

Safe Use of Opioids—Concurrent Prescribing Measure Framing Document

The Centers for Medicare & Medicaid Services (CMS) seeks comments from stakeholders on a proposed concept to measure clinical quality related to opioid use in inpatient and outpatient hospital settings. In this document, we summarize the draft measure and include the following: (1) measure background, (2) measure rationale and intent, and (3) a summary of the measure specifications with questions for public comment.

Background

Opioid overdoses and opioid-related fatalities are a major public health concern in the United States (Rudd 2016). Reducing the number of opioid-related overdoses and deaths has become a priority for the U.S. Department of Health and Human Services and its agencies, including the Centers for Disease Control and Prevention (CDC), the Federal Interagency Workgroup for Opioid Adverse Drug Events, and the Substance Abuse and Mental Health Services Administration (SAMHSA).

CMS's driving priorities to develop a measure related to potential opioid overuse are (1) strong evidence that the behavior associated with the measure would improve outcomes; (2) the feasibility of data collection and reporting for the measure using an EHR; and (3) the measure's ability to meet the highest standards of validity, reliability, usability, and feasibility to be a viable candidate for endorsement by the National Quality Forum. Mathematica and CMS met with the U.S. Veterans Administration, SAMHSA, the Office of the Assistant Secretary for Planning and Evaluation, and the CDC to identify high-priority quality improvement concepts in this area. Inappropriate prescribing and concurrent prescribing of opioids and benzodiazepines stood out as highly important issues during the discussions.

Under direction from CMS, Mathematica reviewed literature on the prevalence of concurrent opioid-opioid and opioid-benzodiazepine prescriptions in order to develop initial specifications for the measure.¹ The intent of the measure is to calculate the proportion of patients ages 18 years and older with active, concurrent prescriptions for opioids or with active, concurrent prescriptions for an opioid and benzodiazepine at discharge. Mathematica presented the concept and specifications to the Expert Work Group (EWG) and external clinical experts, informatics experts, and pharmacists for their feedback. We revised and refined the measure based on the comments received from these experts.

Measure rationale

Prescriptions for opioids and benzodiazepines are prevalent. An analysis of the IMS Health's National Prescription Audit (NPA) found that pharmacies and long-term care facilities dispensed 289 million prescriptions for opioids and primary care specialties accounted for nearly half of all dispensed opioid prescriptions (Levy et al., 2015). Another study, which looked at the benzodiazepine prescriptions among the IMS Health's NPA population in 2008, found that 46.9

¹ For this document and the associated measure specification, concurrent is defined as two or more active opioid prescriptions or active opioid and benzodiazepine prescriptions with overlapping dates of use. The reader may use the words "concurrent" and "overlapping" synonymously.

million benzodiazepine prescriptions were filled, which translates into roughly 75 million benzodiazepine prescriptions nationally (Olfson et al., 2015). Based on the estimates from studies conducted in the hospital care setting including inpatient settings and emergency departments, up to 34.9 million patients may be prescribed an opioid (Herzig et al., 2014; Kea et al., 2016; Kessler et al., 2013; Weiss et al., 2014), and up to 8.09 million patients may be prescribed a benzodiazepine (Bachhuber, 2016).

Concurrent prescriptions of opioids or opioids and benzodiazepines place patients at a greater risk of respiratory depression, overdose, and death (Dowell 2016). An analysis of national prescribing patterns shows that more than half of patients who received an opioid prescription in 2009 had filled another opioid prescription within the previous 30 days (NIDA 2011). Another analysis of more than 1 million hospital admissions in the United States found that more than 43 percent of patients with nonsurgical admissions were exposed to several opioids during their hospitalization (Herzig 2013). Studies of several claims and prescription databases have shown that, among patients who receive opioids in a hospital setting, 5 to 15 percent receive concurrent opioid prescriptions and 5 to 20 percent receive concurrent opioid and benzodiazepine prescriptions (Liu 2013; Mack 2015; Park 2015). Patients with several opioid prescriptions have an increased risk of overdose (Jena 2014). Rates of fatal overdose are 10 times higher in patients who are codispensed opioid analgesics and benzodiazepines than opioids alone (Dasgupta 2015). Furthermore, concurrent use of benzodiazepines with opioids was prevalent in 31 to 51 percent of fatal overdoses (Dowell 2016). Emergency department (ED) visit rates involving both opioid analgesic and benzodiazepine overdoses increased from 11.0 per 100,000 population in 2004 to 34.2 per 100,000 population in 2011 (Jones 2015).

Measure intent

The intent of the measure is to reduce risk of respiratory depression, preventable mortality, and the costs associated with adverse events related to opioid use by (1) encouraging providers to identify patients with concurrent prescriptions of opioids or opioids and benzodiazepines and (2) discouraging providers from prescribing two or more different opioids or opioids and benzodiazepines concurrently. This measure assumes that a provider acts upon the most recent information made available by the patient at the start of an encounter or other health professionals. The measure specifications for which we seek public comment describe ways to identify patients at high risk of receiving concurrent prescriptions, for example, “clinicians should check the 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 when opioids are co-prescribed with other central nervous system depressants” (Dowell, 2016).²

² State-run electronic databases are used to track the prescribing and dispensing of controlled prescription drugs to patients, and monitor this information for suspected abuse or diversion.

