, sickle cell disease, and hospice/palliative care: value sets for all three data elements can be accessed through the VSAC. For the cancer value set, we have included nearly all types of cancer, based on feedback from several clinicians to whom we spoke during qualitative testing. Because the patient experience for many cancers is complex and varied, we elected to keep the definition of this data element broad, to allow for greater provider discretion in management of patient pain during and immediately following cancer treatment. For hospice/palliative care, coding for palliative care is evolving. The current standards rely on SNOMED codes, though we acknowledge that use of these codes underrepresents palliative care treatment. We will continue to refine value sets for this data element to align with the most current coding practices, as needed.

Measure specifications

We received several comments on the measure specifications and the appropriateness of measure exclusions. These comments are organized by themes and summarized below.

a. Measure intent

Seven commenters disagreed that the measure score accurately reflects or would improve quality of care, specifically mentioning that lower scores do not necessarily indicate higher quality of care. *Six commenters* mentioned that the measure does not account for differences in patient populations across health systems or for factors specific to individual patients. *Two commenters* suggested that measure developers consider the patient’s history of opioid use (for example, previous overdoses or multiple opioid prescriptions) and opioid tolerance.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. We will bring the changes you have suggested in your comments to our expert work group for further evaluation. We acknowledge that prescribing patterns and opioid use can vary based on patient and provider characteristics; we will evaluate ways to identify those provider and patient populations that could most benefit from reporting of this quality measure as we work to refine the measure specifications.

Two commenters mentioned that provider specialty and experience should be considered.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. While this measure gives providers information that has been missing from discussions of patient medication risks, no single measure can provide a complete picture of the complex topics of opioid overuse and management of chronic pain. We view this measure as one of several potential tools to reduce the harms of the opioid crisis.

b. Appropriateness of 90 MME threshold

Seven commenters said the use of MME to identify inappropriate opioid use was problematic. Four comments were related to feasibility and are described above under the heading of “Feasibility challenges”. *Three commenters* expressed concern about how MME would be calculated. The first commenter said providers would have to convert patient doses, which could be confusing. The second commenter said there is a lack of agreement on an accepted methodology for converting dosage across various opioid medications. The third commenter said the measure misconstrues how MME is meant to be applied.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. The selection of MME to express inclusion criteria for the measure numerator is a reflection of the standard practice used in consensus-based opioid prescribing guidelines and the literature documenting the strong relationship between high-dose, long-term opioid use and patient harms, including addiction and death. Our intention is to build calculation of MME into the measure logic. If the measure is implemented, we will release value sets for each opioid included in the measure specifications that will include RxNorm codes, which can be mapped to the medication’s units and dose. Providing these tools for calculating MME will decrease provider burden and improve transparency into the populations eligible for inclusion in the measure’s numerator.

Five commenters said the measure only captures a narrow category of high-dose opioid use over a long period and would underestimate the number of patients who are at risk of adverse health

outcomes due to inappropriate opioid use. *Two commenters* mentioned that there is limited evidence to support the use of a 90 MME per day dosage limit for quality measurement.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. The definition of high-dose (90 MME or greater average daily dose) opioid use was selected to align with guidance provided by the Centers for Disease Prevention and Control (CDC) in its Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. We believe the recommendations presented in CDC’s Guideline for Prescribing Opioids for Chronic Pain—United States, 2016 represents the strongest evidence available at this time on an appropriate definition for high-dose opioid use; we do acknowledge, however, that many opioids prescribed at doses below 90 MME can put patients at increased risk of an adverse drug event. We view this measure as one of several potential tools to reduce the harms of the opioid crisis. Other measure developers, agencies, and organizations are undertaking efforts to improve the safety of opioid use in specific patient subgroups, such as those who concurrently use other prescribed medications associated with an increased risk of adverse events.

Two commenters recommended expanding the initial population and denominator to include all patients taking an opioid, and *one commenter* suggested that the measure should consider all sources of controlled substances and concurrent use of medications during the measurement period.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. While this measure gives providers information that has been missing from discussions of patient medication risks, no single measure can provide a complete picture of the complex topics of opioid overuse and management of chronic pain. We view this measure as one of several potential tools to reduce the harms of the opioid crisis.

One commenter mentioned that there is limited evidence that supports 90 MME as a reasonable threshold for a quality measure among the post-acute care and long-term-care populations. The commenter recommended excluding physician-patient face-to-face encounters that take place at a nursing facility from the measure denominator and identifying ways to capture patients in non-hospice palliative care.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. We appreciate your suggestions to refine identification of patients receiving hospice and palliative care treatment. We will bring the changes you have suggested in your comment—including exclusion of additional patients based on their setting of care—to our expert work group for further evaluation.

c. Appropriateness of measure exclusions

Five commenters recommended excluding patients with a medically documented condition that causes severe chronic pain that has not been alleviated through surgery or non-opioid therapies. *One commenter* also suggested excluding long-term opioid patients who are in the process of

tapering to a lower dose. *One commenter* suggested collecting information on the post-trauma diagnosis for an opioid prescription to identify other exclusions.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. The populations excluded from the current initial patient population were evaluated against several criteria, relying on findings from guidelines and peer-reviewed literature, feedback from experts, and results from qualitative and quantitative testing. We will bring the changes you have suggested in your comments—including exclusion of medically complex patients for whom the average daily dose exceeds 90 MME intentionally—to our expert work group for further evaluation.

Four commenters recommended that the measure exclude medications used to treat addiction to prevent further harms associated with opioid abuse. *Two commenters* recommended identifying or excluding buprenorphine prescriptions that are used to treat opioid use disorders.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. We will bring the changes you have suggested in your comments—to our expert work group for further evaluation.

One commenter underscored the importance of pregnant women receiving adequate treatment for opioid use and opioid use disorders; this commenter recommended excluding pregnant women from the denominator.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. We will bring the changes you've suggested in your comment to our expert work group for further evaluation.

One commenter asked that the measure developer share the rationale for excluding sickle cell patients from the measure denominator, including citation of at least one peer-reviewed article about how sickle cell disease is substantially different from other forms of chronic pain that are not excluded from this measure.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. Sickle cell disease was chosen as a measure exclusion not because of a preponderance of evidence suggesting it as an appropriate condition for removal from the initial patient population, but rather due to the face validity of opioid use for treating sickle cell disease pain. In 2014, the National Heart, Lung, and Blood Institute released a guideline on management of sickle cell disease, in which opioids were cited as one effective therapy in management of pain crises for sickle disease patients. Due to the multidimensional challenges faced by providers managing patients with sickle cell disease, we acknowledge that additional provider discretion of opioid dose and duration may be necessary to effectively manage pain in this patient population. If there are other chronic conditions similar to sickle cell disease for which exclusion from the measure's initial patient population would be appropriate, we would welcome this feedback as we continue to refine the measure specifications.

One commenter suggested revising the language of the palliative or hospice care exclusion in the specifications from “patients receiving palliative or hospice treatment” to “patients receiving palliative or hospice care.” The commenter also recommended excluding patients with serious illnesses that are in an advanced stage (for example, end-stage chronic lung disease) who lack access to formal hospice or palliative care.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. We appreciate your feedback on the terminology chosen to describe hospice and palliative care treatment; we will consider your suggestion for describing hospice and palliative care and your recommendation to exclude patients diagnosed with end-stage illnesses when finalizing the measure specifications.

One commenter noted that the 2016 CDC Opioid Prescription Guidelines did not acknowledge and account for the effects of genetic polymorphism in natural variations of opioid metabolism between individuals, which influences the identification of thresholds of addiction risk versus opioid dose.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. We appreciate the concerns you highlighted in your comments. We are committed to limiting the potential harms and unintended consequences of any measure relating to pain management and opioid use. Based on the strong relationship between long-term, high-dose opioid use and patient harms (including addiction and death), however, we believe implementation of this measure will help improve public health and reduce opioid-associated deaths.

One commenter recommended aligning the measure specifications with those of existing measures and stated that the National Committee for Quality Assurance (NCQA) has a measure currently in use with a similar intent.

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. The two opioid measures that are currently in place from the NCQA use claims data to assess performance for health plans, whereas the Potential Opioid Overuse measure uses EHR data to assess provider performance. The measures are meant to be complementary. Our team works closely with developers of other clinical quality measures (like NCQA) to align our specifications whenever possible. We will continue to refine the measure specifications in accordance with guidance from the CDC, feedback from our expert work group, and responses submitted during this comment period.

One commenter suggested changing the name of the measure to “Safer Opioid Use” and revising the description from “percentage of patients aged 18 years or older who received opioid therapy for 90 days or longer and who are prescribed a 90 morphine milligram equivalent (MME) or greater daily dose” to “percentage of patients aged 18 years or older who receive opioid therapy for 90 days or longer and are prescribed an average daily dosage of under 90 milligram morphine equivalents, where higher rates are better quality.”

Response: Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. We will consider the updates you propose in your comment about restructuring the measure specifications as we refine the specifications.

Stakeholder interviews

In addition to collecting comments submitted through JIRA during the public comment period, the project team also conducted interviews with the American Nurses Association (ANA) and the American Academy of Pain Medicine (AAPM) Opioid Task Force. Key messages from both interviews, as well as the project team’s responses to this feedback, are provided below.

Both representatives from the ANA supported the measure rationale and agreed that the 90 MME threshold was appropriate, and that hospice/palliative care and cancer were appropriate exclusions. However, they expressed concerns about the usability and feasibility of the measure. They mentioned unintended consequences that could arise from implementation of this measure, such as limiting patients’ ability to access opioid medications (that is, discouraging providers from prescribing opioids) and undertreatment of patient pain. Both interviewees also encouraged calculation of patient MME by the providers (built into their EHRs or through some decision support tool) to ensure they are explicitly aware of the dose prescribed to long-term opioid users.

The representatives asked questions about the intent of the measure, including whether the measure focuses on all providers’ scores, how the measure would define “outlying” or “poor” performance, and possible strategies to improve performance. We also discussed testing findings and a possible stratification approach for provider scores to account for differences in patient populations across health systems.

The representatives recommended that the project team complete additional testing across provider types and specialties to identify variations in care and differences in patient populations that would warrant refinements to the denominator and/or exclusions.

Response: Thank you for providing feedback on the specifications and testing results for the Potential Opioid Overuse measure. We will consider ways to obtain additional qualitative and quantitative input on the measure, including evaluation of additional populations that could be eligible to report this measure, including advanced practice nurses (APRNs). We are sensitive to the fact that unintended consequences could stem from implementation of this measure, such as provider reluctance to prescribe opioids, increased patient referrals to pain specialists, or undertreatment of pain while patients transition to other therapies. We believe that reductions in long-term, high-dose opioid use—which we aim to assess using this eCQM—should be paired with concurrent policies to encourage optimal patient care. We will continue to refine the measure specifications in accordance with guidance from the CDC, feedback from our expert work group, and responses submitted during this comment period.

Two representatives from the AAPM Opioid Task Force indicated that feedback from the task force was mixed. Several members believed the measure was appropriate and could be useful to deter

potential opioid overuse, but others thought there would be minimal impact on provider behavior because they did not agree that measure scores accurately reflected quality of care or improvement in care. In addition, they expressed concerns about the risk of unintended consequences associated with lack of access to adequate pain management.

Those in favor of the measure recommended additional updates to the measure specifications to broaden its impact. One commenter suggested that buprenorphine, as opposed to other medications used to treat addiction (methadone, for example), should be used exclusively to identify patients under treatment for opioid addiction due to the structural and regulatory challenges in its prescription, and that patients actively engaged in addiction treatment should be excluded from the measure.

The AAPM task force provided feedback on possible unintended consequences related to inadequate pain management, stating that this would be one of the largest concerns for patient care if the measure was implemented. Examples of downstream effects for patients on long-term, high-dose opioids include increased suicide rates and an inability to work because of pain, ultimately leading to a decrease in workforce participation. One representative stated that providers' opinions on opioid use vary significantly, even within a specialty community—for example, pain management specialists may want to be excluded from this measure. The AAPM task force also mentioned that many providers continue use of opioids for pain management in absence of any defined benefit, and that they often write an initial script for opioids without establishing a timeline or plan for completing them. Therefore, inappropriate tapering or discontinuation of opioids for these patients may result in higher suicide rates and a decline in workforce participation due to pain.

The task force suggested investigating the inclusion of drug-drug interactions (for example, opioid-benzodiazepine co-prescription) as a component of the measure. Other recommendations included limiting the initial patient population to new opioid users versus those with a history of opioid use, and considering provider specialty when refining the measure specifications.

Response: Thank you for providing feedback on the specifications and evidence for the Potential Opioid Overuse measure. This measure aims to reduce risks of adverse drug events by creating incentives for providers to review the patient's individual needs and consider all potential alternatives for managing pain. This measure is not intended to limit access to opioids more broadly and does not prohibit physician discretion in making patient-level treatment decisions. We know that the treatment selected for pain management can vary widely based on the individual needs of the patient. We also expect that providers may encounter some patients who have limited alternatives to long-term, high-dose opioid therapy. For this reason, we do not expect provider scores for this measure to reach zero percent consistently. We will continue to refine the measure specifications in accordance with CDC's guidance, feedback from our expert work group, and responses submitted during this comment period.

We are sensitive to the fact that unintended consequences could stem from implementation of this measure. It is possible that providers may be less willing to prescribe opioids, or there could be

under-treatment of pain while patients are transitioning to new non-opioid treatment. It is well documented, however, that long-term, high-dose opioid therapy is associated with significant risks of addiction and adverse events, including death. We will continue to balance recommendations for reducing unsafe opioid use while promoting an increased focus on safer alternatives, including non-opioid therapies and lower doses of opioids.

We will bring the changes you've suggested in your comment—including exclusion of patients seeking addiction treatment and those for whom 90 MME is medically necessary—to our expert work group for further evaluation. We view this measure as one of several potential tools to reduce the harms of the opioid crisis. Other measure developers, agencies, and organizations are undertaking efforts to improve the safety of opioid use in specific patient subgroups, such as those who concurrently use other prescribed medications associated with high risks of adverse events.

Preliminary Recommendations

We will review the commenters' suggestions with CMS and the measure's expert work group to identify how to modify the measure specifications to address feedback on the initial patient population, numerator inclusion criteria, and denominator exclusions. We will also consider providing clarification and integrating additional guidance into the measure rationale and recommendations that may be appropriate. We will make recommendations for next steps based on discussions with CMS and the expert work group.

Overall Analysis of the Comments and Recommendations

Feedback on the Potential Opioid Overuse measure was highly informative—there was some support for the measure, specifically noting its usefulness and importance. However, most commenters expressed concern about restricting patient access to clinically appropriate medications, saying this could result in undertreatment of pain, withdrawal, inappropriate tapering of opioids, and other adverse outcomes. A number of commenters recommended additional denominator exclusions; several requested clarification on the specific data elements and value sets that will be used by the measure. Comments on measure feasibility included a concern about ensuring completeness and accuracy in gathering the information needed to calculate the measure from structured fields in the EHR. We thank commenters for providing their feedback and perspectives on this important measure.

