American Pharmacists Association

February 20, 2024

Subject: Request for Information and Comment: Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements

Submitted electronically via www.regulations.gov to Docket No. FDA-2023-N-4806

Dear FDA Staff:

The American Pharmacists Association (APhA) is pleased to submit comments to the Food and Drug Administration's (FDA) request for information, "Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements" related to the Drug Supply Chain Security Act (DSCSA).

APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA and our members appreciate FDA's "Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act—Compliance Policies," which establishes a 1-year "stabilization period." This provides trading partners additional time, until November 27, 2024, to implement, troubleshoot, and mature their secure, interoperable, electronic systems and processes while supporting the continued availability of products to patients.

Methods

To gather feedback on dispensers' progress on implementation, APhA conducted a survey, which was fielded from January 25th to February 5th to give dispensers time to make progress during the stabilization period and provide FDA with up-to-date information. The survey was sent to a randomly chosen subset of independent pharmacy owners and pharmacists in APhA's database, and the survey link was also shared by the National Alliance of State Pharmacy Associations to their members to generate more responses.

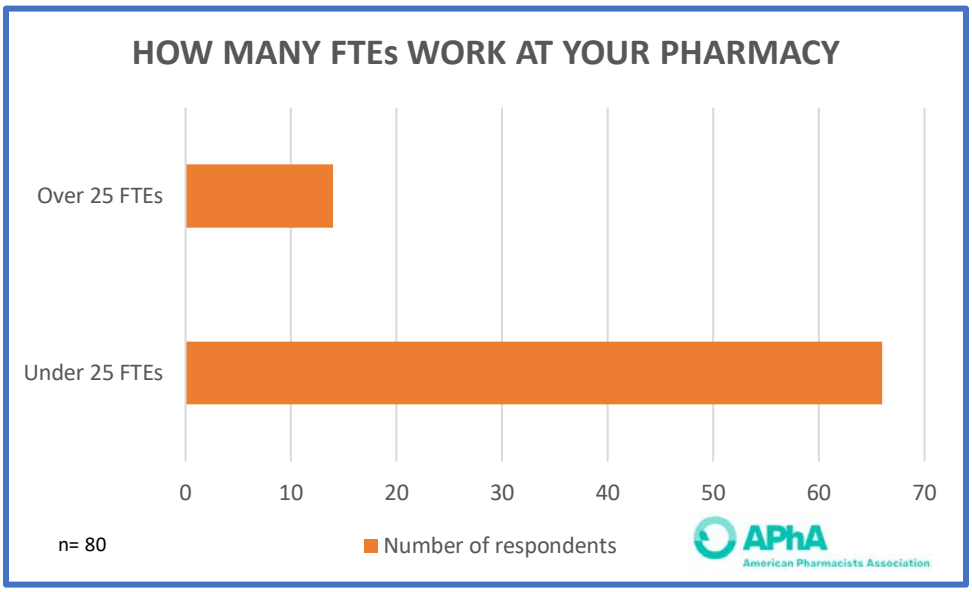
The survey questions were modeled after the questions posed in FDA's RFI, with slight editing for clarity.

Results

Eighty-one respondents completed the survey. The breakdown of practice settings of the respondents is as follows:

- Independent Pharmacy: 76.25%
- Health System: 13.75%
- Chain Pharmacy (4+ stores): 7.5%
- Long-Term Care: 1.25%
- Other: 1.25%

We further note that when asked how many FTEs work at your pharmacy, 82.5% of the respondents work at a DSCSA-defined "small business dispenser," with less than 25 FTEs at the pharmacy.



- **Q1 - Are you familiar with the new DSCSA requirements that went into effect in November 2023?**

Of the 81 respondents, 86.4% stated they were aware of the new DSCSA requirements that went into effect in November 2023.

- **Q2 - How are you using the stabilization period to troubleshoot and mature secure, electronic, interoperable systems and processes for enhanced drug distribution security with your trading partners?**

Participants were given the option to choose one of seven options for this question.

