



American Pharmacists Association[®]
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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville MD, 20852

RE: Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act; Public Meeting; Request for Comments (Docket No. FDA-2016-N-2673)

Dear Sir/Madam:

The American Pharmacists Association (“APhA”) appreciates the opportunity to respond to the Food & Drug Administration’s (“FDA”) Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act; Public Meeting; Request for Comments (hereinafter, “Public Meeting”). APhA, founded in 1852 as the American Pharmaceutical Association, 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, physicians’ offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

APhA is committed to working with FDA and other health professionals and stakeholders to enhance the safety and security of the pharmaceutical distribution supply chain. APhA appreciates the Agency’s efforts to seek stakeholder input as it continues to implement policies resulting from the Drug Supply Chain Security Act (“DSCSA”), including hosting public meetings to encourage and facilitate feedback. Compared to other supply chain participants, such as manufacturers and wholesale distributors, pharmacies are larger in number and often much smaller business entities, making them more vulnerable to burdensome requirements. As such, APhA advocates that FDA consider the unique circumstances that pharmacists face in their role as dispensers at the end of the supply chain as it evaluates implementation of DSCSA product identification requirements and considers pilot projects and opportunities for innovation.

I. Dispensers' implementation and use of product identifiers

a. Dispenser status regarding serialization

As the member of the supply chain who most frequently dispenses medications to patients, the pharmacist plays a vital role in protecting patients from illegitimate products. Thus, dispensers' effective implementation of the DSCSA is crucial to patient safety. While it may be clear that there are substantial variances between pharmacies and other members of the supply chain, differences also exist amongst pharmacies, such as size, resources, type of patients served and business practices, including DSCSA compliance methods. Consistent with previous comments to FDA, APhA urges FDA to consider the variability amongst pharmacies and between them and other drug supply chain participants as it develops, implements and evaluates DSCSA implementation.

Dispensers' variable methods to comply with the DSCSA, including requirements related to the product identifier, is, in part, the result of compliance decisions made by other members of the supply chain. Many pharmacies contract with third parties or rely on wholesalers to comply with DSCSA lot-level requirements and are planning on doing the same with regard to product identifier requirements. Since deadlines related to the product identifier are earlier for manufacturers and wholesale distributors, it is not likely that pharmacies will control the software and/ or hardware selected or used because their systems will need to be compatible with already-established technology of upstream entities.

The disparate abilities and positions of supply chain participants was recognized by Congress in the DSCSA provision requiring the FDA, by May 2022, to contract with a private, independent consulting firm to conduct a technology and software assessment that looks at whether it is feasible for small dispensers (25 employees or fewer) to conduct interoperable, electronic tracing of product at the package level. While APhA appreciates the intent of this provision, given that dispensers will have to comply with DSCSA requirements in advance of 2021, we strongly recommend the FDA begin this assessment as soon as possible so that dispensers' capabilities will be considered as manufacturers and wholesale distributors are developing and implementing their DSCSA processes and technology. In addition, APhA would like to emphasize that many pharmacies, despite having more than 25 employees, are still small businesses and will face the same challenges that those with fewer than 25 employees will face. Therefore, APhA believes that the assessment should not be restricted to testing only the needs of those pharmacies with less than 25 employees. In addition, APhA recommends that pilots testing implementation methods and uses of the product identifier include a wide range of pharmacy practices so that new methods and applications can be applied in different settings.

b. Interoperability

Interoperable systems between trading partners are essential to DSCSA implementation, including effectively verifying packages by using product identifiers. APhA believes that technology capabilities, system and software costs, and the timeframe associated with implementing these systems for the various supply chain stakeholders, are barriers to DSCSA compliance, especially for smaller trading partners. We encourage FDA to work with stakeholders throughout the supply chain to develop and test technology and interoperability requirements.

