September 19, 2018

United States Department of Justice
Drug Enforcement Administration
Attention: DEA Federal Register Representative/DRW
8701 Morrissette Drive
Springfield, Virginia 22152
Docket No. DEA-488P

Re: Comments of the Healthcare Supply Chain Association (HSCA) on DEA 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 [Docket No. DEA-488P]

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) proposed aggregate production quotas for Schedule I and II controlled substances.

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 help our healthcare provider partners leverage their purchasing volume to negotiate competitive prices on healthcare products and services, helping to lower costs for patients, hospitals, payers, Medicare and Medicaid, and taxpayers. GPOs deliver critical cost savings that allow healthcare providers 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 our member healthcare providers support. However, injectable narcotics – including morphine, hydromorphone, and fentanyl – are a medical necessity for hospitals providing post-surgical and medical pain management. Regulation that reduces the availability of inpatient injectable opioids – which are not a significant diversion threat – would lead to the delay or cancellation of many surgical procedures and jeopardize patient wellbeing.

Given our unique line of sight over all aspects of 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:

<u>DEA Should Differentiate Between Outpatient/Oral Opioids and Inpatient/Injectable Opioids</u>

HSCA and its members share DEA's commitment to reducing opioid diversion; however, as DEA considers changes to raw materials allocation and production quotas, we encourage you to specifically

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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 on the Accreditation of Healthcare Organizations (JCAHO), and other oversight bodies.

In addition, and to the extent possible, HSCA recommends that manufacturers submit allocation requirements for injectable products and non-injectable products separately, and clearly identify which manufacturing facilities are producing injectable products versus non-injectable products. 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 (e.g.) 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

Per Section 1303.13 of Title 21 of the Code of Federal Regulations, the administrator 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 production quotas in the event of potential shortages.

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

As DEA considers aggregate production quotas for 2019, DEA should ensure that the quotas are kept at levels sufficient enough 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 cancelation 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. Furthermore, proper dosages vary significantly between narcotics, increasing the

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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.

We appreciate the opportunity to provide our perspective, and we look forward to continuing to work with DEA to address the threat of narcotic abuse and outpatient/oral opioid diversion. 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.

Sincerely,

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