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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: Food and Drug Administration Quality Metrics Reporting Program; Establishment of a Public Docket; Request for Comments (Docket No. FDA-2022-N-0075)

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 Metrics Reporting Program (Docket No. FDA-2022-N-0075) (hereinafter "RFC"). Vizient applauds the FDA for taking steps to advance a quality metrics reporting program and appreciates the agency's efforts to gain stakeholder feedback. Related to quality metrics, Vizient also thanks the agency for hosting and including Vizient in the Quality Management Maturity (QMM) Workshop held in May 2022. Like FDA, Vizient believes quality metrics, among other benefits, are one of several important aspects of QMM program development.

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 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 $100 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 FDA's proposed direction for an FDA Quality Metrics (QM) Reporting Program, as outlined in the RFC. Generally, Vizient uses quality metrics as a factor in strategic sourcing decisions. To enhance quality metrics, information on each measure, per facility, per product, would be most needed. Vizient provides various suggestions for the agency's consideration as it further develops the QM Reporting Program.

Reporting Levels

Do you agree that reporting should be aggregated at an establishment level?

Vizient believes that quality metric reporting that is aggregated at an establishment level would help add transparency to the supply chain. In the RFC, FDA notes that the term "covered

establishment" would mean establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a "covered drug product". Also, FDA clarifies that covered establishments include contract laboratories, contract sterilizers, and contract packagers. Vizient suggests FDA further clarify how a covered establishment would be identified, such as by including a facility's address.

Vizient also suggests that manufacturers disclose and regularly update information regarding which covered drug products are produced at a covered establishment. Vizient believes such information connecting the covered drug product to the covered establishment would help improve our understanding of the quality-related data. Vizient also encourages the collection of National Drug Code (NDC) level data, as we view such information as complementary of establishment level data. Recently, Vizient announced a joint pilot program with RISCS, Inc. where pharmacy suppliers will be asked to provide key information on their supply chains through the request-for-proposal process. The information provided will enable visibility into supply chain aspects such as redundancy in raw material supply, available production capacity and production flexibility, inventory practices, location differentiation and geopolitical risks. Once implemented, the program would use a rating system to enable the evaluation of critical aspects of a resilient supply chain and provide increased transparency.

In addition, requiring that manufacturers update the agency and other stakeholders, such as group purchasing organizations, when changes in production (such as starting and stopping) occur at a covered establishment would be similarly beneficial. Related to the point of production, manufacturers sharing reasons why an establishment is no longer producing a product (e.g., a system taken down for routine maintenance, staffing shortages, facility closures due to safety) would be similarly helpful.

Regarding data aggregation, Vizient encourages the agency to also consider stratifying the data by submission type (e.g., NDA, ANDA, BLA, CMC supplements etc.) and to include an NDC (or at minimum, "labeler" code). Vizient believes reporting in this manner would provide greater transparency.

Lastly, Vizient suggests FDA clarify how quality metrics and related reports would be affected under a range of different circumstances. Examples of circumstances include if a facility changes what is manufactured, receives a 483 (and provides corrections in response), or experiences a manufacturing issue. Vizient believes clarity regarding the impact of these circumstances, in conjunction with information regarding the products presently manufactured at an establishment, would significantly help improve transparency and the meaningfulness of quality metrics.

Would reporting at an establishment level facilitate submission of quality metrics data by contract manufacturing organizations?

Vizient encourages the inclusion of contract manufacturer organizations (CMO). Currently, it can be challenging to determine where different products are originally manufactured, including the manufacturing locale, when establishments use CMOs. Reporting at an establishment level (and potentially stratifying by submission type) and including the labeler code would provide greater transparency, as noted above. Inclusion of CMO firm activity would add detail regarding which products are outsourced and add transparency.

Practice Areas and Quality Metrics

If you think the general practice areas listed in section II of the RFC would not meet the objectives of FDA QM Reporting Program, what other practice areas should FDA consider?

In the RFC, FDA provides the following four general practice areas: Manufacturing Process Performance; Pharmacy Quality System (PQS) Effectiveness; Laboratory Performance; and Supply Chain Robustness. Also, FDA provides that the agency may use the data for the following purposes: to obtain a more quantitative and objective measure of manufacturing quality and reliability at an establishment; to integrate the metrics and resulting analysis into FDA's comprehensive quality surveillance program; and to apply the results of the analysis to assist in identifying products at risk for quality problems (e.g., quality related shortages and recalls). Given the range of the objectives and different ways "quality" may be misinterpreted (e.g., if a product at a highly rated establishment would be misinterpreted to be more safe and more effective than the same product at a different establishment), Vizient suggests FDA consider modifying the title of the program (i.e., FDA Quality Metrics Reporting Program) to better reflect the various practice areas and to avoid confusion.

