



October 11, 2019

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Request for Information for the Development of a CMS Action Plan to Prevent Opioid Addiction and Enhance Access to Medication-Assisted Treatment

Dear Administrator Verma:

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) on ways that the Centers for Medicare & Medicaid Services (CMS) can help address the Nation's opioid crisis through the development of an action plan to prevent opioid addiction and enhance access to medication-assisted treatment (MAT).

As emergency physicians, we see every day the devastating effects that the opioid crisis has had on the communities we serve. We appreciate that CMS is developing an action plan that will review Medicare and Medicaid payment and coverage policies for MAT and the treatment of acute and chronic pain. Yet while we believe that opioids that are administered or prescribed in the emergency department (ED) and other health care settings should only be used for their intended purposes, and therefore support efforts to reduce diversion, we also believe that currently there are numerous federal policies inadvertently inhibiting access to vital treatment. Please find our comments on the specific questions raised in the RFI below.

Questions on Acute and Chronic Pain:

1. ***What actions can CMS take to enhance access to appropriate care for acute and/or chronic pain in Medicare and Medicaid, including:***
 - a. ***For special populations (for example, individuals with sickle cell anemia or individuals living in health professional shortage areas)***

ACEP is concerned about the critical and ongoing challenges that individuals with sickle cell disease (SCD) continue to experience when trying to manage their acute and chronic pain. The clinical complexities associated with pain management for people living with SCD have been a focus of our organizational efforts. We seek to ensure that all patients are able to access quality care for SCD, especially in areas of the country that lack providers with the

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comprehensive knowledge and expertise to care for this population. That is why we formed the Emergency Department Sickle Cell Care Coalition to provide a national forum dedicated to the improvement of the emergency care of patients with SCD in the United States, including the education of ED providers about the appropriate management of SCD-related pain.

We appreciate the work that the U.S. Department of Health and Human Services (HHS) has taken to address issues related to pain management, such as the release of the [HHS' Strategy to Combat Opioid Abuse, Misuse, and Overdose – A Framework Based on the Five Point Strategy](#) and creation of the [HHS Pain Management Best Practices Inter-Agency Task Force](#). We are pleased that the Task Force invited patients with SCD to share their perspective on the unique challenges they encounter managing pain and that the Taskforce's [Final Report](#) reflects this by including a dedicated section on SCD in the *Special Populations* portion of the Report.

We also appreciate the Centers for Disease Control and Prevention's (CDC) recent [clarification](#) of its *Guideline for Prescribing Opioids for Chronic Pain*, which conveys that the guideline is not intended to deny clinically-appropriate opioid therapy to any patients who suffer acute or chronic pain from conditions such as cancer and sickle cell disease, but rather to ensure that physicians and patients consider all safe and effective treatment options for pain management with the goal of reducing inappropriate use.

Despite these important steps, we continue to receive numerous reports that individuals with SCD and their medical providers are unable to obtain access to appropriate levels of medication, because of opioid prescribing policies regarding duration and dosage. We are extremely concerned about these issues and encourage you to take additional action to raise awareness about the challenges that individuals with SCD continue to face.

Specifically, we respectfully request that CMS:

- Make a public statement about the challenges individuals with SCD currently face in receiving the care they need and deserve;
- Highlight the CDC's clarification regarding opioid prescribing in public-facing materials on this issue;
- Encourage health care providers to utilize current and forthcoming clinical practice guidelines specifically addressing pain in SCD to help guide treatment and reimbursement practices; and,
- Call for additional research to understand underlying mechanisms of acute and chronic pain and develop mechanistic nonopioid pharmacologic therapies and nonpharmacologic approaches for SCD pain management.

b. and/or Through remote patient monitoring, telehealth, and other telecommunications technologies?