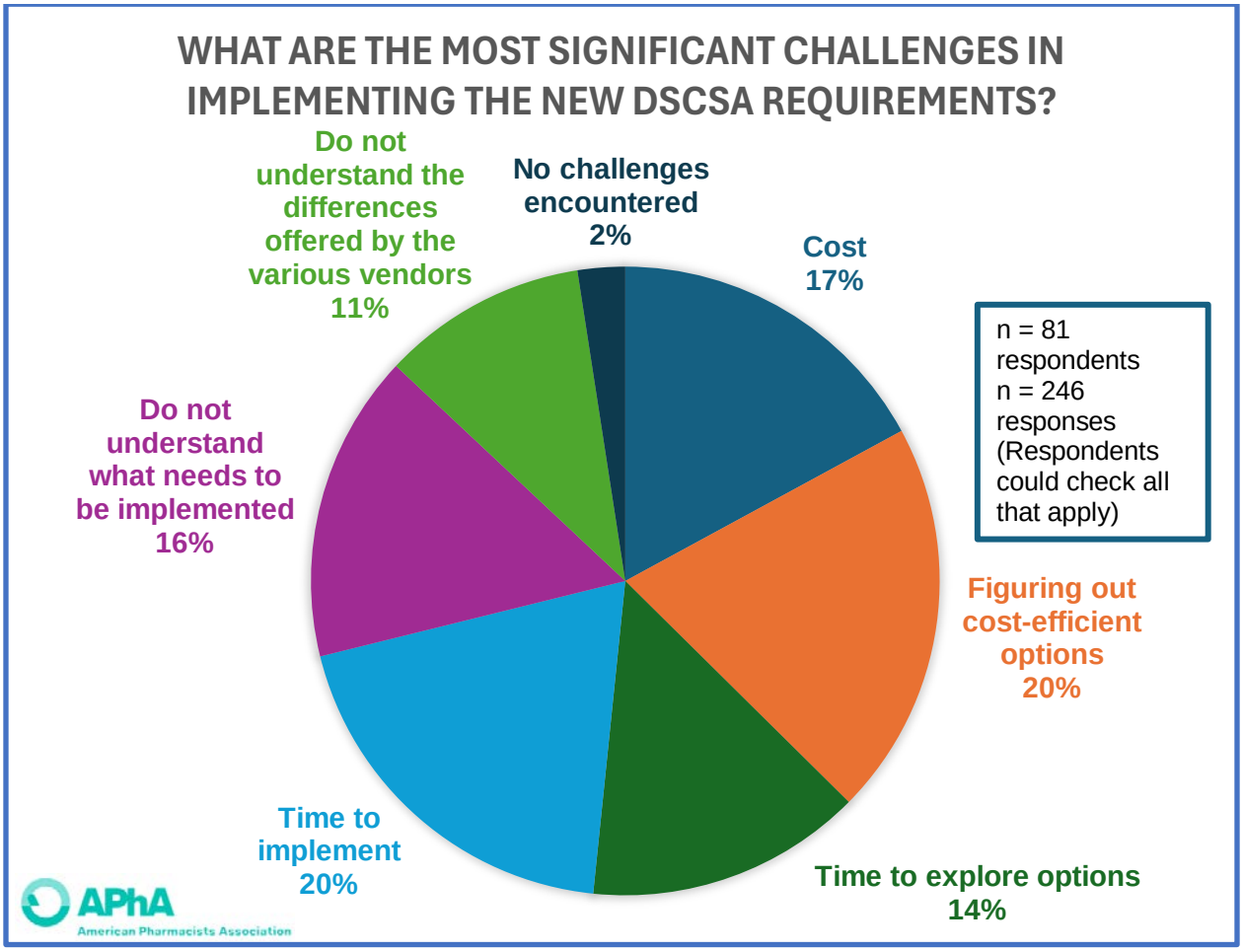
#	Answer	%	Count
1	My pharmacy has not yet looked into implementing new systems and processes for the new requirements.	19.75%	16
2	My pharmacy is exploring different vendors or options with my wholesalers to implement the new systems and processes for the new requirements.	13.58%	11
3	My pharmacy is using a vendor and we are currently working on implementation.	24.69%	20
4	My pharmacy is using a vendor and our systems are implemented and stabilized.	7.41%	6
5	My pharmacy is relying on our wholesaler and we are currently working on implementation.	23.46%	19
6	My pharmacy is relying on our wholesaler and our systems are implemented and stabilized.	6.17%	5
7	Other (Please, explain.)	4.94%	4
	Total	100%	81

In total, only 14.8% of the respondents have fully implemented and stabilized systems. A third of all respondents have either not looked into implementing new systems and processes yet or are still determining the best vendors or options to implement new systems. In the "Other" category, only one respondent stated they have fully implemented – the remaining three pharmacists stated they have not yet been implemented. One noted that vendors are not ready to send data to their solution service provider.

Of the independent pharmacy respondents that completed the survey, 20.3% indicated they have not yet looked into implementing new systems, and an additional 14.1% are still exploring their options. Roughly 10% of the 6 survey respondents who work in an independent pharmacy setting have fully implemented and stabilized systems.

