

May 13, 2024

Re: Agency Information Collection Activities; Proposed Collection; Comment Request; Proposed Small Dispensers Assessment Under the Drug Supply Chain Security Act [Docket No. FDA-2024-N-0668]

Submitted electronically via www.regulations.gov to Docket No. FDA-2023-N-3103

Dear Food and Drug Administration staff,

The American Pharmacists Association (APhA) appreciates the opportunity to submit feedback on proposed collection of information related to FDA's proposed Small Dispensers Assessment under the Drug Supply Chain Security Act.

APhA leads and advances 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's members own and are employed by independent pharmacies across the country.

Concerns with small sample size

We appreciate FDA's ongoing efforts to efficiently implement the DSCSA and are pleased that FDA shortly will be conducting the small dispenser assessment, as required under the law. We reviewed the description of the information collection as outlined in the Federal Register (FR) notice and are concerned that the sample size may be too small. According to various sources, there are roughly 19,450 independent pharmacies in the US.^{1 2} The average independent pharmacy employs 12 full and part time staff.³ Consequently, a majority of independent pharmacies are small dispensers.

According to the FR notice, FDA plans to survey 200 small dispensers, which will represent roughly 1% of the independent pharmacies in the US. It is unclear if such a small sample size

¹ McKinsey & Co. <https://www.mckinsey.com/industries/healthcare/our-insights/meeting-changing-consumer-needs-the-us-retail-pharmacy-of-the-future>, March 17, 2023.

² NCPA & Cardinal Health. <https://www.cardinalhealth.com/content/dam/corp/web/documents/Report/cardinal-health-2023-ncpa-digest.pdf>, October 2023.

³ *Id.*

will provide FDA with sufficient confidence to adequately assess the cost and burdens of the software, hardware, and practical implementation on small dispensers and, if appropriate, determine alternative methods of compliance that do not impose undue economic hardship for small businesses.

Concerns with timing of small dispenser assessment

As APhA noted in our December 7, 2022 letter⁴ to FDA, there are several steps that must be performed under the law related to the small dispenser assessment, including publishing the statement of work for public comment prior to conducting the assessment, conducting the assessment, publishing the final assessment for public comment, holding a public meeting to discuss the assessment, and issuing alternative methods of compliance, if appropriate. It is hard to believe that all of these steps will be complete before the end of the stabilization period. Because FDA knows now that the statutory steps for the small dispenser assessment will not be completed with adequate time for small business dispensers to implement the requirements by November 27, 2024, we would like FDA to consider providing continued enforcement discretion for small dispensers. We will be reaching out shortly with an official request to meet on this issue.

Conclusion

APhA welcomes the opportunity to help FDA in outreach and conduct of the small dispenser assessment. We appreciate FDA's ongoing efforts to assist pharmacists and pharmacies in complying with DSCSA's requirements to improve the safety and security of the drug supply chain. Feel free to contact me for follow up at ibernstein@aphanet.org.

Thank you,



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American Pharmacists Association

⁴ Letter from Ilisa Bernstein, PharmD, JD (APhA) to Jill Furman, JD and Connie Jung RPh, PhD (FDA) *Request for Enforcement Discretion for DSCSA Small Business Dispensers*
<https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=upNwh8oSt34%3d>, December 7, 2022.