November 19, 2023

The Honorable Anne Milgram
Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

Submitted electronically via www.regulations.gov

RE: 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 2024 [Docket No. DEA-1228P]

Dear Administrator Milgram:

Premier Inc. 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 2024"* which was published in the Nov. 2, 2023 Federal Register. The notice proposes reducing the aggregate production quotas (APQs) for several schedule II controlled substances including:

- Fentanyl – 7.6 percent reduction
- Hydrocodone – 0.3 percent reduction
- Hydromorphone – 2.1 percent reduction
- Morphine – 4.3 percent reduction
- Oxycodone – 0.3 percent reduction

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.

Premier appreciates the DEA for contemplating the downstream effects of their annual quota setting process on drug shortages. Specifically, Premier applauds the DEA's work to allocate quotas quarterly and add more transparency to distinguish between quotas for domestic use versus exportation. However, Premier urges the DEA, prior to finalizing 2024 APQs, to carefully consider how a reduction in manufacturing quotas for certain opioids could exacerbate recent drug shortages for injectable opioids and have a negative effect on patients with a legitimate and serious need for these medications. For example, both fentanyl injection and hydromorphone injection have been on the Food and Drug Administration (FDA) drug shortage list since 2017.

As the DEA undertakes the process of developing APQs for 2024, Premier urges the DEA to consider the following as guidelines to help ensure adequate supply of these essential medications as the United States continues to grapple with shortages of these essential medications. Specifically, Premier urges the DEA to implement its existing statutory authority to distinguish between APQs based upon dosage form.

I. BACKGROUND ON PREMIER INC.

Premier is a leading healthcare improvement company and national supply chain leader, uniting an alliance of

4,350 hospitals and approximately 300,000 continuum of care 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. Premier's sophisticated technology systems contain robust data gleaned from nearly half of U.S. hospital discharges, 812 million hospital outpatient and clinic encounters and 131 million physician office visits. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,400 manufacturers to source the highest quality and most cost-effective products and services. Premier's work is closely aligned with healthcare providers, who drive the product and service contracting decisions using a data driven approach to remove biases in product sourcing and contracting and assure access to the highest quality products. 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.

A Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government, and other entities to co- develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare.

II. THE DEA SHOULD ESTABLISH APQS IN TERMS OF PHARMACEUTICAL DOSAGE FORM FOR ALL CII CONTROLLED SUBSTANCES

In 2018, Congress passed the SUPPORT Act[1] giving the DEA new discretionary authority to establish APQs in terms of pharmaceutical dosage form. ***Premier is disappointed that the 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.*** By not implementing this statutory authority, the DEA is ignoring Congressional intent and jeopardizing the availability of essential medications needed to care for patients in the acute setting.

Hospitals, health systems and other providers continue to grapple with acute nationwide shortages of several injectable opioid medications including morphine, hydromorphone and fentanyl.[2] 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. Absent adequate supply of injectable opioids, patient care is threatened by cancelling or delaying surgical procedures and increasing the risk of medication errors.

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.

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

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.

Given the essential role of injectable opioids in providing clinically appropriate care to patients, especially given 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.

III. 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 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 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.

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

V. CONCLUSION

In closing, Premier appreciates the opportunity to share recommendations and considerations as the DEA develops 2024 APQs for certain schedule II controlled substances. 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 me at soumi_saha@premierinc.com or 732-266-5472.

Sincerely,

Soumi Saha, PharmD, JD
Senior Vice President of Government Affairs
Premier Inc.