There are established examples of high quality, cost-effective telehealth programs in the ED setting that allow greater access to an emergency physician in inner city or rural EDs that would not normally be able to economically support that level of provider on a 24/7 basis, if at all. Additionally, telehealth access from the ED setting to other medical specialists such as neurologists or psychiatrists can help provide faster access to specialty care and reduce delays in critically needed treatment and the time these patients remain in the ED waiting for a psychiatric bed to become available (i.e. ED "boarding").

2. What, if any, payment and coverage policies under Medicare and/or Medicaid for the treatment of acute and/or chronic pain, do you believe, may have contributed to the use of opioids? If answering this question, please provide information on how these policies have contributed.

ACEP believes that when appropriate, alternatives to opioids, or simply non-opioid treatments (e.g. physical therapy, trigger-point injections, lidocaine patches, non-opioid oral analgesics, etc.) should be first treatment option for pain. Unfortunately, current Medicare reimbursement policies do not align with that overarching

principle, and sometimes, these alternatives are denied by insurers via therapy caps or by pharmacy benefit managers, who instead encourage opioid prescriptions or make prescribing non-opioid interventions arduous through a time-consuming, pre-authorization process which can be difficult to navigate, with unpredictable responses. It should also be noted that the same frustration applies when prescribing formulations of buprenorphine (a partial agonist opioid, and thus a safer opioid), when an opioid is necessary.

3. *What, if any, payment and coverage policies in Medicare and/or Medicaid have enhanced or impeded access to non-opioid treatment of acute and/or chronic pain?*

CMS in the past has specifically encouraged the use of opioid pain medications in the ED, even when perhaps it was unnecessary to do so. For example, in 2012, CMS added to its ED performance core measures timely pain treatment for long bone fractures, emphasizing parenteral medications (i.e. opioids.)¹ As stated above, access to and reimbursement of alternatives to opioids need to be improved. We encourage CMS to provide additional incentives to providers who use alternatives to opioids and call on CMS to implement a Center for Medicare & Medicaid Innovation (CMMI) model that will test different payment and coverage options around the use of non-opioids for the treatment of acute and chronic pain.

4. *What evidence-based treatments, Food and Drug Administration (FDA)-approved evidence-based medical devices, applications, and/or services and items for the following conditions are not covered, or have limited coverage for Medicare beneficiaries with:*

a. *Acute and/or chronic pain;*

Non-steroidal anti-inflammatory medications and patch form and lidocaine and similar types of analgesics should be readily available. There should also be consideration for non-pharmacological treatment like chiropractic care, osteopathic manipulation, and traditional forms of physical therapy. Finally, yoga, acupuncture, and massage therapy need to be considered as wonderful adjuncts to acute and chronic pain management.

b. *Pain and behavioral health needs requiring integrated care across pain management and substance use disorder (SUDs), with consideration of high-risk patients (i.e. multiple medications, suicide risk)?*

We believe it is critically important to ensure that high risk patients, such as those who are at risk for suicide, receive more integrated care. Currently, many people with behavioral health illnesses have nowhere to go to when they are in crisis, and they routinely wind up in the ED. The ED is often referred to as a “safety net” for vulnerable patients, such as psychiatric patients.

Overcrowding of the ED caused in part by boarding of psychiatric patients is a serious public health issue. ED boarding is extremely costly and increases adverse outcomes and mortality for our most vulnerable patients. Research shows that psychiatric patients’ length of stay in the ED is 3.2 times longer than that of non-psychiatric patients who are awaiting inpatient placement.² In a survey conducted of ACEP members, 48 percent of respondents said that psychiatric patients are boarded **one or more times a day** in their ED. When asked how long the longest patient waiting in the ED for an inpatient bed was boarded, nearly 38 percent of respondents said 1 to 5 days.³

¹ Flomenbaum, N. “The New Opioid Epidemic and the Law of Unintended Consequences,” *Emergency Medicine*. 2017 February;49(2):52, <https://www.mdedge.com/emergencymedicine/article/130490/toxicology/new-opioid-epidemic-and-law-unintended-consequences>.

