

## Safe Use of Opioids—Concurrent Prescribing Public Comment Summary Report

### Project title

Hospital Inpatient and Outpatient Process and Structural Measure Development and Maintenance

### Dates

- The call for public comment ran from July 1, 2016, to July 31, 2016.
- The public comment summary was submitted to the Centers for Medicare & Medicaid Services (CMS) on August 12, 2016.

### Project overview

CMS has contracted with Mathematica Policy Research and its partners to develop, electronically specify, and maintain process and structural clinical quality measures for five CMS hospital quality programs. The programs are the Hospital Inpatient Quality Reporting Program, Hospital Outpatient Quality Reporting Program, Ambulatory Surgical Center Quality Reporting Program, Prospective Payment System—Exempt Cancer Hospital Quality Reporting Program, and Electronic Health Record (EHR) Incentive Program for Eligible Hospitals. The name of the contract is Hospital Inpatient and Outpatient Process and Structural Measure Development and Maintenance (Hospital-MDM); contract number is HHSM-500-2013-13011I/HHSM-500-T0003. As part of its measure development process, CMS has asked interested parties to submit comments on the Safe Use of Opioids—Concurrent Prescribing measure.

### Project objectives

The project has four primary objectives:

- Conduct an environmental scan to identify gaps in existing hospital quality reporting programs where new measures will be useful and important
- Develop, specify, and test new hospital electronic clinical quality measures (eCQMs) for implementation in CMS's quality reporting programs in the areas identified during the environmental scan
- Retool existing measures to facilitate reporting using data extracted from an EHR
- Maintain previously developed hospital measures currently in the five CMS programs named above by monitoring their validity and effectiveness and recommending any needed improvements

### Information about comments received

The project team used extensive outreach methods to notify stakeholders and the general public about the comment period.

- Emails sent to the following:

- CMS listserv groups, including the eHealth provider and vendor work groups
- Project’s Technical Expert Panel
- Project’s Opioids Expert Work Group
- Project’s Clinical and Measure Development Advisory Board
- Project’s Patient and Family Advisory Board
- EHR vendor contacts
- Key federal stakeholders who helped identify this measure concept, including the Centers for Disease Control and Prevention (CDC), the Office of the Assistant Secretary for Planning and Evaluation (ASPE), and the Substance Abuse and Mental Health Services Administration (SAMHSA)
- CMS’s eMeasures Issue (eMIG) Work Group
- Office of the National Coordinator’s Health IT Policy Committee Quality Measures Workgroup
- Stakeholders, stakeholder organizations, and key researchers:
  - ◆ Agency for Healthcare Research and Quality (AHRQ)
  - ◆ America’s Essential Hospitals
  - ◆ American Academy of Addiction Psychiatry
  - ◆ Ambulatory Surgery Center Association
  - ◆ American Academy of Emergency Medicine
  - ◆ American Academy of Family Physicians
  - ◆ American Academy of Pain Medicine
  - ◆ American Academy of Orthopaedic Surgeons
  - ◆ American Academy of Physical Medicine and Rehabilitation
  - ◆ American Academy of Physician Assistants
  - ◆ American Association of Nurse Anesthetists
  - ◆ American Association of Nurse Practitioners
  - ◆ American Association for the Treatment of Opioid Dependence
  - ◆ American Board of Addiction Medicine
  - ◆ American Board of Internal Medicine
  - ◆ American Board of Obstetrics and Gynecology
  - ◆ American Board of Surgery
  - ◆ American Chronic Pain Association
  - ◆ American College of Emergency Physicians
  - ◆ American College of Surgeons Advisory Council for Gynecology and Obstetrics
  - ◆ American College of Occupational and Environmental Medicine
  - ◆ American College of Physicians
  - ◆ American College of Rheumatology
  - ◆ American Congress of Obstetricians and Gynecologists
  - ◆ American Hospital Association
  - ◆ American Medical Association
  - ◆ The American Medical Association Task Force to Reduce Opioid Abuse
  - ◆ American Medical Group Association

- ◆ American Nurses Association
  - ◆ American Osteopathic Academy of Addiction Medicine
  - ◆ American Psychiatric Association
  - ◆ American Psychological Association
  - ◆ American Public Health Association
  - ◆ American Society of Addiction Medicine
  - ◆ American Society of Anesthesiologists® (ASA)
  - ◆ American Society of PeriAnesthesia Nurses
  - ◆ American Surgical Association
  - ◆ Association of American Medical Colleges (AAMC)
  - ◆ Association for Addiction Professionals (NAADAC)
  - ◆ Association for Medical Education and Research in Substance Abuse
  - ◆ Association of periOperative Registered Nurses
  - ◆ Federation of American Hospitals (FAH)
  - ◆ The Food and Drug Administration (FDA)
  - ◆ Institute for Healthcare Improvement
  - ◆ National Alliance of Advocates for Buprenorphine Treatment
  - ◆ National Association of Addiction Treatment Providers
  - ◆ National Institute on Drug Abuse
  - ◆ National Quality Forum eMeasure contacts
  - ◆ Partners Against Pain
  - ◆ Pharmacy Quality Alliance
  - ◆ Physicians for Responsible Opioid Prescribing
  - ◆ Society of Critical Care Medicine
  - ◆ Society for Preventive Research
  - ◆ U.S. Pain Foundation
  - ◆ Roger Chou, MD, Professor of Medicine in the Division of General Internal Medicine and Geriatrics at the Oregon Health & Science University
  - ◆ Sylvia Mathew, PharmD, Medication Safety Manager, UT Southwestern University Hospitals
  - ◆ Harold Minkowitz, MD, Diplomate American Board of Anesthesiology, Hermann Memorial City Medical Center
  - ◆ Richard Payne, MD, Professor of Medicine, Duke University School of Medicine
  - ◆ Matthew T. Popovich, Ph.D., Director of Quality and Regulatory Affairs, American Society of Anesthesiologists
  - ◆ Lynn Webster, MD, Leading Researcher and Physician in Pain Medicine, developer of the Opioid Risk Tool (ORT)
  - ◆ Adam Wright, PhD, Scientist, Brigham and Women’s Hospital; Associate Professor of Medicine at Harvard Medical School
  - ◆ Ryan Koca, PharmD, Director of Clinical Pharmacy, Tenet Healthcare
- Requests to facilitators of the following groups to announce the public comment period during periodic meetings:
  - eMeasures Issue Group Work Group
  - Weekly governance call for measure developers
    - Announcement on the eCQI Resource Center website

- Announcement through the IQR Support Contractor listserv
- Posting on the CMS Public Comment website

We received seven comments, several with multiple comments embedded, during the public comment period, from the following commenters:

- Two health systems (Henry Ford Health System, Memorial Hermann Health System)
- One electronic health record (EHR) vendor (Cerner Corporation)
- Two professional societies (American Association of Orthopaedic Surgeons [AAOS], American College of Emergency Physicians [ACEP])
- One patient safety advocacy group (PULSE NY)
- One group made up of leaders from ambulatory surgery center organizations (Ambulatory Surgical Center Quality Collaboration [ASC QC])

## Stakeholder comments—general and measure-specific

### Support

*Four commenters* expressed support for the measure intent and its efforts to reduce the risk of respiratory depression, preventable mortality, and other adverse events associated with opioid use.

