NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

September 27, 2024

The Honorable Robert M. Califf, MD
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Submitted via email: Commissioner@fda.hhs.gov

Re: Urgent Action Needed Regarding the End of DSCSA Stabilization Period

Dear Commissioner Califf:

The National Association of Chain Drug Stores (NACDS) writes with urgency as follow up from a recent meeting between the dispenser community and representatives from FDA's Center for Drug Evaluation and Research (CDER) regarding anticipated disruptions in patient access to their medications following the end of the Drug Supply Chain Security Act (DSCSA) Stabilization Period on November 27, 2024. Patient access to their prescription medications is in serious jeopardy unless FDA takes action very soon.

We would like to bring to your attention concerns and issues that we raised with CDER representatives during the meeting with the dispenser community.[1] This letter summarizes the concerns discussed in the meeting.

1. **FDA should provide an exemption for dispensers until all trading partners can provide the required interoperable, electronic, package level data to downstream dispensers.** We are asking for a transaction-based exemption for dispensers, with the ability to accept product without package-level data. FDA has stated that it intends to rely on the waiver, exception, and exemption (WEE) process to address products or transactions that are unable to meet the enhanced drug distribution security requirements by the end of the Stabilization Period. FDA should initiate a WEE for dispensers, rather than rely on the individual trading partner WEEs that were submitted by various trading partners across different sectors. An FDA initiated sector WEE will provide consistency across the supply chain for dispensers.

[1] Attendees included representatives from the American Pharmacists Association (APhA), American Society of Consultant Pharmacists (ASCP), American Society of Health-System Pharmacists (ASHP), CVS Health, Federation of American Hospitals (FAH), National Association of Chain Drug Stores (NACDS), National Community Pharmacists Association (NCPA), Publix Super Markets, and Walmart. The National Boards of Pharmacy (NABP) attended as an observer.

2. **Stabilization has been helpful.** The dispenser community greatly appreciates the DSCSA Stabilization Period that FDA provided approximately one year ago in response to concerns about industry readiness for DSCSA compliance. Dispensers have utilized that time wisely to ensure that we have the necessary systems and processes in place.

   Although dispensers have established systems and processes, the connections among all supply chain participants have not yet been fully stabilized. Moreover, the package-level data from our trading partners is not consistently reaching dispensers. Of notable concern is that a significant number of transactions between dispensers and manufacturer and/or wholesale trading partners will not be stabilized by November 27, 2024, the end of the Stabilization Period. Anecdotally, we are hearing from NACDS members that their trading partners are providing accurate, consistent, and complete EPCIS data for only about 25% - 50% of prescription drug products that dispensers receive. Some trading partners provide EPCIS data for certain products but not all, and even then, not consistently for the same products.

   DSCSA transaction data travels downstream, typically from manufacturer to wholesaler to dispenser. With less than 60 days before the Stabilization Period ends, it is clear that there is not sufficient time to complete onboarding and testing and ensure that data is flowing accurately, completely, and consistently for dispensers.

3. **Without more time to stabilize connections, there will be supply disruptions, impacting patient access to medicines.** Without compliant data and transactions, dispensers cannot accept ownership of the product and the product either must be quarantined or rejected and sent back to the trading partner. Dispensers' capacity to procure medications from their suppliers depends entirely on those suppliers' transactions meeting DSCSA requirements. This situation jeopardizes patients' access to prescription drugs, through no fault of dispensers. If trading partners and prescription drug products are not ready by November 27, 2024, it could pose significant risks to patient access to essential medications. This could also exacerbate drug shortages due to disrupted supply of products. If medicines are not available when the patient comes to the pharmacy, they may not come back, leading to decreased adherence or delays in specific regimens, such as for cancer. Another consequence would be long lines and bottlenecks at pharmacies as patients attempt to access their medicines.

Our request for dispenser exemption is not meant to postpone implementation efforts. NACDS members have worked hard to implement and stabilize connections with trading partners. In concert with the exemption, dispensers will continue to work with their upstream trading partners to ensure the EDDS requirements of the DSCSA are consistently, reliably, and accurately met for all products. We request that FDA urgently take action and announce a sector-based dispenser exemption to remove uncertainty and avoid supply chain disruptions.

We would welcome the opportunity to discuss our concerns further. We will be in touch to request a meeting. In the meantime, please do not hesitate to contact Sara Roszak, Senior Vice President, Health & Wellness Strategy & Policy, NACDS at sroszak@nacds.org to answer any questions you may have.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

cc:
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