Public Comment Verbatim Report

Comment Number	Date Posted	Text of Comments	Name and Organization of Commenter	Contact E-Mail	Type of Organization	Recommendations/Actions Taken
1	1/23/2018	<p>I have read your description of the proposed electronic clinical quality measure (eCQM) for potential opioid abuse. I write as a technically trained non-physician subject matter expert in chronic pain and opioid policy, with 20 years of experience in medical research analysis, operations research and advanced technology evaluation. I have multiple published papers in this field. I advise you in the strongest possible terms to withdraw this proposed algorithm and fire the idiots who proposed it. This "measure" is in fact nothing more than a creation out of thin air and surmise, thinly disguised by a layer of gobbledegook and specious "statistics". Patients who have been interviewed as test cases for the "measure" have correctly identified it as a dressed-up excuse for doctors who seek to deny opioid therapy to pain patients for whom no other viable medical alternatives exist. This reality is strongly signaled by the divergence between doctor assessments of the reliability of science involved, versus patient responses to the measure. The biases of the development team are also revealed by their selection of references supporting development of the quality measure. The 2016 CDC Opioid Prescription Guidelines are widely recognized by many medical professionals to be founded upon political bias, cherry-picked research "findings", and conflation of fact which violate the research standards of the CDC itself. Perhaps the largest and most glaring fundamental error of the guidelines is their failure to acknowledge and account for the effects of genetic polymorphism in natural variations of opioid metabolism between individuals. Genetic polymorphism in liver enzymes which accomplish opioid and other metabolism is well established by an ample published literature. This physiology renders moot, any attempt to identify thresholds of addiction risk versus opioid dose. By contrast each patient must be worked up and managed individually. As established by a recently circulated AHRQ Draft Systematic Review, there are presently no viable non-pharmacological replacements for opioids in medical management of chronic pain. From other sources, we also know that medically managed patients do not comprise a significant source for the prevailing "opioid crisis". To restrict opioid prescriptions to people who comprise no significant risk of addiction serves no medical or ethical purpose and may properly be viewed as a violation of human rights. It is time for your organization to face reality and dance. There is no one-size-fits-all chronic pain patient. Nor is there a one-size-fits-all opioid dose regime which can protect doctors from censure or challenge by government bureaucrats who understand little of medical science or practice. Grow a freaking backbone, people! Burn this specious "quality measure" to the ground and DO NOT START OVER!</p>	Richard A Lawhern; Alliance for the Treatment of Intractable Pain	lawhern@hotmail.com	Patient safety advocacy group	<p>Thank you for providing feedback on the specifications and evidence for the Potential Opioid Overuse measure. We appreciate the concerns you highlighted in your comments. We are committed to limiting the potential harms and unintended consequences of any measure relating to pain management and opioid use. Based on the strong relationship between high-dose, long-term opioid use and patient harms, (including addiction and death), however, we believe that implementation of this measure will improve public health and reduce opioid-associated deaths.</p> <p>This measure aims to reduce risks of adverse drug events by creating incentives for providers to review the patient's individual needs and consider all potential alternatives for managing pain. It is not intended to limit access to opioids more broadly and does not limit physician discretion in making patient-level treatment decisions. We know that the treatment selected for pain management can vary widely based on the individual needs of the patient. We also expect that providers may encounter some patients who have limited alternatives to long-term high-dose opioid therapy. For this reason we do not expect provider scores for this measure to reach zero percent consistently. We will continue to refine the measure specifications in accordance with CDC's guidance, feedback from our expert work group, and responses submitted during this comment period.</p>

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1 (cont)	1/23/ 2018					We are sensitive to the fact that unintended consequences could stem from implementation of this measure, such as provider reluctance to prescribe opioids, increased numbers of patient referral to pain specialists, or undertreatment of pain while patients transition to other therapies. It is well documented, however, that long-term, high-dose opioid therapy is associated with significant risks of addiction and adverse events, including death. We will continue to balance recommendations for reducing unsafe opioid use while promoting an increased focus on safer alternatives, including non-opioid therapies and lower doses of opioids.
2	1/23/ 2018	Thank you for the opportunity to provide feedback on the proposed electronic Clinical Quality Measure (eCQM) Potential Opioid Overuse. While we believe the quality measure itself would provide useful information for clinicians, we have concerns regarding the feasibility and validity of the measure due to challenges in accurately extracting the data elements from multiple disparate data sources. As noted in the POTENTIAL OPIOID OVERUSE FRAMING DOCUMENT (pg. 2) "Measure history" section; we can understand why the test results were incongruent. In our large health care system, we are utilizing over 4 EHRs from different vendors that do not exchange data elements that would support this measure and even though we have a common database platform for the EHRs, not all opioid prescriptions are entered electronically. We still have a number of providers that write paper prescriptions for patients and do not record these in the EHR in a discrete format. We believe the measure developer would need to work with organizations like Surescripts and large pharmacy systems like CVS to provide their prescription data to eliminate potential gaps and capture a more accurate representation of this patient population. We do not believe using disparate EHR systems will achieve that level of accuracy and the inability to capture this data will be even more pronounced for providers practicing in rural areas or critical access hospitals. We believe that CMS should start partnering with prescription filling organizations to better capture quality measures such as the one being proposed.	Joseph Kunich; Memorial Hermann Health System	joseph.kunisch@memorialhermann.org	Health system	Thank you for providing feedback on the specifications and evidence for the Potential Opioid Overuse measure. We recognize that some providers currently use EHRs or other record-keeping practices that do not align with the minimum standards set forth to support reporting of this clinical quality measure; we encourage eligible clinicians interested in reporting this measure to evaluate the feasibility of doing so at their site(s). Unfortunately, it is not practical at this time to develop an eCQM that incorporates data from sources external to the EHR (such as pharmacy data). We are sensitive to the fact that unintended consequences could stem from implementation of this measure, such as provider reluctance to prescribe opioids, increased patient referrals to pain specialists, or under-treatment of pain while patients transition to other therapies.

Comment Number	Date Posted	Text of Comments	Name and Organization of Commenter	Contact E-Mail	Type of Organization	Recommendations/Actions Taken
2 (cont)	1/23/ 2018	We also agree with the patients concerns that a potential unintended consequence of publically reporting this data would discourage providers from writing opioid prescriptions when it is appropriate. Therefore, we believe CMS should create a post-measure implementation evaluation process to determine if the measure caused patient harm. While the denominator exclusions are a good start, we encourage the measure developer to incorporate documented exclusions by the provider i.e. post-trauma diagnosis linked to the prescription. This will help refine the measure in future versions by analyzing the reasons a physician feels the length of time and dose is appropriate without penalizing them or encouraging under treating patients. CMS could facilitate this by requiring all narcotic prescriptions have a linked, coded diagnosis. In regards to the clinical usefulness, we believe that looking at only patients with 90 days of 90 milliequivalents of morphine will severely underestimate the number of patients affected by the controlled substance crisis. It does not consider that many of these patients receive their medications from multiple sources as well as the fact that they often mix other controlled substances like benzodiazepines. To address this issue fully, the measure should consider all sources of controlled substances and concomitant use of medications during that same time period				We believe that reductions in long-term, high-dose opioid use—which we aim to assess using this eCQM—should be paired with concurrent policies to encourage optimal patient care. We will continue to refine the measure specifications in accordance with guidance from the CDC, feedback from our expert work group, and responses submitted during this comment period. We view this measure as one of several potential tools to reduce the harms of the opioid crisis. Other measure developers, agencies, and organizations are undertaking efforts to improve the safety of opioid use in specific patient subgroups, such as those who concurrently use other prescribed medications associated with high risks of adverse events.
3	1/25/ 2018	<p>1. Consider changing the measure name to Safer Opioid Use and align the metric accordingly We recommend changing the measure name from Possible Opioid Over Use to Safer Opioid Use. Safer Opioid Use is more affirmative, aligns with patient safety commitments and professional obligations to do no harm, and is consistent with the aim of the quality measure which is to reduce adverse events in patients on long term opioid therapy. On its face, Possible Opioid Over Use seems stigmatizing and suggestive of misuse or abuse – something that ought to be avoided amidst the fear and politicization surrounding the issue. To align the metric descriptively with the Safer Opioid Use nomenclature we propose changing the metric from the “Percentage of patients aged 18 years or older who receive opioid therapy for 90 days or longer and are prescribed an average daily dosage of 90 milligram morphine equivalents or greater, where lower rates are better quality” to the “Percentage of patients aged 18 years or older who receive opioid therapy for 90 days or longer and are prescribed an average daily dosage of under 90 milligram morphine equivalents, where higher rates are better quality.”</p> <p>2. Identify how to measure and minimize patient identified unintended consequences associated with the metric Patients in the CMS feasibility study are rightly concerned that an unintended consequence of the Possible Opioid Over Use metric is undertreatment of pain or inability to find providers willing to prescribe opioids at any dose – a concern that is already a reality in many states. Unfortunately, quality measures are intended to provide systems-level information but are too often used, inappropriately, to guide an individual’s clinical care – often because providers feel pressured to meet the measure – or facilities are financially incentivized. Hence, how will CMS measure and ensure that improved rates on the Possible Opioid Over Use metric, does not result in inadequate or undertreatment of pain or the inability to access care providers? Gains in one quality area should not occur at the expense of quality of care in another area.</p>	Mary Beth Foglia; Veterans Health Administration, National Center for Ethics in Health Care	marybeth.foglia@va.gov	Federal agency	Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. We will consider the changes you suggest to the measure’s specifications to improve its usability and uptake within the clinical community, for patients, and as a public health tool. We will discuss the updates you propose in your comment about restructuring the measure specifications to evaluate appropriate opioid use and the recommendation statements used to describe the measure’s rationale and intent. We will continue to refine the measure specifications in accordance with guidance from the CDC, feedback from our expert work group, and responses submitted during this comment period. We are sensitive to the fact that unintended consequences could stem from implementation of this measure, such as provider reluctance to prescribe opioids, increased patient referrals to pain specialists, or under-treatment of pain while patients transition to other therapies. We believe that reductions in long-term, high-dose opioid use—which we aim to assess using this eCQM—should be paired with concurrent policies to encourage optimal patient care.

Comment Number	Date Posted	Text of Comments	Name and Organization of Commenter	Contact E-Mail	Type of Organization	Recommendations/Actions Taken
3 (cont)	1/25/ 2018	<p>3. Explicitly include informed consent communication process in clinical practice statement that accompanies the metric</p> <p>Decisions about pain management, including the use of opioids, should occur within a framework of shared decision making and a robust informed consent process. We believe that it is important to explicitly include these dimensions of care in all metric-related communications materials including the clinical practice statement in the metric description document. The Veterans Health Administration (VHA) requires a written informed consent process prior to prescribing long term opioids as part of our basic commitment to respect for persons and positive communication between provider and patient. We no longer allow the use of pain contracts – because they are based on an adversarial rather than a therapeutic model and are often punitive, unenforceable, and have the potential to undermine trust between provider and patient. We have included a link to the policy and patient-facing material for your review:</p> <p>VHA Directive 1005, Informed Consent for Long-term Opioid Therapy for Pain: http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3005 .</p> <p>Patient Education Booklet: Taking Opioids Responsibly for Your Safety and the Safety of Others: http://www.ethics.va.gov/docs/policy/Taking_Opioids_Responsibly_for_Your_Safety_and_Safety_of_Others.pdf</p>				
4	1/31/ 2018	<p>Thank you for the opportunity to provide feedback on the proposed eQCM CMS460: Potential Opioid Overuse. As an EHR vendor we recognize the need to collect data in this domain and appreciate this opportunity to contribute to the fight against the opioid epidemic. We want to assist CMS and public health organizations in their efforts to collect data to reduce the number of opiates prescribed and drive continuous care and quality improvement. To achieve these goals, Foothold Technology offers the following feedback on the proposed quality measure:</p> <ul style="list-style-type: none"> Encouraging reconciliation would be beneficial for care and data collection for the measure. Not all opiates will be prescribed by the physician tracking this measure, but all physicians can keep track of medications prescribed and integrate them into a client’s record, encouraging a greater reporting rate. Contributing this data should be encouraged rather than the spectre of the stigma of having a patient with a high dosage opiate in their record (which could encourage a provider to suppress this information even if they didn’t prescribe the opiate. We suggest that the creation of an alternate population measure to credit providers who perform reconciliation on a client’s record that includes a high dosage opiate. Medications are coded into an EHR primarily using a RxNorm code, which generally consists of a medication name and includes a strength and unit. We would encourage the usage of a VSAC OID that contains all medications considered the equivalent of an “an average daily dosage of 90 milligram morphine equivalents or greater” and instead of tracking Medication names by RxNorm and utilizing discrete strength and unit fields. Our thinking is that MME is not a typical unit field and would be difficult to track across different examples of CEHRT and would be challenging to incorporate across systems. 	Alexander Atkinson and David Bucciferro; Foothold Technology	alex@footholdtechnology.com	EHR vendor	Thank you for providing feedback on the specifications and evidence for the Potential Opioid Overuse measure. We view this measure as one of several potential tools to reduce the harms of the opioid crisis. Other measure developers, agencies, and organizations are undertaking efforts to evaluate alternative approaches to pain management, medication reconciliation, and other instruments intended to decrease unnecessary use of opioids. Our intention is to build calculation of MME into the measure logic. If the measure is implemented, we will release value sets for each opioid included in the measure specifications that will include RxNorm codes, which can be mapped to the medication’s units and dose. Providing these tools for calculating MME will decrease provider burden and improve transparency into the populations eligible for inclusion in the measure’s numerator.

Comment Number	Date Posted	Text of Comments	Name and Organization of Commenter	Contact E-Mail	Type of Organization	Recommendations/Actions Taken
4 (cont)	1/31/ 2018	<ul style="list-style-type: none"> The clinical recommendation states: “Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.” However this is not addressed in the quality measure numerator, nor are alternative to high dose opiates. We would encourage the creation of an alternate population measure to reward physicians for secondary follow-up and alternatives to opiates interventions. Thank you for your consideration, Foothold Technology looks forward to supporting this Quality Measure upon its release. 				We will continue to refine the measure specifications in accordance with guidance from the CDC, feedback from our expert work group, and responses submitted during this comment period.
5	2/2/ 2018	<p>The American Nurses Association (ANA) is pleased to provide written comment for the Potential Opioid Overuse measure. ANA is the premier organization representing the interests of the nation’s 3.6 million registered nurses (RNs) through its constituent and state nurses associations, organizational affiliates, and individual members. RNs serve in multiple direct care, care coordination, and administrative leadership roles, across the full spectrum of health care settings. RNs provide and coordinate patient care, educate patients and the public about various health conditions, and provide advice and emotional support to patients and their family members. ANA members also include those practicing in the four advanced practice registered nurse (APRN) roles: nurse practitioners, clinical nurse specialists, certified nurse-midwives and certified registered nurse anesthetists.[1] ANA is dedicated to partnering with health care consumers to improve practices, policies, delivery models, outcomes, and access across the health care continuum. The opioid crisis, substance use disorder (SUD) and the nurse’s role in addressing these issues has been a top priority for ANA and its practice teams for over two decades. For the majority of ANA’s members, the complexity of opioid misuse will continue to be front and center as the nation grapples with changing the trajectory of this tragic epidemic. Today, over 91 Americans die every day from an opioid overdose. [2] According to 2014 data, an estimated 1.9 million people had an opioid use disorder related to prescription pain relievers and an estimated 586,000 had an opioid use disorder related to heroin use.[3] ANA was pleased to have the opportunity to speak with Mathematica Policy Research and the Lewin Group prior to the measure being released to the public. However, we remain steadfast in our comments. ANA encourages the developer to complete additional testing across provider types and specialties to identify variations in care and differences in patient populations that would warrant refinements to the denominator and/or exclusions. It is critical to better understand whether there are other patients for whom prescribing at this level may be appropriate and how the measure performs outside of primary care. ANA supports the measure rationale, but recommends that more providers, including APRNs with prescribing authority, who work in specialized care areas be consulted about the potential impacts and consequences to their patient populations. Because of the recommended dosage, it is important to ANA that patients and providers are not penalized for providing care based on the best clinical guidelines available. We encourage continued exploration of this measure with all potentially affected providers to ensure the measure is feasible, provides accurate representations of performance, and does not unintentionally limit treatment options for patients.</p>	Brooke Trainum and Cheryl Peterson; American Nurses Association (ANA)	Brooke.Trainum@ana.org	Professional society	<p>Thank you for providing feedback on the specifications and testing results for the Potential Opioid Overuse measure. We will consider ways to obtain additional qualitative and quantitative input on the measure, including evaluation of additional populations that could be eligible to report this measure, including advanced practice nurses (APRNs).</p> <p>We are sensitive to the fact that unintended consequences could stem from implementation of this measure, such as provider reluctance to prescribe opioids, increased patient referrals to pain specialists, or under-treatment of pain while patients transition to other therapies. We believe that reductions in long-term, high-dose opioid use—which we aim to assess using this eCQM—should be paired with concurrent policies to encourage optimal patient care. We will continue to refine the measure specifications in accordance with guidance from the CDC, feedback from our expert work group, and responses submitted during this comment period.</p>

Comment Number	Date Posted	Text of Comments	Name and Organization of Commenter	Contact E-Mail	Type of Organization	Recommendations/Actions Taken
6	2/7/2018	<p>On behalf of the American College of Osteopathic Family Physicians (ACOFP), we appreciate the opportunity to provide the comments below on the proposed Potential Opioid Overuse electronic clinical quality measure (eCQM). The ACOFP is the professional organization representing more than 20,000 practicing osteopathic family physicians, residents, and students throughout the United States who are deeply committed to advancing our nation's health care system by improving health care delivery and outcomes, and ensuring that patients receive high-quality care. Overall, as an organization with many osteopathic family medicine physicians in solo, small and rural practices, we recognize the importance of the ongoing opioid crisis that faces the nation. Primary care physicians (PCPs) are at the frontlines of care and often are the first to uncover the presentation of behavioral health symptoms, including opioid addiction. PCPs are also in the unique position of diagnosing, treating and prescribing opioids, when medically necessary and clinically indicated. For these reasons, we believe PCPs are in a unique and critical position to provide input on measure development related to opioid use and alternative methods used to combat the opioid epidemic. Our full comments are detailed on the following pages. Thank you for the opportunity to share these with you. Should you need any additional information or if you have any questions, please feel free to contact Debbie Sarason, Manager, Practice Enhancement and Quality Reporting at (847) 952-5523 or debbies@acofp.org.</p> <p>Patient Access to Clinically Appropriate Medications</p> <p>ACOFP recognizes and supports efforts to combat the opioid crisis. We are concerned, however, that the proposed eCQM may result in unintended consequences. Specifically, we are concerned that this measure will limit patient access to clinically appropriate medications, resulting in under-treatment of pain and other adverse outcomes. We strongly support patient access to clinically appropriate medications and agree there should be additional guidance and clarification on clinical appropriateness regarding opioid prescriptions. We believe that protections and safeguards should exist for physicians who prescribe (or choose not to prescribe) in manners consistent with best medical practices and clinical guidelines. We believe additional clarity and these protections will ensure patients continue to have access to clinically appropriate treatment. A sizable subset of ACOFP members treat those in rural health care settings and the underserved. We have witnessed firsthand the correlation between limited patient access to critical health care treatment and services, and the avoidable cost this places on the health care system. With regards to opioids, if patients have limited access, they will also have untreated pain. Consequently, it is possible that patients will seek alternative medications or alternative sources for pain management. We have significant concerns because of the prevalence of deadly alternatives such as fentanyl, illegal opioids and heroin. For these reasons, ACOFP is concerned that this proposed eCQM will not be useful to assess or improve the quality of care for patients and will instead drive patients out of doctors' offices.</p>	Deborah Sarason; American College of Osteopathic Family Physicians - ACOFP	debbies@acofp.org	Professional society	

