October 15, 2019

The Honorable Uttam Dhillon
Acting Administrator, Drug Enforcement Administration
Attention: DEA Federal Register Representative, DEA-508P
8701 Morrissette Drive
Springfield, Virginia 22152

Submitted electronically at https://www.regulations.gov/

RE: 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

Dear Acting Administrator Dhillon:

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 2020," which was published in the September 12, 2019 *Federal Register*. The notice proposes reducing the aggregate production quotas (APQs) for several schedule II controlled substances including:

- Fentanyl – 31% reduction
- Hydromorphone – 25% reduction
- Oxycodone – 9% reduction

Premier is a leading healthcare improvement company, uniting an alliance of more than 4,000 U.S. hospitals and health systems, 650 long-term care pharmacies, 6,500 skilled nursing facilities, and approximately 165,000 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. Prior to finalizing 2020 APQs, Premier cautions the DEA to carefully consider how a reduction in manufacturing quotas for certain opioids could exacerbate recent drug shortages for injectable opioids[1] and have a negative effect on patients with a legitimate and serious need for these medications.

[1] 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 10.9.2019)

The DEA Should Differentiate CII APQs for Injectables vs. Solid Oral Dosage Forms

Hospitals, health systems and other providers are just recovering from a recent acute nationwide shortage of several injectable opioid medications including morphine, hydromorphone and fentanyl that spanned from the Fall of 2017 to just a few months ago. 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 (see Appendix A) 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 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.

The proposed reduction in APQs does not differentiate between solid oral dosage forms and injectable forms. Given the essential role of injectable opioids in providing clinically appropriate care to patients and ongoing drug shortages, ***Premier urges the DEA to differentiate between solid oral dosage forms and injectables and ensure that quotas for injectable opioids are not impacted by the proposed reduction in APQs.*** Furthermore, Premier urges the DEA to develop a process for temporarily reallocating quotas for injectable opioids to able and operational manufacturers to help alleviate ongoing and future potential shortages of injectable opioids.

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 Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (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. However, Premier also notes that engaging a broad range of stakeholders should not delay finalization or distribution of 2020 APQs but should instead serve as an opportunity for DEA to identify future potential solutions.

Conclusion

In closing, the Premier healthcare alliance appreciates the opportunity to submit comments on DEA–508P. 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, Senior Director of Advocacy, at soumi_saha@premierinc.com or 202-879-8005.

Sincerely,

Blair Childs
Senior Vice President, Public Affairs
Premier Inc.

Appendix A: Utilization of injectable morphine, hydromorphone and fentanyl by Premier members from April 2016 to August 2018, demonstrating consistent utilization over time prior to shortages in late 2017