pharmacists advancing healthcare®

June 16, 2015

Stephen Ostroff, M.D.
Acting Commissioner
Food and Drug Administration
Room 5266, White Oak Office Building 51
10903 New Hampshire Avenue
Silver Spring, MD 20993
Stephen.Ostroff@fda.hhs.gov

Re: Request for Dispenser Enforcement Discretion from DSCSA Requirements

Dear Commissioner Ostroff:

ASHP respectfully submits the following request to the U.S. Food and Drug Administration (FDA) for enforcement discretion to be given to "dispensers" under the requirements of Title II of the Drug Quality and Security Act, set to go into effect July 1, 2015. The uncertainty of the level of compliance among trading partners within the supply chain is cause for concern as hospitals and health systems may not have sufficient time to test or operationalize new data collection and storage systems to track certain prescription drug transaction data. Based upon input provided by hospital and health-system pharmacists nationwide, we believe that significant challenges remain for hospitals and health systems to fully comply with the new requirements by the July 1 deadline. For these reasons, ASHP respectfully requests that FDA allow for enforcement discretion for dispensers until January 1, 2016 to ensure that trading partners are able to comply with the requirements, and to allow dispensers time to successfully implement new data collection and storage systems.

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's more than 40,000 members include pharmacists, student pharmacists and pharmacy technicians. For over 70 years, ASHP has been on the forefront of efforts to improve medication use and enhance patient safety.

Title II of the Drug Quality and Security Act (DQSA) lays out a framework for the tracking of certain prescription drug data through the supply chain, from manufacturer to the end user, or dispenser. The law requires that dispensers collect and store for up to six years transaction information, transaction history, and a transaction statement for prescription drugs not exempt under the law. The ability of hospital and health systems to comply with the new requirements is largely dependent upon the ability of trading partners farther up the supply chain to comply. ASHP continues to gather input from hospital and health-system pharmacists who still have little or no indication that their trading partners farther up the supply chain are prepared to pass the necessary transaction data to their pharmacy customers. Given that the dispenser requirements go into effect in just over two weeks, ASHP is concerned that hospitals and health systems will not have enough time to implement, test and operationalize data collection and storage processes by the July 1 deadline. This is especially concerning for large health

systems that have more than one supplier of prescription drugs and may have to merge several different data collection and storage processes.

In addition to the degree of readiness among suppliers, many pharmacists have raised a number of questions that warrant further clarification or guidance by FDA based upon unique circumstances facing the hospital or health system. Although FDA may be in a position to issue guidance or other clarifying direction on these circumstances, ASHP believes that these examples provide further justification for our request to delay enforcement on the dispenser requirements until January 1, 2016. As noted in previous communications with the Agency, ASHP is eager to work with you to resolve these unanswered questions.

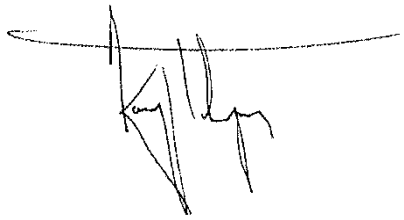
DQSA provides for a number of exemptions from the requirements to collect and store transaction history, statement and information. These include examples such as medications transferred from one hospital to another for emergency purposes, or to meet a specific patient need. ASHP is still uncertain whether medications provided to first responders such as ambulances or law enforcement are included within those exemptions as these products are made available in anticipation of an emergency or specific patient need. For example, a hospital supplying first responders with the opioid antagonist naloxone is generally done prior to an immediate patient need; however, it remains unclear whether medications supplied under these circumstances would fit within the exemptions.

Another area of uncertainty remains over the role of dispensers and the common control exemption in cases of joint partnerships and the provision of contract services. These include hospital and health system dispensers supporting rural health facilities, hospices, and clinics that are disproportionately challenged such as rural or underserved areas. Recognizing that transaction history, information and statement would need to be passed along, ASHP requests clarification from FDA on whether these dispensers would need to obtain a wholesaler license under the DQSA, or if compliance with passing the required transaction data alone would meet the requirement.

Finally, uncertainty exists over verification of transaction history, statement, and information when utilizing wholesaler or other third party data storage systems, compliance standards to demonstrate procedures that mitigate risks of illegitimate product entering system, and best practices to aid in identifying illegitimate products.

For the reasons outlined above, as well as the information we shared during the recent FDA listening sessions with dispensers, ASHP believes that FDA should allow for enforcement discretion of dispensers from the requirements of Title II of the DQSA until January 1, 2016. We appreciate your consideration of this request, and would be happy to talk with you or your staff to answer any questions you may have.

Sincerely,



Kasey K. Thompson, Pharm.D., M.S., M.B.A.
Vice President
Office of Policy, Planning and Communications

cc: Ilisa B.G. Bernstein, Pharm.D., J.D., Deputy Director, Program Operations, Office of Compliance
Connie T. Jung, RPh, PhD, Associate Director for Policy and Communication, Office of Compliance