Summary of measure specifications and questions for public comment

Measure component	Description of draft measure component	Summary of feedback on measure component to date
Proposed measure title	Safe Use of Opioids— Concurrent Prescribing	
Rationale	Concurrent prescriptions of opioids or opioids and benzodiazepines place patients at a greater risk of unintentional overdose because of the increased risk of respiratory depression and preventable mortality.	Concurrent opioid or opioid and benzodiazepine prescriptions are an important issue regardless of the setting, and concurrent benzodiazepine prescriptions with opioids are always dangerous.
Denominator	Patients age 18 years and older on an active opioid or benzodiazepine prescription, discharged from a hospital encounter (inpatient, ED, outpatient) during the measurement period.	Experts recommended that patients given prescriptions for opioids or benzodiazepines should be included in the denominator as both groups of patients are at high risk of adverse drug events due to concurrent prescribing.
Denominator exclusions	Patients with cancer, patients receiving palliative care.	Patients on methadone or buprenorphine were considered for exclusion; however, experts stated that patients on these medications are at high risk for concurrent use. These medications are usually safe when used alone, but they can increase the risk of overdose in combination with other opioids or benzodiazepines.
Numerator	Patients with active, concurrent prescriptions for opioids at discharge or patients with active prescriptions for an opioid and benzodiazepine at discharge.	<p>Most experts supported not limiting the duration of the concurrent period, stating that all clinical scenarios that exhibit concurrent opioid or opioid and benzodiazepine prescriptions are high-risk scenarios and should be captured.</p> <p>Experts agreed that the best practice would be to examine the patient's needs and ensure safe care via appropriate prescribing, while making sure to avoid abrupt cessation of medications in order to prevent poor patient outcomes.</p>

All comments are welcome, but we are particularly interested in feedback in the following areas:

- The usefulness of the measure to assess and improve the quality of care for patients
- The appropriateness of the measure to assess hospital performance (including inpatient, outpatient, and emergency department settings) and any unintended consequences of implementing the measure
- Whether data elements related to the measure are available in structured, extractable fields in hospital electronic health record (EHR) systems
- Whether there are any additional denominator exclusions that should be included in the measure
- 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

Your answers to the questions in the bullets above will help guide measure development and strengthen the usefulness of the final measure.

References

- Rudd, R., N. Aleshire, J. Zibbell et al. "Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014." *Morbidity and Mortality Weekly Report*, vol. 64, no. 50, 2016, pp. 1378–1382. Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>.
- Liu, Y., J. Logan, L. Paulozzi et al. "Potential Misuse and Inappropriate Prescription Practices Involving Opioid Analgesics." *American Journal of Managed Care*, vol. 19, no. 8, 2013, pp. 648–665. Available at <http://www.ajmc.com/journals/issue/2013/2013-1-vol19-n8/Potential-Misuse-and-Inappropriate-Prescription-Practices-Involving-Opioid-Analgesics/>.
- Mack, K., K. Zhang et al. "Prescription Practices Involving Opioid Analgesics among Americans with Medicaid, 2010." *Journal of Health Care for the Poor and Underserved*, vol. 26, no. 1, 2015, pp. 182–198. Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4365785/>.
- Herzig, S., M. Rothberg, M. Cheung et al. "Opioid Utilization and Opioid-Related Adverse Events in Nonsurgical Patients in U.S. Hospitals." 2013. doi: 10.1002/jhm.2102.
- Jones, C.M., and J.K. McAninch. "Emergency Department Visits and Overdose Deaths from Combined Use of Opioids and Benzodiazepines." *American Journal of Preventive Medicine*, vol. 49, no. 4, 2015, pp. 493–501. doi: 10.1016/j.amepre.2015.03.040. Epub July 3, 2015.
- National Institute on Drug Abuse (NIDA). "Analysis of Opioid Prescription Practices Finds Areas of Concern." 2011. Available at <https://www.drugabuse.gov/news-events/news-releases/2011/04/analysis-opioid-prescription-practices-finds-areas-concern>.
- Jena, A. et al. "Opioid Prescribing by Multiple Providers in Medicare: Retrospective Observational Study of Insurance Claims." 2014. *British Medical Journal*, 348, g1393. doi: 10.1136/bmj.g1393.
- Olfson, M. et al. "Benzodiazepine Use in the United States." 2015. *JAMA Psychiatry*, 136-42. doi: 10.1001/jamapsychiatry.2014.1763.
- Levy, B. et al. "Trends in Opioid Analgesic–Prescribing Rates by Specialty, U.D., 2007-2012." *American Journal of Preventative Medicine*, vol. 49, no. 3, 2015, pp. 409–413. doi:10.1016/j.amepre.2015.02.020.
- Dasgupta, N. et al. "Cohort Study of the Impact of High-Dose Opioid Analgesics on Overdose Mortality." *Pain Medicine*, 2015. Available at <http://onlinelibrary.wiley.com/doi/10.1111/pme.12907/abstract>.
- Park, T. et al. "Benzodiazepine Prescribing Patterns and Deaths from Drug Overdose among U.S. Veterans Receiving Opioid Analgesics: Case-Cohort Study." 2015. *British Medical Journal*, 350, h2698. Available at <http://www.bmj.com/content/350/bmj.h2698>.
- Dowell, D., T. Haegerich, and R. Chou. "CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016." *Morbidity and Mortality Weekly Report*, vol. 65 2016. Available at <http://www.cdc.gov/media/dpk/2016/dpk-opioid-prescription-guidelines.html>.

U.S. Department of Veterans Affairs. "Opioid Safety Initiative Toolkit." 2014. Available at http://www.va.gov/PAINMANAGEMENT/Opioid_Safety_Initiative_Toolkit.asp.

U.S. Department of Veterans Affairs. "Opioid Safety Initiative: Opioids (including Tramadol) Used in Combination with Benzodiazepine Derivative Sedatives/Hypnotics." Unpublished, 2016