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

Mr. Robert W. Patterson
Acting Administrator
Drug Enforcement Administration
Department of Justice
8701 Morrisette Drive
Springfield, VA 22152

Re: Controlled Substances Quotas [Docket No. DEA-480]

Dear Acting Administrator Patterson:

Vizient, Inc., respectfully submits our comments on the Drug Enforcement Administration's (DEA) proposed rule regarding "Controlled Substances Quotas" as published on April 19, 2018 in the Federal Register (Vol. 83, No. 76).

Background

Vizient, Inc., is the largest member-driven health care performance improvement company in the country. At Vizient, our purpose is to ensure our members deliver exceptional, cost-effective care. Vizient is member-driven and member-minded, working tirelessly to amplify each organization's impact by optimizing every interaction along the continuum of care.

Vizient provides innovative data-driven solutions, expertise and collaborative opportunities that lead to improved patient outcomes and lower costs. Vizient serves a diverse membership and customer base including academic medical centers, pediatric facilities, community hospitals, integrated health delivery networks and non-acute health care providers. Vizient is headquartered in Irving, TX with locations in Chicago, Washington, D.C., and other cities across the country.

Recommendations

Vizient appreciates the Drug Enforcement Administration's continued efforts to combat our nation's opioid crisis. In the fall of 2016, Vizient issued a call for change to help reduce opioid misuse and addiction. We, and our members, understand that while opioids alleviate pain, the misuse of these substances is resulting in unprecedented death and hardship. By collaborating with our members and industry experts, our goal is to change the face of opioid addiction for the better in America. Hospitals and health systems are on the front lines of the opioid crisis – battling on behalf of their communities and the patients they serve.

At Vizient, we are continuing to compile current resources in an effort to educate and promote collaboration among our members. Vizient's Opioid Utilization and Safety Compendium is

available on the Vizient website, and updated routinely in an effort to provide innovative and proactive strategies that our members can implement to manage the opioid crisis.

We applaud the agency's recent efforts to work with health care industry stakeholders to take steps to alleviate certain drug shortages facing the nation's acute care providers. While combating opioid abuse and addiction remains a top priority for our members across the nation, it is vital that the DEA understands the impact that critical shortages of multiple injectable opioids have on providers' ability to manage and treat post-surgical and medical pain. As a result, we must strike the appropriate balance of preventing and reducing prescription opioid abuse, while ensuring necessary injectable medicines remain accessible to patients in acute care and certain, non-acute (e.g. palliative) settings.

Finding ways to mitigate the impact of drug shortages has been a focus of Vizient for years. While all drug shortages are capable of impacting patient care, some of the most adverse clinical situations have arisen due to shortages of injectable opioid products such as morphine, hydromorphone and fentanyl. The absence and/or limited supply of these products is not just an inconvenience for acute care providers, it is also a critical patient safety issue. In 2010, two patients died after receiving hydromorphone at the intended dose of morphine, which was on shortage. Even when death is not the end result, patient harm can still result from the absence of essential medications used in the acute and critical care settings.

The DEA is seeking comment on the proposal regarding the factors that the Administrator should consider when adjusting the aggregate production quotas and the additional information the Administrator may require from applicants. Vizient expresses its extreme concern that, while well-intentioned, these provisions could inadvertently exacerbate the current shortages of injectable opioid products for the acute care setting. We agree with the DEA that the misuse of controlled prescription drugs, particularly prescription opioids, is central to the tragic statistics in drug overdoses and deaths. However, the agency's proposal to implement these reforms "without delay" in order to "expeditiously" facilitate the "sound proposal and determination of aggregate production quotas for 2019" does not appear to take into account the current opioid shortages impacting health care providers across the nation. Furthermore, the absence of these drugs is extremely problematic, cannot be resolved quickly – and is detrimental to the ability to provide safe and effective patient care.

We appreciate the DEA's proposals to make improvements in the controlled substance regulatory quota system. Vizient urges the DEA to take a more 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 that 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. Vizient suggests that the DEA consider an approach that would separate injectable opioids – which are primarily used in hospitals – to ensure that allocations are not reduced beyond the medically necessary amount, and thus assuring safe and effective care.

Vizient acknowledges that the manufacturing issues experienced by numerous pharmaceutical manufacturers are not the responsibility of the DEA. Vizient continues to work with its members, the Food and Drug Administration (FDA), other professional practice organizations, and the manufacturer community to try and find long term solutions to the plague of shortage. We also recognize that thoughtful intervention by the DEA can help us advance the goal of decreased opioid abuse while preserving accessibility to the injectable medications required in the acute

care environment. We urge the DEA to acknowledge the legitimate uses of controlled substances, and the need to preserve that supply while also combating diversion and abuse.

Conclusion

Vizient welcomes the DEA's request for comments, which provides a significant opportunity for stakeholders to inform the administration. Vizient members are dedicated to combatting the opioid epidemic, and we applaud the DEA for their leadership. We look forward to continuing to work with the Administration to find ways to help hospitals, their patients, and their communities combat this deadly crisis.

Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic medical centers and pediatric facilities. Individually, our members are integral partners in their local communities, and many are ranked among the nation's top health care providers. **We appreciate the DEA's commitment to provide adequate supplies of controlled substances for legitimate needs in the proposed rule. Vizient urges the administration to ensure our members in the acute care setting have access to essential injectable opioid products such as morphine, hydromorphone and fentanyl.**

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) 354-2600 or Chelsea Arnone, Director of Regulatory Affairs and Government Relations (chelsea.arnone@vizientinc.com), if you have any questions or if Vizient can provide any assistance as you consider these issues.

Respectfully submitted,

Shoshana Krilow
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