

March 15, 2018

The Honorable Kevin Brady
Chairman
House Committee on Ways and Means
1102 Longworth House Office Building
Washington, D.C. 20515

The Honorable Richard Neal
Ranking Member
House Committee on Ways and Means
1139E Longworth House Office Building
Washington, D.C. 20515

The Honorable Peter Roskam
Chairman
House Committee on Ways and Means
Health Subcommittee
1102 Longworth House Office Building
Washington, D.C. 20515

The Honorable Sander Levin
Ranking Member
House Committee on Ways and Means
Health Subcommittee
1139E Longworth House Office Building
Washington, D.C. 20515

Dear Chairman Brady, Ranking Member Neal, Chairman Roskam, and Ranking Member Levin:

On behalf of the American College of Emergency Physicians (ACEP) and our 38,000 members, thank you for your continued efforts to respond to the nation's opioid epidemic and address its impact on Americans who depend upon the Medicare program. Emergency physicians are on the front lines of the opioid and substance use disorder crisis, and every day we witness the effects of this epidemic on patients, their families, and our communities. We thank you for the opportunity to share our feedback with the Committee.

By the nature of our profession, many patients seeking care in the emergency department present with severe pain, which may be due to an acute or chronic condition. A primary goal of emergency care is to alleviate pain quickly, safely, effectively, and compassionately. As part of our efforts to help solve the opioid epidemic, emergency physicians rarely prescribe opioids for more than several days. Additionally, ACEP has worked to educate its members on safe prescribing guidelines for many years, and these efforts have shown great success. According to a 2015 American Journal of Preventive Medicine (AJPM) study, the largest percentage drop in opioid prescribing rates between 2007 and 2012 occurred in emergency medicine (-8.9%).

As we work together to develop effective solutions to the opioid epidemic, we believe it is important that our collective response is sufficient and appropriate to address the problem, while still ensuring that legislative responses do not overcorrect and that physicians still have access to effective options to treat pain. Opioids are an appropriate course of treatment for some patients, and the response to the epidemic should not unduly burden physicians and their patients for whom opioids may be a suitable treatment. At the same time, we encourage the development and use where possible of non-opioid alternatives to effectively treat patients and address the devastating impacts of the opioid epidemic on our country. Our responses to the questions posed by the Committee can be found on the following pages.

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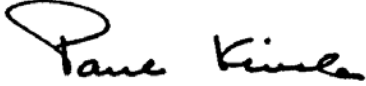
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Dean Wilkerson, JD, MBA, CAE

We are deeply appreciative of the Committee's continued attention to this critical public health issue, and emergency physicians throughout the country stand ready to help implement effective, bipartisan, and patient-centered solutions to improve the lives of our patients who depend upon the Medicare program.

Should you have any questions or require any further information, please do not hesitate to contact Ryan McBride, ACEP Senior Congressional Lobbyist, directly at (202) 370-9299 or at rmcbride@acep.org.

Sincerely,

A handwritten signature in black ink that reads "Paul D. Kivela". The signature is written in a cursive, flowing style.

Paul D. Kivela, MD, MBA, FACEP
ACEP President

Overprescribing/Data Tracking

- 1) Perverse Incentives in Medicare: The Committee seeks input on perverse incentives within Medicare that spur overprescribing of opioids across all settings of care. The Committee seeks input on best practices and policies that would modify prescribing patterns to prevent opioid abuse and misuse and reduce the use of opioids in emergency departments and other outpatient settings.**

In 2017, the Centers for Medicare & Medicaid Services (CMS) issued regulations that revised how pain management is assessed as part of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey. Previously, the survey's questions on pain management were calculated as part of the total performance score under the Hospital Value-Based Purchasing (VBP) program, raising concerns that hospitals would be incentivized to prescribe more opioids to ensure higher HCAHPS scores. Under the changes issued by CMS that went into effect in 2018, the survey questions are now designed to solicit feedback on pain communication as opposed to management. Additionally, while the survey still gathers data on how a patient's pain was treated during their hospital stay, these responses are no longer factored into the total VBP performance score, removing potential incentives that could encourage greater opioid prescribing.

CMS is currently developing a similar survey focused on the emergency department, the Emergency Department Patient Experiences with Care (EDPEC) Survey. As this survey continues to be developed, we would encourage legislators and regulators to ensure that pain-related questions are approached similarly to those in the revised HCAHPS survey, and that the responses to these questions are not tied to payment calculations. Medicare payments must value the physician's best clinical judgement and not penalize them for making decisions that are in the best interests of their patients.

