September 7, 2023

Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2023-N-3103: Development of Small Dispensers Assessment Under the Drug Supply Chain Security Act; Request for Comments

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

Dear Food and Drug Administration Staff:

The American Pharmacists Association (APhA) and the National Community Pharmacists Association (NCPA) appreciates the opportunity to submit feedback on FDA's request for comments titled "Development of Small Dispensers Assessment Under the Drug Supply Chain Security Act." Additionally, APhA and NCPA appreciates FDA's one-year delay for supply chain trading partners to comply with the final enhanced drug distribution security requirements under the Drug Supply Chain Security Act (DSCSA).

APhA is the only organization advancing 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.

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 $78.5 billion healthcare marketplace, employ 240,000 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.

APhA and NCPA have reviewed FDA's proposed questions for the small business dispenser assessment related to dispensers with 25 or fewer full-time employees and interoperable, electronic tracing of products at the package level. We believe that the questionnaire should

include standardized options for the answers to facilitate data analysis and understanding by the respondents. We offer suggestions below.

Key:

BOLD: FDA's proposed questions for the small business dispenser assessment

Italics: Suggested reworded/reframed questions, where applicable

Red: Suggested options for responses to the questions

1. **Have you begun preparations for DSCSA requirements regarding the interoperable, electronic tracing of products at the package level required under section 582(g)(1) of the FD&C Act (i.e., enhanced product tracing or enhanced verification)?**

1. *Have you begun preparations for DSCSA requirements regarding the interoperable, electronic tracing of products at the package level required under DSCSA (i.e., enhanced product tracing or enhanced verification)?*
    - *A) Yes*
    - *B) No*

2. **How are you currently exchanging data with your trading partners (e.g., by paper-based methods, electronic methods, or both)?**

2. *How are you currently exchanging data with your trading partners?*
    - *A) Paper-based methods*
    - *B) Electronic methods*
    - *C) Both*
    - **If not currently exchanging data with trading partners in a fully electronic manner, will you be able to in the near future? If not, what are the barriers? Elaborate on why or how, as appropriate. Please specify issues related to:**
        i. **accessibility of necessary software and hardware;**
        ii. **cost to obtain, install, and maintain necessary software and hardware, particularly if it is prohibitively expensive;**
        iii. **integration of necessary software and hardware into business practices, such as with wholesale distributors;**
        iv. **other relevant information related to feasibility of dispensers with 25 or fewer full-time employees to conduct interoperable, electronic tracing of product at the package level.**
    - *If you are not currently exchanging data with trading partners in a fully electronic manner, will you be able to in the near future?*
        - *A) Yes*
        - *B) No*
    - *What are barriers you are experiencing to exchanging data with trading partners in a fully electronic manner? (Select all that apply)*

A) *Accessibility of necessary software and hardware*
B) *Cost to obtain, install, and maintain necessary software and hardware, particularly because it is prohibitively expensive*
C) *Integration of necessary software and hardware into business practices, such as with wholesale distributors*
D) *Other barriers*

- **What type of software systems and hardware do you currently utilize to facilitate the electronic exchange of DSCSA-related data for transactions of products?**
  A) *Current pharmacy management system*
  B) *Wholesaler ordering system*
  C) *I am paying for a software application to manage my tracing data*
  D) *Paper only*
- **What new or modified software systems and hardware do you anticipate putting in place to comply with the interoperable, electronic tracing requirements?**
  A) *Current pharmacy management system*
  B) *Wholesaler ordering system*
  C) *I will continue paying for a software application to manage my tracing data*
  D) *I will be paying for a new software application to manage my tracing data*
- **How likely are you to change and upgrade your existing software systems that are already in use so that you can comply with the interoperable, electronic tracing requirements?**
  A) *Very likely*
  B) *Likely*
  C) *Not likely*
  D) *Very unlikely*
  E) *I don't know/I am not sure*

3. Have you or do you plan to connect your system(s) with your trading partner(s) (e.g., manufacturer(s), repackager(s), or wholesale distributor(s)) in order to facilitate electronic DSCSA-related data exchange?

3. *Have you established connectivity with your trading partner(s) (e.g., a manufacturer, repackager, or wholesale distributor in order to facilitate electronic DSCSA-related data exchange?*
   A) *Yes, via a portal*
   B) *Yes, via a solution provider*
   C) *Yes, via a combination portal and solution provider*
   D) *No*

- **If so, have you experienced technical issues when attempting to establish connectivity?**
  - *A) Yes*
  - *B) No*
- **If not, how do you or how do you plan to manage electronic DSCSA-related data received from an upstream trading partner (e.g., maintain the data in your dispenser system or use a third-party agreement for another entity to confidentially maintain the DSCSA-related data on your behalf (e.g., use of a secure web portal provided by your wholesale distributor))?**
- *How do you or how do you plan to manage electronic DSCSA-related data received from an upstream trading partner?*
  - *A) Current pharmacy management system*
  - *B) Wholesaler ordering system*
  - *C) I am or will be paying for a software application to manage my tracing data*
  - *D) Paper only*