II. Ongoing DSCSA implementation concerns

a. Federal Licensure Regulations

The DSCSA (Sec. 583 & Sec. 584) calls for national standards, including licensure, for prescription drug wholesale distributors and third-party logistics providers. Although the DSCSA has been enacted, regulations or guidance regarding national licensure standards have yet to be released. APhA urges FDA to issue licensure guidance or regulations as soon as possible. In the absence of these regulations, individual states are developing policies which vary, and thus, are at odds with the DSCSA's goal of uniform licensure standards. Further, in absence of federal standards, private entities have begun requiring specific types of accreditation, adding more variability and potentially creating state-by-state industry licensure standards which unnecessarily limit pharmacies' buying options. Of greater concern, is the impact that arbitrarily limiting buying options, not based on safety or security, can have on patient care and obtaining needed medications in a timely manner.

b. Exceptions, exemptions and waivers

APhA agrees with other stakeholders who voiced their concerns at the Public Meeting that there needs to be additional instruction by the Agency regarding the process by which the Secretary determines exceptions, exemptions and waivers, and the scope of the exception for grandfathering product and transactions in emergency medical situations. Of particular concern is the impact the DSCSA would have on emergency situations, particularly in the period before a public health emergency is declared or in event of a natural disaster or mass casualty event that is not declared a public health emergency. The law provided no detail on when and how DSCSA's requirements apply in emergency situations and none of FDA subsequent regulations and guidances addressed this topic. Also unclear is a DSCSA provision that exempts grandfathered products from product identifier requirements. Because FDA has yet to issue guidance regarding grandfathered products, dispensers' compliance efforts will likely be more cumbersome as they attempt to account for products that are exempt and those that are not. Thus, APhA suggests that FDA provide guidance regarding dispenser tracking and tracing of grandfathered products. In addition, to assist stakeholders trying to comply with the DSCSA, APhA encourages FDA to issue regulations or guidance on the Secretary's process for identifying exceptions, exemptions and waivers and the scope of exceptions and exemptions contained in the law.

c. Standard format barcode

As more and more technology vendors develop products to address serialization and product identification, APhA encourages FDA to work with stakeholders in setting minimum standard criteria for barcode labeling which may include standard format, standard dating format, and standard label placement. Minimum standards will help with consistency and interoperability between supply chain trading partners.

d. Returns and drop shipments

Although DSCSA addresses procedures for manufacturers, wholesale distributors and repackagers regarding drop shipments and returns, the law does not adequately address how dispensers are expected to track and trace these transfers. In regards to drop shipments, it is not clear how, and from whom, dispensers should expect to receive transaction information. This presents implementation concerns as there is variability in information that is being reported, making it more difficult for dispensers to track. We encourage FDA to clarify DSCSA's requirements for drop shipments and returns, and to identify more effective, practical mechanisms and tools for dispensers.

III. Need for Education and Training

As FDA moves forward on implementing the DSCSA, APhA urges the Agency to increase educational outreach efforts to pharmacists and pharmacies. Despite efforts by APhA and other pharmacy organizations to inform pharmacists about DSCSA requirements and compliance, APhA remains concerned that dispensers are not fully aware of DSCSA policies and requirements, and thus, are not prepared to effectively implement future requirements.

Educational efforts could focus on topics that have not been addressed in detail in DSCSA regulations or guidance released to date, such as the identification of suspect and/ or illegitimate products, methods to store and share transaction information, grandfathering provisions related to the product identifier, and future requirements. While APhA will continue to educate its pharmacist members on DSCSA implementation, we believe that FDA involvement would increase awareness and improve message consistency, ultimately advancing compliance and the safety and security of the supply chain. APhA is willing to help FDA's outreach efforts to pharmacies by reviewing and disseminating dispenser-specific materials FDA develops.

Thank you for your leadership and work on this issue. We look forward to supporting FDA's efforts and working to improve the safety and security of the drug supply chain using practical and feasible implementation approaches. If you have any questions please contact, Jenna Ventresca, Associate Director for Health Policy, by email jventresca@aphanet.org or phone (202) 558-2727.

Sincerely,



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Executive Vice President and CEO