It is also imperative that Medicare (as well as Medicaid and other third-party payers) ensure that non-opioid alternatives are appropriately valued and are easily available as treatment options and that artificial barriers do not prevent patients from receiving these treatments. Expanding the availability of alternative treatments will help reduce the need for opioids for pain management.

- 2) Second-Fill Limits: The Committee seeks input on issues that may arise from limiting second-fill opioid prescriptions for acute pain.**

Emergency physicians see patients every day whose pain may be the result of an acute condition or due to one or more chronic conditions. Medicare policies should reflect the unique nature of managing pain in the emergency department and incentivize providers to follow evidence-based best practices and clinical guidelines. Pain treatment and prescribing guidelines should promote adequate pain control, health care access, and flexibility for the physician's clinical judgement. Medical specialties should be the primary sponsors of these guidelines. To this end, ACEP has been actively engaged in developing pain treatment guidelines along with the American Medical Association (AMA), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Office of the National Drug Control Policy (ONDCP), and many others. Creating additional federal work groups or task forces would be duplicative. Safe harbors should also exist for prescribers who follow pain treatment guidelines.

Second-fill limitations for opioid prescriptions could be useful for the purposes of ensuring patients receive appropriate follow-up care, especially if their pain continues, provided other fundamental access issues are addressed. However, we urge Congress to exercise caution and consider how such limitations could negatively affect access to care. For example, if second-fill limits are paired with an arbitrary three-day prescribing limit for acute pain, this could exacerbate access issues and unnecessarily burden both provider and patient. This would be especially difficult for Medicare beneficiaries who may not have reliable access to transportation. Additionally, the unique nature of care in the emergency department can make such policies a major barrier and burden for some patients to receive pain medication that is prescribed by an emergency physician. Emergency physicians operate in shifts, and therefore it may be logistically challenging for a patient or pharmacist to immediately reach out to the physician who treated the patient. We therefore recommend creating a more flexible policy for opioids prescribed by emergency physicians in emergency departments in order to account for situations when a pharmacy or other entity is unable to reach the emergency physician who ordered the prescription.

There are also other potential issues that could arise with the establishment of hard prescribing limits that do not account for medical necessity or take into account appropriate documentation. 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 emergency department 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. We also note that in some extreme situations, such as natural disasters, a limited supply may be insufficient.

ACEP also supports partial filling of Schedule II controlled substances at the request of the prescriber or patient. We urge the Committee to ensure that patients are not burdened by financial disincentives (e.g., additional copays) for requesting partial fills.

3) Tools to Prevent Opioid Abuse: The Committee seeks input on tools currently unavailable in the Medicare program that could be used to curb opioid abuse and dependence.

There are a number of ongoing efforts that can help inform the Committee's work. For example, ACEP supported provisions in the Comprehensive Addiction and Recovery Act (CARA; P.L. 114-198) that created pharmacy/physician "lock in" programs that also ensured appropriate access to needed medications for beneficiaries receiving emergency medical care. ACEP also largely supports the recent draft 2019 Contract Year rule for the Medicare Advantage Program and the Part D Prescription Benefit Program framework for Part D plan sponsors to voluntarily adopt drug management programs through which they can address potential overutilization of frequently abused drugs by identifying potential at-risk beneficiaries, conducting case management, and, if necessary, limiting access to coverage for such drugs through pharmacy or prescriber lock-in, as well as beneficiary-specific point-of-sale claim edit.

Any proposals should uphold the requirements of CARA to first conduct case management, including clinical contact, before coverage of any frequently abused drugs can be restricted. This can help ensure that any eventual limitations are clinically appropriate and that beneficiaries can be ensured sufficient notice that coverage may be restricted.

4) Medication Therapy Management (MTM): The Committee seeks input on the value of adding beneficiaries at-risk of opioid use disorders to the list of targeted beneficiaries under the MTM program.

Adding beneficiaries who are at risk of opioid use disorders to the list of targeted beneficiaries under the MTM program could be valuable, especially considering increasing opioid overdose rates in all age groups, including Medicare-age or near-Medicare-age populations. Initiatives like the state Emergency Department Information Exchange (EDIE), currently operating in more than a dozen states, including Washington, Oregon, and California, can help identify at-risk patients and help decrease opioid prescribing and use. EDIE is an automated tool that is directly integrated with a state's PDMP to improve care coordination. For example, in Washington, when a patient registers in an EDIE-connected emergency department, EDIE processes a patient-specific history and identifies any potential risk patterns, and within seconds automatically pushes this information to the provider in an easily-digestible format. This ensures that relevant information is available to the provider the moment they need it, allowing them to make the most informed clinical decision about a patient's care.