**Response:** Thank you for your support of the measure concept, which aims to reduce inappropriate concurrent prescribing practices and the associated adverse events.

### General comments

*One commenter* noted the importance of involving patients and the community in discussions surrounding appropriate medication use.

**Response:** We agree that incorporating input from patients and communities is important to improving the quality of care provided at hospitals. We will continue to seek feedback from patients, caregivers, and family members through targeted workgroup discussions and public comment opportunities.

*Three commenters* had clarification questions about the measure. One commenter asked which programs we are developing the measure to address, the second asked for more information on the proposed measurement period, and the third asked how CMS will communicate the results of the measure.

**Response:** Thank you for your comments. We are developing The Safe Use of Opioids—Concurrent Prescribing measure for potential use in the Hospital Inpatient Quality Reporting (IQR) and Hospital Outpatient Quality Reporting (OQR) programs. CMS will determine the proposed measurement period at a future date if we implement the measure; for testing purposes we are assuming a 12-month period. We will consider potential burdens of collecting outpatient and inpatient visit documentation when determining the period. Finally, we will determine how we will communicate the measure results as part of the implementation plan following development, testing, and inclusion of the measure in a reporting program or programs.

*One commenter* mentioned that we should not specify the measure for the Ambulatory Surgical Center setting at this time given the paucity of electronic clinical records.

**Response:** Thank you for your comment.

### Measure intent

*Two commenters* expressed concerns about the measure intent.

One commenter thought the measure would be problematic to implement in the emergency department (ED) setting because (1) physicians and pharmacists should both be responsible for determining appropriate medications but most EDs do not always have a pharmacist on duty, (2) more opioids and benzodiazepines are prescribed in the outpatient setting than in the ED, and (3) ED physicians should not be held accountable for discontinuing medications they did not prescribe.

**Response:** Although ED providers may face challenges that are unique to acute pain management, it is not reasonable to exclude them from this measure, due to the high rates of opioid prescriptions from ED settings. For instance, a study that analyzed data on ED discharges from the 2006 through 2010 National Hospital Ambulatory Medical Care Survey found that opioids were prescribed for 18.7 percent of all ED discharges, representing 21.7 million prescriptions per year.<sup>1</sup> Rates of opioids prescriptions in the outpatient settings may be high, but opioid prescription rates from the ED setting are also significant.

We recognize that there will be clinically necessary instances where a patient arrives to the ED with an active opioid or benzodiazepine medication and may require a short-term prescription for a second medication. We expect that such occurrences will occur fairly equally among facilities given that this metric is at the facility level.

*One commenter* thought that the measure would discourage providers from prescribing narcotics, and recommended that the measure intent instead focus more directly on encouraging an interdisciplinary team approach to prescribing and tracking through the prescription drug monitoring program (PDMP).

**Response:** This measure is intended to change current prescribing practices to avoid concurrent prescriptions, but is not prescriptive of how hospitals approach this goal. The suggested practices of using PDMPs and interdisciplinary care teams are means to reach that goal. One of the aims of this measure is to incentivize hospitals to use available resources and to develop best practices to address this area of care by measuring occurrences of concurrent prescription.

### Measure specifications

*Three commenters* recommended expanding the list of denominator exclusions. The suggested exclusions included hospice patients, patients with cancer, patients with small-quantity benzodiazepine prescriptions for procedural sedation (for example, 2–4 tablet prescriptions), patients with sickle cell disease, patients receiving small quantities of medications in the ED setting, and patients receiving medications for opioid use disorder (naloxone, methadone, and buprenorphine). There was also a recommendation to clarify which groups are excluded in the measure logic.

**Response:** Thank you for your comments. Currently, patients receiving palliative care and patients with cancer are excluded from the measure. In regard to the remaining recommendations, we recognize that providers often give peri-procedural benzodiazepine prescriptions; however, per clinical guidelines, it is not recommended that these medications continue post-discharge. Therefore, we do not expect these instances to impact the measure. Throughout development we have had ongoing discussions with our expert work groups regarding single condition exclusions, such as patients with sickle cell disease and patients on methadone or buprenorphine for substance abuse disorder, and we have decided not to exclude these groups because the measure is intended to promote accountability and awareness for dosing, including in these high-risk populations. Our opioids expert work group has provided feedback that patients prescribed methadone and

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<sup>1</sup> Kea, B., Fu, R., Lowe, R., et al. (2016). Interpreting the National Hospital Ambulatory Medical Care Survey: United States Emergency Department Opioid Prescribing, 2006–2010. *American Emergency Medicine*. Wiley Periodicals, Inc. Retrieved [March 2016] from <http://onlinelibrary.wiley.com/doi/10.1111/acem.12862/abstract>.

buprenorphine should remain in the denominator because these medications have the highest rates of adverse outcomes from dual opioid use. Furthermore, we recognize that there may be some clinically appropriate situations for concurrent prescriptions and as such do not expect the measure rate to be zero.

*One commenter* suggested changing the denominator exclusion “Palliative Care” to “Comfort Measures” and also suggested incorporating the following settings into the logic for the denominator exclusion criteria: hospice, dialysis, substance abuse and mental health care, inpatient psychiatric care, and ambulatory surgical centers.

**Response:** The Palliative Care value set for this measure comprises a Comfort Measures value set that is used in other meaningful use measures. We will make further refinements to the measure specifications to clarify this definition. We will consider additional revisions to the value sets to clarify which types of patients are not included in the measure (currently hospice and cancer patients are excluded).

*One commenter* recommended that the measure be calculated at the patient level and stratified by prescription type (opioid, benzodiazepine, or ADHD medication), stating that this would be useful for identifying the percentage of patients receiving even a single prescription of a controlled substance. The commenter also recommended calculating the measure at the provider level so that hospitals can identify providers that may need additional education.

**Response:** Experts in the field are still exploring the long-term effects of ADHD medications; they are not currently included in this measure. With regard to comments about calculating the measure by patient level, provider level, and prescription type, we are still developing this measure. We will explore any needed stratification in testing, but do not plan to expand this measure to the provider level at this time.

### Measure logic

*One commenter* made several suggestions for changing the measure logic with attention on the initial population, denominator exclusions, and numerator. Examples included adding “Intervention, Order” to “Intervention, Performed” in the denominator exclusion for palliative care and replacing “concurrent with start” with “during” in the numerator to identify medications prescribed. Several of the recommendations requested clarification of the timing aspects of the measure.

