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[Submitted electronically via email]

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RE Docket No. FDA-2023-N-4806 – “Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act; Establishment of a Public Docket; Request for Information and Comment.”

Dear Drs. Throckmorton, Kundi, and Verbois,

On behalf of our over 100,000 pharmacist, student pharmacist, and pharmacy technician members practicing in all patient care settings across the country, as well as over 40,000 retail pharmacies, we respectfully request that FDA take additional action to ensure that dispensers can comply with the requirements of the Drug Supply Chain and Security Act (DSCSA). Specifically, we request that FDA implement a phased enforcement approach by providing a blanket waiver, exception, or exemption (WEE) for dispensers until manufacturer-level trading partners can provide all necessary EPCIS data to downstream trading partners. Further, FDA should clearly state that any WEEs granted to upstream trading partners are also applicable to downstream trading partners.

We are hearing from members that although their organizations have DSCSA compliance plans in place, manufacturer-level trading partners will not be ready for the end of the stabilization period on November 27, 2024. Anecdotal reports from members indicate that manufacturer-level trading partners are providing only a small fraction of the requisite EPCIS data. Specifically, we’re hearing that, in many cases, pharmacies are currently receiving only 20 – 40% of the data.

As FDA is aware, pharmacy compliance with DSCSA is fully dependent on the compliance of upstream trading partners. In cases where manufacturers supply partial or no data, the DSCSA provides pharmacies limited recourse beyond rejecting shipments. This may not cause serious disruption if limited to a small percentage of data or to a small number of products, but considering the scope of the missing data, we are concerned that this could potentially jeopardize patient care. For instance, if dispensers move away from one product with a WEE, it may create a demand surge for alternate products, resulting in increased prices or even shortages. In cases where no alternate products are available, patients could be left without medication access.

Additionally, because FDA has indicated that it does not intend to publish a list of WEEs, trading partners are not immediately aware when manufacturers have been granted a WEE. To address these gaps in DSCSA implementation, we urge FDA to apply any WEE granted to manufacturers to all downstream trading partners, with communication from either the agency or the manufacturer that a WEE is in place.

However, the WEE process is not sufficient for full dispenser compliance until manufacturers are ready – as noted above, dispenser compliance is entirely dependent on compliance of upstream trading partners. As FDA has stated that the stabilization period will not be extended, and enforcement discretion still creates risks for dispensers, we believe that phased enforcement through a blanket WEE for dispensers that extends until manufacturers can provide all required EPCIS data to downstream trading partners would be the most expeditious solution. This will allow manufacturers to continue to refine their processes with trading partners and to test implementation of systems without creating an unduly punitive environment for dispensers.

Additionally, we understand that state Boards of Pharmacy are beginning to implement their own DSCSA compliance oversight. We urge FDA to continue to clarify to Boards of Pharmacy that FDA WEEs must be honored by state pharmacy inspectors.

Thank you for your consideration of our comments. Please do not hesitate to contact us if we can provide any further information or assist the agency in any way.

Sincerely,

American Association of Colleges of Pharmacy
American College of Clinical Pharmacy
American Pharmacists Association
American Society of Consultant Pharmacists
American Society of Health-System Pharmacists
National Association of Chain Drug Stores
National Alliance of State Pharmacy Associations
National Community Pharmacists Association