Attachment C Small Dispensers Assessment Under the Drug Supply Chain Security Act

Questionnaire

The survey we are conducting is on behalf of the U.S. Food and Drug Administration (FDA).

INTRODUCTION/START PAGE

(Title/Header) FDA's DSCSA Small Dispensers Assessment

PURPOSE:

- The Drug Supply Chain Security Act (DSCSA) directs FDA to enter into a contract with a private, independent consulting firm with expertise to conduct a technology and software assessment that looks at the feasibility of dispensers with 25 or fewer full-time employees conducting interoperable, electronic tracing of products at the package level. The assessment must determine whether:
  - ☐ the necessary software and hardware is readily accessible to such dispensers;
  - ☐ the necessary software and hardware is prohibitively expensive to obtain, install, and maintain for such dispensers; and
  - ☐ the necessary hardware and software can be integrated into business practices, such as interoperability with wholesale distributors, for such dispensers.
- The DSCSA also instructs FDA to consider the assessment and provide provisions for alternative methods of compliance including establishing a process for small dispensers to request a waiver and establishing timelines for compliance if it is determined that the requirements for interoperable electronic tracing of products at the package level would result in undue economic hardship.

FDA Resources:

[DSCSA Assessment of Small Dispenser webpage](#)
[DSCSA main webpage](#)

ASSESSMENT INFORMATION:

- As we are not asking for specific details about who is responding to the assessment, the information provided in this assessment will be anonymized in any public report or web-posting.
- This assessment has 32 questions. Please complete all questions by choosing the best response that describes your situation or estimate. Responding to all questions to help make this a robust assessment.
- As noted, some responses are required before moving to the next question. In addition, there are opportunities to provided additional information in the free text fields.
- If you exit the assessment before completing all questions, your entries will be saved using a cookie stored in your browser. You can return to your assessment with your previous responses saved, if you use the same device and web browser (without clearing cookies).

CLOSING DATE OF ASSESSMENT:

- Closing date of assessment: Please complete your response by XXX XXX, XXXX, time EST.

ASSESSMENT

A. Demographic Information

1. How many pharmacy location(s) does your business operate?

   [required numeric response]

2. What is the average number of prescriptions filled in a day per pharmacy location? The "per pharmacy" amount can be found by adding up the amounts from all of your pharmacy locations and dividing by the number of your pharmacy locations.

   [required free text response]

3. What is the average annual revenue associated with pharmacy operations per location? The "per pharmacy" amount can be found by adding up the amounts from all of your pharmacy locations and dividing by the number of your pharmacy locations.

   [required free text response]

4. What is the zip code(s) of the pharmacy location(s)? If multiple, please list all.

   [required free text response]

5. **A)** Check any of the following services offered in your daily operations (offered in at least one of your locations). [response required]
   - Medication Therapy Management (general)
   - Chronic Diseases Screening/Management (Diabetes, Blood Pressure, Cholesterol)
   - Immunizations

- Compounding
- Durable Medical Equipment (DME)
- Other services (describe in text box) – [include free text option]
- No additional services offered

B) Describe how these services affect your pharmacy operations [required free text response].

6. How many full-time employees does your business employ to work in pharmacy operations per location (examples: dispensing prescription drugs, technical and operational support, purchasing/procurement of prescription drugs)?

[required numeric response]

B. Current State of Electronic DSCSA Data Exchange

7. Check all the types of software system(s) and hardware you currently utilize to facilitate the exchange of electronic DSCSA data exchange for prescription drugs?
   - In-house pharmacy system
   - A separate software application or system to manage my DSCSA data by a third-party
   - Wholesale distributor(s) (e.g., portal)
   - Manufacturer(s)/Repackager(s) system (e.g., portal)
   - A separate software application or system that manages my trading partner(s) DSCSA data by a third-party
   - Other, please describe below.

   [optional free text]

8. In the last 12 months, how much of the DSCSA data you are exchanging with your trading partners is being exchanged by electronic methods (not only as printed paper data)?
   - None
   - Some
   - All

   Comment field [optional free text]

If the response is None, then only paper-based data questions will be shown.
If the response is Some, both sets of questions will be shown.
If the response is All, then only electronic-based data questions will be shown.

PAPER-BASED DSCSA DATA QUESTIONS:

9. **A)** For DSCSA data received in paper format from a trading partner: In the last 12 months, estimate the average number of orders per pharmacy location for which the DSCSA data was provided only in a printed paper format. The "per pharmacy" amount can be found by adding up the amounts from all of your pharmacy locations and dividing by the number of your pharmacy locations.

