American College of Emergency Physicians®
ADVANCING EMERGENCY CARE

May 4, 2018

Re: DEA-480

Robert W. Patterson
Acting Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Re: Controlled Substances Quotas

Dear Administrator Patterson:

On behalf of our nearly 38,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on the proposed rule that seeks to strengthen the Drug Enforcement Administration's (DEA) control over diversion of controlled substances and makes other changes to how the DEA sets quotas for the production, manufacturing, and procurement of controlled substances. While ACEP supports the DEA's effort to make sure controlled substances are used only for their intended purposes, it is important to set appropriate production quotas of controlled substances to ensure that hospitals and emergency departments have enough drugs and treatments to care for the patients they serve.

ACEP agrees that the diversion of controlled substances from medical to non-medical purposes has become a significant public health problem. The proposed rule includes a number of changes to current regulations that would give the DEA more of an ability to collect information from stakeholders to appropriately account for and monitor diversion, and use the information to establish or modify quotas of controlled substances.

Another pressing problem for emergency providers that the DEA must continue to take action on is the significant drug shortage problem we are facing in this country. A report from the Government Accountability Office (GAO) from 2014 found that both new shortages and ongoing shortages have increased each year since 2007. [1] The GAO report also conducted interviews with providers, who reported that the

WASHINGTON, DC OFFICE
2121 K Street NW, Suite 325
Washington, DC 20037-1886

202-728-0610
800-320-0610
www.acep.org

[1] United States Government Accountability Office, "Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability," February 2014, https://www.gao.gov/products/GAO-14-194

shortages led to "delays in or rationing of care, difficulties finding alternative drugs, risk associated with medication errors, higher costs, reduced time for patient care, and hoarding or stockpiling of drugs in shortage. During a shortage, providers may have to cancel or delay procedures, which can have detrimental health effects on patients. Providers may also have to ration care by prioritizing the patients who have a greater need for the drug."[2] The GAO concluded that the main cause of drug shortages were manufacturer production issues.[3]

With respect to emergency medicine, the shortage crisis affects drugs across all classes of medications. As of June 2017, there are 69 preparations of 28 emergency care medications that are in shortage, including most forms of adenosine, atropine, bicarbonate, calcium, dextrose, dopamine, epinephrine, fentanyl, furosemide, labetalol, magnesium, lorazepam, and paralytic agents.[4] Just this week, a major supplier of medications to emergency providers reports there are 156 emergency medication preparations and 50 intravenous fluid preparations that are not available. This will have a significant impact on emergency patient care.

These drug shortages can last for months, or longer, and constitute a significant risk to patients. Patients need access at all times to medications that are used to treat life-threatening conditions. ACEP is extremely concerned that drug shortages have jeopardized the safety of our patients, especially during and after natural disasters and other mass casualty events. Drug shortages are exacerbated after such large-scale events both because of the need for supplies to react to the disaster, as well as the impact and disruptions disasters can pose to the supply chain and manufacturing of certain drugs, requiring the need to find temporary alternatives to alleviate potentially short-term shortages. As such, we see the issue of drug shortages as a substantial threat to our nation's preparedness and response capabilities, and urge you to seek a coordinated response with the Food and Drug Administration (FDA) and the Office of the Assistant Secretary of Preparedness and Response (ASPR) within the Department of Health and Human Services (HHS).

The overall effect on our nation's hospitals from Hurricane Maria show just how fragile our current system is. Hurricane Maria destroyed much of Puerto Rico's drug manufacturing industry, and for months after the Hurricane hit, hospitals around the country have been facing drug shortages, including of injectable opioids, because they have no alternatives to acquire certain vital medications. Over time, the FDA has narrowed the list of drugs that are in short supply due to the Hurricane, but the recovery effort is still ongoing and much work still needs to be done to get hospital drug supply levels up to where they should be.

We understand that the DEA recently adjusted production quotas for certain injectable opioids to mitigate ongoing drug shortages. We applaud this effort, but believe that the DEA should be much more proactive going forward in listening to stakeholder feedback and identifying and reacting to manufacturer production challenges, issues with the supply chain, and other factors, including large-scale disasters, that impact the ability for hospitals and emergency departments to receive vital medications.

---

[2] Ibid
[3] Ibid
[4] ACEP Now, "Emergency Departments Need Plan to Deal with Drug Shortages," Augustine, James J., 2017, August 15, https://www.acepnow.com/article/emergency-departments-need-plan-deal-drug-shortages/?singlepage=1&theme=print-friendly

While there is no simple solution to the issue of drug shortages and some factors are beyond the control of the DEA, we hope that the DEA will be flexible going forward and adjust quotas when necessary. 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,

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