

June 16, 2020

Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention
1600 Clifton Rd.
Atlanta, GA 30329-4027

Docket No. CDC–2020–0029

Re: Management of Acute and Chronic Pain: Request for Comment

Dear Dr. Redfield:

On behalf of our 40,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on a request for information (RFI) issued by the Centers for Disease Control and Prevention (CDC) on pain and pain management. While the CDC seeks input from a range of stakeholders, our responses to CDC's questions will be solely from the perspective of emergency physicians who routinely care for patients with pain and/or with conditions that complicate pain management, such as those with opioid use disorder (OUD).

The CDC is specifically inviting comments on topics focused on using or prescribing opioid pain medications, non-opioid medications, or nonpharmacological treatments (e.g., exercise therapy or cognitive behavioral therapy).

These topics are as follows:

- Experiences managing pain, which might include the benefits, risks, and/or harms of the pain management options listed above.
- Experiences choosing among the pain management options listed above, including considering factors such as each option's accessibility, cost, benefits, and/or risks.
- Experiences getting information needed to make pain management decisions.

CDC Questions

Experiences managing pain, which might include the benefits, risks, and/or harms of the pain management options listed above.

While ACEP understands that there are certainly circumstances in which the treatment of acute pain with opioids is a reasonable course of action, we also strongly support efforts to promote alternatives to opioids when appropriate. Emergency physicians have already taken steps to address the opioid crisis by implementing innovative alternative treatments to opioids (ALTO) programs. ALTO uses evidence-based protocols like nitrous oxide, nerve blocks, trigger point injections, and other non-opioid pain management tools to treat a patient's pain in the ED. Successful ALTO programs in New Jersey and Colorado have dramatically and

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quickly reduced opioid prescriptions in the ED. In New Jersey, the ALTO program at St. Joseph’s Hospital saw opioid prescriptions drop by 82 percent over two years. This program was replicated at ten hospitals in Colorado, resulting in a 36 percent drop in opioid prescriptions in just the first six months of program implementation. Following those successes, a large hospital system in Florida again replicated these results with a decrease in opioid ordering rates of 51 percent in one year. The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act authorize grants to expand the ALTO program in EDs across the country. We encourage the CDC to look to ALTO as an example as a multidisciplinary approach to treating pain and to further support non-opioid adjunctive therapies, in addition to target directed interventions to the causal nerve, muscle or tendon eliciting pain. We recognize that CDC recommendations on pain management have the potential to influence insurance coverage and prior authorization requirements and ask the CDC to leverage their recommendations to facilitate access to these treatments (to the extent the agency is able to do so).

Further, ACEP believes that non-steroidal anti-inflammatory medications and patch form lidocaine and similar types of analgesics should be readily available. There should also be consideration for non-pharmacological treatment like osteopathic manipulation techniques, transcutaneous electrical nerve stimulation (TENS) units, and traditional forms of physical therapy. Finally, therapies that are complementary to conventional allopathic paradigms such as yoga, acupuncture, meditation and massage therapy should be considered as useful adjuncts to acute and chronic pain management.

Experiences choosing among the pain management options listed above, including considering factors such as each option’s accessibility, cost, benefits, and/or risks.

As emergency physicians, we see every day the devastating effects that the opioid crisis has had on the communities we serve. We also see the devastating effects of the use of long-term prescribed opioids for chronic pain, as well as the downstream consequences from rapid discontinuation of opioid prescriptions without evaluation for and referral to treatment of OUD.

ACEP believes that buprenorphine is the one controlled substance in the United States where there is a major obstacle to “legitimate” patient access. Buprenorphine is the most effective treatment for OUD, which is currently the most lethal disease for Americans between the ages of 20 and 50.¹

We are extremely supportive of using medication for addiction treatment (MAT)² to help treat OUD in the emergency department (ED) and have seen great results with utilizing buprenorphine to help start patients on the path towards recovery. Initiating MAT in the ED helps individuals stay in treatment longer, reduces illicit opioid use and infectious disease transmission, and decreases overdose deaths.³ 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

¹ Centers for Disease Control and Prevention. “Opioid Overdose: Understanding the Epidemic”. www.cdc.gov/drugoverdose/epidemic/index.html.

² This treatment may also be referred to as “medication assisted treatment” MAT (antiquated) or “medication for opioid use disorder” (MOUD) – an even more accurate term.

³ 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.

percent of those who receive a referral alone).⁴ Substantially increased participation in MAT, after ED buprenorphine initiation has been replicated in additional studies.^{5,6,7}

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.⁸ 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.⁹ 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.

