American Hospital Association

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August 28, 2018

Uttam Dhillon
Acting Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

RE: DEA-488P, Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2019

Dear Mr. Dhillon,

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, 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) notice of proposed rulemaking on aggregate production quotas for Schedule I and II controlled substances. We respectfully request that DEA reconsider this third straight year of proposed reductions in order to mitigate ongoing drug shortages. DEA's proposed aggregate production quotas would result in an average 10 percent decrease in manufacturing of certain schedule II opioids compared to 2018 quotas. As DEA may be aware, hospitals and other providers are currently facing critical shortages of a number of injectable opioid medications for which that the DEA recommends quota reductions, including morphine, hydromorphone, and fentanyl. These decreases would exacerbate these already dire shortages.

Intravenous (IV) opioids are used in a variety of practice settings within hospitals and ambulatory surgical centers for the treatment of acute, acute on chronic, or chronic pain that cannot be managed because the patient has a contraindication for oral opioid medications. Some opioids, such as fentanyl, also are used for sedation. Injectable opioids are critical to treating the pain needs of patients undergoing interventional procedures (e.g., cardiac catheterization or colonoscopy) and surgeries. These medications also are frequently used in intensive care units for surgical, trauma, burn, or oncology patients when it is not clinically appropriate to use oral opioids. Injectable opioids dispensed in these clinical settings are tightly controlled and thus pose a far lower risk of diversion than other oral dosage forms dispensed directly to patients. Having diminished supply of these critical drugs, or no supply at all, can cause suboptimal pain control or sedation for patients in addition to creating burdensome workarounds for health care staff.

Severe shortages of injectable opioids may threaten patient care in hospitals and surgical centers. We understand and share the DEA's concern that these medications need to be well-managed and used judiciously to help stem the nation's opioid epidemic. We fully support and use advances in pain management, such as multimodal analgesia, that enable patients to undergo procedures with fewer opioids and less reliance on opioids after surgery. Nonetheless, injectable opioids remain a crucial component of patient management during and immediately after many operations. With no appropriate opioids available, many operations would have to be postponed or cancelled. In some cases, this could prove life-threatening to the patient.

Shortages also increase the risk of medication errors. Rather than selecting a product that might be most clinically efficacious for patients, during shortages prescribers are forced to order whichever IV opioid is available. Furthermore, dosing equivalency between the IV opioids differs significantly, which can lead to dosing errors. Moreover, using a more potent opioid based on supply alone defeats the national efforts to use hydromorphone and fentanyl only when absolutely necessary.

Given the ongoing shortages for these injectable medications, we urge DEA to use its discretionary authority to reconsider its proposal to reduce manufacturing quotas. Our request is specific to these injectable medications and does not extend to other dosage forms or opioid products.

We thank DEA for its ongoing efforts to combat the opioid crisis, and we stand ready to assist the agency in any way possible. Please contact me if you have questions or feel free to have a member of your team contact Caitlin Gillooley, associate director of policy, at (202) 626-2267 or cgillooley@aha.org.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development