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
athompson@aha.org

American Medical Association
Contact: Sandy Marks
Senior Assistant Director, Federal Affairs
sandy.marks@ama-assn.org

American Society of Anesthesiologists
Contact: Ashley Walton
Senior Congressional and Political Affairs Manager
A.Walton@asahq.org

American Society of Health-System Pharmacists
Contact: Jillanne Schulte Wall
Senior Director, Health & Regulatory Policy
jschulte@ashp.org

Association for Clinical Oncology
Contact: Karen Hagerty
Director, Regulatory Affairs
Karen.Hagerty@asco.org

				First date of ASHP Shortage tracking
Sedation / Pain / Palliative Care				
Intravenous/Intramuscular	Form	Preferred package size(s)	Other package size(s)	
Fentanyl*	50 mcg/mL injection, vials or ampules	50 mL and 20 mL	5 mL, 2 mL, 1 mL	August 28, 2015
Midazolam* continuous infusion	5 mg/mL injection vials			September 7, 2018
Midazolam for intubation	1 mg/mL injection or syringe	10 mL and 4 mL		September 7, 2018
Hydromorphone				June 2, 2017
Morphine				May 14, 2009
Remifentanil				not following
Propofol (also for intubation)				March 27, 2020
Lorazepam				February 11, 2016
Dexmetedomidine				January 24, 2018
Ketamine (also for intubation)				February 6, 2018
Etomidate (intubation)				June 10, 2011
Diazepam				not following
Phenobarbital				not following
Pentobarbital				not following
Oral/Enteral options				
Hydromorphone				June 2, 2017
Oxycodone				not following
Morphine (also concentrated liquid for palliative)				May 14, 2009
Lorazepam (also concentrated liquid for palliative)	Tablet			October 4, 2018
Diazepam				not following
Chlordiazepoxide				November 20, 2019
Neuromuscular blockers				
Succinylcholine (intubation)				not following
Rocuronium (continuous or intubation)				February 9, 2017
Vecuronium (continuous or intubation)				September 15, 2015
Cisatricurium				not following
Atricurium				not following
Pancuronium				not following
ICU agitation				
Olanzapine				not following

Quetiapine				not following
Haloperidol				not following
Droperidol				October 15, 2019
Risperidone				not following
Asenaptine				not following
ICU supportive care				
Scopalamine patch (secretions)				not following
Glycopyrrolate (secretions)				not following
Atropine eye drops (secretions in palliative patients)				October 11, 2019
Artificial tears/ophthalmic lubricants (for paralyzed patients)				not following
Lidocaine UroJet or Surgilube for urinary catheter insertion				not following
Cardiovascular support				
Norepinephrine				February 9, 2017
Phenylephrine				not following
Vasopressin				not following
Dopamine				May 20, 2016
Epinephrine				May 1, 2017
Milrinone				not following
Dobutamine				October 23, 2016
Amiodarone				April 19, 2017
Respiratory meds				
Albuterol inhalers				March 22, 2020
Albuterol nebulizer solution				not following
Chlorhexidine (mouth rinse to prevent ventilator associated pneumonia)				not following
Methylprednisolone (severe asthma/COPD)				not following
Prednisone (severe asthma/COPD)				March 22, 2019
Hydrocortisone (adrenal insufficiency)				March 25, 2020
Budesonide inhalation (COPD)				not following
Duoneb				not following
Combivent				not following

Dexamethasone				March 17, 2011
Epoprostenol (Veletri) / Flolan if Veletri not available				not following
GI / Stress ulcer prophylaxis				
Pantoprazole				March 16, 2019
Famotidine injection				had resolved
Omeprazole				not following
Any PPI/H2RA				
Famotidine tablets				November 19, 2019
Ranitidine injection				May 14, 2018
Senna (especially on opioid)				
Docusate (especially on opioid)				not following
Miralax (especially on opioid)				August 8, 2019
				not following
Hematology (DVT prophylaxis/treatment)				
Heparin				January 23, 2017
Enoxaparin				September 5, 2018
Other low-molecular-weight heparins				not following
Fonaparinux				not following
Sequential compression devices				not following
Direct oral anticoagulants with DVT prophylaxis approval				not following
Bivalirudin				May 2, 2019
Argatroban				October 15, 2018
Antimicrobials				
Vancomycin				February 8, 2009
3rd/4th generation cephalosporin				
Ceftazidime				November 22, 2011
Cefoxitin				October 31, 2016
Cefepime				May 14, 2014
Avibactam/ceftazidime				February 21, 2020
Antipseudomonal beta-lactams				Pip/tazo 5/8/2013
Tamiflu				not following
Linezolid				not following

Hydroxychloroquine				March 10, 2020
Chloroquine				March 4, 2020
Azithromycin injection				Injection 1/11/2018
ARDS				
Tocilizumab (along with steroids & paralytics)				not following
IV Fluids / Electrolytes				
Liter bags of fluids (LR, Plasmalyte, NS,				not following
250 mL bags for mixing (NS, D5)				May 4, 2017
Sodium bicarbonate				February 2, 2017
Sodium acetate				May 9, 2017
Sodium citrate				not following
Prismasol/Prismasate (if CRRT)				not following