Comment Number	Date Posted	Text of Comments	Name and Organization of Commenter	Contact E-Mail	Type of Organization	Recommendations/Actions Taken
6 (cont)	2/7/ 2018	<p>Controlling Opioid Prescribing</p> <p>We recognize that prescribing practices should be assessed and evaluated. However, the proposed eCQM to assess physician performance will exacerbate the patient access issue and ignores the other elements involved in the opioid crisis. One likely unintended consequence of this eCQM is a lack of physicians willing to prescribe any opioids. A narrowly defined measure, such as the percent of patients receiving a certain opioid dose over a specified period of time, will drive physicians to not prescribe opioids at all. We believe this will have the following adverse impacts, which are out of the PCP's control.</p> <ol style="list-style-type: none"> 1. Patients will seek alternative pain management solutions. As described above, if patients recognize that they cannot obtain opioids for their pain, they will seek alternative solutions, exacerbating the opioid crisis, which is significantly impacted by the illegal importation and use of fentanyl. 2. Patients will forego regular PCP visits because they will feel that they cannot obtain needed treatment. If patients do not believe they will receive effective pain management solutions from their PCPs, they will be more inclined to forego regular PCP visits. Consequently, PCPs who could identify behavioral health issues, such as an opioid addiction, will miss this opportunity to follow up on patients who they have cared for over time. Patients, who no longer are treated for their chronic pain by one doctor, will "doctor shop" until they find one who will treat their pain. 3. Physicians will be penalized through various satisfaction surveys and other quality measures for following clinically appropriate prescribing standards. Patient satisfaction surveys already have and, because of this proposed eCQM, will continue to skew negatively against physicians who limit or do not prescribe opioids. The 90 day/90 milligram morphine equivalents (MME) dose limit will result in physicians practicing against a threshold to avoid poor quality scores, instead of working with patients on an individualized treatment plan. While we recognize that the measure excludes certain patient populations, our previous experience with such exclusions is that physicians will be subjected to increased administrative burdens and audit exposure to ensure compliance. <p>For these reasons, we do not believe this measure is effective (or appropriate) to assess physician performance. The unintended consequences are outside of the physician's control and we believe this eCQM establishes inappropriate standards and a threshold unrelated to each patient's unique situation. Further, we believe this proposed eCQM discourages the doctor-patient relationship needed to develop an appropriate care plan, and to address the potential for addiction.</p>				

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6 (cont)	2/7/ 2018	<p>Specific Concerns with the Proposed eCQM ACOFPP appreciates the severity of the opioid crisis and the urgency required to address it. We disagree, however, with the certain aspects of the proposed eCQM. Specifically, we have concerns with the 90-day duration, 90 MME dose, and the denominator patient population.</p> <p>90-Day Duration The 90-day duration of opioid prescribing as a component of the eCQM runs in opposition to the CDC definition of chronic pain. In the March 2016 CDC Guideline for Prescribing Opioids for Chronic Pain, chronic pain is defined as, “pain that typically lasts >3 months or past the time of normal tissue healing. Chronic pain can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause.” We are concerned that this e-CQM, which is more a rigid directive, takes away physicians’ ability to utilize best medical judgement in treating chronic pain patients.</p> <p>90 MME Dose By limiting the dose to 90 MME, this proposed eCQM would put family physicians in a situation where they must dose-convert. According to Webster and Fine, “Recent evidence suggests that the use of dose conversion ratios published in equianalgesic tables may lead to fatal or near-fatal opioid overdoses.” Further, they found that the use of dose conversion ratios found in equianalgesic tables may be an important contributor to the increasing incidence of opioid-related fatalities. Therefore, we are concerned that the 90 MME dose and subsequent dose conversion may exacerbate the opioid crisis.</p> <p>Denominator Population and Exclusions In addition to the identified exclusions, we believe the denominator for this eCQM should also exclude any patients who have a medically documented chronic condition which, while not life-threatening are highly likely to last their lifetime, and cause severe chronic pain. This includes patients suffering from: rheumatoid arthritis; back pain (which cannot be alleviated by surgery); osteoarthritis; multiple sclerosis; fibromyalgia; and neuropathy.</p> <p>Conclusion ACOFPP urges CMS to consider the on-the-ground experience of PCPs and the reality of the opioid crisis. Our members will continue to work with our patients to provide clinically appropriate medications and to ensure patients are not unnecessarily suffering from chronic pain. Further, we commit to working to address over-prescribing, but believe an appropriate measure, which includes significant stakeholder feedback, must first be developed. These efforts alone, however, will not be sufficient. Additional efforts must be made by industry to: (1) Curb access to illegal drugs; (2) Develop new, non-addictive analgesics; and (3) Ensure these medications are covered by insurance companies. We ask that CMS consider the above outlined potential adverse impacts and unintended consequences of this eCQM, as well as the stark reality that faces many patients and PCPs. Further, we offer our continued support and to work together on appropriately measuring and assessing physician prescribing behavior.</p>				<p>Thank you for providing feedback on the specifications and evidence for the Potential Opioid Overuse measure. We are sensitive to the fact that unintended consequences could stem from implementation of this measure, such as provider reluctance to prescribe opioids, increased patient referrals to pain specialists, or under-treatment of pain while patients transition to other therapies. We believe that reductions in long-term, high-dose opioid use—which we aim to assess using this eCQM—should be paired with concurrent policies to encourage optimal patient care.</p> <p>Our intention is to build calculation of MME into the measure logic. If the measure is implemented, we will release value sets for each opioid included in the measure specifications that will include RxNorm codes, which can be mapped to the medication’s units and dose. Providing these tools for calculating MME will decrease provider burden and improve transparency into the populations eligible for inclusion in the measure’s numerator. We will bring the changes you’ve suggested in your comment—including the additional conditions you consider appropriate for exclusion from the initial patient population—to our expert work group for further evaluation. We will continue to refine the measure specifications in accordance with guidance from the CDC, feedback from our expert work group, and responses submitted during this comment period.</p>

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7	2/9/2018	<p>Thank you for inviting the American Society of Anesthesiologists® to review and comment on the Center for Medicare & Medicaid Services (CMS) Electronic Clinical Quality Measure (eCQM) related to Potential Opioid Overuse. ASA appreciates this and future opportunities to comment and contribute to measure development activities, especially those related to anesthesiology and pain medicine. As experts in acute pain management, physician anesthesiologists are uniquely positioned to play a key role in addressing the opioid crisis. As some people can experience problems with acute pain following surgery, physician anesthesiologists are already working to address perioperative pain by implementing practices that rely less on opioids and instead employ multimodal and regional anesthetic approaches. Pain medicine specialists also address chronic pain with non-pharmacological methods, including interventional pain therapies. Proper prescribing and dispensing are critical to successfully reducing opioid misuse and abuse. ASA and its members would welcome the opportunity to expand these efforts and work with HHS and measure developers in the future.</p> <p>ASA supports the development of this important measure as-is. Measuring opioid prescription patterns for long-term opioid users is imperative in the national landscape and current opioid crisis. The eCQM is certainly timely and is simple, straightforward and in the best interest of the public. The intended consequence of the measure is to reduce high dosage opioid prescribing, which may lead to serious and detrimental outcomes for patients, such as hyperalgesia, changes in hormonal levels compared to pre-opioid status. In addition, mortality rates for opioid users are significantly higher than most other medications today. We believe that if appropriately implemented, this measure can distinguish quality of pain management between providers and facilities and potentially correlate to a reduction in serious adverse outcomes including death. However, this is only applicable to non-cancer patients. A potential unintended consequence to this measure stems from the numerator which is “Patients with an average daily dosage of 90 morphine milligram equivalents (MME) or greater, prescribed during the measurement year”. While we do not disagree with the current numerator, it will not capture prescriptions that still have high dosage opioids. For example, oxycodone 10 mg q4h or 15 mg q6h, a significant dosage of opioids, but less than 90 MMEs would not be included in the measure. We suggest further refining the numerator in the future to ensure accurate capture of high dose opioid prescriptions. Additionally, an unintended consequence of this measure is the potential for undertreatment of pain. Patients with severe chronic pain may need greater than 90 MME. If appropriate treatment options have been evaluated, this dosage could be reasonable for those patients. ASA recommends that CMS take into consideration those patients when further refining this measure. ASA appreciates the precision used in defining the measure denominator. However, while the denominator population offers a strong start for this measure, we recommend considering expanding the initial population and denominator to include all patients. Additionally, we request clarification on the intended care setting(s) for this measure as well as how individual providers performance will be attributed. We agree that patients with cancer, sickle cell or palliative or hospice care are appropriate exclusions for this measure.</p> <p>Thank you for considering our comments. As leaders in anesthesiology and pain medicine, ASA is committed to working with the CMS and other stakeholders to address the current opioid crisis, including in the development of measures related to opioid use.</p>	Leslie Kociemba; American Society of Anesthesiologists	qra@asa.hq.org	Professional society	<p>Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. The definition of high-dose (90 MME or greater average daily dose) opioid use was selected to align with guidance provided by the Centers for Disease Control and Prevention in its Guideline for Prescribing Opioids for Chronic Pain—United States, 2016; we do acknowledge, however, that many opioids prescribed at doses below 90 MME can put patients at increased risk of an adverse drug event. We view this measure as one of several potential tools to reduce the harms of the opioid crisis. Other measure developers, agencies, and organizations are undertaking efforts to improve the safety of opioid use in specific patient subgroups, such as those who concurrently use other prescribed medications associated with high risks of adverse events.</p> <p>We are sensitive to the fact that unintended consequences could stem from implementation of this measure, such as provider reluctance to prescribe opioids, increased patient referrals to pain specialists, or under-treatment of pain while patients transition to other therapies. We believe that reductions in long-term, high-dose opioid use—which we aim to assess using this eCQM—should be paired with concurrent policies to encourage optimal patient care. We will continue to refine the measure specifications in accordance with guidance from the CDC, feedback from our expert work group, and responses submitted during this comment period. CMS has not yet made a determination on what program(s) and Eligible Clinician type(s) will be eligible to report this measure.</p>

Comment Number	Date Posted	Text of Comments	Name and Organization of Commenter	Contact E-Mail	Type of Organization	Recommendations/Actions Taken
8	2/9/18	<p>On behalf of the more than 5,000 members of the American Academy of Hospice and Palliative Medicine (AAHPM), we would like to thank the Centers for Medicare and Medicaid Services (CMS) for the opportunity to comment on the Potential Opioid Overuse electronic clinical quality measure (eCQM) under development. AAHPM is the professional organization for physicians specializing in Hospice and Palliative Medicine. Our membership also includes nurses and other health and spiritual care providers deeply committed to improving quality of life for patients facing serious or life-threatening conditions, as well as their families and caregivers. The timely and effective management of pain and other distressing symptoms is central to providing these patients with high-quality palliative care, and opioid analgesics are a critical tool in alleviating that suffering. With that in mind, AAHPM is concerned with how best to balance the growing challenges related to managing pain with opioids with the need for ready access to appropriate pain medications for patients with serious or complex chronic illness and those at the end of life – patients for whom high-dose opioids may be necessary and medically appropriate. The Academy recognizes there is an indisputable public health imperative to curb opioid abuse, misuse, and diversion, and is deeply committed to both providing continuing education that results in optimal pain management and optimal care for all patients as well as to collaborating with professional, regulatory and industry stakeholders to maximize individual and public safety. At the same time, AAHPM believes public policies and accountability structures must recognize there is an equally important public health imperative to ensure that our sickest, most vulnerable patients have access to timely, effective treatment of their pain and suffering. In the case of the draft eCQM, while we support the adoption of valid and reliable measures that hold practitioners accountable for responsible opioid prescribing, we have concerns that the measure takes a blunt approach to controlling opioid usage that is not evidence-based and that does not include sufficient protections to ensure access to medically necessary opioid analgesics for the high-need, seriously ill patients that AAHPM members serve. Our concerns and recommendations are detailed further below.</p> <p>Use of Milligram Morphine Equivalents (MME) to Determine Overuse</p> <p>While we recognize that the Centers for Disease Control and Prevention (CDC) has issued guidelines for prescribing opioids for chronic pain, there is limited evidence to support the use of a 90 morphine milligram equivalent (MME)/day dosage limit as a standard of care. Further, lack of agreement on an accepted methodology for converting dosage across various opioids challenges the validity of the 90 MME/day limit upon which the draft measure is based. Additionally, the CDC guidelines do not mandate limits on the dosage of opioids, and they allow for clinically justified use above the 90 MME/day value used under the draft eCQM. With the exception of the limited denominator exclusions (see additional concerns below), the draft measure fails to provide opportunities for clinicians to justify clinically appropriate higher dosages. The measure name itself suggests that the opioid levels prescribed may only signal “potential overuse,” not actual overuse, and it is not clear how clinicians could be held accountable to a performance standard on the measure without additional clinical data for each patient included in the measure’s numerator. AAHPM would be happy to work with CMS to determine how best to address this concern, including through the use of an expanded set of denominator exclusions.</p>	Katherine Ast; American Academy of Hospice and Palliative Medicine (AAHPM)	kast@aa hpm.org	Professional society	

Comment Number	Date Posted	Text of Comments	Name and Organization of Commenter	Contact E-Mail	Type of Organization	Recommendations/Actions Taken
8 (cont)	2/9/18	<p>Insufficient Denominator Exclusions</p> <p>We are concerned that the Potential Opioid Overuse measure fails to respect the balance between appropriate pain relief and opioid overuse, primarily at the expense of seriously ill patients with persistent pain. While we appreciate that the measure includes denominator exclusions for patients receiving palliative or hospice care during the measurement period, as well as for patients with cancer and sickle cell disease, other patients with advanced stage serious illness – for example, end-stage chronic lung disease – who lack access to hospice or formal palliative care would likely continue to be captured in both the numerator and denominator. And while patients such as these may benefit from palliative or hospice care, many barriers prevent access to such services, such as culturally linked patient preferences, residence in rural or underserved communities, or physician failure to refer. As a result, clinicians who appropriately prescribe opioids for the management of their pain may either inappropriately be identified as contributing to opioid overuse, or alternately, inappropriately restrict access to necessary treatment for pain relief. The draft measure also fails to take into account the appropriate use of opioids for the treatment of addiction, including drugs such as morphine sulfate and methadone. A denominator exclusion that considers treatment of addiction during the measurement period would also ensure that these patients would be able to continue receiving treatment necessary to prevent further harms associated with opioid abuse. In addition to concerns about the comprehensiveness of the exclusions, we also have concerns that heterogeneity in the capability of certified electronic health record technology (CEHRT) to capture and code data regarding the delivery of hospice and palliative care may also lead patients to not be accurately coded as receiving such care. We have previously noted the ongoing lack of a standard lexicon to define aspects of palliative medicine for purposes of quality improvement and have urged CMS to invest in the development of a dictionary of data elements that would provide the standardization needed to ensure the accurate collection of information on hospice and palliative care for the purposes of quality measurement and improvement. We believe that such standardization would facilitate the use of CEHRT for quality measurement and data submission and drive patient-centered and family-oriented quality care.</p> <p>Recommendations</p> <p>Given the above concerns, we urge CMS to take a careful approach to the implementation of new electronic clinical quality measures to assess opioid prescribing that takes into account the appropriate use of opioids. Such an approach should ensure that (1) the eCQM provides a valid, reliable, and meaningful measure of accountability that is based on evidence and clinical appropriateness; (2) consistent with the current draft specifications, an exclusion is included for patients receiving palliative or hospice care; and (3) additional exclusions are included for serious illness populations who lack access to palliative or hospice care and for patients undergoing ongoing treatment of addiction. Lastly, we request that CMS update its terminology regarding the palliative or hospice care exclusion. It currently reads “Patients receiving palliative or hospice treatment during the measurement period” (emphasis added). We believe it would be more appropriate to refer to “palliative or hospice care” since both typically focus on providing holistic support to patients with serious illness and their families that may not necessarily include “treatment,” as the term is typically used.</p> <p>Thank you again for the opportunity to provide feedback on the Potential Opioid Overuse eCQM. We look forward to further engagement on this important issue.</p>				<p>Thank you for providing feedback on the specifications and evidence for the Potential Opioid Overuse measure. We believe the recommendations presented in CDC’s Guideline for Prescribing Opioids for Chronic Pain—United States, 2016 represents the strongest evidence available at this time on appropriate definition for high-dose opioid use; we do acknowledge, however, that many opioids prescribed at doses below 90 MME can put patients at increased risk of an adverse drug event. The populations excluded from the current initial patient population were evaluated against several criteria, relying on findings from guidelines and peer-reviewed literature, feedback from experts, and results from qualitative and quantitative testing. We welcome additional suggestions, however, on conditions for which use of long-term, high-dose opioids at doses above 90 MME may be clinically appropriate.</p> <p>This measure aims to reduce risks of adverse drug events by creating incentives for providers to review the patient’s individual needs and consider all potential alternatives for managing pain. This measure is not intended to limit access to opioids more broadly and does not prohibit physician discretion in making patient-level treatment decisions. We know that the treatment selected for pain management can vary widely based on the individual needs of the patient. We also expect that providers may encounter some patients who have limited alternatives to long-term, high-dose opioid therapy. For this reason we do not expect provider scores for this measure to reach zero percent consistently.</p> <p>We appreciate your feedback on the terminology chosen to describe hospice and palliative care treatment.</p>

