March 31, 2020

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

RE: Request to Immediately Increase Allocation of Controlled Substances to Combat COVID-19

The American Hospital Association, American Medical Association, American Society of Anesthesiologists, American Society of Health-System Pharmacists, and Association for Clinical Oncology thank the Drug Enforcement Administration (DEA) for its willingness to engage with us to ensure that controlled substances (CII) supplies are meeting the nation's healthcare needs. As DEA is aware, COVID-19 is straining hospital systems across the country to the breaking point. While the shortages of personal protective equipment and ventilators have been well-documented in the press, hospitals are also facing looming shortages of the supportive CIIs that are necessary to mechanically ventilate patients safely and effectively. The number of patients requiring ventilation has resulted in huge spikes in demand for morphine, hydromorphone, fentanyl and other opioids, some of which were already in shortage prior to the COVID-19 outbreak. To ensure that hospitals can access the medications they need to treat COVID-19 patients, it is imperative that CII supply is rapidly ramped up. We respectfully request that DEA immediately ensure that manufacturers and 503B outsourcing facilities receive increased annual production quota (APQ) allocations to allow them to meet these legitimate, and absolutely critical, patient care needs.

As of March 30, 2020, fentanyl, morphine and hydromorphone all appear on ASHP's drug shortage list. Injectable opioid medications such as these are vital for sedation, pain management, and interventional procedures. While oral dosage forms may be available, these are not clinically indicated for ventilation. Without sufficient IV opioid supply, patients will suffer. To assist DEA in swift APQ allocation, we have attached an initial list of the opioids our members identified as being the most critical and in the shortest supply.

We appreciate DEA's work to protect against diversion and maintain control over the flow of opioids into our communities. However, during this unprecedented health crisis, hospitals must have sufficient CII supply to treat patients. In many hospitals, supplies are dwindling quickly and distributors have placed the drugs on allocation, severely limiting hospitals' ability to increase purchasing to meet acute demand. Manufacturers and 503Bs must receive immediate APQ allocations if they have any hope of meeting the current enormous demand surge, much less produce what will likely be required even two weeks from now. Therefore, we urge DEA to maintain a policy of rapid flexible

APQ allocations for the duration of the declared national emergency. We will work with DEA to provide any information we can to support APQ allocation, including making our member clinicians and hospitals available to DEA to discuss what they are seeing in the field.

On behalf of our members on the front lines of COVID-19 response, thank you for your consideration of our request. We continue to support DEA's efforts to combat the opioid crisis, and we stand ready to assist the agency in any way possible. If you have questions, the appropriate contact person for each of the signatories can be found below.

Sincerely,

# **American Hospital Association**

Contact: Ashley Thompson Senior Vice President, Public Policy <u>athompson@aha.org</u>

## **American Medical Association**

Contact: Sandy Marks Senior Assistant Director, Federal Affairs <u>sandy.marks@ama-assn.org</u>

### **American Society of Anesthesiologists**

Contact: Ashley Walton Senior Congressional and Political Affairs Manager <u>A.Walton@asahq.org</u>

### American Society of Health-System Pharmacists

Contact: Jillanne Schulte Wall Senior Director, Health & Regulatory Policy schultjm@gmail.com

# **Association for Clinical Oncology**

Contact: Karen Hagerty Director, Regulatory Affairs Karen.Hagerty@asco.org