American College of Emergency Physicians®
ADVANCING EMERGENCY CARE

July 17, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD, 21244-8016

CMS-2482-P

Re: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements Proposed Rule

Dear Administrator Verma:

On behalf of our 41,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on a Centers for Medicare & Medicaid Services (CMS) proposed rule that establishes minimum standards for Medicaid Drug Utilization Review (DUR) programs and seeks comment on policies related to the review of opioid prescribing, medication assisted treatment (MAT), and naloxone prescribing.

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Drug Utilization Review Controls in Medicaid

ACEP appreciates the numerous actions CMS has taken to address our nation's growing opioid crisis, as our emergency physician members see its impact every day as they work in emergency departments (EDs) on the front lines of this epidemic all across the country. Overall, we support the effort to institute policies that align with evidence-based guidelines, which will provide flexibility to allow for appropriate clinical judgment and to account for the unique nature of care that is provided in EDs.

We note that this proposed rule establishes Medicaid DUR standards mandated in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act and proposes additional standards that are meant to reduce fraud, misuse, and abuse. The agency defers many of the specific policy details to the states. ACEP supports providing states with the flexibility to tailor their DUR standards to fit the needs of their populations. However, we still believe that CMS should be prescriptive enough to ensure that patients have access to the medications that they need, and that states do not unintentionally implement any policies that restrict physicians' ability to provide appropriate treatment to their patients.

Minimum Standards for DUR Programs

Opioid Safety Edits Including Initial Fill Days' Supply for Opioid-Naïve Beneficiaries, Quantity, Therapeutically Duplicative Fills, and Early Refill Limits

CMS is proposing to require states to include safety edits that address initial prescription fill days' supply for patients not currently receiving opioid therapy; quantity limits for initial and subsequent fills, and early fills on opioids prescriptions.

Initial Day Supply

With respect to a limitation on a day's supply for opioid naïve beneficiaries, CMS cites the Centers for Disease Control and Prevention (CDC) 2016 Guideline that states that opioids prescribed for acute pain in outpatient primary care settings to adults generally should be limited to 3 days or fewer, and more than a 7 days' supply is rarely necessary. CMS is proposing to require that states implement a days' supply limit when an initial opioid prescription is dispensed and to institute safety edits that alerts dispensers at the point of sale when an opioid prescription is dispensed to an opioid naïve patient that exceeds the state-imposed limit. CMS gives states the discretion to choose a specific day supply limit that suits their population.

ACEP believes that safety edits can impose a burden and potential access barrier on patients who receive prescriptions from emergency physicians in the ED. We would like to work with CMS and individual states to implement flexible policies that balance the need to monitor new opioid prescriptions while at the same time not compromising the ability for emergency physicians to provide appropriate pain management treatment to their patients. Evidence shows that emergency physicians are responsible for only a small portion of opioid prescriptions and were declining even before national attention began to increase on the opioid epidemic. A study from 2018[1] showed that between 1996 and 2012, the share of prescription opioids originating from emergency departments declined from 7 percent to 4 percent. Similarly, another study found that between 2007 and 2012, the greatest percentage drop in opioid-prescribing rates across specialties occurred in emergency medicine (–8.9 percent).[2]

We also strongly believe that states should not implement a supply limit that is less than 7 days. There are many cases where a prescription is ordered by an emergency physician on a Friday before a holiday weekend, and the patient is unable to obtain follow-up care with an appropriate specialist until the following week. For example, if a patient is seen in the ED for a limb fracture at the beginning of a holiday weekend, it could easily be up to five days until the patient is able to get in to see an orthopedist who can stabilize and fully set the fracture, and, if needed and appropriate, provide a prescription for additional opioids. While 7 days is generally an acceptable limit, we also note that in some extreme situations, such as natural disasters, a 7-day supply may be insufficient. ACEP recommends that CMS and states consider allowing a longer supply limit in certain exceptional circumstances.

Further, we believe that states must build exclusions into their supply limit policies, in line with CDC' recent guidance. The exclusions should at minimum include active cancer treatment, patients experiencing acute sickle cell crises, and patients experiencing post-surgical pain.

