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

Dr. Robert Califf
Commissioner
Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Quality Management Maturity Program for Drug Manufacturing Establishments; Establishment of a Public Docket; Request for Comments (Docket No. FDA-2023-N-3721)

Dear Dr. Califf:

Vizient, Inc. appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) Request for Comments on the Quality Management Maturity for Drug Manufacturing Establishments (hereinafter "RFC"). Vizient applauds the FDA for taking steps to develop a Quality Management Maturity (QMM) program and appreciates the agency's efforts to gain stakeholder feedback.

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

In our comments, we respond to several of FDA's questions, as provided in the RFC. Generally, Vizient believes that development of the QMM program is one critical step FDA can take to address the multi-faceted challenge of drug shortages. To enhance information related to QMM, Vizient believes that additional information is needed on how each measure, per facility, per product, is relevant for purposes of anticipating drug shortages caused by quality issues, including noncompliance with regulations. Vizient provides responses to several of the questions posed in the RFC, and we note our ongoing support of FDA's work to improve quality.

1. If you are a manufacturer, please identify the types of drug(s) produced in your establishment (*e.g.,* active pharmaceutical ingredients, innovator drugs, innovator biologics, generics, biosimilars, or OTC monograph drugs). If you are not a manufacturer, please specify whether you are a purchaser, payor, pharmacy, healthcare provider, patient, regulator, supplier, distributor, contract service provider, or other (please describe).

Vizient is not a manufacturer. Among other functions, Vizient is a Group Purchasing Organization (GPO). Vizient helps drive quality, efficiency and cost performance across the care continuum. Members, which include acute care providers and ambulatory care providers, achieve cost savings by

purchasing supplies and services through agreements negotiated with Vizient's suppliers. Our member providers also gain insight into clinical, financial and operational performance improvement opportunities through advanced analytics and advisory services. Finally, through proprietary networks, they learn from peers and share leading practices, improve target outcomes for quality and safety, and build market strategies that position them to thrive in today's healthcare industry.

2. What advantages do you anticipate that your sector (*i.e.,* your organization and others like yours) would gain from CDER's voluntary QMM program?

Advantages Vizient would gain from Center for Drug Evaluation and Research's (CDER's) voluntary QMM program would depend on several factors, including industry participation, the degree to which QMM information is shared, the degree to which higher QMM assessment scores correlate with fewer drug shortages and improved supply chain resiliency, and whether the program resulted in manufacturers more broadly enhancing their QMM. This information may be considered during the sourcing process to further understand supplier capabilities and potentially recognize their differentiation related to QMM participation.

Such information, if made available, may also help inform hospitals and other providers' purchasing decisions.

3. How would participation in a QMM program benefit you or your specific organization?

Vizient believes robust manufacturer participation in a QMM program could help improve manufacturing quality, including by preventing or mitigating challenges in manufacturing, which could result in the mitigation of drug shortages or disruptions.

Vizient also believes benchmarking information could help compare manufacturers and their potential drug shortage or supply disruption risk, particularly if information is shared with stakeholders regarding which products are manufactured at a given facility.

In addition, as the QMM program is studied, information regarding how outcomes in a practice area impact a facility's overall reliability would be helpful. In other words, would certain practice areas have a greater weight if such information was used to gauge risks?

4. How would you use information from a QMM assessment if it were provided to your organization? For example, if your organization acts as a supplier or contract organization, would you consider sharing information from a QMM assessment with a potential client? If your organization enters into contracts with purchasers, would you consider sharing information from a QMM assessment with a purchaser? If your organization is a purchaser, would you consider requesting information from a QMM assessment?

As a GPO, Vizient anticipates using information from a QMM assessment, if provided to our organization, as part of the sourcing process to achieve a high quality and resilient supply of pharmaceuticals. In addition, Vizient could use QMM assessment information to validate or supplement information received from manufacturers during the sourcing process.

Vizient would consider sharing information from a QMM assessment with a member under appropriate circumstances. For example, if Vizient was able to obtain permission from FDA or the manufacturer to disclose information from a QMM assessment, then Vizient would consider sharing such information with members. Alternatively, if it was excessively burdensome to obtain or analyze QMM assessment information, or unclear which QMM assessment information could be shared, then Vizient would be

less likely to share information from a QMM assessment with a member. Vizient would also consider risks related to breach of confidentiality, if such confidentiality requirements were in place. Vizient encourages FDA to consider making QMM assessment information publicly available or to provide information to a range of entities that indicate they would like to receive such information.