**Response:** Thank you for your detailed recommendations for changes to the measure logic. We present the following responses by population criteria:

- **Initial population.** We anticipate that a patient who is moved from the ED setting to the inpatient setting will not be counted twice in the measure because we expect that discharge medications will only be prescribed in the setting prior to discharge (the inpatient setting in this scenario).
- **Denominator exclusions.** We will consider adding “Intervention, Order” to “Intervention, Performed” to capture the intended excluded populations for palliative care.
- **Numerator.** The first numerator recommendation was to replace the phrase “concurrent with start” with “during” when describing the logic related to the initial medication (not the second

medication prescribed for discharge). The intent of the measure is to identify patients prescribed opioids or benzodiazepines at discharge who arrive with an active medication. The timing element “during” may capture medications started during the visit, which does not meet the measure intent. The commenter made two suggestions for adjusting the timing aspects of the numerator. For clarification, we included a numerator option that does not use logic describing medications added because we wanted to have an option that described patients who arrived with concurrent medications and were discharged with those same concurrent medications. We will also evaluate the logic to more clearly define that “Medication, Active” is used to represent medications active on arrival or active home medications, as opposed to medications only prescribed at discharge. We will further consider these recommendations and bring them to our expert work group and EHR vendors for input.

*Three commenters* asked clarification questions about the measure logic. The commenters asked for more information regarding the initial population/denominator, the denominator exclusions, and the numerator. Examples include clarifying the Healthcare Encounter definition and the timing aspects of the measure.

**Response:** Thank you for your comments and clarification questions. We present the following responses by population criteria:

- **Initial population/denominator.** The age requirement “18 years or older” refers to patients who are 18 years and older at the start of the measurement period. In regard to the encounter period, this time frame spans from the start of the encounter to the time of discharge; a second encounter after discharge begins a new encounter period. Therefore, it is possible for a patient to have multiple qualifying encounters within the measurement period (CMS will define). The measure will capture patients who are on active, concurrent opioid or benzodiazepine medications at discharge or those who are on active, concurrent medications on intake that continue after discharge from the hospital inpatient or hospital outpatient setting.
- **Denominator exclusions.** Patients are excluded from the measure when a relevant exclusion is present at any time that overlaps with the hospital encounter, not the measurement period.
- **Numerator.** As with the initial population, the numerator time frame is also based on the encounter (from the start of the encounter to the time of discharge), making it possible for a patient to have multiple qualifying encounters within a measurement period.

#### Concerns and challenges

*One commenter* expressed concern that the measure would have an unintended consequence of undertreating pain, and would lead to more patients with uncontrolled pain.

**Response:** Thank you for your comment. We recognize that there will be an inherent conflict between patient satisfaction regarding pain relief and the avoidance of concurrent prescriptions and corresponding adverse drug events. We do not expect facilities to have a score of zero, and hope that this measure will help clinicians achieve a balance between satisfactory pain management and the avoidance of adverse outcomes.

*Two commenters* raised the concern that the measure would penalize providers who prescribe an opioid for break through pain to chronic opioid users when it is clinically appropriate.

**Response:** During the initial development of this measure, we interviewed experts who recognized that there will be clinically necessary instances where a patient with an active opioid or benzodiazepine may require a short-term prescription for a second medication. However, these patients are still at risk of an adverse event and facilities should be aware. We expect that these concurrencies will be equally spread over facilities. As stated in the previous response, we do not expect sites to have numerators of zero, but we do intend the measure to keep providers alert to the risks of concurrent opioid or opioid and benzodiazepine therapy.

*Two commenters* said that prescribers should not be held accountable for patients who arrive with concurrent prescriptions, especially due to the dangers associated with withdrawal from benzodiazepine. They also noted that emergency departments face this challenge with significant frequency.

**Response:** Thank you for your comments. We recognize that this is a concern for the measure and will continue to discuss this matter with our expert work group and test sites. As mentioned above, we encourage providers to follow best-practice care, and recognize that there will be some clinically appropriate instances when concurrent prescribing will occur. However, the measure is intended to hold providers accountable for patients who continue to receive concurrent opioids or opioid and benzodiazepine prescriptions. We recognize that there are particular concerns about emergency department providers but anticipate that such occurrences will be spread relatively equally across facilities.

*One commenter* said that the measure should hold prescribers, not hospitals, accountable for all medication changes.

**Response:** Thank you for your comment. This proposed measure is currently intended for implementation in hospital-level quality reporting programs; therefore, care coordination between all providers and interdisciplinary teams is needed for successful performance in the measure. Any needed stratification will be explored in testing, but we do not plan to expand this measure to the provider level at this time. Furthermore, the measure logic captures patients on concurrent medications active at the start of the encounter that continue after discharge, which would hold a facility accountable for active concurrent medications identified during the medication reconciliation process. The measure does not hold facilities accountable for undocumented opioid or benzodiazepine use or future prescriptions given after discharge.

*One commenter* said that collecting all of the measure's data elements was feasible within their current EHR, but *three commenters* noted difficulties in capturing some of the data elements related to the measure. The three commenters who noted difficulties drew attention to the interoperability issues related to capturing information on active medications through databases such as PDMPs.

**Response:** Thank you for your comments. The measure as currently specified uses data from the hospital EHR. We recognize that data on active prescriptions may not always be available, but we are not holding hospitals accountable for undocumented prescriptions. In addition, we recognize that availability and use of PDMPs may vary by hospital and state, and at present there is no standard for PDMPs that can be used for quality measurement.

*One commenter* commented that this measure is in conflict with another measure that evaluates patient satisfaction of pain control, meaning that performance on the Safe Use of Opioids measure may inversely correlate with performance on the patient satisfaction measure.

**Response:** We appreciate the concern raised through this comment. The purpose of the measure is to reduce adverse outcomes from concurrent prescriptions. Representatives from CMS and the U.S. Department of Veterans Affairs (VA) noted that information gathered through the VA’s opioids safety initiative—which includes a measure similar to this one—has not revealed any systemic occurrences of pain under-treatment. The measure is not intended to discourage pain management using a single opioid medication.

### **Preliminary recommendations**

We will review the commenter suggestions with CMS, experts in the field, and our measure development team to identify how to modify the measure or research questions that will be addressed through measure testing. We will also consider ways to revise the eCQM logic to provide clarification to avoid any confusion. Additionally, we will consider suggestions regarding the measure concept and intent with our expert work group.

CMS will continue to engage the public and key stakeholders as we move through the development and potential implementation process of this measure.

### **Overall analysis of the comments and recommendations**

Feedback received on the Safe Use of Opioids—Concurrent Prescribing measure was highly informative. There was general support for the measure, specifically noting its usefulness and importance. Multiple commenters expressed concern about attribution related to concurrent prescriptions that are present on intake and continued after discharge, as well as withdrawal associated with the abrupt cessation of benzodiazepines. A number of commenters were concerned about the timing aspects of the measure and requested clarification on several other aspects of the measure. Comments on measure feasibility, focused on the feasibility of obtaining data on active medications on arrival when systems such as the PDMP are not consistent on a national basis. We thank commenters for providing their feedback and perspectives on this measure.

