

October 15, 2019

[Submitted electronically via www.regulations.gov]

Drug Enforcement Administration
Attn: DEA Federal Register Representative/DRW
8701 Morrisette Drive
Springfield, VA 22152

RE: Controlled Substances Quotas [Docket No. DEA-508P]

The undersigned groups thank the Drug Enforcement Administration (DEA) for the opportunity to comment on its proposed rule regarding controlled substances quotas. Although we support DEA's efforts to combat diversion, we are concerned that the proposed rule is focused on diversion to the exclusion of another critical factor – drug shortages. To ensure that legitimate medical needs are met, it is imperative that drug shortages be considered as aggregate production quotas (APQ) are set and adjusted.

As DEA is aware, hospitals and other providers continue to face critical shortages of a number of injectable opioid medications, including fentanyl, sufentanil, and hydromorphone. 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 are also frequently used in intensive care units for surgical, trauma, burn, or oncology patients, when it is not clinically appropriate to use oral opioids. 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 healthcare staff.

In previous comments to DEA regarding the ongoing CII shortages¹, we highlighted the necessity of APQ flexibility until the IV opioid shortages resolve. In response, DEA did adjust APQ limits for certain manufacturers, which we greatly appreciated. However, injectable opioids have been in shortage since 2017. These recurring shortages are unlikely resolve in the near term, so additional adjustments to APQs will be needed to ensure adequate supplies are available for legitimate medical purposes.

Although DEA regulations do not require consideration of shortage data per se, they do require that DEA review the "total actual (or estimated) inventories of the class or chemical and of all substances manufactured from the class or chemical, and trends in inventory accumulation."² DEA's discussion of the factors it reviewed when setting the proposed APQs fails to acknowledge shortages as a relevant factor.

¹ Please see Attachment A: Letter to DEA, dated February 27, 2018.

² 84 Fed. Reg. 48171 (Sept. 12, 2019).

We request that DEA reconsider the depth of the cuts to quotas for drugs that are currently in shortage. FDA can provide shortage data broken down by dosage form, which will help contextualize the actual supply and availability of medications. This may also provide a clearer picture of diversion risk, as IV opioids dispensed in clinical settings pose a far lower risk of diversion than other dosage forms dispensed directly to patients. Further, we urge the agency to facilitate APQ flexibility as necessary to ensure that the APQs provide adequate supplies for “legitimate medical needs.”³ Proactively considering shortages when setting and adjusting APQs will safeguard patient health and safety and ensure critical needs are met.

Thank you for your consideration of our comments. We continue to support DEA’s efforts to combat the opioid crisis, and we stand ready to assist the agency in any way possible. If you have questions, the appropriate contact person for each of the signatories can be found below.

Sincerely,

Ambulatory Surgery Center Association

Contact: Kara Newbury
Director, Government Affairs &
Regulatory Counsel
knewberry@ascassociation.org

American Hospital Association

Contact: Ashley Thompson
Senior Vice President, Public Policy
athompson@aha.org

American Society of Anesthesiologists

Contact: Ashley Walton
Pain Medicine and Federal Affairs
Manager
A.Walton@asahq.org

American Society of Clinical Oncology

Contact: Karen Hagerty
Director, Reimbursement Policy
Karen.Hagerty@asco.org

**American Society of Health-System
Pharmacists**

Contact: Jillanne Schulte Wall
Director, Federal Regulatory Affairs
jschulte@ashp.org

Federation of American Hospitals

Contact: Paul Kidwell
Vice President, Policy
PKidwell@FAH.org

Institute for Safe Medication Practices

Contact: Allen Vaida
Executive Vice President
avaida@ismp.org

³ Id. at 48170.

Attachment A: Letter to DEA (Feb. 27, 2018)

February 27, 2018

[Submitted via U.S. Mail]
Robert W. Patterson
Acting Administrator
Drug Enforcement Administration
700 Army Navy Drive
Arlington, VA 22202

[Submitted electronically to ODLP@usdoj.gov]
DEA Diversion Control Division
Attn: Liaison and Policy Section
8701 Morrisette Drive
Springfield, VA 22152

RE: Temporary Changes to Aggregate Production Quotas for IV Opioid Products to Address Shortages

The undersigned groups respectfully request that the Drug Enforcement Administration (DEA) adjust aggregate production quotas (APQ) for certain opioids in order to mitigate ongoing drug shortages. As DEA may be aware, hospitals and other providers are currently facing critical shortages of a number of injectable opioid medications, including morphine, hydromorphone, and fentanyl. 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 are also frequently used in intensive care units for surgical, trauma, burn, or oncology patients, when it is not clinically appropriate to use oral opioids. 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 healthcare staff.

Shortages of these injectable medications are largely attributable to manufacturing delays affecting Pfizer, the primary maker of these products, following its acquisition of Hospira. In a letter to customers, Pfizer indicated that the “anticipated full recovery dates for prioritized prefilled syringes have moved to 1Q19 and deprioritized syringes have moved to 2Q19.”⁴ On January 31, 2018, Pfizer sent customers a further update informing them that, due to a third-party supplier issue, none of these prefilled syringes of injectable opioids are currently being produced or released.⁵

Because these are vital medications, hospitals have been focused on locating alternative sources. We have been informed, however, that other manufacturers have been unable to step in and

⁴ See Attachment A, Pfizer Customer Letters, dated July 20, 2017, and Nov. 27, 2017.

⁵ See Attachment B, Pfizer Customer Letter, dated Jan. 31, 2018.

produce additional product because the DEA is approving only a small number of requests for the requisite pharmaceutical compounds due to current APQ limits. At present, supply options are dwindling.

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, 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 temporarily reallocate or revise APQ to allow other manufacturers to supply product until the shortages resolve. 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. If you have questions, the appropriate contact person for each of the signatories can be found below.

Sincerely,

American Hospital Association

Contact: Ashley Thompson
Senior Vice President, Public Policy
Analysis & Development
athompson@aha.org

American Society of Anesthesiologists

Contact: Ashley Walton
Pain Medicine and Federal Affairs
Manager
A.Walton@asahq.org

American Society of Clinical Oncology

Contact: Karen Hagerty
Director, Reimbursement Policy
Karen.Hagerty@asco.org

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Contact: Jillanne Schulte Wall
Director, Federal Regulatory Affairs
jschulte@ashp.org

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Contact: Allen Vaida
Executive Vice President
avaida@ismp.org