Despite the effectiveness of utilizing buprenorphine for treatment purposes, there are currently significant barriers to its use—the greatest of which is the “X-waiver” requirement mandated by the Drug Addiction Treatment Act (DATA) of 2000. Under the DATA 2000 law, physicians wishing to prescribe buprenorphine outside of opioid treatment programs (OTPs) must take an 8-hour course and receive a waiver from the Drug Enforcement Administration (DEA); physician assistants and nurse practitioners—who make up an increasing share of the acute care and primary care workforce—are required to receive 24 hours of training, an enormous impediment to expanding access to this lifesaving medication. Ironically, any DEA-registered clinician can prescribe far more dangerous opioids that lead to addiction (oxycodone, hydromorphone) without any of the barriers that prevent providers from prescribing buprenorphine, a vastly safer opioid that is used primarily to treat addiction. We firmly believe that the X-waiver requirement has led to misperception about MAT and has increased stigma about OUD and the treatment of this disease. Due to the stigma, some clinicians are not willing to pursue this addendum to their DEA registration or even engage in treatment of patients with OUD. Simply put the X-waiver requirement provides a cover for the stigma, enabling clinicians to say that “treating OUD is not my job.”

While removing the X-waiver would require legislation from Congress, on the regulatory side, **we also strongly support a modification to the current “three-day rule”** (Title 21, Code of Federal Regulations, Part 1306.07(b)). This rule represents a significant barrier to treatment since it requires providers to administer buprenorphine one day at a time, and forces patients to return to the ED or other settings each day to receive treatment. EDs (even without having clinicians with X-waivers) should be able to prescribe or dispense a three-day supply of buprenorphine or administer a dose which will last for at least 3 days (e.g. a depot intramuscular (IM) injection of a buprenorphine product).

⁴ D'Onofrio G, O'Connor PG, Pantalon MV, et al, JAMA. 2015 Apr 28;313(16):1636-44.

⁵ 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.

⁶ 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.

⁷ 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.

⁸ 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.

⁹ 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.

Eliminating the X-waiver barrier and addressing the “three-day rule” are of paramount importance. However, we must further note, that (in large part because of the obstacles, stigma, and misperception created by the X-waiver process) there are other obstacles to overcome:

- Some clinicians do not believe in treating opioid withdrawal with opioids (full or partial agonists);
- Many clinicians thus remain unfamiliar with utilizing buprenorphine as a safer, and more potent partial-agonist analgesic, in patients both with and without OUD, and the dosing adjustments needed between these groups;
- Many clinicians cannot utilize buprenorphine even if they have a waiver because it is either not stocked in the ED, or not stocked in the hospital pharmacy at all (again usually due to misperception, stigma, and/or not understanding the X-waiver rules);
- In most states there is a pre-authorization (PA) approval requirement by payors to prescribe buprenorphine. This is a major obstacle to initiating buprenorphine in the ED, as only 25 percent of the patients in the ED present during normal office hours. While some states (e.g. California, Massachusetts, Michigan, New Mexico, and New Jersey) and a few payors have recently removed the PA for buprenorphine for patients on Medicaid, the PA requirement persists in most states for most payors;
- Low dose buccal and transdermal formulations, which are safer than full agonist opioids, and more appropriate for pain management (particularly in patients who do not have OUD, but who may be at risk), remain prohibitively expensive, and require an obstructive PA process.

Overall, to significantly and consistently improve access to OUD treatment, we may need to engage in a broader educational campaign, and ACEP stands ready to work with the CDC and others to help educate providers about the benefits of MAT and help reduce the stigma and misperception about OUD as a disease and buprenorphine as treatment. The ACGME is currently formulating a cohesive statement and curriculum on addiction. ACEP strongly supports this measure to implement addiction curriculums across all residencies.

ACEP also believes that access to naloxone, which should be a low-cost medication, must be increased. This is truly a life-saving drug, which when used properly can immediately reverse opioid overdose. This medication can be administered intravenously, intramuscularly, or intranasally and is effective within minutes. Victims of opioid overdose often completely stop breathing and without respiratory support death is imminent. However, after the prompt administration of naloxone, the victim begins to breathe again and may quickly become fully conscious, rescued from the edge of death. Naloxone has been utilized in hospitals and by fire and emergency medical services (EMS) personnel for decades. The CDC has advocated for increasing naloxone administration by EMS personnel in an effort to reduce even more opioid-related deaths.¹⁰

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 emergency medical services providers to obtain enough naloxone to treat all the overdose cases they see. In addition, the cost of naloxone products which laypersons can obtain may in some cases be the highest of all, limiting their ability to provide immediate treatment to members of their communities.

Lastly, ED "take home naloxone programs" (THNP) need to be far more prevalent. Research shows that patients who receive a prescription for naloxone are more likely to enter a treatment program, report decreased drug use and

¹⁰ The Centers for Disease Control, “Expanding Naloxone use could reduce drug overdose deaths and save lives,” 24 April, 2015, available at: <https://www.cdc.gov/media/releases/2015/p0424-naloxone.html>.

demonstrate a greater willingness to undergo screening for HIV and hepatitis C.¹¹ A secondary effect has also been noted, in which 28 percent of take-home naloxone kit recipients report training a friend or family member how to use the antidote within three months of receiving the prescription.¹² Dispensing naloxone to high risk patients from the ED is one of the most efficient ways to get naloxone into the hands of individuals at the highest risk of opioid overdose. However, hospitals face regulatory and administrative barriers to dispensing naloxone, the greatest barrier being an inability to bill for or recuperate costs of naloxone that is dispensed. As a result, most EDs with THNPs are either grant-funded or hospital funded. The CDC can take a leading role in making every hospital a distribution point for naloxone. Take home naloxone programs could be much more rapidly, and broadly, implemented if hospitals/EDs were simply permitted to bill insurers, Medicaid, and Medicare for dispensing naloxone products (rather having to rely on a grant-funded naloxone distribution program).

