*Submitted electronically to regulations.gov and https://www.reginfo.gov/public/do/PRAMain*

Dec. 18, 2025

The Honorable Marty Makary, M.D.
Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Ave
Silver Spring, MD 20993

**Re: Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Small Dispensers Assessment Under the Drug Supply Chain Security Act**

Dr. Makary,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to FDA's *Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Small Dispensers Assessment Under the Drug Supply Chain Security Act*.

NCPA represents America's community pharmacists, including 18,900 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members employ 205,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

The 2025 *NCPA Digest*, sponsored by Cardinal Health, reported that the average independent pharmacy had about 12 total workers. Therefore, many of NCPA's members will fall under the FDA's definition of a small dispenser for the exemption to the enhanced drug distribution security requirements granted until November 2026. NCPA recognizes the value to the supply chain of FDA's use of phased exemptions. We are eager for the completion of the small dispenser assessment.

NCPA urges FDA to continue education outreach to dispensers where appropriate. Coordinating with state boards of pharmacy should be expedient because every pharmacy has a permit from a board of pharmacy to operate and a designated pharmacist in charge as primary point of contact. Information on compliance and enforcement carries extra weight when it comes from a regulatory body.

At this time, dispensers of all sizes are adjusting to process changes related to the enhanced drug distribution system around saleable returns and 340B contract pharmacy operations since the end of the distributor exemption in August 2025. For example, poor durability of the 2D barcodes printed on labels may result in an otherwise saleable return being rejected by the wholesale distributor. This problem with the EDDS can disproportionately affect small dispensers that are not part of a larger corporation to absorb the cost. The cost of onboarding with a solution provider continues to be a significant challenge to pharmacies. These costs should be accounted for in dispensing fees that are part of prescription benefit reimbursement calculations, but surveys of the industry show no corresponding increase in reimbursement or an ability to effectively negotiate for it.

As a final, general comment NCPA asks FDA to gather information from the supply chain on best practices for addressing and documenting specific patient need and emergency situations that tracing data or electronic product verification is not available.

Additionally, NCPA provides the following comments to FDA's notice:

**Sample Size**

NCPA appreciates FDA's willingness to increase the estimated number of respondents who will be sent an invitation to 18,430, and increasing the estimated number of respondents who will complete the assessment questionnaire to 922, up from FDA's earlier estimate of 200 respondents. To put this respondent estimate in perspective, past NCPA surveys on various issues to membership have yielded 815 respondents out of 10,000 surveyed (in February 2024); 467 respondents out of 4,135 surveyed (in October 2024); and 405 respondents out of 10,450 surveyed (in September 2025).

NCPA appreciates that FDA's intention of the proposed information collection is to understand the experiences of small dispensers, and to develop descriptions of themes of those experiences.

**Recordkeeping**

FDA recommends that any records generated by a respondent while responding to the assessment questionnaire be maintained as an entity would in the normal course of business. FDA recommends that the responses to the assessment questionnaire be maintained by the respondent for at least 1 year after FDA publishes its final report of the assessment. **NCPA advises FDA to keep this as a recommendation, and not a requirement, for pharmacies.**

**Conclusion**

NCPA appreciates the opportunity to share with FDA our comments to FDA's *Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Small Dispensers Assessment Under the Drug Supply Chain Security Act*. Please let us know how we can assist further, and should you have any questions or concerns, please feel free to contact me at lisa.schwartz@ncpa.org or 703.683.8200.

Sincerely,

Lisa Schwartz
Senior Director, Professional Affairs
National Community Pharmacists Association