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APhA

February 5, 2016

Connie T. Jung, RPh, PhD
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Dispenser-to-dispenser transfers under the DSCSA

Dear Dr. Jung,

The American Pharmacists Association ("APhA") would like to express our appreciation for FDA's continued inclusion of stakeholders in regulatory and implementation efforts related to the Drug Supply Chain Security Act of 2013 (DSCSA). Founded in 1852 as the American Pharmaceutical Association, APhA represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, physicians' offices, long-term care facilities, community health centers, managed care organizations, hospice settings, and the uniformed services. APhA would like reiterate our ongoing concerns related to ambiguity of the specific patient need exception.

APhA is committed to the effective implementation of DSCSA and laud FDA's efforts to strengthen the security and reliability of the nation's drug supply chain. We support the aim of the DSCSA to protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated or otherwise harmful.

I. Recommend FDA clarify which dispenser-to-dispenser transfers are permissible

APhA is concerned that the DSCSA's language can be interpreted by stakeholders to impose wholesale distributor requirements on dispensers transferring products to trading partners or other interested parties (e.g., emergency personnel). Such an interpretation may deter pharmacies from engaging in these small-scale transactions which can be critical to meeting the needs of patients and the health care system generally.

The DSCSA defines wholesale distributor as a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution as defined in section 503(e)(4), as amended by the Drug Supply Chain Security Act). Section 503(e)(4) essentially defines wholesale distribution to mean the sale, trade, loan, or transfer of a prescription drug to entities that are not the final user.[1] Based on the aforementioned definitions, it could be concluded that dispensers engaging in even small-quantity transfers of prescription drugs to other trading partners meet the definition of wholesale distributor and therefore, must satisfy regulatory and licensure requirements. It is not uncommon for dispensers to transfer drug products to other dispensers and to other entities (e.g. emergency services personnel) to meet the needs of patients. These small-volume transfers also help to decrease waste and cost to the healthcare system and environment by minimizing inventory overstocking and the amount of unused product. In fact, many states have regulations explicitly allowing for the transfer of pharmaceuticals within predetermined limits in effort to appropriately balance the need to provide patients medication in a more timely and cost-efficient manner with the need to track products and regulate wholesale distributors. If small-volume transfers trigger wholesale distribution requirements, dispensers will likely decide to stop participating in these small-scale transactions.

We do not believe it was Congress's desire in the DSCSA to require dispensers to adhere to wholesale distributor requirements in order to transfer any amount of product. Congress's decision to include a specific patient need exception for dispenser transfers only has meaning if there are other valid transfers by a dispenser where the dispenser much pass the 3Ts. Therefore, APhA requests FDA remove any ambiguity by articulating that dispensers may make small-quantity transfers to meet patient needs without having to satisfy the requirements for wholesale distributors — a needed clarification which is consistent with congressional intent and the goals of the DSCSA.

II. Recommend FDA clarify the scope "specific patient need"

The DSCSA allows dispensers to transfer pharmaceuticals without passing the transaction history, transaction information, and a transaction statement (the "3Ts") when there is a "specific patient need." Although the DSCSA defines "specific patient need"[2], we believe the term needs additional clarification.

While the definition of specific patient need clearly includes situations in which a dispenser has a prescription in hand, it is not clear whether the exception applies when dispensers have patients who regularly obtain their prescription refills or when the dispenser receives notice that a particular patient will be bringing in a prescription to be filled (*e.g.*, by a provider or the

[1] Both section 503(e)(4) and the DSCSA include an exemption when a licensed retail pharmacy distributes minimal quantities of drugs to licensed practitioners for office use, however, these are not the types of transfers that raises concern.

[2] 21 U.S.C. §581(19) (where "specific patient need" is defined as "the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.")

patient). We consider these additional scenarios to fall within the scope of the specific patient need exception contemplated by Congress and consistent with the goals of the DSCSA. Because these low-volume transfers by dispensers are limited in nature and low-risk to drug supply chain security but significant to patient care (e.g. prevent delay of treatment and maintain patient-pharmacist relationship), APhA believes the exception was not intended to be limited to circumstances in which the prescription is in hand. Additionally, a narrow interpretation runs counter to patient safety since patients may need to obtain prescriptions periodically from multiple pharmacies which, in practice, makes it more difficult for the necessary stakeholders to track patients' medications. Thus, APhA recommends FDA clarify the scope of the specific patient need exception to include scenarios beyond a patient with a physical prescription at the pharmacy.

As noted above, APhA is dedicated to helping pharmacists and FDA with DSCSA implementation. We believe that a necessary step towards more seamless implementation includes clarifying which dispenser-to-dispenser transfers are permissible and the scope of "specific patient need." We strongly agree that strengthening the security and reliability of the nation's supply chain is critical to patient safety. Thank you for the opportunity to provide comments on this important issue. We look forward to continue working with FDA and other stakeholders in implementing the DSCSA. If you have any questions or require additional information, please contact Jenna Ventresca, JD, Associate Director, Health Policy, at jventresca@aphanet.org or by phone at (202) 558-2727.

Sincerely,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Stacie Maass, BSPharm, JD, Senior Vice President, Pharmacy Practice and Government Affairs