

April 1, 2019

ADM Brett P. Giroir, M.D. Assistant Secretary for Health Office of the Assistant Secretary for Health U.S. Department of Health and Human Services 200 Independence Avenue SW Washington, DC 20201

Re: Pain Management Best Practices Inter-Agency Task Force Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations

Re: HHS-OS-2018-0027

Dear Dr. Giroir:

On behalf of nearly 38,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on the Pain Management Best Practices Inter-Agency Task Force's *Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations*. As we continue to tackle the opioid epidemic facing our country, we need to have policies in place that encourage the use of best practices for treating and managing both acute and chronic pain. This draft report is a great step towards achieving that goal, as it contains recommendations that are grounded in evidence and that take into account extensive feedback from a wide range of stakeholders. We applaud the Trump Administration for taking this issue head on.

In general, ACEP supports the recommendations in the draft report, and we have a few comments on specific goals and recommendations that particularly affect emergency physicians and the patients we serve.

2.2.2 Overdose Prevention Education and Naloxone

Naloxone is a life-saving drug that when used properly can reverse opioid overdoses and save lives, and we believe that access to naloxone must be increased. ACEP agrees with the three recommendations included under this section.

However, we believe that the final report could go even further by enhancing the recommendations to address additional issues related to 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 encourage the report to emphasize the recommendations established by

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the Substance Abuse and Mental Health Services Administration (SAMHSA)¹, which encourage physicians to prescribe naloxone to at-risk patients in the following circumstances:

- Discharged from the emergency department (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

We appreciate that the draft report calls for increasing educational programs for first responders. However, we believe that the final report should clearly state that all health care providers that administer naloxone treatment (not just first responders) 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. The administration of naloxone is already part of the core educational curriculum for emergency physicians. ACEP also 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.

We believe that pharmacists should be allowed, but not required, to dispense naloxone over the counter (OTC). 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.

Cost

While the gap addressed in the report states that take-home naloxone distribution is associated with a "cost-effective" reduction in mortality, the recommendations do not address the rising cost of naloxone. 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. ACEP urges the Administration and Congress to do everything in their power to ensure that naloxone is available for community use at an affordable and accessible price.

2.2.1.1 Prescription Drug Monitoring Programs

ACEP agrees with the recommendations around Prescription Drug Monitoring Programs (PDMPs). We support effective and interoperable PDMPs that push prescription data to emergency physicians, rather than requiring them to separately sign into and pull the data from the PDMP. Currently, not all states have optimally functional PDMPs, resulting in highly variable usability and trustworthiness. Some states have not made commitments to make their PDMPs state-of-the-art and as a result they are cumbersome, may not contain real-time data, and the information they contain can be unreliable. In addition, patients may cross state lines for care and not all states are part of InterConnect, which shares interstate information about dispensed prescriptions. One approach to consider would be replacing the piecemeal state-based PDMPs with a highly functional national system, as contemplated by the National All Schedules Prescription Electronic Reporting Act (NASPER). Furthermore, we

¹ 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.

believe that Office of the National Coordinator (ONC) for Health Information Technology should adopt new EHR certification criteria that requires EHRs to integrate PDMPs into their existing capabilities. Finally, the Centers for Medicare & Medicaid Services (CMS) should require all PDMPs to be interoperable and to include certain standards, such as privacy and security protocols that protect patient-sensitive information.

2.1.1 Acute 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. Since the report does not specifically mention treatment efforts in the emergency department (ED), ACEP would like to take this opportunity to discuss programs that emergency physicians are currently implementing. As emergency physicians, we see the devastating effects of the opioid crisis every day. In fact, according to the Centers for Disease Control and Prevention (CDC), there was a 30 percent increase in opioid overdoses presenting in the ED for treatment from July 2016 through September 2017. 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 include the ALTO program in the final report as an example of how non-opioid related treatment can be effectively utilized.

2.7.6 Sickle Cell Disease

ACEP believes that we must do more to improve care for children and adults living with sickle cell disease (SCD) and agree with the fundamental gaps identified in the report that relate to: evidence-based treatment guidelines; availability of opioid medications for use at home for the treatment of unplanned acute pain events; and access to treatment due to stigma and perceived racial bias.

While all the recommendations that the report includes to address the gaps are appropriate, we think that the final report should also emphasize the need to train and educate outpatient providers on how to appropriately treat patients with SCD, so that these patients can receive the comprehensive care they need after acute care management in the ED, hospital, and/or infusion center setting. Enhancing training and education will also help reduce the stigma associated with this disease.

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

Sincerely,

Vidor E. Friedman, MD, FACEP

ACEP President

² The Centers for Disease Control and Prevention, "Opioid Overdoses Treated in Emergency Departments. https://www.cdc.gov/vitalsigns/opioid-overdoses/index.html.