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9	2/9/18	<p>The North Carolina Department of Health and Human Services, Division of Public Health appreciates the opportunity to submit comments on the proposed Electronic Clinical Quality Measure (eCQM) Development and Maintenance for Eligible Professionals (EP eCQM) regarding Potential Opioid Overuse.</p> <p>Summary of comments: as the CMS moves forward in developing this measure of potential opioid overuse, it should continue to consider measure development, face validity, feasibility, usability and the potential use of the draft measure in promoting appropriate prescribing.</p> <p>Comments in specifically requested areas:</p> <ol style="list-style-type: none"> The usefulness of the measure to assess and improve the quality of care for patients: <ul style="list-style-type: none"> This metric is valuable in that it is consistent with various guidelines (including CDC) recommending that clinicians should avoid or carefully justify increasing opioid dosage to ≥ 90 MME/day. The appropriateness of the measure to assess provider performance, including any unintended consequences of measure implementation: <ul style="list-style-type: none"> This metric has usefulness in measuring “risky prescribing.” However, it does not capture the overuse of opioids in general (as the title suggests); rather, it only captures the relatively narrow category of high-dose opioid use for a long duration. The North Carolina Prescription Drug Monitoring Program (PDMP) data shows that only 6.7% of opioid recipients in this state receive an average daily opioid dose of >90MME and this percentage has been decreasing. Care should be taken in how this metric is used to assess provider performance, as it may flag physicians who prescribe higher-dose, higher-duration opioids in conjunction with clinically appropriate practices such as pain contracts, urine drug screenings, PDMP profile reviews, and regular assessments for potential dose titration. This measure would not distinguish these providers from other opioid prescribers who may need education or another intervention. Whether the measure may be calculated directly from electronic health record data or requires additional processing: <ul style="list-style-type: none"> No comments in this area Whether there are any additional conditions for which the use of long-term, high-dose opioids could be appropriate (i.e., conditions that would warrant excluding patients from the measure): <ul style="list-style-type: none"> The denominator exclusions seem appropriate, i.e. palliative or hospice treatment, cancer diagnosis, and sickle cell disease. 	Susan Kansagra; North Carolina Department of Health and Human Services, Division of Public Health	susan.kansagra@dhhs.nc.gov	State agency	Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. We appreciate your support in how the measure’s numerator and exclusions are specified. The long-term, high-dose population evaluated by this measure was chosen due to the high risk of adverse drug events for those patients taking opioids for a long time at a high dose; this population disproportionately suffers adverse drug events, when compared to peers taking opioids at a lower dose over a shorter period. We view this measure as one of several potential tools to reduce the harms of the opioid crisis. Other measure developers, agencies, and organizations are undertaking efforts to improve the safety of opioid use in specific patient subgroups, such as those who concurrently use other prescribed medications associated with high risks of adverse events. We will continue to refine the measure specifications in accordance with guidance from CDC, feedback from our expert work group, and responses submitted during this comment period.

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10	2/9/18	<p>Cleveland Clinic (CC) is a not-for-profit, integrated healthcare system dedicated to patient care, teaching, and research. Our health system is comprised of a main campus, 10 community hospitals, and 21 family health centers with over 3,500 salaried physicians and scientists. Last year, our system had more than seven million patient visits and over 220,000 hospital admissions. We appreciate the dedication of the Agency staff on behalf of the Medicare Program and the work they devote to its administration. We believe it is important for hospitals to share information with CMS so the Agency has a better understanding of the challenges and practicalities faced by the hospitals regarding proposed changes in policy. The following are the comments of Cleveland Clinic in regard to a proposed electronic clinical quality measure (eCQM), Potential Opioid Overuse, for use by eligible clinicians participating in CMS quality payment programs. In general, Cleveland Clinic supports the CMS intent to develop a meaningful measure that would assist healthcare providers to decrease the risk of opioid-related adverse events, harms, or death and to reduce the risk of developing opioid dependence or opioid diversion. The measure, as currently constructed, does raise serious concerns and may not be the right type of measure CMS should adopt at this time as its implementation has the potential to cause serious harm to the chronic pain patient population. Despite the very broad and ambitious goals CMS aims to accomplish through implementation of this proposed electronic measure, we believe there are important points to consider prior to its finalization.</p> <p>Our concerns are generally around two issues:</p> <ol style="list-style-type: none"> 1. The potential for many adverse and unintended outcomes, and 2. The ability to accurately retrieve the data from the current state of electronic health records (EHRs). <p>This eCQM, as described, is a provider-level measure. Given current national concern regarding the use of opioids and opioid dependency, many providers are already mistakenly telling patients that they cannot prescribe opioids, which may lead to under-treatment of pain and/or patients seeking inappropriate referrals to pain management specialists who “can prescribe opioids.” Reporting for this measure could drive behavior in an unintended way, potentially labeling pain management specialists in a negative manner. We are also concerned that the risk to the provider is more about the patient population that the provider cares for, especially if performance is compared provider by provider. It is critical that performance evaluation is based on several factors – the specialty of the provider, the demographics of the patient, and the conditions being treated to include the complexity of chronic pain patients who have failed other types of pain management. Additionally, federal rules protecting the privacy of patients with substance use disorder affect whether addiction specialists may document an SUD diagnosis, thus preventing an apples-to-apples provider comparison. The second concern is the ability to accurately retrieve all of the data needed to support this measure from discrete fields in the electronic medical record. Those concerns are related to the completeness of the problem list, documentation of treatment of end-of-life care, and documentation of addiction and previously failed treatment of pain.</p>	Aaron Hamilton; Cleveland Clinic	paredem@ccf.org	Health system	<p>Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. We are sensitive to the fact that unintended consequences could stem from implementation of this measure, such as provider reluctance to prescribe opioids, increased patient referrals to pain specialists, or under-treatment of pain while patients transition to other therapies. We believe that reductions in long-term, high-dose opioid use—which we aim to assess using this eCQM—should be paired with concurrent policies to encourage optimal patient care. Our intention is to build calculation of MME into the measure logic. If the measure is implemented, we will release value sets for each opioid included in the measure specifications that will include RxNorm codes, which can be mapped to the medication’s units and dose. Providing these tools for calculating MME will decrease provider burden and improve transparency into the populations eligible for inclusion in the measure’s numerator. We recognize that some providers currently use EHRs or other record-keeping practices that do not align with the minimum standards set forth to support reporting of this clinical quality measure, and we encourage eligible clinicians interested in reporting this measure to evaluate the feasibility of doing so at their site(s).</p> <p>We will bring the changes you’ve suggested in your comment—including the additional conditions you consider appropriate for exclusion from the initial patient population—to our expert work group for further evaluation. We will continue to refine the measure specifications in accordance with guidance from the CDC, feedback from our expert work group, and responses submitted during this comment period.</p>

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10 (cont)	2/9/18	<p>Our feedback to the specific CMS questions regarding the proposed measure is outlined below:</p> <ol style="list-style-type: none"> 1. The usefulness of the measure to assess and improve the quality of care for patients – The measure, as currently proposed, will provide minimal usefulness and has the potential to lead to many unintended and adverse outcomes to patient as described above. 2. The feasibility of the measure to assess provider performance and any unintended consequences of implementing the measure – In general, we do not think this a reliable measure of performance. Although the measure will provide information regarding each provider’s administration of long-term opioid treatment, without specific guidelines for the analysis of the data, reporting of this measure could lead to potential under-treatment of pain and/or patient dumping. 3. Whether data elements related to the measure are available in structured, extractable fields in electronic health record systems – Currently the discrete fields necessary to adequately describe the condition of the patient being treated and failure of previous treatments are not available in the electronic medical records system. It is also currently difficult to document, in a discrete field, the need for increasing the dosage of opioids above the 90 MME threshold. 4. Whether the measure should include any additional exclusions – We believe that the measure should also exclude complex, chronic pain patients who, due to the failure of multiple non-opioid therapies, are maintained on higher doses (greater than 90 MME) yet otherwise lead productive, functioning lives <p>Thank you for conducting a thoughtful process that allows us to provide input on the development of this measure and for your consideration of our comments. Should you need any further information, please don’t hesitate to contact me.</p>				
11	2/9/18	<p>The American Medical Association (AMA) is writing in response to the Centers for Medicare & Medicaid Services (CMS) request for comment on a new electronic quality measure (eCQM) focused on the degree of potential opioid overuse. CMS has contracted with Mathematica Policy Research on the following measure: potential opioid overuse, percentage of patients aged 18 years or older who receive opioid therapy for 90 days or longer and who are prescribed a 90 milligram or greater morphine milligram equivalent (MME) daily dose. The AMA is actively working to reverse the opioid epidemic, particularly through the activities of the AMA Opioid Task Force, which was formed in 2014 and includes 26 national medical specialty and state medical associations, the American Osteopathic Association, and the American Dental Association. Performance measurement may be one avenue by which we can track progress and make improvements to reduce the opioid epidemic. The AMA supports every effort underway to meet this need. The AMA does not agree with the fundamental premise of this measure that daily dose and duration of therapy involving prescription opioid analgesics can serve on its own as a measure of quality patient care. Instead, quality measurement needs to focus on how well patients’ pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain. If pain can be well controlled and function improved without the need of high doses of opioids over a long period of time, that is an indication of good patient care; but a reduction in opioid dose alone is not an appropriate goal.</p>	Koryn Rubin; American Medical Association	koryn.rubin@ama-assn.org	Professional society	Thank you for providing feedback on the specifications and evidence for the Potential Opioid Overuse measure. We appreciate hearing the concerns you highlighted in your comments. We are committed to producing a well-specified, evidence-based measure related to high-dose, long-term opioid use while limiting the potential harms and unintended consequences to the patient. The measure is not intended to substitute for a physician’s clinical judgment regarding the relative risks and benefits of including opioids in a care plan for individual patients with chronic pain. It is intended to quantify the proportion of patients who are at elevated risk for severe medication-related adverse events, including addiction and fatal and non-fatal overdose. We believe this information can inform discussions concerning the safe use of opioids in care pathways as well as the ongoing public dialogue regarding the public health impacts of opioid overuse.

11 (cont)	2/9/18	<p>In fact, since the Centers for Disease Control & Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain was issued, there have been many reports of patients who have been successfully managed on opioid analgesics for long periods of time but forced to abruptly reduce or discontinue their medication regimens with sometimes extremely adverse outcomes, including depression, loss of function, and even suicide. Identifying those patients for whom opioid prescriptions exceed => 90 morphine milligram equivalents (MME)/day may serve as an indicator of whether a patient is at risk of overdose and should be coprescribed naloxone, but the AMA believes that significant revisions and testing are required prior to implementing this measure in any federal program. The measure as constructed implies that patients who do not receive => 90 MME/day over a 90-day period receive higher quality care. We do not believe that the measure, with its broad denominator population and limited exclusions, adequately captures the recommendations from the CDC. The recommendations allow for physicians to document a clinical rationale or justification when 90 MME/day is exceeded; yet, the measure does not capture if a justification exists nor does it provide a well-defined and targeted denominator. Originally developed as a guide to switching or rotating various opioid medications, MMEs are estimated equianalgesic doses of other opioid analgesics compared to morphine, where the potency of other members of the class are typically compared to a 10-mg parental dose of morphine. Various equianalgesic conversion tables or calculators exist; calculated MMEs may vary between tools for certain opioids, depending on the algorithm used. Comparative values should be considered approximations only and do not account for genetic factors, tolerance (and incomplete tolerance between various opioids), and the type of pain (i.e., acute vs chronic) and duration of treatment. Patient-specific factors affecting drug disposition (i.e., hepatic function, renal function, age) are very important as well, because individual differences in pharmacokinetics can be substantial. As a result, there is great potential for patients to not receive the care that is needed, particularly for those with chronic pain. Use of the CDC Guideline in this manner is also inconsistent with the intended use of the Guideline. For example, the Guideline states:</p> <p>Clinical decision making should be based on a relationship between the clinician and patient, and an understanding of the patient’s clinical situation, functioning, and life context. The recommendations in the guideline are voluntary, rather than prescriptive standards. They are based on emerging evidence, including observational studies or randomized clinical trials with notable limitations. Clinicians should consider the circumstances and unique needs of each patient when providing care. In addition, the unintended consequences of this measure must be clearly analyzed prior to moving forward. Specifically, if the measure does not adequately define the patients for whom higher doses of opioids may be appropriate, the measure may provide invalid representations of physician performance. There is also a risk that physicians reduce opioid prescriptions in order to score well on this measure and leave patients without access to appropriate therapy.</p> <p>Information on how the measure performed when tested must be released publicly in order for physicians and others to adequately evaluate this measure. For example, it is critical that the measure have been tested in different patient populations and medical specialties to understand whether differences in performance scores are due to the complexity of patient population treated across various specialties. This testing would then allow CMS to identify what additional refinements are needed to reflect evidence-based care, whether the measure is appropriate for all patients receiving opioids for 90-days or longer, and if it should be applied to all medical specialties. The results may also confirm that the measure as defined is not appropriate for quality improvement</p>			<p>We would like to take this opportunity to respond to the concerns communicated in your letter. We have paraphrased our understanding of your specific comments below for reasons of efficiency, but in no way are we attempting to minimize the importance of the concerns you have raised.</p> <ul style="list-style-type: none"> • The metric does not measure quality because use of high-dose opioids is not an indication of poor care. The measure is designed to assess the number of patients at heightened risk of severe adverse events due to high-dose, long-term opioid use, including addiction and fatal and non-fatal overdose. We know that the treatments used in pain management can vary widely based on the individual needs of the patient, and as a result providers may encounter some patients who have limited alternatives. For these patients, high-dose, long-term opioid therapy may be the best treatment option. However this does not mitigate the risk the metric attempts to measure. CMS expects that some provider scores will not consistently reach 0% on this measure. • Unintended consequences could result in significant patient harms, including inadequate control of pain, depression, loss of function and suicide. It is not the intent of the measure to mandate one-size-fits-all changes to treatment plans that are not in the best interest of the patient. The risks of potential extreme adverse events that result when patients with chronic pain are compelled to abruptly reduce their medication dose is documented in the literature. This issue was discussed several times with our expert work group, our measure technical expert panel, our patient and family advisory board, and several specially-convened physician panels; these discussions helped shape specifications for the measure including exclusion criteria. Based on input we received during these discussions we believe the best way to address risks from abrupt discontinuation of opioids is through clinical training and physician education.
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11 (cont)	2/9/18	<p>and/or accountability purposes. Alternative measures or ones that provide complementary information on the quality of care should also be explored, such as the proportion of patients with acute or chronic pain whose pain was well controlled and/or functioning improved without needing > 90 MME opioids for > 90 days.</p> <p>We are also concerned with the feasibility of directly calculating the measure from the electronic health record (EHR). The eCQM is reliant on a function that is not consistently supported by EHR vendors, and participation with the measure would require additional costs or vendor fees placed on the physician. It is our understanding that the EHR does not uniformly capture MMEs and this calculation would be necessary to populate the measure's numerator. There are also Internet, iOS and Android-based apps that perform this functionality, but in order to implement, the physician would need to manually enter patient information and calculate the MME. This would introduce the possibility for human error. In addition, terminology and code mappings play a big role in how well an EHR-based calculator works, but due to the lack of consistency and standardized code mappings the results produced are not very reliable. In addition, it is not clear that a large number of physicians are: (1) able to electronically prescribe controlled substances (EPCS) and; (2) have seamless integration between their EPCS systems and their EHR systems. This could present additional problems in capturing the needed eCQM information. We request that CMS significantly revise the measure, and we welcome the opportunity to work with CMS on the revisions to the measure. Thank you for the opportunity to comment.</p>				<ul style="list-style-type: none"> • Alternative measures that provide complementary information on the quality of pain management care should also be explored. While this measure provides information that has been missing from discussions of patient medication risks, no single measure can provide a complete picture of the complex topics of opioid overuse and management of chronic pain. We view this measure as one of several potential tools to reduce the harms of the opioid crisis. Other measure developers, agencies, and organizations are undertaking efforts to improve the safety of opioid use in specific patient subgroups, such as those who concurrently use other prescribed medications associated with high risks of adverse events. • As specified, the measure has a broad denominator and limited exclusions that do not capture the recommendations of the CDC and does not consider individual patient factors. The measure lacks sufficient specificity for calculation. Development of the final specifications used the Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain—United States, 2016 as a starting point, but it also submitted these criteria to extensive review and input by an Expert Work Group, Technical Expert Panel, and stakeholder groups including physician panels and members of the CDC panel responsible for writing the Guideline. There was uniform agreement that the denominator population should closely align with the CDC Guideline, which identifies cancer as the only exclusion criterion. However, through further review of literature and discussion with our expert partners and physician panels, we identified additional patient populations not included in the CDC Guideline for whom there is strong evidence and broad consensus that they should be added to the list of exclusions. These populations include patients receiving hospice or palliative care and patients with Sickle Cell Disease. If the measure is implemented, we will publish specific values sets for all exclusions with the final measure specifications to ensure that the denominator population
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11 (cont)	2/9/18				<p>is identified consistently for reporting. We encourage the AMA to recommend other specific patient groups to evaluate for exclusion in future revised specifications.</p> <ul style="list-style-type: none"> • The measure does not consider the individual patient factors that contribute to the selection of long-term treatment with high-dose opioids, as recommended by the CDC Guideline. Patients with a documented reason for treatment with long-term high-dose opioids are not excluded from the denominator. We fully support the CDC Guideline and have used the Guideline and consulted with its authors in development of specifications for this measure. The measure is intended to provide a standardized measure of the proportion of patients at elevated risk for severe adverse events due to high-dose, long-term opioid use. It is not intended as a substitute for the clinical judgement of the physician when working with individual patients and patient treatment goals to select among treatment options for long-term pain. Appropriate documentation of the rationale for selecting high-dose, long-term opioid use, among all treatment options, is an important part of the patient's health record. However the measure is intended to quantify the proportion of patients at elevated risk for adverse events, without regard for the rationale that underlies selection of this option. • The measure's ability to appropriately reflect differences in use of opioids across patient population or medical specialties is not known. Publication of measure testing results is essential to allow stakeholders to confirm that it is appropriate for quality improvement and/or accountability purposes. The measure has been subjected to structured statistical tests of reliability and validity using EHR data from the national Medicare population. These tests demonstrated that the measure is sensitive to differences across individual physicians caring for this population. The intent of the measure is to quantify the proportion of patients at elevated risk for severe adverse events due to opioids use. We have not identified any
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11 (cont)	2/9/18				<p>evidence in the literature or through consultation with our experts and physician panels to suggest that the risk of adverse events is different across medical specialties after controlling for individual patient risks. As a result, the measure specifications rely on the characteristics of the patient to determine exclusion from the measure and not the medical specialty of the provider, and the measure has not been evaluated across different types of medical specialties. We anticipate that there will be differences in measure scores at the provider level that are driven by the complexity of patient populations. We know that the treatment selected for pain management can vary widely based on the individual needs of the patient, and as a result providers may encounter some patients who have limited alternatives. For these patients, high-dose, long-term opioid therapy may be the best treatment option. However this does not mitigate the risk the metric attempts to measure. CMS does not expect provider scores for this measure to reach 0% consistently. If the measure is implemented, CMS will determine whether and how the measure will be used in Quality and pay-for-value programs.</p> <ul style="list-style-type: none"> • The measure implies that => 90 MME/day over a 90-day period is a threshold for quality of care; this misconstrues how MME are meant to be applied. Differences in MME conversion tables will produce different scores for the same physician. The measure is not intended to hold the provider to an arbitrary, one-size-fits-all standard of care. It is designed to quantify the proportion of patients at elevated risk for adverse events due to high-dose, long-term opioid use. The selection of MME to express inclusion criteria for the measure numerator is a reflection of the standard practice used in consensus-based opioid prescribing guidelines and the literature documenting the strong relationship between high-dose, long-term opioid use and patient harms including addiction and death. In an effort to reduce confusion and reporter burden, the definitions of long-term (90+ days of
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11 (cont)	2/9/18				<p>opioid use) and high-dose (90 MME or greater average daily dose) opioid use were selected to align with guidance provided by the CDC Guideline and other similar measures. In order to ensure that a consistent calculation of MME is used to apply numerator inclusion criteria we will build calculation of MME equivalency into the measure logic. If the measure is implemented, we will release value sets for each opioid included in the measure specifications that will include RxNorm codes, which can be mapped to the medication's units and dose to ensure consistency of MME calculation. We will continue to refine the measure specifications in accordance with CDC's guidance, feedback from our expert work group, and responses submitted during this comment period.</p> <ul style="list-style-type: none"> • This electronic clinical quality measure presumes functionality within the electronic health record (EHR) system and electronic prescription of controlled substances (EPCS) systems that may not be available. Manual abstraction will result in undue reporter burden and may produce misleading results. During field testing we identified some EMR systems that capture the required data elements for this measure, and we were informed of other systems that are working toward similar solutions. This measure may be the impetus for enhancements to EMR systems in order to facilitate reporting this and other quality measures that rely on precise information from medication orders. We have no knowledge of whether this functionality is widely available in EMR systems today; developing an estimate of its availability is beyond the scope of our measure development activities. Our intention is to build calculation of MME into the measure logic. If the measure is implemented, we will release value sets for each opioid included in the measure specifications that will include RxNorm codes, which can be mapped to the medication's units and dose. Providing these tools for calculating MME will decrease provider burden and improve transparency into the populations eligible for inclusion in the measure's numerator.
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Comment Number	Date Posted	Text of Comments	Name and Organization of Commenter	Contact E-Mail	Type of Organization	Recommendations/Actions Taken
11 (cont)	2/9/18					We appreciate the feedback you have provided to the Potential Opioid Overuse measure and for expressing the viewpoint of the American Medical Association. CMS is committed to developing a well-specified consensus-based measure that considers the concerns you have raised as well as the documented risks posed by high-dose, long-term opioid therapy. We welcome AMA's comments and potential contributions to the ongoing development and refinement of this measure through the full range of avenues available, including by continuing to provide input to the concerns it has outlined in this letter.
12	2/9/18	<p>SPECIFIC QUESTIONS FOR FEEDBACK</p> <p>"The usefulness of the measure to assess and improve the quality of care for patients" The assumption that lower numbers of patients with less than 90 MME is indicative of higher quality care is erroneous and illogical. This measure will not improve quality of care for patients. The main failing with this assumption is that there exists no known cause and effect relationship between simply higher MME's and poor outcome. This is made quite clear in the often cited article, Dunn et al. (Annals of Internal Medicine, 2010) in the limitation section that states "this observational study cannot establish whether overdose risk differences reflect direct effects of differences in opiate dose or patient characteristics." However, there does appear to be an association between higher MME and poor outcome. This again does not mean that lowering opiate doses will improve patient care or outcome (in fact some recent research would support that this is indeed true). An analogy to understand this can be made in the case of diabetes. It is also probably true that patients with diabetes who are on higher doses of insulin have poorer outcomes than those on lower doses. This does not mean that the culprit is insulin. It probably means that patients on higher doses of insulin have diabetes that is more difficult to control and therefore more likely associated with negative outcome. Furthermore to rate a physician's quality on insulin dose is ridiculous. Choosing to taper or reduce insulin would likely lead to even worse outcomes and more expense to the medical system due to unintended effects such as increased hospitalizations, emergency room visits, unnecessary surgeries, unnecessary injections and unnecessary implants of expensive hardware (spinal cord stimulator and implanted medication pumps). It is therefore inappropriate to use percentage of patients with higher MME as a sign of poor quality. More importantly would be how well patients at higher MME are treated. For example, a quality measure might determine what proportion of these patients have been referred for additional help if available such as a pain medicine specialists or an addiction specialist. Another example of quality could be the proportion of patients on higher MME who have had drug screens, informed consent, treatment agreements and functional assessment (also known as "universal precautions").</p>	Taleen Safarian; American Society of Addiction Medicine	tsafarian@asam.org	Professional society	

