

May 4, 2018

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

***Re: Docket No. DEA-480, Controlled Substances Quotas; Notice of Proposed Rulemaking (Vol. 83, No. 76), April 19, 2018.***

Dear Mr. Patterson:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Drug Enforcement Administration's (DEA) proposed rule on controlled substances quotas. Every day, our members are witness to the devastating effects of the opioid crisis in our communities, and we are committed to helping to end this crisis. The death toll in and of itself is staggering. The damage substance use disorders inflicts on both those suffering from this disorder, and their family members and loved ones is devastating. Moreover, too many newborns are filling our neonatal intensive care units as they struggle to withdraw from the drugs taken during pregnancy.

We concur with the DEA that setting quotas for the production of opioid medications can be an effective step in “preventing the accumulation of controlled substances in amounts exceeding legitimate need,” and therefore reduce the chance that these powerful medications will be diverted for non-medical illicit purposes. However, opioids are commonly administered in hospitals to relieve the pain of significant trauma, surgery, cancer that has metastasized to the bone or invaded the brain, severe burns and other significant diseases or disorders. Thus, we believe that in its intense focus on diversion, the DEA is missing another critical challenge – ensuring enough medication to fulfill legitimate and critical medical needs.

**To ensure that legitimate medical needs are met, it is essential that drug shortages be explicitly considered in setting and adjusting aggregate production quotas (APQ) and that**



**resolving shortages be deemed as a relevant factor considered in the procedures for applying for and fixing individual manufacturing quotas.** Proactively considering shortages will safeguard patient health and safety and ensure critical needs are met.

As the DEA is well aware, hospitals and health systems continue to experience critical shortages of a number of injectable opioid medications, such as morphine, hydromorphone and fentanyl, due to both a slowdown in production and a component problem at a major manufacturing facility. These intravenous (IV) opioids are widely used and essential to appropriate patient care in hospitals and in other practice settings for the treatment of acute and chronic pain, and for sedation purposes. Beyond the negative impact on patient care, inadequate supplies of these drugs also creates burdensome and potentially dangerous workarounds for health care staff who must use alternative, often suboptimal products. Another consequence of shortages has been higher drug prices.

In a Feb. 27 [letter](#) to the agency, the AHA and others requested that the DEA temporarily adjust APQs to allow other manufacturers to produce these shortage products until the shortages resolve. We greatly appreciate that, in response, the DEA adjusted the individual quotas for three manufacturers to help fill the gap. However, we understand that while these increases will help increase the supply of needed IV opioid products in the near future, the injectable opioid shortage is not expected to fully resolve until at least the first or second quarter of 2019. Therefore, additional adjustments to APQs will be needed to ensure adequate supplies are available for legitimate medical purposes over the next year. In an April 10 press release, the DEA indicated it “is communicating actively and directly with all entities impacted and is committed to making further adjustments to individual procurement quotas as necessary and will also consider other measures that may be necessary to address potential shortages for these products.”

**Given its commitment to addressing injectable opioid shortages, the AHA strongly recommends that the DEA amend its proposed rule to ensure that, in addition to diversion, that drug shortages be considered when APQs are set and adjusted. Specifically, we recommend that the DEA include drug shortages as a factor for both setting and adjusting APQs under Sections 1303.11 and 1303.13 of the proposed regulation. In addition, we recommend that the intent to resolve drug shortages be added as a relevant factor considered in the procedure for both applying for and fixing individual manufacturing quotas, under the proposed rule Sections 1303.22 and 1303.23, respectively.**

**Furthermore, we recommend that the DEA routinely consult with the Food and Drug Administration’s (FDA) drug shortage staff, which collects and publishes relevant data on all national drug shortages, when establishing and adjusting quotas.** Obtaining such shortage data from the FDA will help to ensure that the DEA’s annual APQs are set to provide “adequate supplies for the United States’ legitimate needs.” The FDA can produce shortage data broken down by dosage form (such as injectable versus oral forms), providing more granular data about the actual supply and availability of medications used by hospitals and health systems. This may provide a clearer picture of diversion risk, as IV opioids dispensed in clinical settings are tightly

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controlled and thus pose a far lower risk of diversion than other oral dosage forms dispensed directly to patients.

We appreciate your consideration of these issues. The AHA understands the complexities involved in the DEA's efforts to both fight the opioid epidemic and to ensure that legitimate medical needs are met. Indeed, we also are involved on multiple fronts in efforts to reduce the use of prescription opioids and provide opportunities for treatment and recovery to those with substance use disorder. Information on our efforts to stem the tide of the opioid epidemic is available at [www.aha.org/opioids](http://www.aha.org/opioids).

Please feel free to contact me if you have questions or have a member of your team contact Roslyne Schulman, director of policy, at (202) 626-2273 or [rschulman@aha.org](mailto:rschulman@aha.org).

Sincerely,

/s/

Thomas P. Nickels  
Executive Vice President  
Government Relations and Public Policy