- **Q3 - What are the most significant challenges in implementing the new DSCSA requirements?**

Participants were given several options to choose from and could select all that apply.

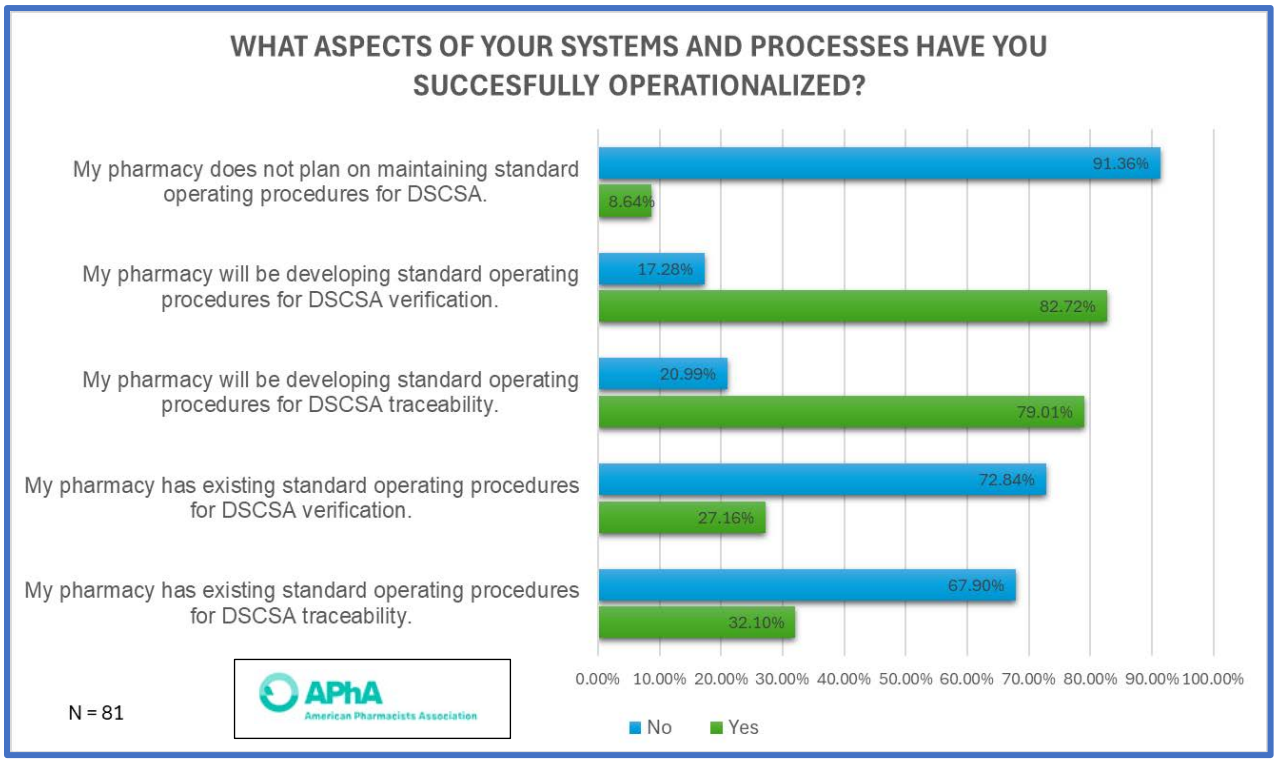


Roughly 40% of all respondents acknowledged that cost is a challenge in implementing the requirements. Roughly 35% acknowledged that finding time to implement the requirements has been a challenge and 25% do not understand what needs to be done as a next step.

For the independent pharmacy respondents, over half identified cost, time to implement, and understanding what needs to be implemented as significant challenges.

- **Q4 - What aspects of your systems and processes have you successfully operationalized?**

Participants were given 5 options to choose from. Because the other questions were focused on whether the dispenser had implemented and stabilized their systems and processes, we posed this question to focus on whether the respondents had standard operating procedures (SOPs) that would sustain and support operationalization.



Over 91% of the respondents said that they plan to maintain SOPs for DSCSA, generally. However, most respondents reported that they did not have SOPs, but plan to develop them. Sixty-eight percent and 73% of respondents indicated that their pharmacy does not have existing SOPs for DSCSA traceability and verification, respectively. However, 79% and 83% of the respondents stated that their pharmacy will be developing those SOPs, for verification and traceability, respectively.

