

July 14, 2023

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Submitted via email: DrugTrackandTrace@fda.hhs.gov

Re: Request for Phased Implementation of the Upcoming DSCSA Requirements

Dear Doctors Throckmorton, Verbois, and Jung:

The American Pharmacists Association (APhA), National Association of Chain Drug Stores (NACDS), and National Community Pharmacists Association (NCPA), are jointly requesting that the Food and Drug Administration (FDA) adopt a phased, stepwise approach to the implementation of the enhanced drug distribution security (EDDS) requirements of the Drug Supply Chain Security Act (DSCSA) that are scheduled to take effect on November 27, 2023. We are aware that FDA currently is considering a request for this approach from the Healthcare Distribution Alliance (HDA). We support HDA's request and strongly believe a phased approach would best achieve DSCSA's prescription drug product traceability and

security goals while also minimizing the potential for supply disruptions and ensuring there are no interruptions to patient care.

Our member organizations support a phased, stepwise approach to ensure that all sectors of the pharmaceutical supply chain have adequate time to stabilize the complex systems and processes necessary for efficient transactions across the supply chain. To be clear, our support for this approach is not to delay all implementation activity. We believe during the phased period it is important for trading partners to continue on the path toward package-level tracing and enhanced supply chain security Congress envisioned when it enacted the DSCSA ten years ago.

We understand that, although some trading partners are or will be ready to be compliant with the DSCSA by November 27, many will not. This is concerning, particularly for dispensers, because the package-level interoperable data exchange that Congress envisioned under the DSCSA is interdependent on all supply chain trading partners. In other words, the ability of pharmacies and pharmacists to purchase medications from manufacturers and wholesalers is completely reliant on their ability to comply with DSCSA requirements.

The inability to be ready by November 27 would cause significant risk to patients' access to their lifesaving medications. If upstream trading partners cannot accurately exchange interoperable package-level data to subsequently provide to dispensers, then the DSCSA is structured to prohibit dispensers from purchasing such product to meet their patients' needs. This could potentially cause significant harm and drug shortages for patients who rely on these medications.

To prevent this potentially devastating scenario, **our organizations jointly recommend that FDA act immediately to announce a phased approach across the supply chain for the DSCSA's upcoming EDDS requirements. Specifically, we request FDA use its authority under the law for dispensers to comply with the EDDS requirements no earlier than February 27, 2026.** This would enable the supply chain to come into full compliance and for systems among all trading partners to be tested to ensure there are mechanisms in place to ensure connectivity and address potential/inadvertent data errors.

Note that we are requesting enforcement discretion for 27 months instead of two years, as we are aware other supply chain stakeholders are requesting, because November through January are very busy and hectic times for pharmacies due to holidays, and cough, cold, and flu season, as well as changes in patients' prescription benefit programs that occur. Pharmacies' having to come into full DSCSA compliance during this time would be unduly and unnecessarily burdensome. For these reasons we request enforcement discretion until February instead of November.

We would welcome the opportunity to discuss further our concerns. Please do not hesitate to contact Ilisa BG Bernstein, Senior Vice President, Pharmacy Practice & Government Affairs, APhA at ibernstein@aphanet.org; Sara Roszak, Senior Vice President, Health &

Wellness Strategy & Policy, NACDS at sroszak@nacds.org; or Ronna Hauser, Senior Vice President, Policy & Pharmacy Affairs, NCPA at ronna.hauser@ncpa.org for further engagement or to answer any questions you may have.

Sincerely,

Michael D. Hogue, Pharm.D., FAPhA, FNAP, FFIP
Executive Vice President and Chief Executive Officer
American Pharmacists Association



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



B. Douglas Hoey, RPh, MBA
Chief Executive Officer
National Community Pharmacists Association

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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. Visit www.pharmacist.com.

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NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including

155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org.

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Founded in 1898, the National Community Pharmacists Association is the voice for the community pharmacist, representing over 19,400 pharmacies that employ nearly 240,000 individuals nationwide. Community pharmacies are rooted in the communities where they are located and are among America's most accessible health care providers. To learn more, visit www.ncpa.org.