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12 (cont)	2/9/18	<p>This measure doesn't indicate better quality patient care, it only provides a screening indicator of higher risk for accidental opioid overdose death due to higher opioid dose, but doesn't take into account important factors such as:</p> <ul style="list-style-type: none"> • Prescriber <ul style="list-style-type: none"> ○ Experience ○ Education ○ Commitment to monitoring patients on opioids for aberrant medication-taking behaviors ○ Ongoing consultation with pain and/or addiction medicine specialists • Patient <ul style="list-style-type: none"> ○ Doctor-shopping (since the score is for an individual provider, not a patient, it doesn't take into account that the patient may have multiple opioid prescriptions from multiple providers) ○ Opioid tolerance ○ Previous overdoses ○ Comorbid mental health diagnoses (including opioid use disorder) ○ Criminal activities (diversion) <p>"The feasibility of the measure to assess provider performance and any unintended consequences of implementing the measure"</p> <p>The measure should have a disclaimer acknowledging that it is a screening tool only and specific guidance that it should not be used as a basis for any provider sanctions, but as a starting point for exploration of other factors that more accurately indicate the practitioner's quality of patient care regarding opioid prescribing and monitoring.</p> <p>Although it would be feasible to measure the percentage of patients who have MME greater than 90, as clarified above we do not believe this would be indicative of provider performance or quality. As far as unintended consequences of implementing the measure, we have already seen the negative impact of the CDC guidelines in the treatment of patients with chronic pain. Over the last year, it has become very common for physicians to see patients both in the inpatient and outpatient setting who have been inappropriately tapered rapidly or abruptly discontinued on opiate medications primarily due to provider fear of continuing the medications. This often commonly occurs when patients move and need to change primary care physicians, and the receiving physicians are now very frightened due to media and regulatory attention to opiate prescribing. Our concern is that this measure will also reinforce the implication that taking care of these patients will lead to a lower quality practice and sanctions by CMS. These 9-10 million chronic pain patients eventually become abandoned. ASAM is aware that patients are hospitalized because of this situation. Many of these patients have Medicare or Medicaid and this is a very costly mistake for the healthcare system. Furthermore, some patients have resorted to using illicitly obtained opiates to control their pain, and the consequences have been devastating from a healthcare perspective. There have been cases of hospitals declaring that they were going to "aggressively reduce opiate prescribing". The result is hundreds of patients unnecessarily suffering and many requiring hospitalization.</p> <p>Fear has caused well-meaning and compassionate providers to vilify opiates. It is caused them to take their eyes off the patient which certainly leads to lower quality care and poor outcomes. We strongly support measures that will allow providers to focus on patients and not drugs.</p>				<p>Thank you for providing feedback on the specifications and evidence for the Potential Opioid Overuse measure. We are sensitive to the fact that unintended consequences could stem from implementation of this measure, such as provider reluctance to prescribe opioids, increased patient referrals to pain specialists, or under-treatment of pain while patients transition to other therapies. We believe that reductions in long-term, high-dose opioid use—which we aim to assess using this eCQM—should be paired with concurrent policies to encourage optimal patient care.</p> <p>We view this measure as one of several potential tools to reduce the harms of the opioid crisis. Other measure developers, agencies, and organizations are undertaking efforts to evaluate alternative approaches to pain management, medication reconciliation, and other instruments intended to decrease unnecessary use of opioids.</p> <p>We will bring the changes you've suggested in your comment to our expert work group for further evaluation. We acknowledge that prescribing patterns and opioid use can vary based on patient and provider characteristics; we will evaluate ways to identify those provider and patient populations that could most benefit from reporting of this quality measure as we work to refine the measure specifications. We will continue to refine the measure specifications in accordance with guidance from the CDC, feedback from our expert work group, and responses submitted during this comment period.</p>

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12 (cont)	2/9/18	<p>Other unintended consequences include:</p> <ul style="list-style-type: none"> This measure must be able to explicitly and reliably exclude prescribing of buprenorphine (Suboxone, Subutex, Zubsolv, Bunavail, and generic versions) for medication-assisted treatment of opioid use disorder, or it may dissuade practitioners from offering this life-saving treatment (See attached letter from CDC regarding the CDC Guideline for Prescribing Opioids for Chronic Pain and buprenorphine dosage thresholds). If the overarching goal is for patients to be on lower total opioid doses, practitioners must have resources available for training or referral to treatment for patients already on high-dose opioids, or else those patients will turn to illegal opioids such as heroin (contributing to the opioid overdose death rate anyway), or end up suffering more with resultant high utilization of scarce healthcare resources. We would very much like to see CMS support high quality, well thought-out care as opposed abject reduction of medication which would likely lead to wasted healthcare dollars. A lack of understanding of addiction, tolerance, dependence and chronic pain management has led to a blurring of these issues and unnecessary suffering for many patients. <p>“Whether data elements related to the measure are available in structured, extractable fields in electronic health record systems” We believe the data could be easily extracted with the appropriate query. Implementation of this measure may be improved by linkage with state prescription drug monitoring programs as opposed to (or in addition to) EHRs. “Whether the measure should include any additional exclusions”. It is difficult to answer this question as we believe the underlying assumptions driving the measure are flawed. Again, we would support that patients on high MME should be provided with “universal precautions” and referral to appropriate specialist to determine if the current regimen is appropriate or should be modified. We would not endorse any measure that would discourage providers from accepting and compassionately caring for this fragile group. We would also exclude from calculation patients who are on partial opioid agonist therapy (buprenorphine) for opiate dependency. “Whether any refinements to the existing measure exclusions are needed”. Regarding the exclusion of patients with sickle cell disease, we recommend that the measurement discussion documentation provide an explanation of the rationale for this, including citation of at least one peer-reviewed article about how sickle cell disease if substantially different from other forms of chronic pain being evaluated in general for this measure.</p>				<p>Sickle cell disease was chosen as a measure exclusion not because of a preponderance of evidence suggesting it as an appropriate condition for removal from the initial patient population, but rather due to the face validity of opioid use for treating sickle cell disease pain. In 2014, the National Heart, Lung, and Blood Institute released a guideline on management of sickle cell disease, in which opioids were cited as one effective therapy in management of pain crises for sickle cell disease patients. Due to the multidimensional challenges faced by providers managing patients with sickle cell disease, we acknowledge that additional provider discretion of opioid dose and duration may be necessary to effectively manage pain in this patient population. If there are other chronic conditions similar to sickle cell disease for which exclusion from the measure’s initial patient population would be appropriate, we would welcome this feedback as we continue to refine the measure specifications.</p>
13	2/9/18	<p>We appreciate the opportunity to offer our feedback on CMS’s project, Electronic Clinical Quality Measure (eCQM) related to Potential Opioid Overuse. As developers of ONC- certified EHR solutions designed to contribute to the improvement of population health, NextGen Healthcare appreciates the seriousness of the opioid overuse epidemic in the US. Additionally, our technical and clinical staff have vast experience supporting, implementing and reporting eCQMs for our physician clients. In this capacity, we believe our feedback could be helpful to CMS in achieving the goals outlined in its rationale for this potential new quality measure. Regarding the usefulness of this measure to assess and improve the quality of care for patients, we believe this measure will be a valuable tool to inform prescribers of their overall prescribing patterns as well as giving them a useful tool for monitoring opioid dosing and chronicity within their patient populations. Regarding the appropriateness of the measure to assess provider performance, we believe that the ongoing opioid epidemic in the United States requires a something like this proposed measure – a useful tool for informing prescribers of their overall opioid prescribing patterns as well as population and individual patient-level data on opioid use and patterns of use.</p>	Andy Riedel; NextGen Healthcare	ariedel@nextgen.com	EHR vendor	<p>Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. We are sensitive to the fact that unintended consequences could stem from implementation of this measure, such as provider reluctance to prescribe opioids, increased patient referrals to pain specialists, or under-treatment of pain while patients transition to other therapies. We believe that reductions in long-term, high-dose opioid use—which we aim to assess using this eCQM—should be paired with concurrent policies to encourage optimal patient care.</p>

Comment Number	Date Posted	Text of Comments	Name and Organization of Commenter	Contact E-Mail	Type of Organization	Recommendations/Actions Taken
13 (cont)	2/9/18	<p>At the same time and with respect to potential unintended consequences of implementing the measure, we urge CMS to take steps to avoid inadvertently penalizing providers who are taking appropriate steps to reduce and curtail opioid abuse, as discussed below.</p> <p>With respect to CMS’s question regarding availability of data elements related to the measure as structured, extractable fields* in electronic health record systems, we believe structured data to support this measure are generally available in commercial EHRs. However, we request that CMS provide morphine equivalents for every medication listed. We also request the use of RxNorm codes for each medication to be included in the medication list. CMS has asked whether any additional conditions should be excluded from the measure, or whether any refinements to the existing measure exclusions are needed. Though not strictly speaking a “condition”, we believe CMS should consider an exclusion for long term opioid users already in the process of tapering to a lower dose. If a patient has been on >90 milligram morphine equivalents and is in the process of tapering down/off with an appropriate plan in place, we believe that this should constitute an exception. If a patient is taking >+ 90 milligram morphine equivalents, they must have a plan in place. We believe it is problematic that this measure does not take into account tapering efforts as this will penalize those providers already in the process of tapering the medication. Also, CMS lists denominator exclusions for patients: receiving palliative or hospice treatment during the measurement period; with cancer during the measurement period; and with sickle cell disease during the measurement period require a value set. Regarding palliative or hospice treatment we would point out that palliative and hospice treatment are not one and the same. We ask that CMS define palliative treatment for the purposes of this measure. Regarding opioids and cancer patients, we would point out that opioid dosing and prescribing patterns may differ based on the type of cancer. Should a patient with a nasal basal cell cancer be treated the same as someone with pancreatic cancer? We ask CMS to provide SNOMED/ICD codes for cancers to be included in the denominator exclusion. A value set for these will be necessary. Finally, as relates to measure calculation, we ask CMS to address scenarios where providers in group settings may write overlapping prescriptions. For example: If a provider A in a practice gives a prescription for 60 days of 90 milligram morphine equivalents to a patient, and provider B in the same practice prescribes 30 days of 90 milligram morphine equivalents within less than 7 days’ time of provider A’s 60-day prescription ending, do both providers numerators for this measure increment or not increment? What if both of those providers are reporting under the same Tax ID Number (TIN) as a group? If the TIN reports this measure by group would the measure count prescriptions for all prescribers in that TIN that totaled 90 consecutive days?</p> <p>NextGen Healthcare thanks you for considering our comments on this important initiative. We look forward to continued collaboration with CMS and other stakeholders working toward a solution to the current US opioid crisis.</p>				<p>Our intention is to build calculation of MME into the measure logic. If the measure is implemented, we will release value sets for each opioid included in the measure specifications that will include RxNorm codes, which can be mapped to the medication’s units and dose. Providing these tools for calculating MME will decrease provider burden and improve transparency into the populations eligible for inclusion in the measure’s numerator. We will bring the changes you’ve suggested in your comment—including the additional conditions you consider appropriate for exclusion from the initial patient population—to our expert work group for further evaluation. To your questions about the definitions of cancer, sickle cell disease, and hospice/palliative care: value sets for all three data elements can be accessed through the VSAC. For the cancer value set, we have included nearly all types of cancer, based on feedback from several clinicians to whom we spoke during qualitative testing. Because the patient experience for many cancers is complex and varied, we elected to keep the definition of this data element broad, to allow for greater provider discretion in management of patient pain during and immediately following cancer treatment. For hospice/palliative care, coding for palliative care is evolving. The current standards rely on SNOMED codes, though we acknowledge that use of these codes underrepresents palliative care treatment. We will continue to refine value sets for this data element to align with the most current coding practices, as needed. We view this measure as one of several potential tools to reduce the harms of the opioid crisis. Other measure developers, agencies, and organizations are undertaking efforts to evaluate alternative approaches to pain management, medication reconciliation, and other instruments intended to decrease unnecessary use of opioids. We will continue to refine the measure specifications in accordance with guidance from the CDC, feedback from our expert work group, and responses submitted during this comment period.</p>