Regarding the four practice areas and associated metrics[1], Vizient supports their inclusion but also notes that too many metrics may place an undue burden on manufacturers if not actually utilized. Additional information regarding the benefit of each metric and various use cases may be beneficial. Based on the information shared in the RFC, it is difficult to determine which of the metrics FDA may weigh more heavily, particularly as related to each of the potential uses of the data. Vizient encourages the agency to provide additional context regarding the measures provided.

Vizient also suggests that manufacturers report and make available information that is not necessarily included in a metric. For example, information regarding the location of source of active pharmaceutical ingredients (APIs) can be important to stakeholders looking to better understand a given supply chain.

If FDA were to consider Quality Culture as one of the general practice areas, what are the critical components of a robust quality culture and can any of these components be measured quantitatively? If so, how do you recommend quality culture information be captured as a quantitative metric (e.g., near misses, APR on-time, binary response to Quality Culture survey, or other numerical metrics/KPIs)?

Vizient believes that insights to Quality Culture can be gained by considering the following three questions: whether the quality unit has autonomous authority to make quality decisions; how the organization responds to and addresses quality issues; and whether the organization strives for continual improvement. However, Vizient also understands that it may be difficult to measure this information quantitatively. Therefore, if trying to obtain a metric, a binary response to a

[1] The four practice areas with associated metrics, as provided in the RFC, are: Manufacturing Process Performance (i.e., Process Capability/Performance Indices (Cpk/Ppk), Lot Acceptance Rate, Right-First-Time Rate, Lot Release Cycle Time); PQS Effectiveness (i.e., CAPA Effectiveness, Repeat Deviation Rate, Change Control Effectiveness, Overall Equipment Effectiveness, Unplanned Maintenance); Laboratory Performance (i.e., Adherence to Lead Time, Right-First-Time Rate, Invalidated/Overturned Out-of-Specification Rate, Calibration Timeliness); Supply Chain Robustness (i.e., On-Time In-Full (OTIF), Fill Rate, Disposition On-Time, Days of Inventory On-Hand)

Quality Culture survey that also includes specific proof (e.g., SOP change documents) may be helpful.

Do you think that any of the examples of quality metrics proposed by FDA would not be an appropriate measure for the designated practice area?

In reviewing the quality metrics in the RFC, Vizient understands that certain metrics (e.g., process capability/performance indices) may already be provided in a manufacturer's process validation trials and data submitted to FDA. As such, Vizient encourages FDA to clarify how it envisions the use of such data in the QM Reporting Program.

Regarding lot acceptance rate (LAR), Vizient believes this information may be useful. We suggest that the quantification be clarified so meaningful information can be gleaned and understood (e.g., LAR of lots completed/lots attempted would be different from lots completed/lots released). Alternatively, FDA could include lot reconciliation rates (i.e., percent of the actual lot released vs. lot rejected) followed by the number of lots attempted/lots approved. Such information, if included for reporting, should be provided across product lines within an establishment, as it would provide a better view of how product reconciliation rates trend and give insight into difficult to process batch history.

Lastly, regarding Lot Release Cycle Time, Vizient questions whether this metric provides meaningful value. If the product meets specifications and is released within its validated parameters, the cycle time calculation may add an undue burden.

What other metrics should FDA consider for a designated practice area?

Vizient suggests FDA also consider a metric related to complaints. For example, in any given quarter, the number of complaints, types of complaints, response closure times and repeat complaints would help stakeholders understand how establishments respond to and close issues. Currently, Vizient requests this type of information from suppliers, as it is helpful in making product extension decisions.

A metric may need to be changed or adjusted by an establishment to better monitor PQS effectiveness, inform appropriate business strategy, or capture insightful trends, thereby driving continual improvement behaviors. What criteria should be applied to justify changing or modifying a quality metric (by either the establishment or by FDA)? How frequently would you expect changes or modifications to be needed?

Vizient encourages the agency to share how the agency will evaluate whether a change or adjustment is warranted and information regarding the frequency of evaluations of metrics. This information will help stakeholders anticipate when changes may occur and will help ensure that metrics remain relevant.

Should a metric change or be adjusted, Vizient urges that any changes be communicated as soon as possible since stakeholders may build systems based on information previously defined by FDA. Where possible, opportunities for stakeholder input regarding revisions would be beneficial. Once metrics are established, Vizient would not expect frequent changes.