Public Comment Verbatim Report

Date posted	Name and organization of commenter	Text of comment	Email address	Type of organization	Response
7/6/16	Ilene Corina, President, PULSE of New York	<p>People who are taught about medication safety at a young age will not abuse or misuse medication later in life.</p> <p>This is not something I have ever done before but wanted to bring to your attention the need for patient and community involvement.</p>	icorina@aol.com	Patient safety advocacy group	<p>Thank you for your comment. CMS recognizes the importance of patient and family input to improve the quality of care provided at hospitals, and understands that improvement may involve open communication between patients and providers and education on the impacts of decisions in care. We will continue to seek input from patients, caregivers, and family members through targeted workgroup discussions and public comment opportunities. Patients and families have a unique perspective to bring to the measure development process and, as a result, CMS aims to give patients and their families an opportunity to provide feedback on what care is measured, how it is measured, and how it is communicated.</p>
7/26/16	Donna Slosberg, RN, BSN, LHRM, CASC, Executive Director of Ambulatory Surgical Center Quality Collaboration	<p>The Centers for Medicare &amp; Medicaid Services (CMS) has contracted with Mathematica Policy Research to develop, electronically specify, and maintain process and structural clinical quality measures for five CMS hospital quality programs: Hospital Inpatient Quality Reporting (IQR), Hospital Outpatient Quality Reporting (OQR), Ambulatory Surgical Center Quality Reporting (ASCQR), PPS-Exempt Cancer Hospital Quality Reporting (PCHQR), and the EHR Incentive Program for Eligible Hospitals.</p> <p>Mathematica is currently working to develop the Safe Use of Opioids—Concurrent Prescribing measure. Mathematica presented the concept and specifications to the Expert Work Group (EWG) and external clinical experts, informatics experts, and</p>	donnaJeanandjack@yahoo.com	Ambulatory surgery center collaborative	<p>Thank you for supporting the current focus of hospital settings for the Safe Use of Opioids—Concurrent Prescribing measure. At this time, per CMS direction, this measure will continue to maintain a focus on the Hospital Inpatient Quality Reporting (IQR) and Hospital Outpatient Quality Reporting (OQR) programs.</p>

Date posted	Name and organization of commenter	Text of comment	Email address	Type of organization	Response
		<p>pharmacists for their feedback and then revised and refined the measure based on the comments received from these experts.</p> <p>As currently specified, the proposed concept would measure clinical quality related to opioid use in inpatient and outpatient hospital settings. We agree with limiting the measure focus to these hospital settings given the paucity of electronic clinical records in the ambulatory surgical center (ASC) setting.</p>			
7/26/16	Lynn Baldwin, Solution Manager, Cerner Corporation	<p>1. Please clarify program for which this measure is being developed—Hospital OQR?</p> <p>2. What is proposed measurement period? If measurement period is whole year (taking opioid "at some point during measurement period"), electronic documentation for all opioid use - across ED, Outpatient and Inpatient visits would be a challenge; the various visits may or may not all be in the EMR. Different visits will have different forms of documentation. Ideally all would be on same EMR but that is not common.</p> <p>3. IPP: Clarify if age is 18 at any point during the measurement period or if age 18 at the START of the measurement period.</p>	lbaldwin@cerner.com	EHR vendor	<p>Thank you for your comments and questions.</p> <p>Response 1: We are developing the Safe Use of Opioids– Concurrent Prescribing measure for potential implementation in both the Hospital Inpatient Quality Reporting (IQR) and Hospital Outpatient Quality Reporting programs (OQR).</p> <p>Response 2: CMS will determine the measurement period at a future date if the measure is implemented in the Hospital OQR and IQR programs; the measure calculation is based on the qualifying encounter. When defining the encounter period, CMS and the measure developer will consider the potential burden of collecting outpatient and inpatient visit documentation in a heterogeneous electronic health record (EHR) environment. We will also consider revising the measure to assess patients with active opioids during the qualifying encounter, rather than patients with opioids active at some point during the measurement period, as currently stated in the specifications.</p> <p>Response 3: In order to harmonize this measure with other electronic clinical quality measures, the phrase “18 years or older” is used in the specification to refer to patients who are 18 years and older at the start of the measurement period.</p>

Date posted	Name and organization of commenter	Text of comment	Email address	Type of organization	Response
		<p>4. IPP: \$Healthcare Encounter - clarify scenario where patient moves from ED to IP. How do you keep them from being included twice in IPP?</p> <p>5. Denominator Exclusions: Suggest changing Palliative Care to Comfort Measures to align with other emeasures.</p> <p>6. Denominator Exclusions: Suggest adding Intervention, Ordered along with Intervention, Performed</p> <p>7. Denominator Exclusions: logic does not reflect exclusions in description of measure: inpatient psych, hospice, substance abuse or mental health, dialysis, ancillary core or ambulatory surgical center</p> <p>8. Numerator: Suggest replacing "concurrent with start.." with "during", if this is intended to represent medications during stay. It is unlikely that the medication would be given at the same time that the encounter starts, which concurrent indicates.</p> <p>9. Numerator: under 1st OR statement, consider adding "start", 4th bullet, 3rd sub-bullet; "starts during Occurrence A of \$HealthcareEncounter". Additionally, this bullet seems to conflict with first bullet; #Patient on active opioid on arrival .... vs DURING Occurrence A of \$HealthcareEncounter. The logic needs to be clear as to what</p>			<p>Response 4: In a potential scenario where the patient is moved from the emergency department setting to the hospital inpatient setting, it is anticipated that the encounter would be attributed to the inpatient setting, as discharge medications would likely be prescribed from the inpatient setting only. We will bring this comment to future discussions with expert work groups, EHR vendors, and testing sites.</p> <p>Response 5: The palliative care value set drafted for this measure comprises a comfort measures value set that is used in other meaningful use measures. There will be further refinements to the measure specifications to clarify this definition.</p> <p>Response 6: We will consider this suggestion further during the testing phase for this proposed measure.</p> <p>Response 7: The value sets that accompany this measure and the definitions included in the specifications are intended to provide guidance for the qualifying encounters and care settings that are appropriate for inclusion or exclusion for this measure. We will consider additional revisions to these value sets through the quantitative and qualitative testing period. Additionally, Ambulatory Surgical Centers are excluded from this measure as it is not intended to be implemented in the Ambulatory Surgical Center Quality Program (ASCQR).</p> <p>Response 8: The intent of the measure is to capture opioids or benzodiazepines that are active at the start of the qualifying encounter. The timing element “during” may capture medications started during the visit that do not meet the measure intent.</p> <p>Response 9: The temporal operator “during” is used because “starts during” is not an option for referring to the encounter. Additionally, we will adjust the logic to more clearly define that “medication, active” is used to represent medications active on arrival or active home medications, as opposed to medications only prescribed at discharge.</p>