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[1] "Emergency Department Contribution to the Prescription Opioid Epidemic." Axeen, Sarah et al. *Annals of Emergency Medicine*; Available at http://www.annemergmed.com/article/S0196-0644(17)31969-8/fulltext

[2] "Trends in Opioid Analgesic–Prescribing Rates by Specialty, U.S., 2007–2012." Levy, Benjamin et al. *American Journal of Preventive Medicine*, Volume 49 , Issue 3, 409-413; Available at http://www.ajpmonline.org/article/S0749-3797(15)00089-6/ppt

Quantity Limits

CMS is proposing that states be required to implement quantity limits on opioids prescriptions (both initial and subsequent fills) to help identify abuse, misuse, excessive utilization, or inappropriate or medically unnecessary care. While ACEP agrees that quantity limits may be appropriate in general, we wish to reiterate our comments above and request that states build in exceptions for emergency and extreme situations where it may not be possible for patients to have access to a pharmacy to receive a refill if needed.

Early Fill Limitations

CMS is proposing to require that states establish safety edits to alert the dispenser before a prescription is filled early for an opioid product, based on the days' supply provided at the most recent fill or as specified by the state. While ACEP supports the concept of early fill limitations, states should build in appropriate flexibilities and exceptions. For example, patients receiving MAT may need to have their medication dose adjusted at the beginning of their treatment. The patient may be started on one dose of buprenorphine and get a few days in and need to increase their dose. As such, following their physician's advice, they may run out of medication early and need a refill sooner on that new dose.

Maximum Daily Morphine Milligram Equivalent (MME) Limits

CMS is proposing that states must include in their DUR programs safety edit limitations identified by the State on the maximum daily morphine milligram equivalent (MME) for treatment of pain and a claims review automated process. Although CMS notes that the SUPPORT Act specifically addresses MME limitation in the context of chronic pain, CMS is requiring that states establish MME threshold amounts regardless of whether the prescription is for the treatment of chronic or acute pain.

ACEP does not support this proposal, especially since it goes beyond the intent of the SUPPORT Act and does not correspond to current CDC guidelines. The current CDC guideline only addresses treatment protocols for chronic pain. We do note that earlier this year, the CDC established a workgroup called the Opioid Workgroup that will be charged with both updating the existing opioid prescribing guideline for chronic pain and developing a new one for acute pain. CMS should hold off finalizing any new requirements around the treatment of acute pain until the new CDC Opioid Workgroup has a chance to convene, consider current evidence and best practices, and issue recommendations.

Medication Assisted Treatment

CMS is proposing to require states to establish prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state, to identify cases where a beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for MAT or had an OUD diagnosis within a specified number of days (as determined by the state)-- without having a new indication to support utilization of opioids (such as a new cancer diagnosis, new palliative care treatment or entry into hospice).

In all, ACEP is extremely supportive of using MAT[3] to help treat opioid use disorder (OUD) in the ED and have seen great results with utilizing buprenorphine to help start patients on the path towards recovery. Initiating MAT

[3] This treatment may also be referred to as "medication for addiction treatment' or "medication for opioid use disorder" (MOUD) – an even more accurate term.

in the ED helps individuals stay in treatment longer, reduces illicit opioid use and infectious disease transmission, and decreases overdose deaths.[4] In addition, the available data demonstrate that patients with OUD who are started on buprenorphine in the ED -- and for whom there is a clinic to maintain treatment after treatment in the ED – are twice as likely at 30 days to remain in treatment for OUD, than patients who receive a referral alone (78 percent of patients started on MAT in the ED remain in treatment at 30 days, compared to only 37 percent of those who receive a referral alone).[5] Substantially increased participation in MAT, after ED buprenorphine initiation has been replicated in additional studies.[6][7][8]

Furthermore, studies of patients with OUD in California and elsewhere have demonstrated an instantaneous reduction in mortality after buprenorphine-assisted detoxification, justifying its use in the ED even when access to long-term maintenance and follow-up is not available.[9] Finally, a study conducted using a retrospective chart review of 158 patients treated at a single ED with buprenorphine for opioid withdrawal found a greater than 50 percent reduction (17 percent versus 8 percent) in return-rate to the same ED for a drug-related visit within one month, compared to the return-visit rate after usual care.[10] In all, research suggests that the sooner we can start patients on the right path, and keep them engaged in treatment, the more successful their recovery can be.