Experiences getting information needed to make pain management decisions.

Emergency physicians play a critical role in our health care system, serving as the safety net in our communities. However, it may be challenging for us to provide comprehensive care to patients who arrive in our EDs without a medical record that we can easily access. In many cases, we see patients with acute conditions whom we have never seen before and who may not be able to communicate due to their health condition. We deal with life and death situations and must make near-instantaneous critical decisions about how to treat our patients with limited information.

We support effective and interoperable Prescription Drug Monitoring Programs (PDMPs) which push prescription data to emergency physicians, rather than requiring them to sign into and pull the data from the PDMP separately. The government should work to integrate the PDMP into the electronic medical record. This has been done in several health systems already, and greatly improves ease of access for providers.

Unfortunately, not all states have optimally functional PDMPs, resulting in highly variable usability and trustworthiness. In addition, patients may cross state lines for care, and not all states are part of InterConnect, which shares interstate information about dispensed prescriptions. Although interstate data sharing has improved, it is still difficult to access; we should work towards replacing the piecemeal state-based PDMPs with one highly functional national system, as was envisioned nearly 20 years ago when the National All Schedules Prescription Electronic Reporting Act (NASPER) law was signed -- but not funded. The Office of the National Coordinator (ONC) for Health Information Technology could also take action by requiring all PDMPs to be interoperable and to include specific standards, such as privacy and security protocols that protect patient-sensitive information.

Another specific initiative that ACEP supports is the Collective Medical Technologies' (CMT) EDIE™ (a.k.a. PreManage ED) software. EDIE™ is an information exchange which provides EDs with critical information on patients, such as how many ED visits patients have had in the last year, where they presented, their medication history, other providers who are involved with the patients, and, finally, whether there is a patient-specific care management plan that could guide treatment. The platform improves patient care by allowing emergency physicians to make more informed clinical decisions and better direct a patient's follow-up care. It can also help identify individuals who have gone to the ED frequently. Finally, it lowers health care costs through a reduction in redundant tests and through

¹¹ McDonald R, Strang J. Are take-home naloxone programmes effective? Systematic review utilizing application of the Bradford Hill criteria. *Addiction*. 2016;111(7):1177-1187. doi:10.1111/add.13326.

¹² Strang J, Manning V, Mayet S, et al. Overdose training and take-home naloxone for opiate users: prospective cohort study of impact on knowledge and attitudes and subsequent management of overdoses. *Addiction*. 2008;103(10):1648-1657. doi:10.1111/j.1360-0443.2008.02314.)

better case management, which in turn, reduces hospital readmissions. Washington state, in the first year alone, experienced a 14 percent reduction of super-utilizer visits, and realized a state Medicaid savings of more than \$32 million.¹³ However, hospitals (and especially EDs) often are responsible for the fees to use this service, even though it greatly benefits the health system overall.

While PDMPs have evolved greatly over the past several years, there is still much work to be done. For example, most PDMPs provide a list of prescriptions without any suggestion for interpretation of the data, making the determination of the prescriber subjective. As an example, many PDMPs focus primarily on “morphine milligram equivalents” (MME). This approach can create a negative perception of buprenorphine (because of the high MME of buprenorphine), despite the fact that buprenorphine has a far better safety profile than other opioids. This reporting method indirectly discouraged clinicians from prescribing this life-saving, life-transforming, medication. Graphical representations of the data and identification of "red flags" when risk factors are present may be a solution. It is imperative that the government evaluate the current situation in which one vendor provides the PDMP for 44 states; evaluation of data security and the great expense to states to provide the PDMP should be considered, as should the feasibility of a government-programmed system that would not incur an annual expense to states (e.g. as has been done in Wisconsin).

We appreciate the opportunity to share our comments. We recognize that the public comments the CDC is collecting will help complement its ongoing work assessing the need for updating or expanding the CDC Guideline for Prescribing Opioids for Chronic Pain, published in 2016. 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. Having an emergency medicine representative on the workgroup will be critical. ACEP formally nominated Aimee Moulin, MD MAS to serve as a member of the workgroup, and we ask that all due consideration be given to her nomination.

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

¹³ Anderson, S. “Emergency Department Information Exchange Can Help Coordinate Care for Highest Utilizers,” ACEPNow, <https://www.acepnow.com/article/emergency-department-information-exchange-can-help-coordinate-care-highest-utilizers/2/>.