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14	2/9/18	<p>Since the implementation of the law in Maine, many clinicians, particularly mid-levels, will no longer prescribe opioids at all - leaving many chronic pain patients without any help. Physicians left in the area absorbed many of these patients - we are also the physicians treating opioid addicted patients. Our practices have become skewed - therefore the data points are now skewed and it would be misleading, arbitrary and WRONG to assume that if we have X number of patients taking > 90MME of opioids that we are practicing bad medicine. Additionally that guidance feature put out by the CDC does not account for skewed population centers of older sicker patients. It is an arbitrary way to make a judgement about a practice.</p>	<p>Cathleen London, MD; Door to Door Doctors</p>	<p>drchaya@gmail.com</p>	<p>Family medicine practice</p>	<p>Thank you for providing feedback on the specifications and evidence for the Potential Opioid Overuse measure. We appreciate the concerns you highlighted in your comments. We are committed to limiting the potential harms and unintended consequences of any measure relating to pain management and opioid use. Based on the strong relationship between long-term, high-dose opioid use and patient harms (including addiction and death), however, we believe implementation of this measure will help improve public health and reduce opioid-associated deaths.</p> <p>This measure aims to reduce risks of adverse drug events by creating incentives for providers to review the patient's individual needs and consider all potential alternatives for managing pain. This measure is not intended to limit access to opioids more broadly and does not prohibit physician discretion in making patient-level treatment decisions. We know that the treatment selected for pain management can vary widely based on the individual needs of the patient. We also expect that providers may encounter some patients who have limited alternatives to long-term, high-dose opioid therapy. For this reason, we do not expect provider scores for this measure to reach zero percent consistently. We will continue to refine the measure specifications in accordance with CDC's guidance, feedback from our expert work group, and responses submitted during this comment period.</p> <p>We are sensitive to the fact that unintended consequences could stem from implementation of this measure, such as provider reluctance to prescribe opioids, increased numbers of patient referral to pain specialists, or undertreatment of pain while patients transition to other therapies. It is well documented, however, that long-term, high-dose opioid therapy is associated with significant risks of addiction and adverse events, including death. We will continue to balance recommendations for reducing unsafe opioid use while promoting an increased</p>

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14 (cont)	2/9/18					focus on safer alternatives, including non-opioid therapies and lower doses of opioids.
15	2/9/18	<p>The Society is the only medical specialty society representing the community of over 50,000 medical directors, physicians, nurse practitioners, physician assistants, and other practitioners working in the various post-acute and long-term care (PA/LTC) settings. The Society's 5,500 members work in skilled nursing facilities, long-term care and assisted living communities, continuing care retirement communities (CCRC), home care, hospice, PACE programs, and other settings. In serving this population, these clinicians care for the most high-risk and costly group of beneficiaries covered by Medicare and Medicaid programs. The Society recognizes and supports efforts to combat the current epidemic of opioid abuse, misuse and diversion. The challenge, however, is that we must carefully balance the need to make every effort to curb this national crisis with the clinical needs of the most medically complex and vulnerable patients our members serve, and who require sound clinical pain management and care. The development of quality measures has the potential to significantly influence provider behavior. Given that quality measures are currently being tied to reimbursement and value-based reporting programs, clinicians and other providers carefully consider the ramifications of each measure on their performance and act accordingly. Thus, it is imperative that these measures carefully consider all consequences and provide exclusions so that they are applied appropriately to the clinicians and the population they are intended to measure.</p> <p>With this in mind, we believe that the proposed eCQM is flawed and has unintended consequences for residents and patients in PA/LTC settings. Residents and patients in these settings are vastly different from the typical ambulatory setting where most of the issues surrounding abuse, misuses and diversion occur. We detail our reasoning in answering the specific questions CMS asked in the measure announcement:</p> <p>**The usefulness of the measure to assess and improve the quality of care for patients?</p> <p>The feasibility of the measure to assess provider performance and any unintended consequences of implementing the measure? **To address these two questions together, we believe this measure is not useful to assess and improve the quality of care for the PA/LTC patient population. Pain management in the PA/LTC population and appropriate medications are a major concern. However, we believe the measure would probably have the unintended consequence of impeding appropriate patient care in this setting. There are several reasons for this. One is the patient population itself. This month, the Journal of the American Geriatrics Society (JAGS) (attachment) provided national data on nursing facility residents. The article states that one in seven residents is on long-acting opioids and the prevalence rate for use of long-term opioids at a dose of 90 mg morphine equivalents or greater is 16%. This is twice as prevalent as the outpatient community at large. The prevalence of use of pain adjuvants was 50%, indicating that opioid-sparing alternatives were tried. Other alternatives such as non-opioid pharmacotherapies included prescribed nonsteroidal anti-inflammatory drugs (NSAIDs; excluding aspirin), which are not good choices for frail elders because of significant risks of life-threatening adverse gastrointestinal, renal and cardiac complications, were 16%. We have concerns that even more vulnerable chronic pain patients in the PA/LTC setting would be placed at risk because of physicians choosing to use these kinds of medications in place of opioids because of fear of being docked on this measure.</p>	Alex Bardakh; The Society for Post-Acute and Long-Term Care Medicine	abardakh@paltc.org	Professional society	

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15 (cont)	2/9/18	<p>The article concluded, “Recent guidelines on opioid prescribing for pain recommend reducing long-term opioid use, but this is challenging in NHs [nursing homes] because residents may not benefit from non-pharmacological and non-opioid interventions. Studies to address concerns about opioid safety and effectiveness (e.g., on pain and functional status) in NHs are needed.” These data and conclusions point to a potential unintended consequence of the measure—that is, use of potentially contraindicated medication that could be linked to "alternative pain management options". In addition to the NSAID use, 33% were benzodiazepines (also relatively contraindicated in the geriatric population) and 13% on two or more psychotropic medications.</p> <p>The second concern is that the nursing facility environment is a highly-regulated environment. Specific to the chronic pain management issue, nursing facilities find it challenging to comply with Federal Regulation F-Tag 697, Pain Management as codified in the Centers for Medicare & Medicaid Services (CMS) State Operations Manual, Appendix PP- Guidance to Surveyors for Long Term Care Facilities. The potential conflict may result in inadequate or inappropriate treatment of pain in the nursing facility. Nursing facilities are penalized on their quality measures for patients who report moderate to severe pain. Given that Medicare Part B measures in the Merit-Based Incentive Payment (MIPS) program are not necessarily aligned with the facility, the physician is put in a challenging position of either scoring poorly on the quality measure or complying with the Federal nursing home regulations. This is clearly not the intent of any value-based program or this specific measure.</p> <p>While we recognize that the Centers for Disease Control and Prevention (CDC) has issued guidelines for prescribing opioids for chronic pain, there is limited evidence to support the use of a 90-morphine milligram equivalent (MME)/day dosage limit as a reasonable quality metric for the PA/LTC patient population. Opioids have tolerance, with some patients requiring higher doses over time to produce adequate pain relief. Further, lack of agreement on an accepted methodology for converting dosage across various opioids challenges the validity of the 90 MME/day limits upon which the draft measure is based. The Society is currently working on an evidence-based position statement that addresses the CDC guidelines and provides more specific recommendations for use of opioids in the PA/LTC setting. But in the meantime, we requesting consideration of eliminating the 90 MME limit in nursing home residents (POS 31 and 32) as a quality measure. These patients are in a controlled environment where they do not have access to the entire supply of medication, and hence cannot easily take an excessive quantity—since the medications are administered by professional nursing staff, they are only consumed in accordance with medical orders. Also, these patients are monitored medically with frequent vital signs and visual observation and are in a setting where it is improbable that they can mix illicit drugs or alcohol that could produce over dosage. We also stand with other professional organizations, including the American Academy of Hospice & Palliative Medicine, in supporting the exclusion of patients receiving hospice and palliative care from this measure. However, we are unclear on how non-hospice palliative care patients will be identified so that they can be excluded. Nursing homes have many such patients and the Society is concerned that they will be subjected to inadequate pain relief if they are being included in this measure. The Society stands ready to work with CMS and other stakeholders to craft measures that align well with the goal of the nursing facility and provide appropriate pain management for residents and patients in this setting.</p> <p>*Whether data elements related to the measure are available in structured, extractable fields in electronic health record systems? *</p>				<p>Thank you for providing feedback on the specifications and evidence for the Potential Opioid Overuse measure. We believe the recommendations presented in CDC’s Guideline for Prescribing Opioids for Chronic Pain—United States, 2016 represents the strongest evidence available at this time on appropriate definition for high-dose opioid use; we do acknowledge, however, that some populations are disproportionately impacted by the burdens of opioid use and may require additional management beyond the principles laid out in this measure’s specifications. The populations excluded from the current initial patient population were evaluated against several criteria, relying on findings from guidelines and peer-reviewed literature, feedback from experts, and results from qualitative and quantitative testing. We welcome additional suggestions, however, on conditions for which use of long-term, high-dose opioids at doses above 90 MME may be clinically appropriate.</p>

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15 (cont)	2/9/18	<p>It is not clear which data elements will be used to gather data for this measure. We seek clarification from CMS on this issue and hope to provide additional information on how to best collect the right data elements from Minimum Data Set (MDS) and other records to achieve desired measure specifications. Whether the measure should include any additional exclusions? We applaud and support CMS for including patients receiving palliative or hospice treatment during the measurement period in the in the exclusions list of the measure. However, we believe that the measure needs to add SnomedCT taxonomy codes for all Nursing Facility face-to-face encounters to the exclusions list. This would effectively exclude all residents and patients receiving care in Places of Services 31 (Skilled Nursing Facility) and 32 (Nursing Facility). We believe this additional exclusion is necessary given 1) the unintended consequences outlined above and 2) the difficulty in identifying what constitutes “palliative treatment” and identifying patients who are receiving this type of care. Physicians providing care in the SNF/NF could very well be providing palliative treatment but may not be identified on the basis of the definitions set out in these measures. Thus, exclusion of SNF/NF encounters defined by CPT code 99304-99318 is our recommended solution. This is an extraordinarily ill, vulnerable and functionally dependent population, and they should not be placed in a situation where physicians are likely to skimp on pain medication because of worries about their performance on a measure. There are limited options for pain control in the frail geriatric patient, and the goals of care are often focused on comfort, relief of pain, dignity, and quality of life. As mentioned, they are residing in a controlled, medically supervised, institutional healthcare environment—similar to a hospital in many ways—and they should be recognized as the unique population they are. PA/LTC patients should not be subjected to this well-intentioned quality measure that may be reasonable for the general outpatient population, but that is highly likely to cause unnecessary suffering and inadequate pain relief in the nursing home.</p>				<p>This measure aims to reduce risks of adverse drug events by creating incentives for providers to review the patient’s individual needs and consider all potential alternatives for managing pain. This measure is not intended to limit access to opioids more broadly and does not prohibit physician discretion in making patient-level treatment decisions. We know that the treatment selected for pain management can vary widely based on the individual needs of the patient. We also expect that providers may encounter some patients who have limited alternatives to long-term, high-dose opioid therapy. For this reason, we do not expect provider scores for this measure to reach zero percent consistently.</p> <p>We appreciate your suggestions to refine identification of patients receiving hospice and palliative care treatment. We will bring the changes you have suggested in your comment—including exclusion of additional patients based on their setting of care—to our expert work group for further evaluation.</p>

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16	2/9/18	<p>1. The usefulness of the measure to assess and improve the quality of care for patients –</p> <ul style="list-style-type: none"> a. minimal usefulness and (whats the point of this?) b. has the potential to lead to unintended and adverse outcomes to the chronic pain patient c. will lead to potential under-treatment of pain and/or patient dumping possibly on ED and resulting in multiple short term prescribing of narcotic and pushing patients to street drugs like heroin/fentanyl products with possible increasing mortality). I would argue from the standpoint of the PMD, this is a useful measure to gather data on number / extent of prescriptions. Again – not sure if it makes a big impact on the ED workflow given the numerator & denominator. <p>2. The feasibility of the measure to assess provider performance and any unintended consequences of implementing the measure –</p> <ul style="list-style-type: none"> a. Doubt this is a reliable measures of provider performance. Would need to see an analysis <p>Unintended consequences as above. This is completely a utilization measure – how much are you prescribing? There are patient factors that come into play here. This will likely drive down primary care providers from giving access to narcotic prescriptions, increasing utilization of pain management services.</p> <p>3. Whether data elements related to the measure are available in structured, extractable fields in electronic health record systems</p> <ul style="list-style-type: none"> a. Doubtful that the fields necessary to adequately describe the condition of the patient and the reason they are being treated and failure of previous treatments are not available in discreet fields. There are no exclusions in the measure specs. This may actually be able to be extracted in HER from structured fields. b. difficult to document in a discreet field the need for increasing the dosage of opioids above the 90 MMEs however this may be captured in other data base's like OARS(Ohio) or pharmacy data bases <p>4. Whether the measure should include any additional exclusions –</p> <ul style="list-style-type: none"> a. the measure should also consider excluding managed complex pain patients who are maintained on higher doses (greater than 90MMS.) b. not sure if we should ask for exclusion for ED doctors but doubt they would accept and if we are supposed to check an OARS (PMP) system prior to prescribing/providing there may need to be an exclusion for md working in states that don't have an OARS (PMP) <p>This measure will be impacted by state programs already being passed. For instance, in NC, EDs are limited to 5 days of opioid prescriptions. Acute surgical procedures to 7 days.</p> <p>Would you have to exclude patients in MAT programs? Without a universal acceptable MAT program unlikely going to be very useful measure at this time.</p>	Meredith Mayo; American College of Emergency Physicians	mmayo@acep.org	Professional society	<p>Thank you for providing feedback on the specifications and evidence for the Potential Opioid Overuse measure. We are sensitive to the fact that unintended consequences could stem from implementation of this measure, such as provider reluctance to prescribe opioids, increased patient referrals to pain specialists, or under-treatment of pain while patients transition to other therapies. We believe that reductions in long-term, high-dose opioid use—which we aim to assess using this eCQM—should be paired with concurrent policies to encourage optimal patient care.</p> <p>Our intention is to build calculation of MME into the measure logic. If the measure is implemented, we will release value sets for each opioid included in the measure specifications that will include RxNorm codes, which can be mapped to the medication's units and dose. Providing these tools for calculating MME will decrease provider burden and improve transparency into the populations eligible for inclusion in the measure's numerator. We will continue to refine the measure specifications in accordance with guidance from the CDC, feedback from our expert work group, and responses submitted during this comment period.</p> <p>We will bring the changes you've suggested in your comment—including exclusion of medically complex patients for whom the average daily dose exceeds 90 MME intentionally—to our expert work group for further evaluation.</p>

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17	2/9/18	<p>As a member of the chronic pain community for 37 years, I applaud the effort to mitigate the risks and potential negative outcomes of freely or rather, hastily prescribing opioid medications for acute, chronic, and intractable pain. However, the knee-jerk reaction to a decades-long issue (the management of (chronic) intractable pain), has resulted in far greater harm than the initiative to reign in prescribing opioid medications supposedly intended to prevent. The harm is as clear as day and yet the system, the government, the vast majority of the medical community, and of course the mainstream media repeatedly refuse to publicly address the issue, they sweep chronic pain refugees under the rug, and they continue to work toward lowering the daily dose of opioid medications and in doing so causing irreparable harm. It does not take much effort to look around Facebook groups and other social media networks to gain perspective on the ubiquitous resultant harm and suffering among people with (chronic) intractable pain and to then garner some insight into the multitude of problems that have been caused by the prohibition of opioids in the treatment of chronic pain. Many patients who have been abandoned now have a suicide plan in place, many are now suffering from clinical depression, many people have lost their jobs and families, and a staggering number of people have actually committed suicide as a direct result of having been forcibly titrated down from their historically stable dose or removed from their medications entirely. The last time I checked our veterans are committing suicide at a rate of twenty-two people per day and sadly many of these deaths are also a direct result of having lost their pain medications and therefore their quality of life. It is certainly logical to keep track of physicians who prescribe opioid analgesic medications with the primary intent of preventing unscrupulous "doctors" from establishing unsafe clinics which historically came to be known as "pill mills". The government needs to publicly admit that pill mills have been entirely eradicated. The DEA must stop strong-arming doctors and threatening their practices. The DEA knows full well that just because a physician treats patients from out of state it does not mean they are a pill mill. Many physicians are seeing refugees from other states because far too many physicians in the patient's home state have either stopped practicing pain medicine, their waiting lists are months and even years long, or they are unable to find a physician that is willing to prescribe the dose they need in order to work, go to college, care for their families, and to simply not writhe in bed all day and all night. While I realize travel from one state to another in the past was often a sign of an unscrupulous practice that simply is not the case in this day and age. The vast majority, if not all, of the bad "physicians", have been weeded out of the system.</p> <p>We must move forward with a more thoughtful, logical, practical, and humane solution. Providing incentive to medical practitioners (basically by bullying them with the notion that they will be tracked like cattle and pinged if they prescribe too high a dose and especially to too many patients), not to prescribe opioids for pain management and certainly never above the (unsubstantiated) guidelines set by the CDC and its anti-opioid cohorts, will cause harm to legitimate patients and result in another uptick in overdoses caused by illicit sources. By persecuting physicians that are still willing to live by their oath and treat people with chronic pain the system is creating an unintended consequence of patients who will choose to self-medicate rather than commit suicide. Furthermore, by favoring physicians that refuse to take on the refugees of the Drug War aka the war on prescription opioids the system is taking away the physician's right to choose to care for patients that no one else wants to take the time to care about. Is this the legacy the system wants to leave for future generations? During a time of great doubt, the system chose to err on the side of supposed caution and began</p>	Kara A. Rowe; Chronic Pain Reform	karaarowe@gmail.com		