Date posted	Name and organization of commenter	Text of comment	Email address	Type of organization	Response
		<p>types of meds are being evaluated:</p> <p>10. Numerator: under 5th OR statement, AND: Count&gt;=2: Union of: section. Is this section needed, or does section above this cover the same logic?</p>			<p>Response 10: This option was not included to capture patients whose concurrent opioid prescriptions are unrelated to prescribing at discharge, but rather those patients whose concurrent prescriptions on arrival are maintained at discharge. We will discuss this logic further with expert working groups and hospital settings during the testing period of the measure.</p>
7/28/16	<p>Michelle Schreiber, M.D., Senior Vice President, Chief Quality Officer, Henry Ford Health System</p>	<p>The Henry Ford Health System submitted an attached letter for the public comment period. The below information is the full text from the letter:</p> <p><b>Re: eMeasure: Safe Use of Opioids—Concurrent Prescribing Measure (Identifier 506)</b></p> <p>Henry Ford Health System appreciates the opportunity to provide comments on the concept of an electronic clinical quality measure (eCQM) for the safe use of opioids-concurrent prescribing in inpatient and outpatient hospital settings.</p> <p>HFHS is an integrated delivery system serving metropolitan Detroit and the Jackson, Michigan area. The system has six acute care hospitals and one hospital specializing in inpatient psychiatric care. HFHS provides outpatient behavioral health services, including addiction treatment and chronic pain management, at locations across the region. HFHS is a recipient of the 2011 Malcolm Baldrige National Quality Award and strives to provide high-quality care across the system to every</p>	dvalade1@hfhs.org	Health system	<p>Thank you for the comment and for expressing your support for this measure.</p> <p>We understand the concerns raised by your comment about patient satisfaction regarding pain relief and the avoidance of concurrent prescriptions. Representatives from CMS and the U.S. Department of Veterans Affairs (VA) noted that information gathered through the VA’s opioids safety initiative—which includes a measure similar to this one—has not revealed any systemic occurrences of pain under-treatment. The purpose of the measure is to reduce adverse outcomes from concurrent medication use. The aim of this measure is also to assist hospitals achieve a balance between adequate pain management and the avoidance of adverse outcomes. There are no limitations on adequate pain management using a single opioid within the measure. At this time, the measure is still in development and has not yet been implemented in any quality reporting programs.</p> <p>Similar to other measures used in CMS programs, if this proposed measure is implemented and concurrent prescriptions of opioids or opioids and benzodiazepines decrease to extremely low rates over time—that is, the measure is “topped out”—CMS may choose to retire it from the reporting programs. As this measure has not yet been implemented in a reporting program, the threshold of compliance or a change in performance over time has yet to be defined.</p> <p>CMS and the measure developer have engaged in numerous discussions with experts regarding inclusion or exclusion of patients on methadone, buprenorphine, and naloxone. Experts felt that patients on these medications are at higher risk of adverse outcomes from concurrent benzodiazepine or opioid use and came to a consensus</p>

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		<p>patient.</p> <p>Henry Ford Health System’s (HFHS) comments focus on the five areas in which feedback was requested.</p> <p>1. The usefulness of the measure to assess and improve the quality of care for patients</p> <p>As stated by CMS, the intent of the proposed measure is to calculate the proportion of patients ages 18 and older with active, concurrent prescriptions for opioids at discharge or with active concurrent prescriptions for an opioid and benzodiazepine at discharge. HFHS believes the proposed measure is a useful measure to track at this point in time. Although currently there is some baseline data available, this measure may help clarify, among prescribers and other health care providers, what needs to be worked on and by which prescriber/health care provider, to help reduce the number of concurrent opioid prescriptions.</p> <p>2. The appropriateness of the measure to assess hospital performance (including inpatient, outpatient, and emergency department settings) and any unintended consequences of implementing the measure</p> <p>HFHS has the following concerns about unintended consequences:</p> <ul style="list-style-type: none"> <li>• A measure designed to favor</li> </ul>			<p>that it is necessary to include this group in the Safe Use of Opioids—Concurrent Prescribing measure. At the time, these patients will remain in the denominator.</p> <p>We are developing the measure at this time for implementation in programs at the hospital level.</p> <p>Although only certified providers can write prescriptions for scheduled substances, the facility is held accountable at the reporting level. The scenarios provided are outside of the qualifying encounter period of the measure. The measure is defined by medications documented in the EHR upon initial evaluation and those documented at discharge from the care encounter. The facility is not accountable for undocumented opioid or benzodiazepine use or future prescriptions given after discharge. We agree that addressing instances of concurrent use outside of the hospital is important for public health and safety and could be a separate measure concept, but such instances are outside the scope of this measure at this time.</p>

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		<p>reduced use is going to conflict in some ways with other measures about patient satisfaction and about effective pain control. There has to be a balance in the measure portfolio as there is in the decision-making for every individual patient. HFHS wants satisfied patients who are as pain-free as possible, but also not addicted to opioids. The measures used in pay-for-performance programs have to be chosen and balanced in such a way as to not distort the relationships among those goals.</p> <ul style="list-style-type: none"> <li>• There is a great fear-within the community of patients with pain-that the focus on reduction of opiates will result in more pain going untreated.</li> <li>• It appears that improvement will be measured by a “decreased rate of concurrent prescriptions” in the identified population. This may be problematic, in the long-term, because there is a point at which the rate cannot be decreased further without getting to an inappropriately low use rate. That rate will need to be determined before linking the rate to quality of care and/or pay-for-performance.</li> </ul>			

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		<ul style="list-style-type: none"> <li>If a prescriber/healthcare provider has a low rate and then has a slight (non-significant) increase the next year, there needs to be a method to ensure that the insignificant increase is not considered a failure.</li> </ul> <p>3. Whether data elements related to the measure are available in structured, extractable fields in hospital EHR systems</p> <p>HFHS believes the data elements are currently available in our EHR system</p> <p>4. Whether there are any additional denominator exclusions that should be included in the measure.</p> <p>HFHS recommends that patients on treatment with buprenorphine and naloxone (suboxone) and or/methadone should be excluded. We want to promote treatment, and these are clearly treatments for an opioid use disorder and not problematic.</p> <p>5. Whether the prescriber should be held accountable if a patient has concurrent, active prescriptions for opioids or opioids and benzodiazepines before intake and then maintains that previous regimen after discharge</p> <p>HFHS believes the prescriber should be held accountable. This is not the same, though, as</p>			

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		<p>saying that the hospital should be held accountable. A physician, not a hospital, is the prescriber of medications. Our belief is that a prescriber is responsible for all medications started unless the prescriber gives clear instruction that they should be stopped. As an example: An Emergency Department (ED) physician sees a patient with severe acute injury that requires 23 days of opiates, but gives a 30 day supply with no instructions to stop. The patient then goes to his/her primary care physician and has it refilled. In this instance, HFHS believes that both the ED physician and the primary care physician are accountable. On the other hand, if the ED physician prescribes a 3 day supply of opiates with instructions to change to NSAID, and another prescriber decides to continue the opiates then the second prescriber should be held accountable.</p> <p>The same would be true if a patient is admitted to a physician's service and is on an inappropriate opiate regimen. Once this physician writes to continue the opiates, then that prescriber should be held accountable.</p> <p>One concern is whether physicians/prescribers are equipped to deal with possible detox/withdrawal; as a result of stopping these regimens.</p> <p>Thank you again for the</p>			

