



October 14, 2019

The Honorable Uttam Dhillon
Acting Administrator
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, Virginia 22152

Re: Comments of the Healthcare Supply Chain Association (HSCA) on 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 2020 [Docket No. DEA-508P]

On behalf of the Healthcare Supply Chain Association (HSCA), we appreciate the opportunity to provide comments on the U.S. Drug Enforcement Administration’s (DEA or Agency) proposed aggregate production quotas for Schedule I and II controlled substances. HSCA supports DEA’s efforts to support interagency collaboration around controlling opioid diversion. We are concerned, however, that absent differentiation of injectable opioids from solid dosage form for purposes of the rule, these changes to aggregate production quotas could lead to injectable narcotic shortages that threaten patient care.

HSCA represents the nation’s leading healthcare group purchasing organizations (GPOs), the sourcing and purchasing partners to virtually all of America’s 7,000+ hospitals, as well as the vast majority of the 68,000+ long-term care facilities, surgery centers, clinics, and other healthcare providers. We work with healthcare providers to negotiate competitive prices and support a safe and reliable supply of healthcare products. We play a critical role in helping to lower costs for patients, hospitals, payers, Medicare and Medicaid, and taxpayers. One [report](#) estimated that GPOs reduce supply-related purchasing costs by 13.1 percent annually and will reduce healthcare spending by up to \$456.6 billion between 2017 and 2026. The value that GPOs deliver allows healthcare providers and physicians to focus on their core mission: providing first-class patient care.

Controlling narcotics use – particularly outpatient prescription opioid abuse – is a public health priority that HSCA, its member GPOs, and the healthcare providers that we serve support. We applaud DEA for taking steps to increase coordination between the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), and other authorities regarding aggregate production quotas for controlled substances. At the same time, we must consider that injectable narcotics – including morphine, hydromorphone, and fentanyl – are a medical necessity for hospitals providing post-surgical and medical pain management. Regulation that reduces

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the availability of inpatient injectable narcotics – which are not a significant diversion threat – could lead to the delay or cancellation of many surgical procedures and jeopardize patient wellbeing.

Given our unique line of sight over the healthcare supply chain, HSCA respectfully makes the following recommendations to help control narcotics use while also protecting provider access to injectable opioids that are critical to patient care:

DEA Should Differentiate Between Outpatient/Oral Opioids and Inpatient/Injectable Opioids

HSCA and its members share DEA’s commitment to reducing opioid diversion. As DEA considers changes to raw materials allocation and production quotas, *we strongly encourage DEA to specifically differentiate between outpatient/oral opioids and those injectable opioids used in an inpatient hospital and healthcare provider setting.* Injectable opioids are critical to a wide variety of practices in the inpatient setting where it is not clinically appropriate to use oral opioids, including for treatment of some acute and chronic pain; sedation; pain management during interventional procedures such as cardiac catheterization and colonoscopy; and in intensive care units for some surgical, trauma, burn, or oncology patients, among other settings.

Simply put, there is not a significant threat of diversion of injectable opioids in the inpatient hospital setting. Robust institutional security and tracking practices make hospitals one of the safest and most controlled environments for dispensing controlled substances. Hospitals have sophisticated software and systems in place to track the flow of controlled substances, and these institutions are regularly inspected by state boards of health and pharmacy, the Joint Commission, and other oversight bodies.

Thus, *HSCA recommends that manufacturers submit allocation requirements for injectable products and non-injectable products separately.* This will help draw a clearer distinction between the needs of the hospital and outpatient markets. *Differentiating between outpatient/oral opioids and inpatient/injectable opioids – and not taking a blanket approach to reduction of aggregate volume of raw materials – will help DEA attack the root of the problem and avoid unintended consequences that jeopardize patient access to care.*

DEA Should Outline a Process for Quickly Adjusting Production Quotas in the Event of Shortages

HSCA also encourages DEA to take the important step of outlining an efficient, timely process for adjusting production quotas in the event of shortages. Consistent with the Agency’s authority to adjust quotas in 21 CFR 1303.13, DEA may increase or reduce production quotas at any time. Such flexibility can be particularly important in helping hospitals combat shortages of injectable opioids. However, DEA response to previous injectable opioid shortages has taken three to four months. In order to ensure a more efficient and timely response to supply issues, *HSCA encourages DEA to outline a process for quickly identifying and rectifying potential problems, including a timeframe for how quickly DEA will move to adjust and reassign production quotas in the event of potential shortages.* This is a critical and necessary step to support hospitals and healthcare providers having critical medicines needed for patient care.

DEA Should Ensure Production Quotas Remain at Levels Sufficient Enough for Adequate Treatment

As DEA considers aggregate production quotas for 2020, DEA should also ensure that the quotas are kept at sufficient levels to provide adequate treatment for patients in need of injectable narcotics. A significant reduction in production levels could result in an inadequate supply of injectable narcotics, causing the cancellation or postponement of numerous medical procedures across the country and endangering patient care. Narcotic shortages also increase the risk of medication and dosing errors, as

medical personnel are forced to prescribe narcotics based on availability rather than effectiveness during shortages. Moreover, proper dosages vary significantly between narcotics, increasing the likelihood of dosage errors and, in turn, adverse patient outcomes. As a result, *HSCA urges DEA to keep production quotas at levels that will sufficiently ensure adequate treatment of patients in need of injectable narcotics.*

DEA Should Engage with Public and Private Stakeholders to Understand the Needs of Institutional Providers

Before implementing further changes to aggregate production quotas, DEA should pursue private and public stakeholder engagement to understand and fully consider the legitimate needs of institutional providers. This will help support critical discussion on legitimate provider needs in the in-patient setting, how proposed reductions may impact patient care, and short and long-term policy implications. Given some of the products impacted are currently listed as in shortage in the FDA Drug Shortage Database (i.e., hydromorphone hydrochloride injection and fentanyl citrate injection), this underscores the importance of this dialogue for this and any future quota allocations. HSCA strongly encourages this stakeholder engagement as a high public health priority.

We thank you for the opportunity to provide our comments, and we look forward to continuing to work with DEA to address the threat of narcotic abuse and outpatient/oral opioid diversion. We believe HSCA and its member GPOs can be a resource for DEA on inpatient/injectable opioid usage. Please do not hesitate to contact me directly should you have any questions. I can be reached at (202) 629-5833 or info@supplychainassociation.org.

Sincerely,

A handwritten signature in black ink that reads "Khatereh Calleja". The signature is written in a cursive, flowing style.

Khatereh Calleja, J.D.
President & CEO
Healthcare Supply Chain Association