4. **Have you considered data integrity and security concerns when establishing agreements with third-party entities (e.g., solution providers or wholesale distributors) for electronic data exchange and maintenance?**
   - *A) Yes, and my concerns are resolved*
   - *B) Yes, but my concerns remain*
   - *C) No*
   - **Have you ever received transaction information from a trading partner, such as your wholesale distributor, that does not match the product that you received? If so, how long did it take to resolve the discrepancy on average? What if any unique challenges arose from these situations? How often does this happen?**
   - *How often do you receive transaction information from a trading partner, such as your wholesale distributor, that does not match the product you received?*
     - *A) Every Day*
     - *B) Every Week*
     - *C) Every Month*
     - *D) Less Frequently than Once a Month*
     - *E) I do not receive this data from any trading partners*
   - *If so, how long did it take to resolve the discrepancy on average?*
     - *A) A few hours*
     - *B) 6-12 hours*
     - *C) 12-24 hours*
     - *D) 1-3 days*
     - *E) 4-7 days*
     - *F) A week*

G) *Longer than a week*

5. **If you currently routinely scan a 2D data matrix barcode, how often do you receive a 2D data matrix barcode of the product identifier that cannot be scanned or read? Why are you unable to scan or read the 2D data matrix barcode (e.g., barcode quality, scanner performance, software issue) and what is your process for handling these situations, including when manual steps are taken by your staff when an automated process was inadequate or failed?**

5. *How often do you scan/attempt to scan 2D data matric barcode of the product identifier that cannot be scanned or read?*
    - A) *Every Day*
    - B) *Every Week*
    - C) *Every Month*
    - D) *Less Frequently than Once a Month*
    - E) *I do not routinely scan 2D data matrix barcodes*

6. *What is your process for handling unscannable or unreadable 2D data matric barcodes?*
    - A) *[Open-ended response requested]*

- **If you currently routinely scan the 2D data matrix barcode, how often you encounter a 2D data matrix barcode with missing or inaccurate data? What are the reasons for this and what is your process for handling these situations, including when manual steps are taken by your staff when an automated process was inadequate or failed?**
- *How often do you encounter a 2D data matric barcode with missing or inaccurate data?*
    - A) *Every Day*
    - B) *Every Week*
    - C) *Every Month*
    - D) *Less Frequently than Once a Month*
    - E) *I do not routinely scan 2D data matrix barcodes*
- *What is your process for handling 2D data matric barcodes with missing or inaccurate data?*
    - A) *[Open-ended response requested]*
- **What new demands do you expect the DSCSA requirements in section 582(g)(1) of the FD&C Act to have on your current staff resources?**
    - A) *[Open-ended response requested]*
- **How long do you expect it will take to train staff on the new requirements, how to use any new software or hardware, and any process changes? What additional resources do you anticipate needing to comply with the interoperable, electronic tracing requirements?**

- *How long do you expect it will take to train staff on the new requirements, how to use any new software or hardware, and any process changes?*
    - *A) A few hours*
    - *B) 1-2 days*
    - *C) A Week*
    - *D) Several weeks*
    - *E) A month or longer*

- *What additional resources do you anticipate needing to comply with the interoperable, electronic tracing requirements?*
    - *A) [Open-ended response requested]*

7. **Are there additional challenges not already identified when operationalizing new systems and processes for interoperable, electronic tracing of products at the package level required under section 582(g)(1) of the FD&C Act (i.e., enhanced product tracing or enhanced verification)?**
    - *How much have you spent to comply to date with the interoperability provisions of DSCSA?*
        - *A) Less than $50,000*
        - *B) $50,001 - $100,000*
        - *C) $100,001 - $150,000*
        - *D) More than $150,000*

    - *How much more do you expect to spend to comply with the interoperability provisions of DSCSA?*

        - *A) Less than $50,000*
        - *B) $50,001 - $100,000*
        - *C) $100,001 - $150,000*
        - *D) More than $150,000*

- *How many additional FTEs do you anticipate adding to be able to comply with the interoperability provisions of DSCSA?*
    - *A) I do not anticipate adding any FTEs*
    - *B) 0.25 to less than 0.5 FTE*
    - *C) 0.5 FTE to less than 1 FTE*
    - *D) Greater than 1 and less than 2 FTEs*
    - *E) Greater than 2 FTEs*

    - *Are there any other comments you would like to provide to FDA?*
        - *A) [Open-ended response requested]*

8. *When do you believe that you will be able to fully comply with the interoperability provisions of DSCSA?*
    - *A) I am ready to comply now.*
    - *B) November 27, 2024 (the current date that FDA will enforce such provisions)*
    - *C) May 27, 2024 (Approximately 6 months from November 27, 2024)*
      D) November 27, 2025 (Approximately 1 year from November 27, 2024)
    - *E) Later than November 27, 2025 (More than 1 year from November 27, 2024)*

Conclusion

We appreciate the opportunity to provide feedback on the questions and format. We believe that closed-ended questions may aid in facilitating data collection and the analysis process. These types of questions may reduce the amount of time needed to answer the survey and potentially increase the response rate overall. The drafted response recommendations can provide the FDA with additional data to better understand the progress that dispensers have made thus far and provide further insight into small dispensers' ability to comply with the DSCSA. We look forward to continuing to work with the FDA on dispenser compliance with DSCSA's requirements for enhanced drug distribution security for tracing at the package level. If you have any questions or need any additional information, please contact Heather Boyd, APhA's Director, Health Policy at hboyd@aphanet.org and NCPA's Ronna B. Hauser, Senior Vice President, Policy & Pharmacy Affairs at ronna.hauser@ncpa.org.

Sincerely,

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