When would you rely on multiple metrics versus a single metric as an indicator when assessing a particular practice area (e.g., two metrics are considered in combination because one metric influences the other)? What combination of metrics have been meaningful and useful?

As noted above, complaints and response closure times viewed together have provided meaningful and useful information for contracting purposes.

Other Considerations

Are there considerations unique to specific product categories (e.g., generic drug products, OTC drug products, or biological products) that should be addressed in the QM Reporting Program?

Should there be variation in metrics or reporting requirements as part of the QM Reporting Program based on specific product categories, Vizient encourages FDA to share this information with stakeholders, along with information describing why such variation exists. Sharing this information may help stakeholders better understand differences between product categories.

What would be the optimal reporting frequency for quality metrics data submissions (e.g., monthly, quarterly, or yearly, and segmented by quarter or month)?

While Vizient strongly supports transparency and timely sharing of data, we have not identified an optimal reporting frequency. For example, as noted above, Vizient recently began a pilot project with RISCS, which updates ratings on a quarterly basis. Alternatively, Vizient believes it would also be beneficial for reporting to occur in circumstances where an establishment's rating would likely be meaningfully impacted as a result. It is similarly important to clarify when quality metrics were last submitted and reviewed. For example, should an establishment be forced to shut down for any number of reasons, it would be important that metrics can be modified or reported in a way that is not misleading. For example, metrics could be time-based and appropriate caveats provided such that information is not in conflict with actual circumstances (e.g., a facility that is closed due to a quality issue should not continue to be reported as having a high quality score unless more information is provided to reconcile the conflicting points).

In instances where a manufacturer is not able to extract domestic data and its submission to FDA contains both U.S. and foreign data, how can these data be submitted to FDA in a manner that would still be informative?

Vizient suggests FDA and manufacturers provide additional information regarding the circumstance in which an establishment cannot extract domestic data or disseminate such data to FDA or other stakeholders. As noted above, Vizient believes utilizing the labeler code would help provide additional transparency.

Are there any other aspects of FDA's proposed direction for the program that FDA should address in future policy documents?

As the program advances, Vizient believes it is critical that FDA consider additional communication and education regarding the intent of the QMM program. Vizient does have concerns, as noted above, that a lower rating in the QMM program may be misinterpreted to mean that an establishment produces less safe or less effective products than a higher rated establishment. As a result, this could negatively impact patient and provider perspectives regarding the approval process, including the safety and efficacy of approved products. Communications regarding the QMM program must aim to ensure that confidence in medications from a safety and efficacy perspective is not compromised. For example, even

utilizing the term “quality” has the potential to be misleading. An alternative approach for FDA could be to better emphasize the practice areas, such as supply chain robustness, in communications. Conversely, in order for the QMM program to gain acceptance and utility, the metrics captured must meaningfully correlate to supply performance (i.e., higher scores should translate to fewer shortages). Therefore, defining accurate expectations of the QMM program is critical to success.

Vizient appreciates the range of metrics provided by FDA in the RFC. Vizient believes that more information regarding the relative importance of each measure in the context of a given use would add value to the program and additional clarity. Further, Vizient encourages FDA to work with stakeholders on how best to communicate results of QM reports, as purchasers may utilize the metrics in different ways so a single score may not be as helpful when compared to multiple data points.

Also, Vizient notes that it is currently unclear who would have access to the data reported and whether validation would occur, especially if the data are not publicly reported. Vizient encourages sharing information publicly. As changes occur, Vizient suggests that FDA also consider how manufacturers share this information with the agency and publicly. For example, Vizient would prefer proactive communications from manufacturers regarding changes, rather than having to initiate communications to verify information or a lack of changes.

As noted above, Vizient is aware of different benefits of metrics at the establishment-level and at the NDC-level. Information at each level would be beneficial, and therefore attention should be paid regarding how best to connect establishment-level information, especially when CMOs are involved, with NDC-level information.

Lastly, Vizient notes that the entire health system, not just providers, must share in the investment to support a more resilient supply chain. It is important that increased financial investments to support consistent access to quality medications actually have a meaningful impact on patient care. Thus, broad stakeholder communication and collaboration, including payer involvements, should be considered in the QM Reporting Program and as other QMM efforts evolve.

Conclusion

Vizient applauds FDA’s efforts to release the RFC and provide an opportunity for stakeholder input as it develops a QM Reporting 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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