Comment Number	Date Posted	Text of Comments	Name and Organization of Commenter	Contact E-Mail	Type of Organization	Recommendations/Actions Taken
17 (cont)	2/9/18	<p>a slow descent into the prohibition of historically safe opioid medications (in comparison to the majority of alternatives), and used biased PROPaganda via mainstream media to generate hysteria over the evils of opioid addiction which everyone involved knows the risk of which is astonishingly low.</p> <p>As the system works to improve prescribing practices among practitioners it should be advised not only to reward physicians for keeping daily opioid doses as low as possible by following the CDC guidelines but the system should also be set up to reward the physicians that choose to handle the tougher cases, the patients that are rapid opioid metabolizers, the patients who require an ultra-high dose due to tolerance, and all the outliers that no one truly understands... because, here in lay the real meaning of medicine and of being a caregiver. By speaking for and standing by those who are unwanted by most other practitioners, a physician becomes the very embodiment of healing. In their ability to guide their patient through their most horrific of symptoms caused by their illness/disease/injury - chronic, unrelenting, intractable pain the true healer should never need to be afraid of a system that is supposed to protect everyone involved. We must move to better educate prescribers, dispensers, and patients alike. The system and policymakers need to realize that "over-prescribing" does not relate to physicians that prescribe high doses to certain patients with life-altering, unrelenting, and chronic intractable pain. The term itself is very misleading. A more fitting description should be something like "freely prescribed" with emphasis on the past tense while making certain the public knows this is no longer happening. However, on that note, the system must realize and correct the fact that far, far too many legitimate chronic intractable pain patients who lost their medications due to the perverted policies and fear mongering among physicians still need their medications returned to them and until every single patient that has been abandoned by their doctor has been reevaluated and returned to their prior level of functioning we simply cannot celebrate that prescriptions are down in number. I am running out of time to write and so I just want to leave you with one last thought. Please, for the love of god, think twice about the policies you are creating. Be careful with how you justify their necessitation. Be more humane and a lot more patient with actual science. We have a lot more to learn about chronic pain and subjective illnesses like chronic pain will always be in question but, in all reality, it doesn't have to be that way because we can have faith in one another and we can trust.</p> <p>Thank you.</p>				<p>Thank you for providing feedback on the specifications and evidence for the Potential Opioid Overuse measure. We are sensitive to the fact that unintended consequences could stem from implementation of this measure, such as provider reluctance to prescribe opioids, increased patient referrals to pain specialists, or under-treatment of pain while patients transition to other therapies. We believe that reductions in long-term, high-dose opioid use—which we aim to assess using this eCQM—should be paired with concurrent policies to encourage optimal patient care.</p> <p>This measure aims to reduce risks of adverse drug events by creating incentives for providers to review the patient’s individual needs and consider all potential alternatives for managing pain. This measure is not intended to limit access to opioids more broadly and does not prohibit physician discretion in making patient-level treatment decisions. We know that the treatment selected for pain management can vary widely based on the individual needs of the patient. We also expect that providers may encounter some patients who have limited alternatives to long-term, high-dose opioid therapy. For this reason, we do not expect provider scores for this measure to reach zero percent consistently.</p> <p>We view this measure as one of several potential tools to reduce the harms of the opioid crisis. Other measure developers, agencies, and organizations are undertaking efforts to evaluate alternative approaches to pain management, medication reconciliation, and other instruments intended to decrease unnecessary use of opioids. We know that management of patient pain is intensely personal and must involve shared decision-making to identify an individualized care management plan involving shared decision-making between patients and providers. We will continue to refine the measure specifications in accordance with guidance from the CDC, feedback from our expert work group, and responses submitted during this comment period.</p>

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18	2/9/18	<p>The American Academy of Pain Medicine (AAPM) is pleased that the Centers for Medicare & Medicaid Services (CMS) is taking steps to address the epidemic of opioid addiction, overuse, overdose and mortality that is affecting our country. The proposed measure is appropriate, useful and practicable. While the 90 MME threshold is arbitrary, as any number would be, it falls within the range of recommendations of medical societies, state medical boards and the Centers for Disease Control. Any number from 80 to 120 will likely produce nearly identical results on the anticipated measure.</p> <p>We have, however, a number of concerns:</p> <ul style="list-style-type: none"> • There is no description provided of the anticipated use of the measure. Statements to the effect that it is expected to lead to improvements in practice, mortality, etc., fail to describe a mechanism by which measurements are translated into behavioral change on the part of providers. There are thus concerns that some form of adverse consequences (reimbursement, publications designed to “expose” those falling outside desired parameters, sanctions, etc.) would befall practitioners without evidence of substandard care. We have anecdotal reports of this happening in several states, including Pennsylvania and Washington, as well as with CVS Pharmacies. • Provided documents make the unsupported assumption that lower scores (i.e., lower dose opioid prescribing) equates to higher quality care. This is especially a concern among pain medicine specialists, to whom are referred patients who have been unresponsive to primary (and often specialty) care and who therefore almost by definition require more aggressive treatment than “typical” patients with chronic pain. • The documents assert that lower prescribing will improve productivity and function; however, this belief is not substantiated, given the near complete absence of outcome data for long-term and high-dose opioid treatment. • It can be argued that the proposal focuses on that which is easily quantifiable to the neglect of that which is most important; i.e., many would hold that the number of milligrams of opioids prescribed daily is far less important than the following items, which are not measured: <ul style="list-style-type: none"> ○ Continuation of opioid therapy in the absence of demonstrated benefit or in the presence of demonstrated harms and/or aberrant behavior. ○ Initiating high-dose opioids without knowledge of how to perform comfortable and safe weaning. ○ Co-prescribing opioids with sedatives. • The measure does not account for patients who both need and benefit from higher dose treatment. • The measure threatens to curtail a treatment without promoting alternatives. • Assuming the measure leads to meaningful consequences, there is risk of unintended effects, which may include: <ul style="list-style-type: none"> ○ Opioid deserts in which essentially all providers have concluded that the workload and risks of providing opioids are not sustainable, and therefore ceased prescribing. ○ Providers who precipitously stop or reduce opioids, leading to withdrawal symptoms, hyperalgesia, and high-risk patient behaviors intended to reduce these symptoms. ○ Patients who have resumed function thanks to opioids may become disabled socially, vocationally, or avocationally in their absence. ○ Potential patient suicides in response to withdrawal and increased pain. 	Mary Kay Ams; American Academy of Pain Medicine	mams@Connect2amc.com	Professional society	<p>Thank you for providing feedback on the specifications and evidence for the Potential Opioid Overuse measure. This measure aims to reduce risks of adverse drug events by creating incentives for providers to review the patient’s individual needs and consider all potential alternatives for managing pain. This measure is not intended to limit access to opioids more broadly and does not prohibit physician discretion in making patient-level treatment decisions. We know that the treatment selected for pain management can vary widely based on the individual needs of the patient. We also expect that providers may encounter some patients who have limited alternatives to long-term, high-dose opioid therapy. For this reason, we do not expect provider scores for this measure to reach zero percent consistently. We will continue to refine the measure specifications in accordance with CDC’s guidance, feedback from our expert work group, and responses submitted during this comment period.</p> <p>We are sensitive to the fact that unintended consequences could stem from implementation of this measure. It is possible that providers may be less willing to prescribe opioids, or there could be under-treatment of pain while patients are transitioning to new non-opioid treatment. It is well documented, however, that long-term, high-dose opioid therapy is associated with significant risks of addiction and adverse events, including death. We will continue to balance recommendations for reducing unsafe opioid use while promoting an increased focus on safer alternatives, including non-opioid therapies and lower doses of opioids.</p> <p>We will bring the changes you’ve suggested in your comment—including exclusion of patients seeking addiction treatment and those for whom 90 MME is medically necessary—to our expert work group for further evaluation. We view this measure as one of several potential tools to reduce the harms of the opioid crisis. Other measure developers, agencies, and organizations are undertaking efforts to improve the safety of opioid use in specific</p>

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18 (cont)	2/9/18	<ul style="list-style-type: none"> The measure does not clearly specify that opioid treatment of addiction should be excluded from both numerator and denominator, though the list of included drugs describes buprenorphine “for pain management.” It should be clear that opioid treatment of addiction is not included in the measure. 				patient subgroups, such as those who concurrently use other prescribed medications associated with high risks of adverse events.
19	2/9/18	<p>On behalf of the American College of Obstetricians and Gynecologists (ACOG), the nation’s premier women’s health care membership organization with over 58,000 members, thank you for the opportunity to provide comments on the Centers for Medicare & Medicaid Services’ (CMS) proposed measure specification on Potential Opioid Overuse.</p> <p>As discussed in ACOG Committee Opinion #711: Opioid Use and Opioid Use Disorder in Pregnancy, the use of opioids in pregnancy has escalated dramatically in recent years and parallels the epidemic seen in the general population throughout the country. Women who use opioids during pregnancy represent a diverse group and it is critically important to recognize and differentiate between opioid use in the context of medical care, opioid misuse, and untreated opioid use disorder. Referral for treatment of pregnant women with opioid use and opioid use disorder are proven to improve both maternal and infant outcomes. The importance of pregnant women receiving adequate treatment for opioid use and opioid use disorder cannot be overstated; inadequate maternal methadone dosage may result in mild to moderate opioid withdrawal signs and symptoms that may cause fetal stress and maternal drug cravings, which increase the likelihood of relapse and treatment discontinuation. If a woman has been treated with a stable methadone dose before pregnancy, pharmacokinetic and physiologic changes that occur during pregnancy may require dose adjustments, especially in the third trimester. Because of metabolic changes in pregnancy, a single daily dosage may not control withdrawal symptoms over a 24-hour period. Rapid metabolism often develops during pregnancy, especially in the third trimester and in these cases, split dosages may be optimal. Due to the unique timing and dosing issues associated with treatment and the dire consequences that stopping or limiting treatment has on a pregnant woman and her developing fetus, we are asking that you exclude pregnant women from the denominator of this measure. Further, we ask that when developing the exclusion criteria, you consider that the use of live birth data alone will not identify all pregnancies. Careful consideration should be made to ensure all pregnant women, regardless of outcome, are excluded. Additionally, we would like to express concern regarding the ability to accurately parse out the data when attempting to identify buprenorphine use for pain management vs. for treatment, both in pregnant women and in the general population. Obtaining this level of data will be extremely difficult, if not impossible, to do accurately. Failing to recognize buprenorphine use for pain management versus treatment will have significant negative consequences on both the patients receiving this treatment and on their providers. Further, consistently identifying accurate dosage levels for all listed opioids will also be incredibly difficult given the limited availability of consistently accurate prescribing data. Failing to obtain accurate dosage data will affect patients receiving buprenorphine or methadone – both of which are given in doses that may be smaller than 90 mg for periods longer than 90 days. Currently there are data to support that doses between 4 mg to 24 mg a day may be appropriate for buprenorphine stabilization in the non-pregnant, general population. This circumstance is due in part to variability in sublingual absorption of</p>	American College of Obstetricians and Gynecologists	Not provided	Professional society	<p>Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. Our intention is to build calculation of MME into the measure logic. If the measure is implemented, we will release value sets for each opioid included in the measure specifications that will include RxNorm codes, which can be mapped to the medication’s units and dose. Providing these tools for calculating MME will decrease provider burden and improve transparency into the populations eligible for inclusion in the measure’s numerator.</p> <p>The definitions of long-term (90+ days of opioid use) and high-dose (90 MME or greater average daily dose) opioid use were selected to align with guidance provided by the Centers for Disease Control and Prevention in its Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.</p> <p>We will bring the changes you’ve suggested in your comment—including additional evaluation of using buprenorphine prescriptions to identify patients for the initial patient population and exclusion of pregnant women—to our expert work group for further evaluation. We will continue to refine the measure specifications in accordance with CDC’s guidance, feedback from our expert work group, and responses submitted during this comment period.</p>

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19 (cont)	2/9/18	<p>buprenorphine, its subsequent metabolism, and patient response. As with methadone, the primary goal in choosing a stable dose of buprenorphine for a given patient should be to attain a level that suppresses opioid withdrawal effects, and hence, provides the best opportunity to retain the patient in treatment. Failing to accurately identify smaller dosages in patients who are receiving either treatment option for periods longer than 90 days will result in suboptimal performance results for providers who are providing treatment. These results may lead to patients being pulled off their treatment regimen, which will result in even greater consequences.</p> <p>Lastly, we question the selection of both the 90-day duration and 90 mg dosage as the selected performance thresholds in this measure. Should this measure move forward we would like to see additional data to support these as the selected thresholds.</p>				
20	2/9/18	<p>Anthem appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed Electronic Clinical Quality Measure (eCQM), Potential Opioid Overuse. As detailed by CMS, the measure seeks to assess the percentage of patients age 18 years and older who receive opioid therapy for 90 days or longer and are prescribed an average daily dose Morphine Milligram Equivalent (MME) of 90 milligrams or greater. Anthem is working to transform health care with trusted and caring solutions. Our health plan companies deliver quality products and services that give their members access to the care they need. With over 73 million people served by its affiliated companies, including more than 40 million within its family of health plans, Anthem is one of the nation's leading health benefits companies. For more information about Anthem's family of companies, please visit www.antheminc.com/companies. The opioid crisis has reached a critical point. This epidemic continues to devastate communities, demanding an impactful response. Anthem recognizes the serious need for early and accurate identification and treatment of Substance Use Disorders (SUD). We are committed to the reduction of opioid abuse while promoting clinically appropriate care. Opioids can be an effective treatment for acute pain syndromes and painful conditions when properly administered, but carry significant risks when misused. Opioid misuse, SUDs, and substance use-related conditions are chronic conditions, best managed through an integrated approach to care and services, which requires evidence-based treatment to maintain stability and recovery. Given the importance placed on evidence-based models for addressing opioid misuse and abuse, we appreciate that CMS has worked to develop a quality measure aimed at deterring inappropriate prescribing and misuse of opioid pain relievers.</p> <p>Anthem supports the underlying intent of the proposed eCQM. However, in order to create meaningful, widely adopted clinical quality measures, we recommend seeking alignment with existing measures. For instance, the National Committee for Quality Assurance (NCQA) has a measure in place with similar intent; however, the NCQA measure assesses a duration of 15 days or longer at a dosage of greater than 120 MME. While we do not take issue with assessing the percentage of patients prescribed opioid therapy for 90 days or longer at a dosage equal to or greater than 90 MME, we do believe conflicting quality measures in various stages of implementation can cause confusion. In the absence of a standardized, evidence-based measure to detect risk of opioid misuse or abuse, adding a new measure to the mix could result in confusion throughout health care service delivery systems.</p>	Anthony Mader; Anthem, Inc	hilary.felton-reid@anthem.com	Health insurance company	<p>Thank you for providing feedback on the specifications for the Potential Opioid Overuse measure. We appreciate your support of the measure's intent. The definitions of long-term (90+ days of opioid use) and high-dose (90 MME or greater average daily dose) opioid use were selected to align with guidance provided by the Centers for Disease Control and Prevention in its Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. The two opioid measures that are currently in place from the NCQA use claims data to assess performance for health plans, whereas the Potential Opioid Overuse measure uses EHR data to assess provider performance. The measures are meant to be complementary. Our team will work closely with developers of other clinical quality measures (like the National Committee for Quality Assurance) to align our specifications whenever possible. We view this measure as one of several potential tools to reduce the harms of the opioid crisis. We will continue to refine the measure specifications in accordance with guidance from the CDC, feedback from our expert work group, and responses submitted during this comment period.</p>