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		<p>opportunity to provide comments on this potential quality measure at an early stage of development.</p> <p>Sincerely,</p> <p>Michelle Schreiber Senior Vice President, Chief Quality Officer Henry Ford Health System</p>			
7/28/16	<p>Kyle Shah, Clinical Quality and Medical Affairs Coordinator, American Association of Orthopaedic Surgeons</p>	<p>On behalf of over 18,000 board-certified orthopaedic surgeons represented by the American Association of Orthopaedic Surgeons (AAOS), we appreciate the opportunity to provide feedback on the Safe Use of Opioids—Concurrent Prescribing measure under the Hospital Inpatient and Outpatient Process and Structural Measure Development and Maintenance (Hospital-MDM). The AAOS believes that a comprehensive opioid program is necessary to decrease opioid use, misuse, and abuse in the United States. New, effective education programs for physicians, caregivers, and patients; improvements in physician monitoring of opioid prescription use; increased research funding for effective alternative pain management and coping strategies; and support for more effective opioid abuse treatment programs are needed.</p> <p>The AAOS commends Mathematica Policy Research for</p>	shah@aaos.org	Professional society	<p>Thank you for your comments and for supporting the intent of this measure concept.</p> <p>The proposed measure aims to change current prescribing practices to avoid concurrent prescriptions, not to limit appropriate narcotic use. The suggested practices of utilizing PDMPs and interdisciplinary care teams are a means to reach that goal; to give more flexibility, the measure does not dictate exactly how hospitals should reach the goal. The measure is intended to incentivize hospitals to use available resources and to develop best practices to address this area of care by measuring occurrences of concurrent prescription. Within the clinical recommendation statement of the current measure specification are included some recommendations, such as discussing information from the PDMP with patients and promoting patient awareness of concurrent use. The measure specifications include documented medications that are active at the initiation of the qualifying encounter; facilities are not accountable for medications that are not documented at the time of medication reconciliation during the care encounter. We recognize that use of PDMPs may be variable and there may be limited participation from state-to-state, which is why this measure does not require the use of PDMPs.</p> <p>During the initial development of this measure, we interviewed experts who recognized that there will be clinically necessary instances where a patient has documented chronic use of an opioid or benzodiazepine and may require a short-term prescription for a second medication that would be counted as concurrent prescriptions through the measure. Providers should use</p>

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		<p>seeking stakeholder input on the Safe Use of Opioids—Concurrent Prescribing measure and is supportive of the efforts to reduce risk of respiratory depression, preventable mortality, and the costs associated with adverse events related to opioid use. The AAOS has concerns about the usefulness of the measure to assess and improve the quality of care for patients, as the measures may indirectly affect the intent by discouraging providers from writing narcotic prescriptions. We are concerned this will result in a “change in care” habit, which does not address the fundamental issues related to chronic pain management. We believe the measure should focus on a multi-disciplinary team approach and discourage multiple provider prescribing patterns. We suggest that the measure should more directly encourage providers to identify drug seeking behavior by utilizing state based prescription drug monitoring program (PDMP) for concurrent controlled medications prescribed by other clinicians and should consider involving pharmacists and pain specialists as part of the management team, by requiring every patient to be screened with the PDMP prior to writing the prescription. This will avoid unintended</p>			<p>best-practice care in such instances. According to feedback from them, experts in the field expect that these conflicts will be spread equally over facilities. We do not expect that the numerator will approach zero, but with similar measures in the past, if measure performance is consistently high, CMS may choose to retire the measure. It is not the intent of the measure to have necessary medications altered, but rather to keep providers alert to the risks of concurrent opioid or opioid and benzodiazepine therapy. Furthermore, this measure is specified at the hospital level, not the provider level, as it aims to incentivize hospital-wide practices.</p> <p>In regard to the comment on when in the care continuum the denominator occurs, as it is currently defined, the measure will capture patients who are on active, concurrent opioid or benzodiazepine medications at discharge or those who are on active, concurrent medications on intake that continue after discharge from the hospital inpatient or hospital outpatient setting.</p> <p>Concerning the low-dose prescriptions for procedural sedation, we recognize that peri-procedural benzodiazepine medications are often given as a means of sedation for a number of medical procedures; however, per clinical guidelines, it is not recommended that patients continue on these medications post-discharge once the procedure is completed. As a result, there should be limited instances involving concurrency with these medications and opioids at the time of discharge. For these reasons, these instances are not expected to impact the measure, but they will be considered further for exclusion during the testing of this measure, as needed.</p> <p>We also recognize that attribution is a concern for this measure and we will continue to discuss and explore this issue further with CMS, our expert work groups, and testing sites. As stated before, there may be clinically necessary instances where a patient has documented, chronic use of one of these medications and may require a short-term prescription for a second medication that would be captured as concurrent prescriptions in this measure. We would like to reiterate that providers use</p>

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		<p>consequences of implementing the measure.</p> <p>Additionally, the measure does not address or provide a clear pathway for addressing acute pain management needs from injury or surgery in the chronic opioid user. This raises the question of how acute pain can be managed in a patient on chronic narcotics. If a patient is on Vicodin (hydromorphone &amp; acetaminophen), is it appropriate to give them additional hydromorphone? Is there a distinction between giving Vicodin versus hydromorphone? If a provider changes the prescription, how will the measure verify the old prescription (which the patient has already filled and is in the possession of) is terminated? Furthermore, the measure does not clearly indicate when, in the care continuum, the denominator takes place. Is it only for patients who begin a given patient encounter with an active narcotic or narcotic/benzodiazepam prescription? AAOS encourages Mathematica to consider these questions when refining the measure.</p> <p>The AAOS agrees with the denominator exclusions and also requests including denominator exclusions for small 2-4 tablet prescriptions of benzodiazepines given for purposes of procedural</p>			<p>best-practice care in such instances.</p> <p>Finally, as this measure is currently still being developed and tested, we have yet to determine its potential implementation and public reporting.</p>

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		<p>sedation. AAOS is very concerned with the prescriber being held accountable if a patient has concurrent, active prescriptions for opioids or opioids and benzodiazepines before intake and then maintains that previous regimen after discharge, as it may result in multiple unintended consequences. While opioid withdrawal is very unpleasant, it is not itself dangerous. However, this is not the case with benzodiazepine withdrawal. Benzodiazepine withdrawal can be harmful and potentially fatal. In addition, effective chronic pain management is a multi-disciplinary team effort and assigning provider accountability is not conducive to promoting this type of care. AAOS suggests removal of holding the prescriber entirely accountable. Lastly, AAOS requests more information about how the results of the measure will be communicated.</p> <p>Thank you for your time and consideration of the American Association of Orthopaedic Surgeons' (AAOS') response to solicitation of comments on Safe Use of Opioids—Concurrent Prescribing measure. AAOS looks forward to working closely to reduce risk of respiratory depression, preventable mortality, and the costs associated with adverse events related to opioid use. Should you</p>			