EDIE looks for high utilizers – identified as individuals who present in the emergency department more than five times a year. Many of these patients have a concomitant mental health disorder, and many also have a substance use disorder or history of substance use disorder. The value of this tool in the emergency department is apparent given the time-sensitive nature of emergency medical care, but its ability to identify beneficiaries at risk of opioid use disorders could also be of value in adding targeted beneficiaries under the MTM program. However, as the Committee notes, there are existing challenges regarding CMS' access to state PDMPs that would likely need to be addressed.

5) Electronic Prior Authorization: The Committee seeks input on the value of standardizing the electronic prior authorization process and other improvements that could be made to improve coordination and prevent abuse.

Prior authorization rules must not pose a barrier to patients seeking access to emergency care. Insurance coverage, regardless of payer, does not affect the obligation of an emergency physician to perform a medical screening examination and provide necessary stabilizing treatment or appropriate transfer, nor the financial obligation incurred for such evaluation and care. Patients should be granted the expectation of coverage when seeking emergency care. While standardizing the electronic prior authorization process could reduce some of the burden, it still does not fully address the fundamental problems of the prior authorization process and the delays in care delivery.

- 6) **Prescription Drug Monitoring Program (PDMPs):** Currently, CMS does not have access to state PDMPs. The Committee seeks input regarding state PDMP data-sharing with CMS and other health care entities. Specifically, the Committee seeks information on potential barriers to implementation.

ACEP supports effective, interoperable, and voluntary state prescription drug monitoring programs (PDMPs) that push prescription data to emergency department providers, rather than requiring them to separately sign into and pull the data from the PDMP. PDMP use can and should be seamlessly integrated into physician workflows, and to encourage greater adoption of these technologies, electronic health record (EHRs) products should be required to provide such capability before they are certified. Ideally, PDMP data should be available in real time to identify any potential patient risks and help inform the physician's clinical prescribing decisions.

Due to the current limitations and widely varying capabilities of state PDMPs, we caution against mandated use of these programs. This is due in part to limited optimization of and standardization between programs, and the lack of a mechanism to allow effective interstate communication. To help address some of the existing limitations of data sharing and coordination between PDMPs, Congress reauthorized the National All Schedules Prescription Electronic Reporting Act (NASPER) as part of CARA, and authorized additional funding through 2021. We urge Congress to ensure stable and adequate funding to promote the continued improvement of these programs. To the extent possible, Congress should incentivize the development of interstate, frequently updated, multiple-drug-schedule, easily accessible, and widely used PDMPs.

Communication and Education

- 1) **Beneficiary Notification:** The Committee seeks input on the types of communications that would be appropriate for notification of the adverse effects of prolonged opioid use and alternative pain management treatment options.

More emergency departments are implementing alternative pain treatment protocols and are directly engaging with patients to treat their pain with non-opioid alternatives, such as the Alternatives to Opiates (ALTO) program that has seen significant positive results in New Jersey and Colorado. More information on the ALTO program is provided in our response to the Committee's questions under the "Treatment" section below.

ACEP also supports expanding the number of disposal sites for unwanted prescription medications and drug take-back programs, and Medicare beneficiaries should be made aware of such programs. These programs are an essential part of an effective approach to reducing the abuse of controlled substances. Drug take-back programs should be available at no cost to patients, and there should be no legal sanctions against those who turn in unused controlled substances.

- 2) **Prescriber Notification and Education:** The Committee seeks input on the best methods for provider education on the adverse effects of prolonged opioid use, clinical guidelines for alternative pain treatments, and clinical guidelines for opioid prescribing. The Committee also seeks input on effective ways to notify providers who prescribe such medicines in excess of their peers.

Emergency physicians are well-educated and trained in treating pain, including prescribing of opioids. ACEP supports voluntary efforts by physicians to complete continuing medical education (CME) regarding opioid prescribing. We urge caution in considering the addition of new federal requirements for mandatory CME on opioid prescribing, given the potential for significant overlap with existing requirements already imposed on physicians by their state or specialty board, as well as additional administrative burden.

High prescribing patterns are not by themselves an indicator of inappropriate prescribing patterns, and care should be taken to analyze health professionals based upon factors that reflect their specialty, the care provided, and the patient population they treat. Solutions should avoid a "one-size-fits-all" approach.

Prescribers should be notified on a regular basis on how their prescribing patterns compare to their peers in the same specialty, geographic region, and even, where possible, facility size or type. Using existing available data within these programs, priority should be placed on identifying outliers using statistically sound and relevant methods. Notifications should be frequent enough to ensure prescribers have an accurate picture of their prescribing patterns, but not so frequent that they become burdensome or ineffective. We would suggest quarterly notifications as a starting point. These efforts can also be informed by threshold reporting that already occurs at the state level.