- **Q5 - What additional information do you need to successfully implement the new DSCSA requirements by November 27, 2024?**

Participants were given a free text box to respond to this question and were required to insert text into the box to complete the survey.

Several respondents reported that the additional costs of implementing DSCSA is overwhelming for independent pharmacies and as reflected above, additional resources and time are needed to implement the security requirements. For example:

> *"The financial situation of community pharmacy makes it nearly impossible to initiate ANY additional regulatory mandates now or in the future. The payment model of pharmacy is beyond unsustainable."*
>
> *"We cannot afford any additional cost in equipment or labor to implement DSCSA. I don't know how we are going to afford to do this."*

Overwhelmingly, respondents indicated that clearer guidance for pharmacies/dispensers is needed. Many respondents requested template SOPs or clearer clarification of what is expected and required for dispensers. For example:

> *"Exact clear-cut directions. What is required and what isn't. Does every item need [to be] scanned on ordered receipt? Does every item need [to be] scanned when filling /document which lot and expiration the patient gets? Just too many unknowns."*
>
> *"Not sure where to even start. Little to no guidance in independent pharmacy."*
>
> *"Exactly what pharmacies are supposed to do! No one has put in plain words what we are to do."*
>
> *"To know what the heck it is, and how to implement it. Lack of information and guidance has been a hindrance."*
>
> *"Clearer and timely guidance from our vendor."*
>
> *"Clear bullet point requirements."*

Several respondents described challenges that they have encountered during implementation, particularly related to upstream connections and GLNs. For example:

> *"Wholesalers are NOT ready and we cannot comply until they are ready."*
>
> *"There have been significant hurdles with GLNs what is active, what is not, who is maintaining, where did some come from, etc."*

"Pending clarification of our GLNs assigned by the wholesaler (they don't match), information on how information will be transmitted/obtained, and pharmacy software's roll-out of their program."

"The GLN process is messy and confusing. Many inaccuracies exist and need to be corrected."

"We need real EPCIS data so we can work through the item receiving verification workflow and then the data exception handling and its reporting to the supplier and then how they will resolve the exceptions."

Discussion

- ***Progress***

APhA appreciates FDA's establishment of the 1-year stabilization period for supply chain trading partners to comply with the final enhanced drug distribution security (EDDS) requirements under DCSCA that went into effect on November 27, 2023. We strongly believe that this delay will help achieve DSCSA's prescription drug product traceability and security goals while minimizing supply disruptions and avoiding interruptions to patient care.

Although the survey received 81 responses, it was higher than expected given that pharmacies of all sizes currently are dealing with significant economic challenges due to new Centers for Medicare & Medicaid Services (CMS) regulatory requirements and pharmacy benefit manager (PBM) business practices that went into effect on January 1, 2024. These challenges are so great that pharmacies are closing at a disheartening rate throughout the country, and it is a struggle to keep pharmacy doors open. Pharmacies and pharmacists are focusing on providing patient care amid this crisis.

As the survey results show, the respondent dispensers have made some progress in implementing the DSCSA requirements. Although there may be a perception by some that dispensers are not aware of these DSCSA requirements, the data shows that nearly 87% are aware, but there are several hurdles to fully implement. Nearly 20 percent have not started implementing, yet nearly 50% are working on implementation and roughly 14% report that they have implemented and stabilized systems and processes.

- ***Challenges***

Not surprising, cost is a significant concern for dispensers. They are on a quest for cost-efficient options, but nearly 34% do not have the time to explore options or begin to implement. There continues to be confusion about what they need to do and how to compare the services that different vendors offer. Although not explored in the survey, APhA has heard from members that vendors regularly are contacting them with offers and packages, but dispensers are unclear what elements are needed to meet the requirements of DSCSA and what are unnecessary bells and whistles. Independent pharmacy dispensers are yearning for information. APhA has

provided educational sessions at conferences and webinars, but the messages need to ring farther, wider, and come from authoritative sources, such as FDA and boards of pharmacy.

- ***Upstream stabilization***

Some respondents that have implemented the requirements through solution service providers are frustrated that they are paying a monthly fee, but no data is flowing from their provider. As FDA is likely to hear from this RFI, manufacturers have not universally put in place systems and processes and stabilized exchange of data with their wholesaler trading partners. As a result, data is not flowing from manufacturers to wholesalers, so data is not subsequently flowing to dispensers. Stabilization of systems and processes flows downstream, and stabilization must be implemented in a stepwise approach. The findings in APhA's survey showing that only a small percentage of respondent dispensers have implemented and stabilized the new requirements are not surprising. Universal interoperability and stabilization in the dispenser sector will only be realized after the upstream supply chain has implemented and stabilized their connections and systems and processes. Many wholesalers are still focusing on maturing connections with their manufacturer trading partners and are either just beginning to discuss onboarding with dispensers or have yet to begin. As a result, dispensers cannot stabilize and mature interoperable connections with their trading partners until the data consistently and reliability flows from upstream manufacturers, repackagers, and wholesalers.