² Nicks, BA & Manthey, David. (2012). The Impact of Psychiatric Patient Boarding in Emergency Departments. *Emergency medicine international*. 2012. 360308. 10.1155/2012/360308.

³ American College of Emergency Physicians, “ACEP Physician Poll on Psychiatric Emergencies September 28 – October 6, 2016,” available at: newsroom.acep.org/download/psychemergencypoll2016.pdf

EDs are also typically loud and chaotic and can easily overwhelm these patients. They often do not have readily available, if any, mental health or psychiatric consult to refer or coordinate care of psychiatric patients, which frequently leads to delays in care. Furthermore, EDs are already overwhelmed with patients. Many times, it can be challenging for emergency physicians to ensure that psychiatric patients are connected to any available treatment or community services. Thus, these patients wind up waiting in ED hallways, sometimes for days, waiting to be admitted to the hospital or an inpatient psychiatric facility, discharged back to the community, or transferred to another type of facility. A lack of available in-patient beds, decreased outpatient services, lack of psychiatric and mental health providers and many other factors all contribute to the issues around boarding. Having access to a 3-digit mental health dialing code could help ensure that patients access the right level of care for their needs.

Efforts to decrease boarding and create safe alternatives for patients with mental health disorders are ongoing. Some EDs across the country have created crisis stabilization units or other appropriate, hospital-based outpatient programs that accept psychiatric patients in crisis that are specially designed and staffed to treat psychiatric patients. These units allow patients to escape the noisy ED. They include large, open spaces where patients can easily self-access food, drinks, linens, phones, books, games, and TV. There is space to move about and engage in socialization, discussion, and therapy. Within a 24-hour period, patients are evaluated by a psychiatrist, treated by a multi-disciplinary team, provided resources about outside services and providers, and safely discharged. Hospitals and EDs that have incorporated these units have seen a significant reduction in admission rates. For example, Iowa City opened up such a unit, and within five weeks, psychiatric inpatient admission rates for patients presenting to the ED decreased from approximately one in two to one in four and 70 percent of patients were discharged within 24 hours.⁴ Other promising alternatives to the ED involve interventions such as, telemedicine psychiatric consults, ED case management, or mobile crisis intervention teams that can de-escalate crisis before patients get to the ED.⁵ CMS should consider covering these services for Medicare beneficiaries, perhaps through a CMMI model.

5. *What payment and service delivery models, such as those that utilize multimodal and multi-disciplinary approaches to effectively manage acute and chronic pain and minimize the risk of opioid misuse and OUD, could be tested by the Center for Medicare and Medicaid Innovation or through other federal demonstration projects?*
 - a. *What existing models, treatments or strategies identify and effectively manage the population of individuals misusing prescription opioids or using illicit opioids who then develop new or exacerbating pain?*

The management of acute pain in a patient who already has opioid use disorder (OUD) is a real challenge. Nonetheless these patients require expertise in the management of acute and chronic pain and the stigma of the disease makes treatment much more complicated.

6. *What can CMS do to better ensure appropriate care management for Medicare beneficiaries with pain who transition across settings, and/or between pain therapies?*

ACEP believes that having interoperable electronic health records and highly-trained patient navigators can help improve the management of complex pain issues. However, the stigma of management of acute and chronic pain still is a major impediment to good caregiving.

⁴ Iowa City Press-Citizen, “Five weeks in, Crisis Stabilization Unit shows promise,” Smith, Zachary Owen, 26 November, 2018, available at: <https://www.press-citizen.com/story/news/2018/11/26/five-weeks-crisis-stabilization-unit-shows-promise/2116173002/>

⁵ American College of Emergency Physicians, “Care of the Psychiatric Patient in the Emergency Department – A Review of the Literature,” October 2014. Available at: <https://www.acep.org/globalassets/uploads/uploaded-files/acep/clinical-and-practice-management/resources/mental-health-and-substance-abuse/psychiatric-patient-care-in-the-ed-2014.pdf>

7. *How can Medicare and Medicaid data collection for acute and chronic pain better support coverage, payment, treatment, access policies, and ongoing monitoring?*

Data collection on individual patients as well as on populations is important to better understand how people respond to acute and chronic pain management. More studies need to be conducted looking at genetic predispositions to opioid use disorder, as well as genetic variations in the responses to pain medications (including opioids).