   [required free text response]

B) In the last 12 months, estimate the average number of orders per pharmacy location that you received had at least one discrepancy between the physical product and the DSCSA data received in paper format from a trading partner? The "per pharmacy" amount can be found by adding up the amounts from all of your pharmacy locations and dividing by the number of your pharmacy locations.

[required free text response]

C) What are the most frequent types of errors you have encountered with DSCSA data received in paper format? – e.g. Missing product, extra product, duplicate data, missing data, incorrect data. Please explain [required free text response]

10. **A)** For DSCSA data received in paper format from a trading partner: In the last 12 months, estimate how long it took in calendar time [in business days], on average, to resolve a discrepancy from the time of discovery (resolution may include coordinating and reaching an agreement with the selling trading partner)?
[required free text response]

    B) What unique challenges arose from these situations? [required free text response]

11. For DSCSA data received in paper format from a trading partner: In the last 12 months, estimate how long it took in actual employee time spent [in business days], on average, to resolve a DSCSA data discrepancy from the time of discovery (resolution may include coordinating and reaching an agreement with the selling trading partner)? 1 business day defined by an 8 hour work day for an FTE
[required free text response]

ELECTRONIC-BASED DSCSA DATA QUESTIONS:

12. **A)** For DSCSA data received in electronic format from a trading partner: In the last 12 months, estimate the number of orders per pharmacy location for which DSCSA data was provided in an electronic format.
[required free text response]

    B) In the last 12 months, estimate the number of orders per pharmacy location that you received had at least one discrepancy between the physical product and the electronic DSCSA data received from a trading partner?
[required free text response]

    C) What are the types of errors you have encountered with DSCSA data received in electronic format? – e.g. Missing product, extra product, duplicate data, missing data, incorrect data. Please explain
[required free text response]

13. **A)** For DSCSA data received in electronic format from a trading partner: In the last 12 months, estimate how long it took in calendar time [in business days], on average, to resolve a DSCSA data discrepancy from the time of discovery (resolution may include coordinating and reaching an agreement with the selling trading partner)?
[required free text response]

   B) What unique challenges arose from these situations? [required free text response]

14. What has your business done in preparation for the DSCSA requirements for interoperable, electronic tracing of products at the package level? [required response]
    - Our business has systems and processes in place for electronic DSCSA data with our trading partners, and we are receiving electronic DSCSA data from our trading partners.
    - Our business has systems and process in place for electronic DSCSA data with our trading partners, but we are not receiving electronic data yet.
    - Our business is currently testing systems and processes for exchange of electronic DSCSA data with our trading partners.
    - Our business is in discussions with our trading partners for options for e exchange of electronic DSCSA data.
    - Our business has not started any steps toward exchange of electronic DSCSA data.

    Provide any additional information here: [optional free text response]

15. Estimate the amount of money and time (in the three categories listed below) your business has already spent per pharmacy location to implement DSCSA requirements for interoperable, electronic tracing of products at the package level. The "per pharmacy" amount can be found by adding up the amounts from all of your pharmacy locations and dividing by the number of your pharmacy locations.

    Capital expenditure (hardware and software) per pharmacy already spent [in $]: Required free text
    Personnel Costs (total including management) per pharmacy already spent [in $]: Required free text
    Personnel Time (total including management) per pharmacy already spent [in business days]: Required free text

16. If your business has connected DSCSA system(s) with a trading partner(s), have you experienced significant technical issues?
    A) Not applicable as our business has not connected our DSCSA system(s) with trading partners
    B) Yes, we have connected and have experienced significant technical issues
    C) No, we have connected and have not experienced significant technical issues

       If yes, please describe the type of significant technical issues experienced [optional free text response]

17. If your business uses a DSCSA portal provided by a trading partner(s), have you experienced significant technical issues?
    A) Not applicable because we do not use a DSCSA portal
    B) Yes, we use a DSCSA portal and have experienced significant technical issues
    C) No, we use a DSCSA portal and have not experienced significant technical issues
       If yes, please describe the type of technical issues experienced [optional free text response]

18. In the last 12 months per pharmacy location: for prescription drugs that are encoded with a product identifier, including a 2D data matrix barcode, estimate the number of times that your business has scanned or read the data encoded in a 2D data matrix barcode?

    [optional free text response]
    - Or, our business has not been routinely scanning or reading the 2D data matrix barcodes on prescription drugs during any pharmacy operations

    - Provide additional information here [optional free text reponse]

19. In the last 12 months per pharmacy location: for prescription drugs that are encoded with a product identifier, including a 2D data matrix barcode, estimate the number of times that your business had problems scanning or reading the data encoded in the 2D data matrix barcode?

