

December 4, 2023

The Honorable Anne Milgram
Administrator
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrisette Drive
Springfield, VA 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. FDA-2016-D-0643)

Dear Administrator Milgram,

Vizient, Inc. appreciates the opportunity to respond to the Drug Enforcement Administration's (DEA's) Notice "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" (hereinafter, "Notice") which includes information regarding forthcoming regulatory changes and administration of individual quotas for 2024. Vizient appreciates DEA's commitment to ensuring that all Americans can access appropriately prescribed medications and DEA's efforts to better understand supply chain dynamics.

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 60% of the nation's acute care providers, which includes 97% 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 \$130 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

Vizient appreciates DEA's efforts to learn more about shifts impacting the prescribing of Schedule II stimulants, however we encourage the agency to consider opportunities to learn more about the prescribing patterns of a broader scope of controlled substances. Further, Vizient looks forward to the opportunity to comment on future detailed proposals that will lead

to the development of more precise quotas for medical, scientific, research and industrial needs, in addition to the establishment and maintenance of reserve stocks, while also reducing opportunities for diversion.

Although the Notice indicates that DEA has focused efforts on Schedule II stimulants, Vizient recommends DEA consider a similar approach for other types of controlled substances, as this may help ensure patients receive needed medications without delay. Recently, Vizient has heard from providers, particularly hospitals and health systems, that their orders for controlled substances, such as opioids, are not being consistently fulfilled by wholesale distributors, particularly when there are changes to normal ordering patterns. Notably, these challenges tend to occur when a provider is expanding operations (e.g., new site of care opening), when there has been a spike in demand (e.g., a retail pharmacy closure causing patients to receive prescriptions elsewhere, seasonal changes in certain illnesses) or when there are more frequent orders of smaller quantities. Also, the reason an order is not fulfilled is often unclear to the provider (e.g., exceeding previous ordering levels, drug shortage, or other). Yet, the reason an order is not fulfilled is notable because in setting aggregate production quotas (APQs), DEA may be relying on data that may not reflect accurate demand or trends (e.g., new or expanded facilities) which ultimately results in ongoing access challenges, including potential challenges related to setting APQs.

Vizient is in the process of gaining more insight regarding these access challenges through a survey of our membership. However, we encourage DEA to consider these challenges as it evaluates the scope of forthcoming regulatory changes.

Conclusion

Vizient thanks DEA for issuing the Notice which outlines future regulatory options the DEA is considering. Vizient encourages DEA to work with providers closely as regulatory changes are contemplated to ensure that current and future patient care needs can be met. Please feel free to contact me or Jenna Stern at jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these issues.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Shoshana Krilow".

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