HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

May 4, 2018

United States Department of Justice
Drug Enforcement Administration
Attention: DEA Federal Register Representative/DRW
8701 Morrissette Drive
Springfield, Virginia 22152
Docket No. DEA-480

Re: Comments of the Healthcare Supply Chain Association (HSCA) on DEA Proposed Rule on Controlled Substances Quotas [Docket No. DEA-480]

On behalf of the Healthcare Supply Chain Association (HSCA), we appreciate the opportunity to provide comments on the U.S. Drug Enforcement Administration (DEA) proposed rule on annual opioid production limits.

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, hospitals and other healthcare providers are currently experiencing critical shortages of a number of injectable opioid medications – including morphine, hydromorphone, and fentanyl – that are an essential element of treatment for inpatient post-surgical and medical pain management. Regulation that further reduces availability of inpatient injectable opioids – which are not a significant diversion threat – would lead to the delay or cancellation or 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

HSCA understands Section 1303.13 of the proposed rule to allow the administrator to increase or reduce production quotas at any time. Such flexibility could 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. If DEA includes Section 1303.13 in the final rule, we encourage you 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 Use Available Data to Inform Decisions about Adjustments to Quotas

DEA already has access to information that would be helpful in addressing production quotas in the event of drug shortages. Form 222, for example, provides data about product volume and location that would allow DEA to work with distributors and other stakeholders to address problems as they arise. To the extent that the proposed rule provides for the collection of additional data, we encourage DEA to put processes in place to ensure that all available data is being used in a timely fashion to help anticipate and address potential shortages.

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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,

Todd Ebert

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President and CEO
Healthcare Supply Chain Association

HSCA MEMBER COMPANIES

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