8. *What other issues should CMS consider to improve coverage and payment policies in Medicare and Medicaid to enhance access to and effective management of beneficiaries with acute and/or chronic pain?*

While ACEP understands that there are circumstances in which the treatment of acute pain with opioids is the best 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 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. These results were replicated at ten hospitals in Colorado, where hospital systems noted a 36 percent drop in opioid prescriptions in just the first six months of the program. The recently enacted 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 you to look to ALTO as an example of how non-opioid related treatment can be effectively utilized.

Questions on Substance Use Disorders, including Opioid Use Disorders:

1. *What, if any, payment and coverage policies under Medicare and/or Medicaid for the treatment of SUDs, including MAT, do you believe, may help address the Nation's opioid crisis? If answering this question, please provide information on how these policies may help?*

In the Calendar Year (CY) 2020 Physician Fee Schedule (PFS) proposed rule, CMS sought comment on the use of MAT in the ED setting (including initiation of MAT and referral or follow-up care) and whether it should consider separate payment for such services in future rulemaking. **ACEP is extremely supportive of a future policy that would pay separately for MAT initiation in the ED and strongly encourages CMS to include such a proposal in next year's rule.** Emergency physicians working in the ED are on the front lines treating patients who overdose, but unfortunately there are a large number of patients treated in the ED who survive to be discharged, but do not receive sufficient attention or treatment afterwards. A recent study found that 1 in 20 individuals treated in EDs for nonfatal opioid overdose died within a year.⁶ We believe this study demonstrates the importance of initiating MAT (e.g., buprenorphine) in the ED and intervening on these high-risk patients when we have the opportunity to do so while they are in the ED.

We have seen great results with initiating treatment in the ED and starting patients on the path to recovery. By implementing this treatment regimen, we can address an OUD patient's immediate symptoms and cravings, which allows time to coordinate care and provide a "warm handoff" to substance use disorder

⁶ Weiner, SG, et al. "One-Year Mortality of Patients After Emergency Department Treatment for Nonfatal Opioid Overdose." *Ann Emerg Med.* 2019 Jun 19. pii: S0196-0644(19)30343-9.

specialists and other community resources who can appropriately carry out the long-term treatment. There are numerous study results showing promise for ED-initiated buprenorphine and its effectiveness in treating opioid use disorder. Initiating MAT in the ED has shown to be more successful than simple referral – after one month, 78 percent of patients started on MAT in the ED remained in treatment programs, compared to 37 percent who only received a simple referral.⁷ Furthermore, studies of patients in California and elsewhere with opioid addiction 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 Another study tracked patients on buprenorphine for MAT for up to 43 months. The cohort still taking buprenorphine at 12 months had a 17.5 percent less than the expected rate of ED visits.⁹ Finally, a study conducted using a retrospective chart review of 158 patients treated at a single ED with buprenorphine for opioid withdrawal found no instances of precipitated opioid withdrawal (a potential medical complication of buprenorphine), and 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 for 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.

In terms of payment, currently there is no way to capture the work it takes to initiate MAT programs in the ED outside the E/M levels of service (CPT codes 99281-99285). It takes a significant amount of time (sometimes two to three hours) to titrate the appropriate dosage. Therefore, ACEP strongly encourages CMS to ensure that the payment adequately funds ED-initiated MAT along with the other necessary wrap-around features of MAT such as treatment management and counseling. ACEP would be happy to work with CMS on finding the appropriate crosswalk to set a proper reimbursement rate for these services.