5. What, if any, unintended consequences, roadblocks, or other concerns do you anticipate with a voluntary QMM program? What barriers to participation do you anticipate? Please explain. Which of these unintended consequences might be unique to stakeholders like you? Why?

A voluntary QMM program may have limited participation for a variety of reasons including lack of incentives for manufacturers to participate, lack of understanding of what the ratings reflect, and lack of use to drive sourcing and purchasing decisions by providers.

In order for the program to function, a critical mass of manufacturers would need to participate. If only a subset of suppliers take part, the relevance of the program is diluted, as there would be no common methodology by which to judge quality metrics across manufacturers.

In addition, benefits and risks, including public perception, of a voluntary QMM program would need to be clearly delineated where possible. Also, testing and validation of QMM assessments, including communication of those efforts, may be challenging.

Misunderstanding of the QMM program is a risk that could deter participation. Vizient would suggest that FDA provide extensive information and resources to a range of stakeholders regarding how to interpret QMM assessments, including what each part of an assessment means in the context of a drug shortage risk. For example, should a prototype assessment protocol include benchmarking information where a manufacturer is above the benchmark in one practice area but not the others, it could be challenging for stakeholders to interpret this information when considering risk of drug shortages related to quality. Also, it could be challenging for stakeholders to know which of the five practice areas may be most impactful in terms of drug shortage risk. Vizient encourages FDA to work with a range of stakeholders to determine how best to communicate findings from the assessment protocol to stakeholders in the context of drug shortages or supply chain resiliency.

From a provider perspective, Vizient anticipates additional incentives (e.g., financial, increased reimbursement) are needed to encourage use of QMM ratings when making purchasing decisions as we would anticipate additional investment in quality and resilience that results in higher QMM scores, could increase costs which would be passed on to the provider. Therefore, those additional expenditures must be recognized, such as by payors in reimbursement or other payments to providers.

6. FDA anticipates that each establishment would be provided with a detailed report following their QMM assessment. What would you want such a report to contain?

Vizient encourages FDA to share a potential sample report so that we may more effectively respond to this question. Vizient encourages FDA to consider whether aspects of a report could be shared publicly to help inform stakeholder decisions. For example, FDA could redact certain information like what is done when an FDA Form 483 is made available. Also, Vizient believes it would be helpful for each establishment’s report to also include information regarding the products manufactured at a given facility.

7. With respect to the outcomes of a QMM assessment, what are your thoughts about making outcomes public? Would your thoughts be different if the outcomes were generally qualitative (*e.g.,* descriptive information) versus quantitative (*e.g.,* a numerical rating)?

Vizient encourages FDA to make outcomes publicly available. Vizient also recommends that FDA share more information regarding the evaluation tools it is considering using as part of the QMM assessment and information regarding how these tools have been validated. Based on our experience with qualitative information in FDA Form 483, each organization may have a different interpretation of the content. As such, Vizient believes quantitative information would help ensure more consistent interpretation across the industry.

Vizient urges FDA to consider how to best measure and communicate QMM assessment outcomes in the context of drug shortages. For example, it would be helpful to know which measures or combination of measure scores suggest a facility would be more resilient to quality related drug shortages.

8. What other feedback would you like the FDA to consider for a voluntary QMM program?

Vizient appreciates FDA's ongoing work regarding a voluntary QMM program. As noted in our comments, Vizient encourages FDA to consider how best to demonstrate the QMM scores in the context of drug shortage risk, particularly when such shortages stem from a quality issue.

In addition, given FDA is interested in feedback regarding a voluntary QMM program, we suggest the agency identify potential barriers manufacturers face when determining whether to participate in the program. Further, should opportunities for improvement become available, we suggest the agency work with other government stakeholders, including the Centers for Medicare and Medicaid Services (CMS) to consider whether incentives or other funds to support investments in QMM could be made available.

Conclusion

Vizient applauds FDA's efforts to release the RFC and provide an opportunity for stakeholder input as it develops a voluntary QMM Program. Vizient has engaged in numerous efforts to support access to medications, including publishing a regularly updated essential medicines list and a bi-annual Pharmacy Market Outlook, as we believe transparency is a critical element to prevention and mitigation efforts related to drug shortages. In closing, on behalf of Vizient, I would like to thank FDA for providing the opportunity to respond to this RFC. 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 recommendations.

Respectfully submitted,

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