With respect to CMS' proposal, we agree that it is important for a patient receiving MAT not to receive another opioid medication that could possible interfere with the effectiveness of the treatment or impact the patient's health. Therefore, in general, we support CMS' proposal. However, we believe that states must build in some flexibilities and exceptions to their MAT policies. While we appreciate that CMS includes some examples of when it may be appropriate to prescribe additional opioid medications to patients receiving MAT, we do not believe this is an exhaustive list. There are other situations where physicians may need to prescribe additional opioids, such as when patients experience acute traumatic injuries (for example, breaking a leg) while receiving buprenorphine.

Naloxone

CMS is proposing and seeking comment on requiring states to establish prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state, to identify beneficiaries who could be at high risk of opioid overdose and should be considered for co-prescription or codispensing of naloxone with the goal of expanding appropriate utilization of naloxone to individuals at risk of opioid overdose.

ACEP agrees that the co-prescribing of naloxone can truly benefit patients, and in general, we believe that access to naloxone must be increased. There are still regulatory and legislative barriers in place that inhibit the ability for both health care professionals and laypersons to gain access to and appropriately use naloxone to treat patients. Naloxone is a life-saving drug that when used properly can reverse opioid overdoses and save lives. We would like to respond

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4 Bao YP, Wang RJ, et al. Effects of medication-assisted treatment on mortality among opioids users: a systematic review and meta-analysis. Mol Psychiatry. 2018 Jun 22.

5 D'Onofrio G, O'Connor PG, Pantalon MV, et al, JAMA. 2015 Apr 28;313(16):1636-44.

6 Kaucher K, Caruso E, Sungar G, et al. Evaluation of an emergency department buprenorphine induction and medication-assisted treatment referral program. Am J Emerg Med. 2019 Jul 30.

7 Hu T, Snider-Adler M, Nijmeh L, Pyle A. Buprenorphine/naloxone induction in a Canadian emergency department with rapid access to community-based addictions providers. CJEM. 2019 Jul;21(4):492-498.

8 Edwards F, Wicelinski R, Gallagher N, et al. Treating Opioid Withdrawal with Buprenorphine in a Community Hospital Emergency Department: An Outreach Program. Ann Emerg Med. 2020 Jan;75(1):49-56.

9 Elizabeth Evans et al., "Mortality Among Individuals Accessing Pharmacological Treatment for Opioid Dependence in California, 2006-10," Addiction 110, no. 6 (June 2015): 996-1005.

10 Berg ML, Idrees U, Ding R, Nesbit SA, Liang HK, McCarthy ML. Evaluation of the use of buprenorphine for opioid withdrawal in an Emergency Department. Drug Alcohol Depend. 2007;86:239-244.

to CMS' comment solicitation by highlighting ACEP's positions on a number of important issues: 1) guidelines for prescribing naloxone; 2) education and training; and 3) cost.

Guidelines for Prescribing Naloxone

ACEP believes that an effective naloxone program requires appropriate prescribing guidelines. We support the recommendations established by the Substance Abuse and Mental Health Services Administration (SAMHSA)[11], which encourage physicians to prescribe naloxone to at-risk patients in the following circumstances:

- Discharged from the ED following opioid intoxication or poisoning;
- Taking high doses of opioids or undergoing chronic pain management;
- Receiving rotating opioid medication regimens;
- Having a legitimate need for analgesia combined with a history of substance abuse;
- Using extended-release/long-acting opioid preparations;
- Completing mandatory opioid detoxification or abstinence programs; and/or
- A recent release from incarceration and past misuser of opioids.

Education and Training

Health care providers that administer naloxone treatment must undergo proper training. They should complete an educational program regarding the signs and symptoms of opioid overdose, naloxone effects and side effects, and indications for naloxone administration. ACEP believes Good Samaritan laws should be implemented in every state in order to shield health care personnel and lay persons from liability when administering naloxone to individuals suspected of opioid overdose. The administration of naloxone is part of core education for emergency physicians who are board certified by the American Board of Emergency Medicine (ABEM) or by the American Osteopathic Board of Emergency Medicine (AOBEM). Emergency physicians must take a comprehensive exam every ten years as well as an annual exam that focuses on recent changes to clinical protocols. Therefore, ACEP would suggest that additional educational requirements should not be added to physicians who participate in the Maintenance of Certification by ABEM and AOBEM.

