CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

September 19, 2018

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

SUBJECT: 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, Notice, Federal Register (Vol. 83, No, 161), August 20, 2018

Dear Acting Administrator Dhillon:

The California Hospital Association (CHA) — representing more than 400 hospitals and health systems and 97 percent of patient beds in the state — thanks the Drug Enforcement Administration (DEA) for the opportunity to comment on its notice of proposed rulemaking related to 2019 aggregate production quotas (APQs) for Schedule I and II controlled substances and the List 1 chemicals ephedrine, pseudoephedrine and phenylpropanolamine.

The DEA's proposed APQs would reduce manufacturing quotas for six frequently used opioids by an average of 10 percent. CHA requests that the DEA reconsider this reduction, in light of the ongoing drug shortages in California's hospitals. We urge the agency to use its discretionary authority to reconsider its proposal to reduce manufacturing quotas specifically for injectable medications used in hospitals, separate from other dosage forms or opioid products.

Section 306 of the Controlled Substances Act (21 U.S.C 826) requires the attorney general to establish aggregate production quotas for each basic class of controlled substances listed in Schedules I and II, as well as for the List I chemicals ephedrine, pseudoephedrine and phenylpropanolamine. These quotas were developed using the following determinants: (1) total net disposal of each class or chemical by all manufacturers, (2) trends in the national rate of net disposal of the chemical, (3) total actual (or estimated) inventories of the class or chemical, and (4) projected demand for each class or chemical as indicated by procurement and import quotas.

However, the controlled substances quotas final rule, which took effect August 15, 2018, established two additional factors that were not included in this 2019 APQ decision-making: the extent of any diversion of controlled substances and relevant information obtained from the Department of Health and Human Services. This includes information from the Food and Drug Administration, the Centers for Disease Control and Prevention and the Centers for Medicare & Medicaid Services, along with relevant information obtained from states. If the DEA had information related to these additional factors, it may have better understood critical opioid drug shortage issues affecting our state.

499 So. Capitol Street SW, Suite 410, Washington, DC 20003 • *Telephone:* 202.488.3740 • *Facsimile:* 202.488.4418
1215 K Street, Suite 800, Sacramento, CA 95814 • *Telephone:* 916.443.7401 • *Facsimile:* 916.552.7596 • www.calhospital.org
Corporate Members: Hospital Council of Northern and Central California, Hospital Association of Southern California, and Hospital Association of San Diego and Imperial Counties

As the DEA is aware, California hospitals and health systems continue to experience critical shortages of a number of injectable opioid medications — such as morphine, hydromorphone and fentanyl — due to a slowdown in production and a component production problem at a major manufacturing facility. These medications are widely used for legitimate treatment of acute and chronic pain, as well as for sedation purposes. CHA staff and key members spoke with the DEA on May 31, 2018, to share the severe nature of the injectable opioid shortage. They also detailed the intense mitigation measures underway, which cause extended use of additional resources — for instance, time and money to find solutions, such as alternative drugs and routes — as well as patient safety issues, such as dosing factors with less widely administered drugs.

These shortages and risk factors have not decreased. Today, the FDA reports continued shortages for morphine, hydromorphone and fentanyl. Pfizer, the main manufacturer and supplier of intravenous opioids, states that we should not expect the shortage of its manufactured drugs to resolve until the first or second quarter of 2019. This continued manufacturer backlog, combined with reduced APQs, will likely extend these conservative projections.

We concur that setting production quotas for opioid medications can be an effective step in preventing these controlled substances from accumulating in amounts that exceed legitimate need. However, we are concerned that the limited information the DEA considered when developing these quotas does not reflect hospital patients' legitimate need for essential medication. While the August 2018 controlled substances final rule did reference conferring with FDA drug shortage staff, it was not used as a determination factor.

Additionally, the FDA has established a new drug shortage task force to advance long-term solutions and prevent shortages. In its 2017 *FDA Report on Drug Shortages*, the FDA reiterated the need for close coordination between FDA and DEA when responding to potential shortages of controlled substances. The report outlined further steps — including provisions for improved FDA/DEA coordination and communication about quota adjustments, specifically for legitimate opioid use — to assure tight controls while preventing shortages. The FDA and DEA developed a memorandum of understanding for efficiently tracking and exchanging relevant information.

CHA strongly urges both agencies to continue this improved coordination and communication to proactively leverage critical portions of the drug supply chain to decrease controlled substance diversion, as well as to prevent shortages of legitimate controlled substances. In addition, CHA suggests that important agencies such as the FDA be consulted — and specific information on state shortages and drug manufacturer production problems be included — in the formal decision-making process. CHA looks forward to engaging in the stakeholder process and public meeting scheduled for November 2018.

To ensure that legitimate medical needs are met, it is essential that drug shortages and manufacturer production issues be explicitly considered in setting and adjusting APQs. Resolving shortages should be deemed a relevant factor in the procedures for applying for and fixing individual manufacturing quotas.

CHA suggests adding the two factors approved through the Controlled Substances Act of 2018 to improve the accuracy of the 2019 APQs approved through this rule, along with additional consideration of drug shortages and major manufacturer production issues affecting the supply chain.

In previous years, the DEA decreased APQs by 25 and 20 percent — before manufacturer production issues became a major stopgap. Decreasing production, combined with decreased chemical supply amounts, jeopardized legitimate pharmaceutical use in hospitals. In February 2017, the American Hospital Association and others requested that the DEA temporarily adjust APQs to allow other manufacturers to produce these shortage products until the shortages resolved. We greatly appreciated that, in response, the DEA adjusted the individual quotas for three manufacturers to help fill the gap. However, these three manufacturers have had minimal effect on the California supply issues; this was brought to the DEA's attention earlier this year. While we understand that these increases may have helped other states, California continues to be in a critical shortage situation. Therefore, additional adjustments to increase APQs are needed to ensure adequate supplies are available for legitimate medical purposes as soon as possible.

CHA fully understands the extent of diversion and opioid substance abuse issues. Every day, our hospitals and health systems witness the devastating effects of illegitimate use of diverted drugs as well as opioid misuse, abuse and death. We are also keenly aware of the negative impact of the shortage of legitimate intravenous opioids, which are essential for treatment modalities such as sedation, interventional procedures, surgical trauma, burn care and oncology. A diminished supply — or no supply at all — of these critical drugs leads to sub-optimal pain control or sedation for patients. Substitution of less optimal drugs creates burdensome, unsafe workarounds for health care staff.

We appreciate the DEA's consideration of these issues. We fully understand the complexities involved in the DEA's efforts to combat the opioid epidemic while simultaneously ensuring legitimate medical needs are met. California's hospitals are involved on many fronts to reduce the use of prescription opioids and provide treatment and recovery opportunities for those with substance use disorder.

CHA appreciates the opportunity to comment on the notice of proposed rulemaking on APQs for Schedule I and II controlled substances. If you have any questions, please do not hesitate to contact me at akeefe@calhospital.org or (202) 488-4688.

Sincerely,

/s/
Alyssa Keefe
Vice President, Federal Regulatory Affairs