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		<p>have questions on any of the above responses or concerns, please do not hesitate to contact AAOS' Medical Director, William O. Shaffer, MD, at 202-548-4430 or via email at shaffer@aaos.org.</p>			
7/29/16	<p>Joe Kunisch, PhD, RN-BC, Enterprise Director of Clinical Quality Informatics-Regulatory Performance at Memorial Hermann Health System</p>	<p>Thank you for the opportunity to respond to the Safe Use of Opioids - Concurrent Prescribing Proposed eCQM specifications. Memorial Hermann is the largest not-for-profit healthcare system in Texas with a total of 3,557 beds and 5,500 affiliated physicians across our organization. We are an organization that has invested over \$100 million in our EHR technologies and infrastructure since 2000 to successfully achieve our clinical quality and patient safety goals. In 2009, we were recognized by the National Quality Forum with the National Healthcare Quality Award for our efforts. We would like to provide the following comments;</p> <p><b>General Comments</b></p> <p>We recommend sub-dividing the controlled substances into categories of opioids, benzodiazepines and ADHD meds to identify patterns of potential abuse for each category. In addition, we recommend that the population be based on all patients receiving scripts for a given provider stratified by these categories. This would be useful for</p>	joseph.kunisch@memorialhermann.org	Health system	<p>Thank you for your comments and for your support on this measure topic.</p> <p>The intent of this measure is to encourage providers to identify concurrent prescriptions of opioids and benzodiazepines at the hospital-level and discourage providers from prescribing opioids and benzodiazepines concurrently, whenever possible (in accordance with the <i>2016 CDC Opioid Prescribing Guidelines for Chronic Pain</i>). While the long term effects of ADHD medications are being explored, and experts in the field have recognized a link between the ADHD medications and adverse outcomes, the scope of this measure is limited to benzodiazepine and opioid medication use, which studies have shown are linked to serious adverse outcomes and respiratory depression. Identification of all prescriptions and providers for the targeted education may be a relevant goal in the future, but it is outside the scope of this measure.</p> <p>We recognize and understand the potential clinical and technical challenges to collecting and reporting data from the various hospital settings this measure would be implemented in. We will review these challenges further in the testing phase to minimize reporting burden, and will make refinements to the measure accordingly.</p> <p>The encounter period, as it is currently defined, spans the interval from the start of the encounter to the time of discharge. Medication reconciliation at the time of discharge is the proposed mechanism to establish whether an overlap is present from the medical record. A second encounter after discharge, should that occur, begins a new encounter period. The measurement period for a facility with regard to performance and reporting is to be determined by CMS. Thus, it is possible to have multiple encounter measures within a year for the same</p>

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		<p>identifying the percentage of patients that are receiving even a single script of controlled substance. We believe this will better facilitate 1) Identifying providers that may need additional education on appropriate controlled substance prescribing practices and 2) Assist physicians to identify patients that may be at risk for adverse events and/or substance abuse issues. We do not believe the same information will be provided if the patient population is based strictly on encounters.</p> <p>We agree with and fully support the need for a quality measure to support the safe use of opioids and prevent concurrent subscribing practices. We also realize that in the electronic health record landscape, there remain many siloed sources of health care data not only across the nation, but even within our local system. It is because of this that the barriers to incorporating data across multiple types of encounters in a yet to be defined time period, will make capturing the data for this measure very difficult. While we are not discouraging CMS to pursue this quality measure, we are requesting that CMS and the eMeasure developer work diligently to adjust the logic of this measure to be able to capture the data available in light</p>			<p>beneficiary.</p> <p>Regarding time period of the exclusions and the proposed scenario for the numerator, we would like to clarify that the time period specified in the measure is the hospital encounter, not the measurement period. Patients will be captured in the measure at any time that overlaps the encounter period.</p>

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		<p>of current EHRs limited ability to share data.</p> <p><b>Initial Population</b></p> <p>Healthcare Encounter- While we understand and agree with the need to view this population across multiple encounters, accomplishing this presents numerous challenges and will be extremely difficult to achieve accuracy. In addition, there is no guidance on the timespan of the healthcare encounter. We request more clarity around the expected start date:time as it relates to the end of the measurement period which we assume is the inpatient encounter discharge date:time. How or who will determine this time period?</p> <p><b>Denominator Exclusions</b></p> <p>We are requesting more clarity on the denominator exclusions in relation to the Healthcare Encounter. It appears that the diagnosis or palliative care can occur during anytime of the defined time period. So if for example, the time period is defined at 6 months and multiple opioid prescriptions were present throughout that time period but the last date of the encounter a cancer diagnosis occurs; is that patient excluded from the population for the entire time period?</p> <p><b>Numerator</b></p> <p>It appears from the logic that the</p>			

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		<p>measure is looking for any opioid/benzodiazepine prescription during the healthcare encounter when a similar prescription is ordered at discharge for an inpatient encounter. It does not appear to take into account the date:time or quantity of the prescriptions to determine if the patient is actively taking the medication. For example, if the healthcare encounter is defined as a 2 month look back for all encounters prior to inpatient discharge and the patient was prescribed an opioid with a 2 week supply at the beginning of that time period, it appears that the patient would be pulled into the numerator because there is no logic or data element identifying that the prescription time period ended and the patient is not actively taking it. If the logic is to assume that the medication is not active because it did not appear on the admitting medication list, then what is the purpose of the look back period?</p>			
7/29/16	Sandra Schneider, MD, FACEP, President, American College of Emergency Physicians	<p>On behalf of more than 34,000 members of the American College of Emergency Physicians (ACEP), thank you for the opportunity to comment on the proposed measure "Safe Use of Opioids - Concurrent Prescribing." The American College of Emergency Physicians applauds the attempt to improve</p>	sschneider@acep.org	Professional society	<p>Thank you for your comments. The aims of the Safe Use of Opioids–Concurrent Prescribing measure are (1) to encourage providers to identify patients with concurrent prescriptions of opioids or opioid-benzodiazepine prescriptions and (2) to discourage providers from prescribing two or more opioids concurrently or opioid-benzodiazepine prescriptions concurrently, in order to reduce adverse drug events (ADEs) associated with concurrent prescribing. Studies have found that Emergency Department (ED) visit rates involving both</p>

