American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

October 11, 2019

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

Re: Docket No. DEA-508P, 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 Quotas; Notice with Request for Comments (Vol. 84, No. 177), Sept. 12, 2019.

Dear Mr. Dhillon:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Drug Enforcement Administration's (DEA) proposed notice on aggregate production quotas for schedule I and II controlled substances.

Every day, our members witness the damaging effects of the opioid crisis in their communities, and we are committed to helping to end this crisis. The death toll in and of itself is staggering. The damage substance use disorders inflicts on those suffering from this disorder, their family members and loved ones, and our society is devastating. Equally tragic, infants are filling our neonatal intensive care units as they struggle to withdraw from the drugs taken during pregnancy.

We understand that setting quotas for the production of opioid medications is an effective step in preventing the accumulation of controlled substances in amounts exceeding legitimate need, and therefore reduces the chance that these powerful medications will be diverted for non-medical illicit purposes. However, opioids are commonly administered in hospitals to relieve the pain of significant trauma, surgery, cancer that has metastasized to the bone or invaded the brain, severe burns and other significant diseases or disorders. Thus, we believe that in its intense focus on diversion, the DEA must also address another critical challenge – ensuring enough medication to fulfill legitimate and critical medical needs.

To ensure that legitimate medical needs are met, it is essential that drug shortages be explicitly considered in setting and adjusting aggregate production quotas and that resolving shortages be deemed as a relevant factor considered in

the procedures for applying for and fixing individual manufacturing quotas. Proactively considering shortages will safeguard patient health and safety and ensure critical needs are met.

As the DEA is well aware, hospitals and health systems continue to experience critical shortages of a number of injectable opioid medications, such as morphine, hydromorphone and fentanyl, due to both a slowdown in production and a component problem (i.e., issue with making part of the medication) at a major manufacturing facility. These intravenous opioids are widely used and essential to appropriate patient care in hospitals and in other practice settings for the treatment of acute and chronic pain, and for sedation purposes. Beyond the negative impact on patient care, inadequate supplies of these drugs also creates burdensome and potentially dangerous workarounds for health care staff who must use alternative, often suboptimal products.

Another consequence of shortages has been higher drug prices. **The AHA is concerned that the large reductions in aggregate production quotas proposed by the DEA – including reductions of 31% for fentanyl, 19% for hydrocodone, 25% for hydromorphone and 55% for oxymorphone – would exacerbate existing shortages of injectable opioids and make the supply chain of these critical medications more vulnerable to shortages when there are even small fluctuations in demand or problems in manufacturing.**

In a 2018 letter to the agency, the AHA and others requested that the DEA temporarily adjust aggregate production quotas to allow other manufacturers to produce these shortage products until the shortages resolve. We greatly appreciate that, in response, the DEA adjusted the individual quotas for three manufacturers to help fill the gap. In an April 2018 press release, the DEA indicated it "is communicating actively and directly with all entities impacted and is committed to making further adjustments to individual procurement quotas as necessary and will also consider other measures that may be necessary to address potential shortages for these products."

Given its commitment to addressing injectable opioid shortages, the AHA strongly recommends that the DEA explicitly account for drug shortages in addition to diversion, in establishing its proposed aggregate production quotas for these five classes of schedule II controlled substances. We believe that the current factors that the DEA administrator must consider in determining the aggregate production quotas could easily be interpreted to include consideration of drug shortages. For instance, the sixth factor requires the DEA to consider "relevant information obtained from HHS, including from the FDA..." Given the Food and Drug Administration's (FDA) role in tracking manufacturers' drug shortage information and its work to prevent or reduce the impact of shortages, such information would be readily available for the DEA's consideration. In addition, the seventh factor is a catch-all that requires consideration of "other factors affecting medical…needs of the United States..." Certainly consideration of shortages is such a factor affecting medical need.

Furthermore, we continue to recommend that the DEA routinely consult with the FDA's drug shortage staff, which collects and publishes relevant data on all national drug shortages, when establishing and adjusting quotas. Obtaining such shortage data from the FDA will help to ensure that the DEA's annual production quotas are set to provide adequate supplies for the United States' legitimate needs. The FDA can produce shortage data broken down by dosage form (such as injectable versus oral forms), providing more granular data about the actual supply and availability of medications used by hospitals and health systems. This also may provide a clearer picture of diversion risk, as intravenous opioids dispensed in clinical settings are tightly controlled and thus pose a far lower risk of diversion than other oral dosage forms dispensed directly to patients.

We appreciate your consideration of these issues. The AHA understands the complexities involved in the DEA's efforts to both fight the opioid epidemic and to ensure that legitimate medical needs are met. Indeed, we also are involved on multiple fronts in efforts to reduce the misuse of prescription opioids and provide opportunities for treatment and recovery to those with substance use disorder. Information on our efforts to stem the tide of the opioid epidemic is available at www.aha.org/opioids.

Please feel free to contact me if you have questions or have a member of your team contact Roslyne Schulman, director of policy, at rschulman@aha.org or Caitlin Gillooley, senior associate director, at cgillooley@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President
Government Relations and Public Policy