

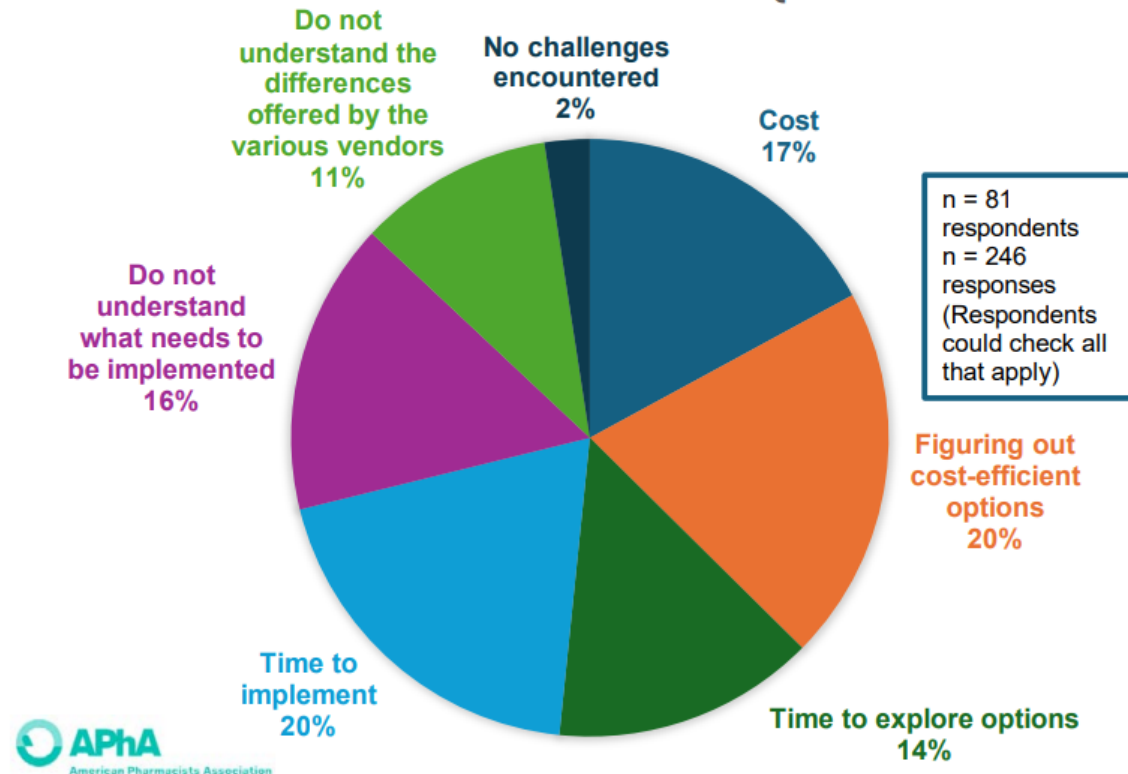


PDG-FDA Town Hall

September 24, 2025

Most Significant Challenge in 2024

WHAT ARE THE MOST SIGNIFICANT CHALLENGES IN IMPLEMENTING THE NEW DSCSA REQUIREMENTS?

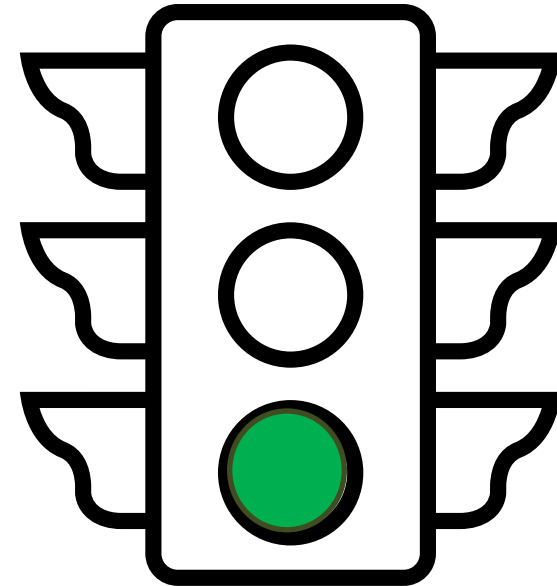


Concerns Previously Raised By Members

- Funding Cost of Implementation
- Finding Time to Implement
- Understanding Requirements
- Developing and Maintaining SOPs
- Training Staff

Member Update Today

- Members have appreciated the extensions and have been preparing for the anticipated compliance date.
- As such, members have asked APhA for compliance assistance for dispensers.



APhA Asks FDA to:

- 1) Provide simplified, up-to-date educational resources for community pharmacies.
- 2) Plan for future responses to presidential disasters and emergency declarations, to allow FDA to promptly temporarily waive or modify requirements and provide guidance to pharmacists and pharmacies regarding any flexibilities and remaining in compliance in response to natural disasters and other uncontrollable events.
- 3) Permit bona fide business reasons and other actions taken in good faith by dispensers when coming into compliance during the initial start, particularly when dispensers cannot comply due to other upstream members of the supply chain being out of compliance.
- 4) Use enforcement discretion with individual pharmacies when the employer, rather than the pharmacist, is out of compliance with DSCSA protections when the pharmacist acts in good faith and in accordance with their professional judgment.
- 5) Recognize that pharmacists and pharmacies may not be responsible for vendor technology errors or failures.



Thank you!

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