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APhA

June 9, 2014

Food and Drug Administration
Division of Dockets Management (HFA–305),
5630 Fishers Lane, Room 1061
Rockville, MD 20852.

[Submitted electronically to regulations.gov]

RE: Docket No. FDA–2014–N–0337; Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format; Public Workshop; Request for Comments.

Dear Sir/Madam,

The American Pharmacists Association (APhA) appreciates the opportunity to offer comments to FDA on the topics discussed at the May 8-9, 2014 public workshop on developing standards for the interoperable exchange of information for tracing of human, finished, prescription drugs, in paper and electronic format. 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, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

A. Introduction

APhA applauds the work of FDA to strengthen the security of our nation's drug supply chain. We also appreciate FDA's willingness to work with stakeholders to gather information and ideas on standards development for the exchange of the Transaction Information (TI), the Transaction History (TH), and the Transaction Statement (TS) that will accompany a product through the supply chain. During this information-gathering phase in developing interoperable standards for the exchange of information, it is important to note that some dispensers may not have sophisticated inventory management systems in place and these newly-formed standards may create substantial financial and logistical challenges for small businesses. APhA remains committed to working with FDA and other

stakeholders in developing these standards and the subsequent draft guidance scheduled for release in late November.

B. Transaction Information

I. Proprietary names

APhA recommends consistent and standardized naming practices in the TI such as reporting brand name drugs by their proprietary name and generic drugs by their chemical name.

II. National Drug Code (NDC) of the product

APhA would like clarity on how the NDC should be reported in the TI. APhA notes that various inventory management systems store NDC numbers differently and NDC numbers vary in length of digits and/or hyphenation.

III. Container size

APhA suggests that the container size recorded in the TI reflect the smallest salable unit of product actually transferred in the transaction.

IV. Number of containers

APhA suggests that the number of containers reported in the TI be based on the amount of product actually exchanged, down to the smallest salable unit. Thus, ambiguous terms, such as “package” or “case” should be avoided.

V. Date of transaction

APhA would like some clarity on whether the date of transaction is the day the purchase order is sent, the purchase order is received, the inventory is marked to the order, or when the order is packaged to be shipped.

VI. Date of the shipment, if more than 24 hours after the date of the transaction

APhA would like more clarity on whether the date of shipment means the date products are packaged for shipping, the date products are picked up by the courier, or the date the downstream supply chain participant comes into possession or control of the products.

VII. Business name and address of the person from whom ownership is being transferred

APhA would like more clarity on which corporate name should be used on the TI (e.g., the parent, subsidiary, assumed business, doing business as, etc.). Also, clarification regarding whether entities should report the address as it appears on the certificate of incorporation, the principal place of business, or the address of the facility where the products were last shipped from is necessary. Further, at present it is unclear whether the movement of products to different facilities owned or operated by a single corporation needs to be reported on the TI.

VIII. Business name and address of the person to whom ownership is being transferred

APhA would like more clarity on whether the parent, subsidiary, assumed business, doing business as, or company names should be on the TI. Additionally, it is unclear which corporate address should be reported on the TI—the corporate address as it appears on the certificate of incorporation, the corporation's principal place of business, or the address of the facility receiving the products.

C. Transaction History

APhA is concerned that the proposed TH framework places a significant burden on the dispenser to maintain six years of transaction histories on thousands of product purchases. In addition to the costs of storing the transaction histories, the dispenser also bears the compliance risks associated with the retention and maintenance of these records. Pharmacies are already subject to numerous state and federal record retention requirements - some requiring the storage of prescription records for a minimum of 10 years. Furthermore, pharmacies occupy smaller facilities than other participants in the supply chain, with limited space available to dedicate to storage.

D. Transaction Statement

I. Transferor is authorized to transfer ownership

APhA supports the use of an abbreviated certification statement such as "DSCSA Compliant."

II. Transferor received the product from an authorized person

APhA would like clarity on specific verification requirements and the responsibilities of supply chain participants.

III. Transferor received TI and a TS from the prior owner of the product

APhA would like clarity on what constitutes receipt of TI and TS. It is important to note that it may not be feasible for some pharmacists to store thousands of paper records, have access to an electronic inventory management system with the capability to store records, or install an electronic inventory management system that is interoperable with the upstream supply chain participant's electronic system. Given that product TI and TS are being stored at the wholesale distributor level, we suggest that the statutory requirement to "capture" this information may be satisfied by the dispenser's ability to access records in the wholesale distributor's database through an authenticated dispenser account.

IV. Transferor had verification systems and processes in place

APhA would like clarity on requirements for systems and process to comply with verification requirements. APhA is committed to helping maintain the quality and security of our drug supply chain, but are concerned that requirements should not be unduly burdensome and/or disrupt workflow and patient care.

E. Conclusion

Thank you for considering our feedback as part of FDA's mission to strengthen the security of our nation's drug supply chain. The DSCSA affects all participants in the drug supply chain, from global manufacturers, to the small pharmacies who service our underserved communities. In developing standards of interoperability, APhA asks FDA to consider the disparities between the supply chain participants and their feasibility to implement new requirements. APhA thanks FDA for considering our feedback on this important public health initiative and we look forward to working closely with FDA and other stakeholders throughout the regulatory process. If you have any questions or require additional information, please contact Michael H. Ghobrial, PharmD,JD, Associate Director of Health Policy, at mghobrial@aphanet.org or by telephone at (202) 558-2727.

Sincerely,

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