October 1, 2020

The Honorable Timothy Shea
Acting Administrator, Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

RE: [Docket No. DEA-688P] 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 2021

Dear Acting Administrator Shea:

The Premier healthcare alliance appreciates the opportunity to submit comments on the Drug Enforcement Administration (DEA) notice with request for comments titled "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 2021," which was published in the September 1, 2020 Federal Register. The notice proposes reducing the aggregate production quotas (APQs) for several schedule II controlled substances for the fifth year in a row including:

- Fentanyl – 18% reduction
- Hydromorphone – 8% reduction
- Oxycodone – 16% reduction

Premier is a leading healthcare improvement company, uniting an alliance of more than 4,100 U.S. hospitals and health systems, 650 long-term care pharmacies, 6,500 skilled nursing facilities, and approximately 175,000 other providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. A 2006 Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. A key component of our alliance is our integrated pharmacy program, which combines essential clinical data with purchasing power to deliver reduced costs, improved quality and safety, and increased knowledge-sharing with other healthcare professionals.

Premier supports a holistic, comprehensive, multi-stakeholder and multi-faceted approach to address the opioid epidemic and recognizes the need to develop sustainable solutions that balance preventing diversion and abuse of opioids with ensuring adequate supply for clinically appropriate care. As such, Premier strongly supported the DEA's notice titled "*DEA- 508A, Adjustments to Aggregate Production Quotas for Certain Schedule II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine and Pseudoephedrine for 2020, In Response to the Coronavirus Disease 2019 Public Health Emergency*" issued on April 10, 2020. In response to increased utilization and demand of several schedule II controlled substances required for the treatment of COVID-19 patients, the DEA increased 2020 APQ by 15 percent for certain substances including fentanyl, morphine, hydromorphone, codeine, ephedrine, pseudoephedrine. For example, according to a Premier analysis, demand for injectable fentanyl increased by 100% throughout the country and over 500% in hot

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spots such as New York during the height of the pandemic.[1] The DEA's nimbleness and regulatory flexibility in adjusting 2020 APQs was critical to stabilizing the drug supply chain for these essential medications and minimizing drug shortages.

Given the ongoing prevalence of COVID-19 cases throughout the country, and an anticipated resurgence of the disease in the fall and winter, Premier is concerned that reducing APQs for these critical medications needed to treat COVID-19 patients may be premature and may inadvertently lead to further shortages. Prior to finalization of the 2021 quotas, Premier cautions the DEA to carefully consider how a reduction in manufacturing quotas for certain opioids at this time could exacerbate recent drug shortages for injectable opioids and have a negative effect on preparedness and readiness for a resurgence of COVID-19 cases. In addition, DEA should consider increased demand in 2021 due to federal and state stockpiling requirements that are in the process of being implemented.

The DEA Should Establish APQs in Terms of Pharmaceutical Dosage Form for All CII Controlled Substances

In 2018, Congress passed the SUPPORT Act[2] giving the DEA new discretionary authority to establish APQs in terms of pharmaceutical dosage form. While Premier appreciates the DEA updating its regulations to incorporate this new discretionary authority, ***Premier is disappointed that DEA continues to use its current process of establishing APQs in terms in kilograms and has stated that implementation of dosage form APQs will be rare occurrences.***

Hospitals, health systems and other providers continue to grapple with acute nationwide shortages of several injectable opioid medications including morphine, hydromorphone and fentanyl.[3] These medications are critical to control pain during surgeries, interventional procedures, traumas, burns and other procedures where treatment with alternative pain therapies may not be clinically appropriate. Furthermore, these medications are critical for treating COVID-19 patients requiring ventilation. Absent adequate supply of injectable opioids, patient care is threatened by cancelling or delaying surgical procedures and increasing the risk of medication errors. In the case of COVID-19, shortages of these drugs may inhibit a patient from being ventilated.

Injectable opioids are administered under the supervision of healthcare professionals in healthcare settings that have stringent policies and procedures in place to prevent diversion. Specifically, injectable opioids are distributed, stored and administered in tightly controlled environments, and are overseen by no fewer than five government agencies to ensure their appropriate handling and use (i.e., the DEA, State Bureau of Narcotic Enforcement, State Department of Health, Joint Commission and State Board of Pharmacy). Injectable opioids have historically not been the drugs of concern in the opioid epidemic, and data demonstrates that utilization has been consistent for many years and did not experience the spike in utilization that solid oral dosage opioids have in the past few years. Furthermore, the Food and Drug Administration (FDA) Current Good Manufacturing Practice (cGMP) requirements for sterile injectable medications are very different than solid oral dosage medications, thereby making it more difficult to mitigate shortages for injectable medications due to sterility and quality assurance testing involved with manufacturing sterile products.

