799 9th Street NW
Suite 210
Washington, DC 20001

T (202) 354-2600
vizientinc.com

vizient®

October 15, 2019

Submitted via the Federal eRulemaking Portal: http://www.regulations.gov

Mr. Uttam Dhillon
Acting Administrator
Drug Enforcement Administration
Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

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 2020 [Docket No. DEA-508P]

Dear Acting Administrator Dhillon:

Vizient, Inc. appreciates the opportunity to comment on the Drug Enforcement Administration's (DEA) proposed 2020 aggregate production quotas for controlled substances in schedule I and II of the Controlled Substances Act (CSA) and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine ("Controlled Substances Quotas") as published on September 12, 2019 in the Federal Register (Vol. 84, No. 177).

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality and market performance for more than 50% of the nation's acute care providers, which includes 95% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $100 billion in annual group purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

Vizient supports the DEA's ongoing efforts to combat the crisis of opioid addiction and abuse and recognizes the unprecedented pain and hardship caused by the misuse of opioids. Vizient is actively working to alter the current crisis in collaboration with our members, who are on the front lines of this battle. We continue to develop and revise resources such as our Opioid Utilization and Safety Compendium to support members in their implementation of novel strategies to improve opioid stewardship and mitigate opportunities for diversion and/or abuse.

At the same time, Vizient is also committed to assisting our members in addressing another crisis – that of drug shortages. For the last two decades, the U.S. pharmaceutical supply chain has been challenged with interruptions of numerous medications essential to the delivery of

patient care. A recent Vizient survey identified that U.S. hospitals devote approximately 8.6 million labor hours annually (estimated $359 million in salary expense) managing shortages. In this survey as well as through other direct communications, our members have identified controlled substances such as morphine, hydromorphone, and fentanyl among the list of critical drugs needed for the delivery of high quality and safe patient care. Specifically, our members are concerned about how potential shortages of multiple injectable opioids would affect their ability to manage and treat post-surgical and medical pain. As a result, we must work diligently to ensure we address both of these crises effectively.

Vizient appreciates and recognizes that the DEA is required to consider "relevant information obtained from the Department of Health and Human Services [HHS], including from the Food and Drug Administration [FDA]," when setting an aggregate production quota (APQ) for controlled substances listed as schedule I or II. We also appreciate that per 21 CFR 1303.11(b), the DEA's calculation of quotas now includes critical information from agencies, including the FDA, such as "changes in the currently accepted medical use in treatment with the class or the substances which are manufactured from it, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires."

However, it is unclear whether, in accordance with these requirements listed above, the DEA must seek insight from the FDA's Drug Shortages Task Force to obtain the data needed to adjust APQs, specifically regarding the current supply limitations for the opioids morphine, hydromorphone, and fentanyl. All of these products are presently on the drug shortages list developed by the University of Utah Health, a Vizient member, and published on the website of the American Society of Health-System Pharmacists.[1] The FDA Drug Shortages Task Force, which was established to identify the root causes of drug shortages and advance potential long-term solutions, would be an excellent source of information to ensure the finalized quotas reflect the manufacturing challenges that could prevent active pharmaceutical ingredients (APIs) from resulting in finished formulations.

Vizient also asks that the DEA remain agile in its ability to adjust APQs given unanticipated barriers or issues that disrupt normal manufacturing processes. As we have seen in recent years, quality manufacturing issues beyond simply the supply of APIs have compromised the ability to produce critical drugs. Given the current fragility of the supply chain, it remains possible that adjustments in previous stated allocations may be required. For example, Vizient was recently informed by a manufacturer that they are nearing the limit of their present APQ and will soon have to initiate an allocation process for their products, thus limiting the extent to which health systems can acquire needed versions of critically important medications. Vizient applauds the DEA's willingness to make such adjustments in 2018 and would appreciate continued consideration should similar unanticipated challenges arise.[2]

Vizient acknowledges that the manufacturing issues experienced by pharmaceutical companies are not the responsibility of the DEA but respectfully requests that the DEA recognize the

---

[1] Drug Shortages. (n.d.). Retrieved September 27, 2019, from https://www.ashp.org/Drug-Shortages.
[2] DEA Working To Avoid U.S. Drug Shortages. (2018, April 9). Retrieved September 27, 2019, from https://www.dea.gov/press-releases/2018/04/09/dea-working-avoid-us-drug-shortages.

legitimate uses of controlled substances, and the need to preserve that supply, while also combating diversion and abuse. Vizient has previously and continues to respectfully request that the DEA take a proactive role in the management of allocations by monitoring supply and, when appropriate, transferring allocations in a timely manner. This approach will ensure that these vital drugs are available for the patients who need them, when they need them. Waiting for shortages to develop before addressing this issue compromises care and deprives hospitals of the essential supplies they need.

Conclusion

Vizient would like to thank the DEA for the opportunity to provide this insight. We, along with our members, remain dedicated to combating the opioid epidemic and applaud the DEA for its leadership in this most critical public health initiative. We appreciate the DEA's commitment to provide adequate supplies of controlled substances for legitimate needs and look forward to continuing to work with the Administration on ways to combat this crisis.

In closing, on behalf of Vizient, Inc., I would like to thank the DEA for providing us this opportunity to comment on this important proposal. Please feel free to contact me at (202) 354-2607 if you have any questions or if Vizient can provide any assistance as you consider these issues.

Respectfully submitted,

Shoshana Krilow
Vice President of Public Policy and Government Relations
Vizient, Inc.