2. *What, if any, payment and coverage policies in Medicare and/or Medicaid have enhanced or impeded the identification of, and access to the treatment by, beneficiaries with SUDs, including OUD?*

As stated in the response to the last question, ACEP supports coverage and payment of MAT services initiated in the ED. Beyond Medicare and Medicaid coverage issues, one significant barrier to providing medication-assisted treatment (MAT) outside of OTPs 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 OTPs must take an 8-hour course, receive a waiver from the Drug Enforcement Agency (DEA), and comply with numerous logging and audit requirements. The presence of this requirement has led to a misperception about MAT and increased stigma about OUD and the treatment of this disease. In surveys that ACEP has conducted on the X-waiver, we have found that many physicians are not receiving an X-waiver for prescribing buprenorphine, and even if they are, they are still not prescribing the medication. Many physicians are not familiar with the drug and its side effects/dosing; others cannot order or administer buprenorphine in the ED even if they have an X-waiver because it is not permitted to be stocked in their hospital’s ED pharmacy, or may not even be included in the hospital’s formulary; and finally, due to misperception, some do not believe in treating opioid withdrawal with opioids. Again, ACEP believes that the existence of the X-waiver contributes to these misperceptions and barriers.

⁷ D’Onofrio G, O’Connor PG, Pantalon MV, et al. “Emergency Department-initiated Buprenorphine/Naloxone Treatment for Opioid Dependence: a Randomized Clinical Trial.” JAMA. 2015;313(16):1636-1644.

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 Schwarz R, Zelenev A, Bruce RD, et al. Retention on Buprenorphine Treatment Reduces Emergency Department Utilization, But Not Hospitalization, Among Treatment-seeking Patients with Opioid Dependence. *J Subst Abuse Treat.* 2012 Dec;43(4):451-7

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 improve access to OUD treatment, we may need to engage in a broader educational campaign, and ACEP stands ready to work with CMS and other agencies including SAMHSA to help educate providers about the benefits of MAT and help reduce the stigma and misperception around both this disease and treatment protocol. While removing the X-waiver would require legislation from Congress, on the regulatory side, we also strongly support 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 each day over a three-day period, thus forcing patients to return to the ED or other settings each day to receive treatment – a substantial and often unsurmountable challenge for patients struggling with opioid withdrawal – not to mention the increased costs of transportation, child-care, time away from work, and the additional direct costs to CMS and other payers

3. *What evidence-based treatments, FDA-approved evidence-based medical devices, applications, and/or services that treat or monitor SUD, including OUD, monitor substance use withdrawal and/or prevent opioid misuse and opioid overdose are not covered, or have limited coverage, in Medicare?*

ACEP strongly believes that MAT initiated in the ED for patients with OUD should be reimbursed by Medicare, and Medicaid, without a pre-authorization requirement. Pre-authorization requirements greatly impede buprenorphine prescribing from the ED (if not only for the time required to complete the paperwork, but that the majority of patients seen in the ED are seen outside of usual business hours).

Additionally, there are interventions that can be implemented in the ED for other substances as well, beyond opioids. Individuals with SUDs regularly access emergency care, with nearly half of all ED visits in the US categorized as relating to SUDs.¹¹ The ED can serve as a critical point in screening for and identification of alcohol misuse and for implementation of ED based interventions across the spectrum of patients with alcohol use and alcohol use disorders including harmful, hazardous, at-risk and dependent drinkers. These ED interventions can range from a focus on reducing frequency or quantity of alcohol use, to injury prevention (i.e. alcohol-related injury, reduced drinking and driving, increasing seat belt use, etc.), and enhancing motivation to enter treatment. There is concrete evidence that these interventions are successful,¹² and it is essential to ensure that CMS adequately covers these treatments for all forms of SUD.