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[1] Premier Inc. Data Shows Drugs Essential to Providing Care for COVID-19 Patients Quickly Slipping into Shortage. Available at: https://www.premierinc.com/newsroom/press-releases/premier-inc-data-shows-drugs-essential-to-providing-care-for-covid-19-patients-quickly-slipping-into-shortage

[2] Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), Public Law 115-271.

[3] According to the FDA drug shortage database, injectable fentanyl has been in shortage since May 2017 and hydromorphone injection has been in shortage since October 2017. https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm (Accessed 12.23.2019)

Given the essential role of injectable opioids in providing clinically appropriate care to patients, especially COVID-19 patients, and ongoing drug shortages, ***Premier urges the DEA to utilize its discretionary authority to establish APQs in terms of pharmaceutical dosage form for all CII controlled substances.*** Ensuring that injectable opioids are always available for clinically appropriate care should not be a rare occurrence for the DEA – it must be a priority.

The DEA Should Reconsider Modifications to the Inventory Allowance

In a proposed rule titled "*Management of Quotas for Controlled Substances and List I Chemicals,*" which was published in the October 23, 2019 Federal Register, the DEA proposed to modify the process for inventory allowances and to only grant additional APQ requests if a manufacturer's inventory is less than 20 percent of the manufacturer's estimated net disposal. ***Premier is concerned that this number is too low to permit manufacturers to remain nimble and flexible to address situations such as drug shortages, natural disasters, global pandemics, medical demand, and other scenarios that would require an increase in production of critical medications***. This is especially critical for injectable opioids that must follow cGMP and have stringent sterility and quality assurance testing requirements per the FDA. Therefore, ***Premier urges the DEA to utilize its discretionary authority to differentiate inventory allowances in terms of dosage form.*** For example, manufacturers of injectable opioids should be permitted to request additional APQ at the current threshold of 30 percent of the manufacturer's net disposal. Furthermore, Premier urges the DEA to also consider exceptions where APQ requests may be granted at a higher inventory threshold to address specific scenarios warranting swift action, such as unprecedented demand due to a global pandemic.

The DEA Should Collaborate with Data Partners to Better Understand Injectable Opioid Utilization and Diversion

The DEA has historically spoken to the need for additional data inputs to understand utilization and diversion. The Premier Healthcare Database (PHD) is one of the most comprehensive electronic healthcare databases containing robust data on more than 108 million inpatient admissions and 765 million outpatient encounters for over 208 million unique patients. The PHD has been leveraged by hospitals, health systems, academia, pharmaceutical manufacturers, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), the National Institutes of Health (NIH) and others to use real-world data to conduct evidence-based and population-based analyses of drugs, devices, other treatments, disease states, epidemiology, resource utilization, healthcare economics and clinical outcomes. ***Premier welcomes the opportunity to discuss how the Premier Healthcare Database and its dedicated staff of skilled professionals trained in medicine, pharmacy, epidemiology, public health, economics and statistics can partner with the DEA to support data collection regarding the utilization of injectable opioids in acute settings, including specifically for the treatment of COVID-19 patients, and the diversion risk***. Premier's data capabilities can also serve as an early warning system for potential drug shortages and other scenarios that may warrant proactive action from the DEA to mitigate impact to patient care.

The DEA Should Collaborate with a Broad Range of Stakeholders to Identify Sustainable Solutions

Premier believes there is no single solution to address the opioid epidemic and that Congress, federal agencies and the public will have to work together to identify sustainable solutions to really make an impactful difference. To this end, ***Premier urges the DEA to collaborate with a broad range of stakeholders on how the DEA can help address the opioid crisis while ensuring an adequate supply of opioids for clinically appropriate care.*** The DEA should engage stakeholders such as the FDA, CMS, pharmaceutical manufacturers, providers, pharmacists, organizations such as Premier, and others through a variety of mechanisms such as roundtable discussions,

listening sessions, or a public hearing. Broad stakeholder engagement and collaboration will also allow stakeholders to share best practices for opioid stewardship and self-audit protocols to prevent diversion and abuse of opioids.

Conclusion

In closing, the Premier healthcare alliance appreciates the opportunity to submit comments on DEA–688P. Premier looks forward to working with the DEA and other stakeholders to develop sustainable solutions that balance preventing diversion and abuse of opioids with ensuring adequate supply for clinically appropriate care.

If you have any questions regarding our comments or need more information, please contact Soumi Saha, Vice President of Advocacy, at soumi_saha@premierinc.com or 732-266-5472.

Sincerely,

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Premier Inc.