    [optional free text response]

    - Our business has not had problems scanning or reading the data encoded in the 2D data matrix barcode on prescription drugs during any pharmacy operations

    Provide additional information here [optional free text response]

20. Check all the reasons that your business experienced problems scanning or reading the data encoded in the 2D data matrix barcode in the last 12 months?
    - Barcode quality
    - Multiple barcodes on the same package
    - Missing or inaccurate data
    - Scanner performance (hardware)
    - Software issue
    - Other (please describe below)

    What is your process for handling barcode discrepancies, including when manual steps are taken by your staff after an automated process was inadequate or failed? [required free text response]

C. General Perceptions of the Future State of Electronic DSCSA Data Exchange

21. In your business's current understanding of DSCSA requirements for enhanced drug distribution security/interoperable, electronic tracing of products at the package level: if cost was not an issue, is the necessary software and hardware readily accessible to your business? (Please note costs are asked about in subsequent questions.)
    - Yes
    - No

    Please explain how or why [required free text response]:

22. In your business's current understanding of DSCSA requirements for interoperable, electronic tracing of products at the package level: can the necessary software and hardware be integrated into business practices between trading partners such as wholesale distributors and your business?
    - Yes
    - No

    Please explain how or why (required free text response):

23. Estimate how much it will cost per pharmacy location to implement interoperable, electronic tracing of products at the package level requirements in the categories below. Potential upfront considerations include the money and time it might take to research requirements, purchase, install, and quality check necessary equipment and technology, train employees, etc. Potential on-going maintenance considerations include the money and time to quality check systems, maintain systems, update systems, trouble shoot systems, provide refresh training to employees, etc. The "per pharmacy" amount can be found by adding up the amounts from all of your pharmacy locations and dividing by the number of your pharmacy locations.

Expected Upfront Capital Expenditure (hardware and software) per pharmacy [in $]: Required free text
Expected On-going Maintenance Expenditures per pharmacy [in $ per year]: Required free text
Expected Upfront Personnel Costs (total including management) per pharmacy [in $]: Required free text
Expected Upfront Personnel Time (total including management) per pharmacy [in business days]: Required free text
Expected On-going Personnel Costs (total including management) per pharmacy [in $ per year]: Required free text
Expected On-going Personnel Time (total including management) per pharmacy [in business days per year]: Required free text

24. Estimate how many additional full-time employees you expect to hire to be able to comply with DSCSA requirements for interoperable, electronic tracing of products at the package level?

    [Required numeric response]

25. In your business's current understanding of DSCSA requirements for interoperable, electronic tracing of products at the package level: would obtaining, installing, and maintaining the necessary software and hardware create undue economic hardship for your business?
    - Yes
    - No

    Please explain how or why with any specific causes of undue economic hardship or not (required free text response):

Specifics of the Future State of Electronic DSCSA Data Exchange

26. Do any of your business practices or operations need to change to meet the DSCSA requirements for interoperable, electronic tracing of products at the package level?
    - Yes
    - No

    Please explain how or why [required free text response]

27. Aside from what you already have in place, check all possible new software and hardware types that you anticipate using to comply with DSCSA requirements for interoperable, electronic tracing of products at the package level.
    - In-house pharmacy system
    - A separate software/hardware system to manage my DSCSA data n by a third-party
    - Wholesale distributor(s) system (e.g., portal) or their system managed by a third-party
    - Manufacturer(s)/Repackager(s) system (e.g., portal) or their system managed by a third-party

28. How likely are you to make changes to your software and hardware so that you can comply with the DSCSA requirements for interoperable, electronic tracing of products at the package level?
    A) Very likely
    B) Somewhat likely
    C) Somewhat Unlikely
    D) Very unlikely

29. If your business is not currently exchanging DSCSA data with trading partners in a fully electronic format, do you expect to be able to do so by November 27, 2026?
    - Yes
    - No

    Please explain how or why [required free text response]

30. If you do not expect to be fully compliant with the DSCSA requirements for interoperable, electronic tracing of products at the package level by November 27, 2026, what are the key barriers? Check all that apply. Please elaborate on why or how in the free text portion of the response.
    - Accessibility of necessary software and hardware
    - Cost to obtain, install, and maintain necessary software and hardware
    - Integration of necessary software and hardware into business practices, e.g. in-house pharmacy or connectivity with trading partners
    - Available personnel with relevant skills
    - Quality check
    - Data security concerns
    - Other barriers

    [optional free text response]

31. What other impacts do you expect DSCSA requirements for interoperable, electronic tracing of products at the package level to have on your business?

    [required free text response]

32. Are there additional challenges (including data security concerns) when operationalizing systems and processes for the DSCSA requirements for interoperable, electronic tracing of products at the package level not addressed in this assessment?

[required free text response]