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		<p>opioid prescribing in the US. We see first-hand the increasing numbers of patients who are taking opioids, and the tragic result of unintended opioid overdoses. We believe that a measure such as the one proposed may be useful, but will be problematic for the emergency provider. While the measure provides a rationale for safe prescribing/use of opioids, which is laudable, the amount of opioids/benzodiazepines prescribed from the emergency department pales in comparison to the outpatient setting. While the physician still bears ultimate responsibility, we believe the practicing pharmacist should provide the final safeguard before dispensing an opiate or benzodiazepine combination. However, most EDs do not have a pharmacist available 24/7.</p> <p>ED providers do not choose their patient population, and per EMTALA, are required to care for all patients who present for care. ED providers are not primary</p>			<p>opioid analgesics and benzodiazepine overdoses increased from 11.0 in 2004 to 34.2 per 100,000 population in 2011.<sup>2</sup> During our literature review, a study that analyzed data on ED discharges from the 2006 through 2010 National Hospital Ambulatory Medical Care Survey found that opioids were prescribed for 18.7 percent of all ED discharges, representing 21.7 million prescriptions per year.<sup>3</sup></p> <p>ED physicians are among the top five specialties for the highest rates of opioid prescriptions.<sup>4</sup> Given the widespread and escalating nature of adverse outcomes from opioid use nationally and the high risk of concurrent opioid use, this proposed measure is being considered for potential implementation in both the Hospital Inpatient Quality Reporting (IQR) and the Hospital Outpatient Quality Reporting (OQR) programs, which would include patients on concurrent prescriptions discharged from the emergency department.</p> <p>Although ED providers may face challenges that are unique to acute pain management, it is not reasonable to exclude them from this measure, due to the rate of opioid prescriptions from the ED settings. We agree that interdisciplinary teams and care coordination are essential in successful performance of this proposed measure. This measure would be implemented at the facility level; if it is implemented in a CMS program, compliance with the measure is expected to be a joint responsibility within the entire hospital clinical care team setting, including pharmacists and providers.</p>

<sup>2</sup> Jones, C. M., & McAninch, J. K. (2015). Emergency department visits and overdose deaths from combined use of opioids and benzodiazepines. *American Journal of Preventive Medicine*, 49(4), 493–501. Retrieved [April 7, 2016] from <http://ajph.aphapublications.org/doi/full/10.2105/AJPH.2016.303061>.

<sup>3</sup> Kea, B., Fu, R., Lowe, R., et al. (2016). Interpreting the National Hospital Ambulatory Medical Care Survey: United States Emergency Department Opioid Prescribing, 2006–2010. *American Emergency Medicine*. Wiley Periodicals, Inc. Retrieved [March 2016] from <http://onlinelibrary.wiley.com/doi/10.1111/acem.12862/abstract>.

<sup>4</sup> Pappa, A. (2013). Prescribing and Dispensing Opioids in the Emergency Department. Emergency Medicine Patient Safety Foundation. Retrieved on [August 2016] from <http://www.premiersafetyinstitute.org/wp-content/uploads/Prescribing-Dispensing-Opioids-ER-Hallam-Final.pdf>.

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		<p>care physicians and do not have control over the medications that the patients have been prescribed prior to arrival to the emergency department. ED providers deliver episodic care and are not in a position to disrupt an established physician-patient relationship that the patient has with their primary care physician, and as such are not in a position to stop medications that patients are being prescribed by their primary care physician. Therefore, performance on this measure is largely outside of the control of ED providers, especially when they present to the ED with active opioid and benzodiazepine prescriptions.</p> <p>Regarding "Whether the prescriber should be held accountable if a patient has concurrent, active prescriptions for opioids or opioids and benzodiazepines prior to intake and maintains that prior regimen after discharge" the answer is categorically no. The emergency physician or other emergency provider should not be held accountable for medications s/he does not prescribe, and should not be held responsible to modify a treatment regimen that was established prior to the patient's ED visit.</p> <p>The measure is heavily reliant upon PDMP data. At this time not all states have an optimally</p>			<p>Regarding the comment on medications that are active prior to the encounter, this topic has generated considerable discussion among experts in the clinical and measurement fields during the development of this measure. It is relevant to all providers, but the particular impact upon ED physicians is recognized. Although the measure specification is derived from documented medications that are active at the initiation of the encounter, facilities are not accountable for medications that are not documented (although it is hoped the measure raises awareness to use ancillary sources of information). For the measure, only documented medications that are active via the EHR are used in the specification. Medications not documented in the EHR are not included.</p> <p>Additionally, there will clearly be clinically appropriate instances where a patient has documented chronic use of one of these medications but may require a short-term prescription for a second medication that the measure would count as concurrent prescriptions. Providers should use best-practice care in such instances. We expect that such occurrences will be spread fairly equally among facilities. In keeping with our response above regarding chronic use of such medications, this metric is designed to encourage upholding best practices in multiple settings, which includes providers determining when coexisting prescriptions are occurring and taking actions to correct for them when appropriate.</p> <p>Regarding the comment on PDMP data, the measure as currently designed does not use data from a PDMP, but rather draws from the EHR data used during the hospital encounter. Incorporating PDMP data into this measure would be challenging because PDMPs are state programs and, therefore, have different structures, variables, and data formats that would make it difficult to assess utilization nationally. However, the primary aim of this measure is to motivate providers to think more carefully about their prescribing practices related to opioids; PDMPs are one of many ways to accomplish that goal, especially as states are making their programs more robust. We recognize that data on active prescriptions at arrival may</p>

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		<p>functional PDMP. Common problems with the PDMP system include that trustworthiness is highly variable, it can be cumbersome, may not contain real time data, and the information can be unreliable. In addition, patients may cross state lines for care and not all states are part of InterConnect to share information interstate about dispensed prescriptions. Until a coordinated system is in place, this measure should not advance as part of a quality and patient safety initiative for emergency physician scoring. While the combination of a benzodiazepine and opioid in large doses can be problematic, there is concern that patients on small doses of a benzodiazepine for a chronic problem (anxiety, insomnia) might not be able to be given opioids if they have an acute injury or fracture. There is also a real threat of creating withdrawal in a patient who has been on long standing opioids with concurrent benzodiazepines. Suddenly stopping one of the medications will often cause withdrawal, which can be life-threatening in some cases. Weaning from medication is done over protracted periods of time, and not in the scope of care of an emergency physician.</p> <p>Another challenge for emergency physicians is that we do not</p>			<p>not always be available. The specification of the measure is based only on documented medications on presentation and at discharge. We recognize that use of PDMPs may be variable and there may be limited participation from state-to-state, which is why this measure does not require the use of PDMPs.</p> <p>Finally, patients who are receiving hospice services and patients diagnosed with cancer are currently excluded from the measure. Excluding patients with sickle cell disease is under consideration. There is no plan at present to incorporate dose size into the metric, but this may be a consideration in the future.</p>

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		<p>always have access to a list of a patient's medications. In an ideal world, we should know the patient's medications, but our experience is that often the patients themselves do not know their medications. Most of the information available from the EMR represents the last inpatient visit, and medications may, and do, change with subsequent outpatient visits.</p> <p>If this measure is adopted, we recommend that several groups be excluded. These include Hospice patients, those with cancer and those with sickle cell disease. These groups generally require a baseline opioid with additional, often different, opioid for break-through pain. We suggest this measure be limited to large quantities of medications. This would provide the option for emergency physicians to continue a patient's multiple opioid or opioid/benzodiazepine regimen for a 5 day period.</p> <p>Thank you for the opportunity to share our concerns and comments. We look forward to working with your staff on any future revisions. If you have any questions, please do not hesitate to contact, Sandra Schneider MD FACEP, Director of Director, EM Practice at 1800-798-1822 ext. 3234 or <a href="mailto:sschneider@acep.org">sschneider@acep.org</a></p>			