

Submitted electronically to: www.regulations.gov

May 13, 2024

Dockets Management Staff
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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](#)]

Dear Dockets Management Staff:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to FDA on its *Agency Information Collection Activities; Proposed Collection; Comment Request; Proposed Small Dispensers Assessment Under the Drug Supply Chain Security Act* notice.

NCPA represents America's community pharmacists, including 19,400 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 represent a \$94 billion healthcare marketplace, employ 230,000 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.

According to the FDA, after the proposed DSCSA Small Dispensers Assessment is established, volunteers interested in participating will enroll by submitting participant information in the following webpage: <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-dscsa-assessment-small-dispensers>. Only one point-of-contact per company should be provided for the enrollment. The respondents will be expected to provide the following information:

- Contact information (name, email address, phone number, mailing address)
- Confirmation that the respondent is a dispenser that has 25 or fewer FTEs or you are an individual representing a small dispensers' third-party entity (e.g., solution providers, wholesale distributors, consultants)
- Commitment to answer the questions contained in the assessment within 45 days of receiving
- Applicable state license number

The assessment is expected to be completed within the proposed duration of 45 days of receiving, and participants will be expected to provide responses to FDA via the designated FDA online tool/platform. FDA estimates that no more than 200 respondents (i.e., the submitter or point of contact) will submit an enrollment.

FDA estimates reporting, record-keeping, and disclosure burdens for the DSCSA Small Dispensers Assessment to be as follows:

Annual reporting. FDA estimates that no more than 200 respondents (i.e., the submitter or point of contact) will submit an enrollment, and that it will take, based on the various levels of resources by company, an average of 0.5 hours to complete an enrollment to FDA. FDA estimates that it will receive no more than 100 participants for the assessment. The estimated total time for respondents to submit an enrollment to participate in the assessment is 100 hours. FDA estimates that it will take, based on the various levels of resources by company, an average of 2 hours to compile and submit a response to the assessment per response. The estimated total number of hours for submitting a response to the assessment would be 200 hours. The total hours for the estimated reporting burden are 300 hours.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

DSCSA small dispensers assessment	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Enrollment	200	1	200	0.5	100
Assessment Questions Response	100	1	100	2	200
Total	300	300

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Annual recordkeeping. FDA estimates that no more than 200 respondents will have recordkeeping activities related to assessment participation. FDA believes that it will take 0.5 hour per response to ensure that the documents related to enrollment to participate in the assessment are retained properly for a minimum of 1 year after the assessment is completed (as recommended by FDA). The resulting total to maintain the records related to submitting a request is 100 hours annually. For retaining records related to the response to the assessment properly for a minimum of 1 year after the assessment is completed (as recommended by FDA), FDA estimates that it will take approximately 0.5 hour. As noted above, FDA estimates that the 100 respondents will submit one response for the assessment. The estimated total for maintaining records related to the assessment is 50 hours. The total recordkeeping burden is estimated to be 150 hours.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

DSCSA small dispensers assessment	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records related to enrollment	200	1	200	0.5	100
Records related to Assessment Questions Response	100	1	100	0.5	50
Total	300	150

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Annual third-party disclosure. For those assessment participants that involve third-party activities, FDA is taking into consideration the time that participants will spend coordinating with third-party entities (e.g., solution providers, wholesale distributors, consultants). For the enrollment, FDA estimates that 75 respondents will work with their respective partnering entities and the average number of partnering entities will be 2. FDA estimates that each respondent will spend 2 hours coordinating with each third-party entity. Thus, for 150 respondents with an average of 2 partnering entities, the estimated total burden for coordinating with partnering entities related to the enrollment is 75 hours. FDA estimates that for each of the 100 lists of assessment responses, it will take approximately 2 hours to coordinate with each partner, resulting in a total of 200 hours. The total estimation for third-party disclosure burden is 275 hours:

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN¹

DSCSA small dispensers assessment	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Coordination with third-party entities related to enrollment	75	2	150	0.5	75
Coordination with third-party entities related to assessment questions response	50	2	100	2	200
Total	125	275

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Given that NCPA represents 19,400 independent community pharmacies, NCPA believes that a sample size of 200 respondents is rather small, and NCPA advises FDA to seek a greater sample size. NCPA members stand ready to assist FDA in its DSCSA Small Dispensers Assessment, and we would like further guidance and advice on how we can help assist disseminating the Assessment. Approximately, 95 percent of our independent pharmacy locations have 25 or fewer FTEs. According to our most recent digest, in 2022, independent pharmacy owners on average employed 12 total full-time (7.4 average FTEs) and part-time (4.5 average FTEs) equivalent employees per location.¹

Please let us know how we can assist further, and should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,



Steve Postal, JD
 Director, Policy & Regulatory Affairs
 National Community Pharmacists Association

¹ 2023 NCPA Digest. October 2023.