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20 (cont)	2/9/18	<p>Many prevention and assessment measures exist currently. These include measures such as tracking dosage levels, tracking only the duration of the prescription, and tracking prescriber history patterns identifying multiple prescribers, potentially indicating “doctor-shopping”. Further complicating matters, embedded within the varying assessment methods are different criteria, such as the level of dosage or duration.</p> <p>Anthem requests that CMS look to align the new eCQM for Potential Opioid Overuse to one that is currently utilized, such as the NCQA measures Use of Opioids at High Dosage and Use of Opioids from Multiple Provider. Alternatively, CMS could work with the NCQA and health care delivery system stakeholders to establish a standardized measure agreeable to all and generally accepted as industry best practice based on available research. To reiterate, while we support the ultimate intent to curb inappropriate opioid prescribing practices and reduce opioid overuse, we believe for ease of implementation and to garner greater adherence to the adoption of a measure that a single, standardized measure would best accomplish this goal.</p> <p>We value the partnership that we have developed with CMS, and welcome the opportunity to discuss our recommendations to develop a standardized opioid overuse quality measurement.</p>				
21	2/9/18	<p>Under a CMS Contract “Electronic Clinical Quality Measures Development and Maintenance for Eligible Professionals”, the Lewin Group proposes a quality metric defined as, “Percentage of patients aged 18 years or older who receive opioid therapy for 90 days or longer and are prescribed an average daily dosage of 90 milligram morphine equivalents or greater.” We write to register our opposition to this binary high--stakes metric on three distinct grounds. They are as follows:</p> <ol style="list-style-type: none"> 1. Reliance on a simple binary dose metric is an extremely poor method to identify persons at--risk for adverse events while receiving opioids, as it is both extremely insensitive and non--specific. 2. A high stakes binary dose metric of this nature incentivizes medical practices that are not based on evidence and that have proven dangerous, both in our observation and in the emerging literature on opioid dose reduction. 3. High stakes binary numeric metrics for care quality have a robust history of incentivizing harmful medical practices. Tragic outcomes are even more likely in the context of parallel initiatives from governmental and non--governmental agencies mandating or incentivizing opioid dose reduction without reference to patient safety. <p>We first underscore our clinical and research expertise to comment on this issue. All three signatories are general internal medicine physicians with deep experience in opioid safety, addiction care, and primary care. All three of us are board--certified in addiction medicine. Dr. Stefan G. Kertesz is Professor of Medicine at the University of Alabama at Birmingham School of Medicine and Birmingham VA Medical Center, serving on the Opioid Safety Initiative and Opioid Advice Team for the Birmingham VA Medical Center. He has published over 60 articles on addiction and primary care of homeless populations. Dr. Adam J. Gordon is Professor of Medicine and Psychiatry at the University of Utah and the Chief of Addiction Medicine at the Salt Lake City VA Health Care System.</p>	Stefan G. Kertesz, Ajay Manhapra, and Adam J. Gordon; University of Alabama School of Medicine	skertesz@uab.edu	Academic research university	

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21 (cont)	2/9/18	<p>He directs the national “Buprenorphine in the VA” initiative and leads the national Coordinating Center for Addiction Fellowships in the VA. He is also Editor in Chief for Substance Abuse, the scholarly journal of the Association for Medical Education and Research on Substance Abuse. He has published over 167 papers on care of addiction populations. Dr. Ajay Manhapra directs the Advanced PACT Pain Clinic at the Hampton VA Medical Center, serves as lecturer at Yale University and Department of Physical Medicine and Rehabilitation and Psychiatry, Eastern Virginia Medical School, Norfolk, VA. He is a leading national teacher on complex persistent dependence occurring in high--risk patients who have received opioids for pain. All three of us have direct experience and extensive observational contact with tragic harms to patients that result from physicians who have acted under regulatory inducements to curtail opioid doses, slowly or quickly. Having regularly observed suicides, medical deteriorations, and overdoses resulting from such pressures, we have re--evaluated the available data on dose thresholds as a method to enforce opioid safety. We present below our scientific and clinical concerns about a quality measure that will further incentivize a harmful and non--evidenced based alteration to care.</p> <p>1. Reliance on a simple binary dose metric is an extremely poor method for identifying persons at risk for adverse events while receiving opioids. It is insensitive and non-- specific.</p> <p>Based on our research and primary care experience, we fully appreciate the observed correlation between opioid dose and risk of adverse outcome among persons who have received a prescription for opioids at some time in the prior year. This may suggest that on whole, a lower dose ought to be safer than a higher dose, all things being equal. However, the effort to stratify dangerous or high--risk patients from low--risk patients based on dose will not succeed, because the 90 MME threshold misses the overwhelming number of persons who suffer overdose events, and it reflects a fundamental misconception of the event we term “overdose”. Among overdose events in persons who have received a prescription, the dose is typically low or nonexistent at the time of the lethal event, as the published data makes very clear. In a case-- control study from the Veterans Administration, the median dose for an overdose patient was 60 MME. In publicly reported Veterans Administration--wide data for Fiscal Year 2013, 86% of overdose/suicide events occurred at <90 MME, and VA has approved submission of a manuscript showing that these percentages are similar when overdose and suicide are tabulated separately. Similarly, in published analyses of 1452 opioid overdose events in Washington state citizens who had received opioid prescriptions, only 21% occurred at a time when the patient received opioid doses exceeding 90 MME. Fully 42.6% occurred at a time when the Medicaid recipient had no prescription whatsoever on hand, while 27.8% occurred while receiving a dose under 50 MME. Were it the case that dose could be used as a method of identifying prescription recipients who would die from overdose, the proposed 90 MME threshold would ignore and fail to protect roughly 70--90% of persons at risk, suggesting that this is at the very least an insensitive measure. The correlation between dose prescribed and overdose event is a real finding). However, high prescription dose appears in large part to serve as a marker for multiple psychological and social vulnerabilities. This does not mean that every person receiving high doses has such vulnerabilities. However, it does suggest such vulnerabilities are likely to play a confounding role in the prediction of overdose events in large correlational data analyses in contemporary studies that more sensitively measure other characteristics of persons who suffer overdose, opioid dose turns out to be either a weak</p>				

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21 (cont)	2/9/18	<p>predictor of overdose, or it loses its predictive power altogether. One study, published this year, looked at 42,828 chronic opioid recipients in the Kaiser system, where access to care is high and where diagnoses for mental illness are more likely to be applied in a timely fashion. In appropriately adjusted models, mental health diagnoses, tobacco dependence, substance abuse/dependence diagnoses and long-acting agents were independent predictors of overdose. Dose, however, did not independently predict overdose at all.</p> <p>The VA Stratification Tool for Opioid Risk Mitigation (STORM) system was used to assess VA-- wide risk of overdose or suicidal events (prior models demonstrated that the same variables predicted both overdose and suicide). A report from STORM did find a statistically independent association between opioid dose and risk. However, the augmentation of risk related to dose was weaker than cardinal determinants of risk such as mental illness (including PTSD), substance use disorder (in remission or active), and the co-- administration of other sedating medicines. For example, a man with post--traumatic stress disorder and a dose of 20 MME would be a higher risk than a man with no similar risk but a dose of 200 MME. Historic heroin overdose literature helps to explain why dose itself is so poor at predicting an adverse event. In that literature, most events we call "overdose" transpire at low doses, even with heroin. Death occurred when heroin was combined with other substances and the patient took the heroin outside of normal circumstances. Put another way, opioid users develop tolerance over time, if opioid dose is regular and consistent and not combined with other substances in dangerous ways. This does not mean opioids are risk--free at any dose. They are a deeply problematic drug treatment with real risk at any dose, most notably the reality of dependence, which can take less or more devastating forms. But to the extent that the goal is to prevent overdose, a single dose threshold is simply at odds with the literature as we know it. Even worse, the proposed metric is also at odds with the CDC Guideline on Prescribing Opioids for Chronic Pain, at least in one way. The CDC Guideline drew a crucial distinction between initial dose escalation and the care of legacy patients, a distinction that the proposed measure ignores. The Guideline's recommendations 1--5 focus on caution in initiation and escalation of dose. Even those recommendations do not prohibit a dose above 50 or 90 MME. Rather, they call upon clinicians to carefully consider risk and benefit before dose escalation.</p> <p>For patients already on opioids, recommendation 7 applies. It sets no dose target whatsoever. It demands an individualized decision based on the patient's current benefit and harm. This was an intentional decision of the CDC's experts, and reflected a conspicuous lack of data to support dose reduction in such patients, save when they are voluntarily seeking dose reduction and are properly supported. We are distressed that the proposed metric ignores such a central component of the CDC Guideline. By taking numeric thresholds and ignoring key evidence considerations that went into that Guideline, the proposed measure undermines the Guideline itself. In this, we want to note that fully 80 experts in addiction and pain, including four who assisted the CDC Guideline's development, formally protested when the National Committee for Quality Assurance sought to advance a similar metric. 2. A high stakes binary dose metric of this nature incentivizes medical practices that are not based on evidence, and that have, sadly, proven harmful to patients, both in our observation and in the emerging literature on opioid dose reduction.</p> <p>The inevitable result of a binary numeric metric of 90 MME is that it will contribute to the many pressures already operating on clinicians to force doses downward, even when doing so is both dangerous and unproven as medical</p>				

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21 (cont)	2/9/18	<p>practice. Today's physicians are under mandates from other quality metric agencies, state regulators, medical boards, and threat of investigation to force doses downward in currently stable patients. For them to protect their patients despite such pressure, already entails professional risk. We question the outcomes achieved through the intense focus on dose control. High dose prescriptions have fallen by 48% since 6 years ago. The decline does not appear to have reduced overdose events of any kind, either those involving illicit or licit opioids. The period of late 2016 through 2017 featured many reports of pain patients subject to opioid termination who committed suicide, attacked physicians, died in withdrawal, suffered medical decline, or overdosed on illicit opioids. Indeed, preliminary data from the US Department of Veterans Affairs, reported publicly on the website for the 2018 National Rx Drug Abuse and Heroin Summit (for presentation on April 4, 2018) show that opioid discontinuation (between one fiscal year and the following one) was not associated with any reduction in overdose, but was associated with a rise in suicide. We recognize that this analysis does not assess "taper to lower dose" per se, but it should signal an additional warning beyond the many anecdotes. It is tempting, but incorrect, to assert that such events simply reflect tapering "too quickly". We have personally observed and publicly reviewed many cases of slow tapers that produced the same outcomes. One, written about in The Hill, and later presented at a scientific meeting, involved a patient who lost capacity to take renal transplant protection medications after a taper over a year. The reason for deterioration is dependence. The opioids' utility for pain, for some, is intimately bound up with their effect on reward/affect in the brain. Slow taper in a person with dependence does not routinely resolve the long-term brain changes that have occurred.</p> <p>3. High stakes binary numeric metrics for care quality have a robust history of incentivizing harmful medical practices. Tragic outcomes are even more likely in the context of other parallel initiatives from governmental and non-governmental agencies. Finally, we caution that history depicts the harms that result from embracing simple numeric indicators of quality care when there is a conspicuous lack of properly-conducted trial data to show that such quality metrics protect patients.</p> <p>On this matter, the trial data to support forced dose reductions that will be incentivized by the proposed metric do not exist. In the most exhaustive review of opioid dose tapers ever published, Frank et al cautioned that they identified "no prospective studies" of involuntary dose reduction, and that there were serious risks of overdose, suicidality, and resurgent mental health symptoms if mandates of this nature were applied. The embrace of a simplistic numeric indicator of quality care, based on observational data alone, finds ominous precedent in the application of the 7% hemoglobin A1c metric for care of diabetes. While helpful to some patients, subsequent randomized controlled trials found that the efforts to minimize glucose to "ace the metric" caused death for a number patients. The later trial data made clear that lives had been lost as a result of well-intentioned efforts to improve performance using all-or-nothing binary performance targets based on alluring numbers. Indeed, today's problems of opioid over-prescription are similarly attributable to a scientifically unsound, clinically inappropriate, dangerous and yet well-intentioned effort to optimize precisely one number, the pain score, in the absence of sufficient trial data. We fully appreciate the constructive intent that lies behind current efforts to reconfigure opioid prescribing. We regard the run-up in prescribing from 1999 to 2011 as tragic, as we believe that the distribution and redistribution of those pills contributed to market of new patients with addiction. Similarly, we</p>				<p>We are sensitive to the fact that unintended consequences could stem from implementation of this measure, such as provider reluctance to prescribe opioids, increased patient referrals to pain specialists, or under-treatment of pain while patients transition to other therapies. We believe that reductions in long-term, high-dose opioid use—which we aim to assess using this eCQM—should be paired with concurrent policies to encourage optimal patient care.</p> <p>We view this measure as one of several potential tools to reduce the harms of the opioid crisis. Other measure developers, agencies, and organizations are undertaking efforts to evaluate alternative approaches to pain management, medication reconciliation, and other instruments intended to decrease unnecessary use of opioids. We know that management of patient pain is intensely personal and must involve shared decision-making to identify an individualized care management plan involving shared decision-making between patients and providers.</p> <p>We will bring the changes you have suggested in your comment to our expert work group for further evaluation. We will continue to refine the measure specifications in accordance with guidance from the CDC, feedback from our expert work group, and responses submitted during this comment period. We acknowledge that prescribing patterns and opioid use can vary based on patient and provider characteristics; we will evaluate ways to identify those provider and patient populations that could most benefit from reporting of this quality measure as we work to refine the measure specifications. We will also consider ways to evaluate quality of care for those patients newly prescribed high-dose opioids versus those for whom prescriptions have been written over time.</p>

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21 (cont)	2/9/18	<p>have certainly seen pain patients sedated to death, typically with multiple psychoactive substances (rather than just a carefully titrated opioid). And we have seen many patients where the institution of opioid therapy was clearly harmful. At the same time, we take note of the profound, relentless harms to patients that result from the untested, unscientific, and nonpatient-centered dose reductions that many simultaneous initiatives have caused to take place. This quality metric will accelerate that harm. It is not carefully rooted in the science of overdose. It does an injustice to the CDC Guideline. We heartily credit the good intentions that lie behind such a metric, but we must strongly urge its rejection as both insensitive, nonspecific, and likely to cause harms we will later come to regret. Please note that views presented here are solely those of the authors, and do not represent positions of the US Department of Veterans Affairs, any other agency of the US Federal Government, or any of our employing universities.</p> <p>Seven comments on this subject were submitted in a comment thread on the usability of the measure. In particular, commenters noted the potential harms associated with the measure, such as undertreatment of pain and increased rates of depression and/or suicide, and suggested that the measure consider individual differences in patients who are prescribed opioids.</p>				We appreciate the additional comments appended onto the University of Alabama School of Medicine letter submitted on February 08. The seven comments submitted in response to the UAB letter agreed with the points raised by its authors. We reiterate that a patient-centered approach to pain management must complement the use of this eCQM; we view the potential implementation of this measure as but one tool available in the management of the opioid crisis, including alternative forms of pain management and other resources put in place by federal and state agencies (such as prescription drug monitoring programs).
22	2/9/18	<p>“You get what you measure” is a cliché in business but obviously not in the medical world. The CMS proposal to measure physician success by counting the number of patients who receive a total opioid dosage of 90MME or high can already be predicted:</p> <ol style="list-style-type: none"> 1. Doctors are paid for their services. Lower-rated doctors have difficulty finding patients and make less money due to complex reimbursement processes already in place. To ensure the highest rating, doctors will simply STOP prescribing opioid doses higher than 90MME. 2. Patients with severe pain after major surgery, severe trauma, and those suffering from cancer and other painful diseases at the end of their lives will be limited to 90MME. 3. Patients that can afford to pay out of pocket for pain care will receive adequate care, while the majority of the country that relies on insurance will suffer. <p>I recognize the dangers of opioids, however, doctors should have the final say in the dosage that is appropriate for an individual’s care. If this lower dosage is an attempt to stop deaths from opioid drug overdoses, I ask you to consider the last 5 years: Since 2012 opioid prescriptions have been falling dramatically, yet opioid deaths are climbing rapidly. In 2016 the United States hit a 10 year LOW in opioid prescriptions and 10 year HIGH in opioid deaths (see attached chart). Simply enacting restrictions on prescriptions based on very faulty science will not have the intended impact of lowering death rates from opioids. The measure will have the following impact:</p> <ol style="list-style-type: none"> 1. Some patients will move to the black market for pain relief increasing their chances of death 2. Some patients will mix opioid medications with alcohol 3. Some patients will commit suicide to avoid the suffering <p>Please reconsider setting any metrics for doctors that will discourage them from using their clinical judgment to relieve suffering.</p>	Paul Short; Alliance for the Treatment of Intractable Pain	paul@atipusa.org	Patient safety advocacy organization	<p>Thank you for providing feedback on the specifications and evidence for the Potential Opioid Overuse measure. We appreciate the concerns you highlighted in your comments. We are committed to limiting the potential harms and unintended consequences of any measure relating to pain management and opioid use. Based on the strong relationship between long-term, high-dose opioid use and patient harms (including addiction and death), however, we believe implementation of this measure will help improve public health and reduce opioid-associated deaths.</p> <p>This measure aims to reduce risks of adverse drug events by creating incentives for providers to review the patient’s individual needs and consider all potential alternatives for managing pain. This measure is not intended to limit access to opioids more broadly and does not prohibit physician discretion in making patient-level treatment decisions. We know that the treatment selected for pain management can vary widely based on the individual needs of the patient. We also expect that providers may encounter some patients who have limited alternatives to long-term, high-dose opioid therapy. For this reason, we do not expect provider scores for this measure to reach zero percent consistently. We will continue to refine the</p>

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22 (cont)	2/9/18					<p>measure specifications in accordance with CDC's guidance, feedback from our expert work group, and responses submitted during this comment period. We are sensitive to the fact that unintended consequences could stem from implementation of this measure, such as provider reluctance to prescribe opioids, increased numbers of patient referral to pain specialists, or undertreatment of pain while patients transition to other therapies. It is well documented, however, that long-term, high-dose opioid therapy is associated with significant risks of addiction and adverse events, including death. We believe that reductions in long-term, high-dose opioid use—which we aim to assess using this eCQM—should be paired with concurrent policies to encourage optimal patient care. We will continue to balance recommendations to reduce unsafe opioid use, while promoting an increased focus on safer alternatives, including non-opioid therapies and lower doses of opioids.</p>