We believe that pharmacists should be allowed, but not required, to dispense naloxone over the counter (OTC). As with prescribing health care professionals, appropriate related indemnification should be extended to involved pharmacists. If a pharmacist chooses to distribute/dispense OTC naloxone, they should provide the patient with information regarding the signs and symptoms of opioid overdose, the importance of promptly accessing emergency medical services via 911, naloxone effects and side effects, indications for naloxone administration, and at minimum, chest compressions for suspected cardiopulmonary arrest. As the OTC dispersal of naloxone becomes more common, it may also be worthwhile to provide support for research into the full implications and downstream consequences of this growing trend.

Laypersons should also be allowed to administer this medication for cases of suspected opioid overdose. Seconds matter in overdose cases, and it may be necessary for a bystander who could be a stranger (or who could be a friend, family member, or an off-duty EMT, nurse, or physician) to provide the treatment to save a patient's life. A study conducted by the CDC found that at least 26,500 opioid overdoses in the United States were reversed by laypersons

[11] Substance Abuse and Mental Health Services Administration. SAMHSA Opioid Overdose Prevention Toolkit. HHS Publication No. (SMA) 14-4742. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.

using naloxone from 1996 to 2014.[12] While naloxone is relatively safe, it is nevertheless important that any regulatory or legislative efforts to expand naloxone to the public be accompanied by robust public education programs to improve the chances of correct patient selection and proper naloxone administration.

Educating the public can also help address the stigma that often goes along with overdoses. It is a common misperception that a patient rescued from an opioid overdose who wakes up agitated is "angry" and that someone has "ruined" his/her "high." That is an extremely rare viewpoint of the patient. The truth is that naloxone when administered to an opioid-dependent patient usually results in a medical condition known as naloxone precipitated withdrawal (NPW), which can last an hour, or sometimes several hours (depending on the dose of naloxone administered). This withdrawal state can be very distressing to the individual and produces several symptoms, including agitation, anxiety, and restlessness (as well as potentially abdominal pain, vomiting and diarrhea). However, this is certainly an acceptable "adverse" or "side" effect of the drug, if the alternative is death or an anoxic brain injury. Therefore, public education may be helpful so that laypersons understand what to expect when administering the drug and are not led to believe that they have injured the recipient of naloxone.

Cost

While there has been a movement to increase prompt access to naloxone for opioid overdose victims over the last several years, the price of naloxone in nearly all forms of packaging has been steadily climbing in this country. These rising prices have affected the ability of EMS providers to obtain enough naloxone to treat all the overdose cases they see. In addition, the cost of naloxone products that laypersons can obtain may in some cases be the highest of all, limiting their ability to provide immediate treatment to members of their communities. ACEP urges CMS to do everything in their power to ensure that naloxone is available for community use at an affordable price.

Beyond the principles we lay out above, going forward, we recommend scientific research to study the consequences of naloxone distribution. Widespread use of a therapeutic agent should be embraced based on sound scientific evidence of its efficacy to patients. We also recommend societal resources to offer treatment for opioid addiction, including making inpatient and outpatient treatment available to all patients who need treatment, regardless of gender, age, income, education level, or ability to pay.

Exclusions

CMS is proposing that the DUR policies would not apply for individuals who are receiving hospice or palliative care or those in treatment for cancer; residents of a long-term care facility, an intermediate care facility for the intellectually disabled, or of another facility for which frequently abused drugs are dispensed for residents through a contact with a single pharmacy; or other individuals the state elects to treat as exempted from such requirements.

ACEP strongly recommends that CMS require states to exclude patients with sickle cell disease from their DUR programs. We believe that we must do more to improve care for children and adults living with sickle cell disease especially by improving access to treatment due to stigma and perceived racial bias. Requiring states to exclude this patient population from DUR programs can help reduce some of the barriers to treatment and address some of the stigma that exists around the disease.

[12] The Centers for Disease Control, Morbidity and Mortality Weekly Report (MMWR), "Prevention Programs Providing Naloxone to Laypersons — United States, 2014," 19 June 2015, available at https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6423a2.htm

We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs, at jdavis@acep.org.

Sincerely,

William P. Jaquis, MD, MSHQS, FACEP

ACEP President