Recommendations

We appreciate the outreach and education that FDA has done to inform stakeholders of the DSCSA EDDS requirements and expectations during the stabilization period. However, we respectfully suggest that FDA bolster and intensify the level of outreach and education for drug supply chain interoperability to be stabilized by November 27, 2024. We commit to do the same and APhA is available to support FDA's efforts. Here are some recommendations for FDA to consider in enhancing outreach and education:

- ***Phased targeted outreach***

Drug supply chain stakeholders, including APhA, called on FDA to set forth a phased, stepwise approach for implementation of the EDDS requirements. A stepwise approach would have facilitated implementation focus and stabilized connections from upstream to downstream. As the survey results show, data is likely not flowing to dispensers because the focus is on manufacturer to wholesaler upstream connections. More outreach and education are needed upstream to ensure stable and mature interoperability between manufacturers and wholesalers, before focusing on dispensers. Therefore, we recommend that FDA establish a plan and schedule to conduct intensified phased, targeted outreach to trading partner sectors, starting with manufacturers and repackagers, then wholesalers, then dispensers.

This outreach, across stakeholders, can come through letters and other communications to FDA-registered manufacturers and repackagers for finished prescription drugs (or specifically DSCSA covered products), letters and other communications to wholesalers registered in FDA's Wholesale Distributor and Third-Party Logistics Provider database, and letters and other communications to state licensed pharmacy dispensers via the National Association of Boards of Pharmacy (NABP) and the state boards of pharmacy.

Additionally, FDA should consider holding virtual and/or in-person town halls regionally and globally to reach stakeholders, again, in a phased targeted approach for stakeholder sectors.

- ***Clear, concise messages***

The DSCSA has many requirements that have been implemented at various times over the past 10 years. FDA has done a masterful job providing regulatory guidance to the supply chain on what the requirements are, interpretations of statutory language, and how to comply with the many requirements. That said, for many stakeholders, the regulatory and statutory language is difficult to understand, and it is unclear how to apply it to a dispenser's day to day systems and operations. As the survey data shows, some respondent dispensers are confused about what they need to do to comply. They want clarity.

We recommend that FDA focus on clear messaging for dispensers, both from FDA and in educating boards of pharmacy to amplify messaging and educate state pharmacy licensees. For example, most independent pharmacy dispensers will either work with their wholesaler(s) or a solution service provider. Messaging should be focused on the types of ways dispensers can facilitate compliance and what questions they could ask to determine the right pathway. It is unrealistic for FDA to expect busy dispensers/pharmacists to read the guidances and understand the nuances. Focus should be on simplified messages of what they need to know. Additionally, FDA could do more to help pharmacies understand that they should have SOPs for what they need to do to comply related to traceability and verification. The survey data shows that most of the respondents did not have SOPs, but plan to have them. It is unclear from the survey responses if they understand what should be included in SOPs.

- ***More outreach to boards of pharmacy***

The boards of pharmacy are essential in providing outreach and education to state pharmacy licensee dispensers regarding implementation, obligations, and expectations under DSCSA. We highly recommend that FDA provide more hands-on outreach and education to boards of pharmacy, including providing a train-the-trainer approach so board staff and members can amplify the materials and messaging.

- ***Heightened two-way communication with stakeholders***

APhA believes that increased and enhanced two-way communication is essential to ensure stabilized interoperability across the drug supply chain by November 27, 2024. We recommend monthly, formal or informal, two-way discussions for supply chain stakeholders and associations that represent them to share progress, challenges, and identify ways that FDA can support continued progress. FDA could also repeat this request for information on a quarterly basis to identify progress across the supply chain. Quite simply, we cannot stress enough how important we believe it is for FDA to be more hands on in two-way communications with the supply chain.

Conclusion

APhA appreciates FDA's ongoing efforts in developing guidance, standards, and other information to assist dispensers in complying with DSCSA's requirements. We look forward to continuing to support FDA's efforts and working to improve the safety and security of the drug supply chain. If you have any questions or require additional information, please contact me at ibernstein@aphanet.org.

Thank you,

Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President, Practice, Policy, and Partnerships