4. *What payment and service delivery models that identify and treat people with pain who are at risk of, or have a past history of, OUD, could be tested by the Center for Medicare and Medicaid Innovation, or through other federal demonstration projects?*

CMMI could test an episode-based payment model that funds MAT services for Medicare beneficiaries that bundle in all the treatment management and counseling services that patients with OUD require. CMMI could also explore different payment mechanisms and incentives for rewarding the use of alternatives to opioids for managing acute or chronic conditions for patients with a past history of OUD.

¹¹ The DAWN Report. “Highlights of the 2010 Drug abuse Warning Network (DAWN) Findings on Drug-related Emergency Department Visits.” <https://www.samhsa.gov/data/sites/default/files/DAWN096/DAWN096/SR096EDHighlights2010.htm>.

¹² Hawk, K, et al. “Emergency Department Screening and Interventions for Substance Use Disorders.” *Addict Sci Clin Pract* (2018) 13:18. <https://doi.org/10.1186/s13722-018-0117-1>.

5. *What actions could CMS take to improve access to evidence-based, FDA-approved MAT or other therapies in Medicare and Medicaid, including for special populations (for example individuals living in health professional shortage areas)?*

ACEP believes that CMS must do more to help eliminate the stigma associated with delivering evidence-based MAT to patients with OUD. CMS can also more appropriately reimburse for these services. As stated above, ACEP strongly supports a concept raised in the CY 2020 PFS proposed rule to pay for MAT services initiated in the ED.

6. *What can CMS do to expand program access to the treatment of SUDs, including OUD, in Medicare and Medicaid through remote patient monitoring, telehealth, telecommunications and other technologies?*

In the CY 2020 PFS Proposed Rule, CMS proposes to add the G-codes for SUD monthly bundled payments to the list of Medicare telehealth services for CY 2020. ACEP strongly encourages CMS to allow emergency physicians providing SUD treatment to be able to bill for these services, both in-person and via telehealth. In all, ACEP strongly supports the delivery of telehealth services by board-certified emergency physicians.

7. *What recommendations do you have for data collection in Medicare and/or Medicaid*
a. On the treatment of SUDs, including OUD, to better support coverage, payment, treatment, access policies, and ongoing monitoring, and/or
b. To facilitate research, policy development, and inform coverage and payment policies to prevent OUD?

ACEP supports effective and interoperable Prescription Drug Monitoring Programs (PDMPs) as a means to help inform the treatment of patients with OUD. 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 that 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 that have gone to the ED frequently. Finally, it lowers health care costs through a reduction in redundant tests and through better case management that reduces hospital readmissions. Washington state, in the first year alone, experienced a 14 percent reduction of super-utilizer visits, and 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 they greatly benefit the health system overall.

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/>.

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. Graphical representations of the data and identification of "red flags" when risk factors are present may be a solution. It is imperative that 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).

8. *What recommendations do you have to lower prices of drugs used to reverse opioid overdoses (e.g., naloxone) for consumers?*

ACEP 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 reverse opioid overdoses and save lives. 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 injection 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 Centers for Disease Control (CDC) has pushed for increasing naloxone administration by EMS personnel in an effort to reduce even more opioid-related deaths.¹⁴

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 its 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 are in need of treatment, regardless of gender, age, income, education level, or ability to pay.

9. *What other issues should CMS consider to improve coverage and payment policies in Medicare and Medicaid to enhance the identification of, treatment access by, and the treatment of beneficiaries with SUDs, including OUD?*

Medicare and Medicaid need to make prevention, treatment, and harm reduction interventions and resources more affordable and widely available to manage the crisis of untreated and undertreated SUDs in this country.

¹⁴ 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>.

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,

A handwritten signature in black ink, appearing to read "Vidor E. Friedman". The signature is fluid and cursive, with a large, sweeping loop at the end.

Vidor E. Friedman, MD, FACEP
ACEP President