Treatment

- 1) Opioid Treatment Programs (OTPs) and Medication Assisted Treatment (MAT):** The Committee seeks input from providers around best practices for identification and referral to OTPs, as well as how an OTP benefit could be integrated into the Medicare fee-for-service program – whether through bundled payments or otherwise. The Committee seeks input on the types of providers that are involved in the delivery of MAT, best practices to promote coordinated and managed care, and current reimbursement challenges providers face through Medicaid and commercial plans.

Access to Medication-Assisted Treatment (MAT) is also an integral component of responding to substance use disorder and starting patients on a path to rehabilitation. ACEP supports the expansion of MAT, including the increasing of the caps on how many patients may be treated by physicians and physician-led provider teams who are appropriately trained to dispense narcotics for maintenance and detoxification.

Initiating MAT in the emergency department and ensuring a “warm hand-off” to long-term MAT providers can help ensure that beneficiaries with an opioid use or substance use disorder enter into a successful treatment program. Studies have shown that ED-initiated MAT is significantly more effective in increasing engagement in addiction treatment, reducing self-reported illicit opioid use, and decreasing use of inpatient addiction treatment services.¹ However, while treatment can be initiated in the emergency department, there must be adequate resources and available providers to carry out the longer-term MAT in the appropriate setting.

ACEP supports physician prescribing of naloxone to at-risk patients, per recommendations of the Substance Abuse and Mental Health Services Administration (SAMHSA), and education of overdose recognition and safe naloxone administration by non-medical providers, such as family members. These efforts should be paired with legislation that would make health care providers and lay users of naloxone immune from liability for failure or misuse of bystander naloxone.

Cost and access to naloxone is a growing concern. The nationwide prevalence of the opioid epidemic and the increasing potency of heroin laced with fentanyl or carfentanil mean that overdoses now tend to require larger doses of naloxone to reverse. Further, necessary efforts at both the state and federal levels to increase the availability of naloxone have also contributed to rising prices for this drug. Ensuring affordable access to naloxone should continue to be a priority.

- 2) Reimbursement:** The Committee seeks input from providers around resource use and reimbursement issues that should be considered for the Medicare population when expanding treatment options.

As noted earlier, Medicare should ensure that opioid alternatives and treatment options are easily accessible and that unnecessary barriers do not prevent patients from receiving timely care. In order to facilitate emergency department initiated MAT, prior authorization requirements should be eliminated for buprenorphine, at least for the short term while starting patients on the path toward longer-term treatment.

- 3) Alternative Options for the Treatment of Pain:** The Committee is interested in ways to effectively address pain and ideas for innovative ways to encourage multimodal treatment of pain through payment reforms or benefit changes.

For many patients, their first encounter with the health care system is through the emergency department, so emergency physicians also have a role in ensuring that patients do not go from a prescription to an addiction. Alternatives to opioid pain management must be easily accessible to Medicare beneficiaries and be adequately covered as options for the first line of pain treatment.

We encourage the Committee to examine and promote successful programs like the emergency department-based Alternatives to Opiates (ALTO) program at St. Joseph’s Hospital in Paterson, NJ. This program uses targeted non-

¹ Gail D’Onofrio, MD, MS; et al. Emergency Department–Initiated Buprenorphine/Naloxone Treatment for Opioid Dependence: A Randomized Clinical Trial. *The Journal of the American Medical Association*. Volume 313, Number 16 (2015). 1636-1644.

opioid medications, trigger-point injections, nitrous oxide, and ultrasound-guided nerve blocks to treat a variety of acute pain diagnoses, including headache, bone fractures, back pain, and many others. In many cases, these treatments are as effective or more effective than opioids as they are specifically tailored to the patient and the type of pain. Within five months, the ALTO program reduced opioid use in the emergency department by 38 percent, and nearly 75 percent of patients were successfully treated with non-opioid protocols². For those patients who are eventually treated with opioids, the emergency department ensures they are aware of the potential risks of opioid treatment and connects patients with providers who can help manage their pain symptoms, such as primary care physicians, pain management specialists, physical therapists, and psychiatrists.

ACEP also supports expanded research into and manufacturing of opioids with abuse-deterrent properties. However, there remain significant challenges that may limit use of abuse-deterrent products as an alternative to opioids already on the market. Many of these products are significantly more expensive than their non-abuse-deterrent counterparts, and additional research is still needed to accurately determine their effectiveness compared to traditional opioids. Regardless, expanding access to abuse-deterrent opioid therapies is just one part of the solution and should occur in conjunction with expanded research and promotion of other evidence-based, non-opioid treatments and prevention strategies.

² <https://www.aha.org/system/files/content/16/16behavhealthcaseex-stjosephs.pdf>