Pharmacies in hospital and retail settings faced a deadline of November 1, 2015, for complying with new Food and Drug Administration (FDA) drug-tracing requirements. The FDA had delayed the previous implementation deadline of July 1, 2015, for “dispensers” — generally pharmacies — under the 2013 Drug Supply Chain Security Act (DSCSA) because of pleas from pharmacies that they were not ready to comply. It isn’t clear that they are any more ready now.

In a June letter to the FDA asking for a deadline extension to January 1, 2016, Kasey K. Thompson, PharmD, Vice President of the Office of Policy, Planning, and Communications at the American Society of Health-System Pharmacists (ASHP), cited “significant challenges” to compliance. “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,” he wrote.

The DSCSA was passed to establish a tracing system within the drug distribution channel to reduce the threat of patients receiving counterfeit drugs. On January 1, 2015, manufacturers and wholesalers started to pass and receive a “DSCSA compliance document.” It includes transaction information, a transaction statement, and a transaction history (TI/TS/TH); what needs to be included in all three elements is defined by the FDA. That document is being called a “T3.”

Now, as of November 1, pharmacies must capture this information, which will be passed from wholesalers and distributors either in paper or electronic form. Some wholesalers will pass the information directly to pharmacies; others will use a third-party company such as Track-TraceRx or TraceLink. These service providers function as intermediaries, accept the transaction data from the seller, store it on their proprietary Web portals, and make the data available to their pharmacy clients — for a price, of course.

About half of the 12,000 members of the Yankee Alliance would be considered dispensers, according to John Vlahopoulos, PharmD, RPh, Vice President for Pharmacy Services. The alliance just established a relationship with the TraceLink that will enable its dispensers to use the TraceLink portal at an ostensibly reduced rate. Dr. Vlahopoulos says standard product track subscription rates are $250 per month, or $2,500 annually per software license, and one license is required for every pharmacy location that receives shipments of prescription medications from suppliers. Customers also pay a modest one-time set-up fee to facilitate the creation of all vendor and supplier connections on the TraceLink network of close to 200,000 pharmaceutical suppliers.

A concern with that model, according to Bill Fletcher, Managing Partner of Pharma Logic Solutions, LLC, is that not all of a pharmacy’s suppliers may be connected to that Web portal or be able to supply the portal with information in the format it requires. A simpler, less expensive solution, says Fletcher, is for the pharmacy to log in a seller’s transaction data, which the seller is required to supply under the law. If it is in electronic form, it gets stored as a PDF and is searchable. If it is paper, it can be converted to a PDF.

The question is whether the packing slip contains the batch or lot number, which is the critical piece of data the pharmacy will need if the FDA starts looking for a “suspect” product. That search needs to be done in 24 hours. Most packing slips contain the lot number already, but there for purposes of aiding a recall. If the data do not include a lot number, the pharmacy must retrieve it from the shipper case or product label, either via a barcode scanner or manually, and then enter it into a PDF. The potential problem with this simpler solution is that the PDFs are not indexed, so a search for a lot number could take a while, although not likely exceeding the 24-hour limit.

Pharmacies, too, may have to pass on T3s to other dispensers, although exclusions apply. However, the FDA hasn’t clarified those exclusions. One has to do with a hospital pharmacy transferring a drug to another hospital for emergency purposes or to meet a specific patient need. In his June letter, Thompson stated:

“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.”

Uncertainty also 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. Joe Hill, Director of Federal Legislative Affairs for the ASHP, says the FDA had not clarified the exemption policy as of early September.

Despite the passage of the November 1 deadline, the FDA’s ability to police pharmacy compliance with the DSCSA is severely limited. So pharmacies probably have additional time to establish a system that works for them and meets the mandates of the law.

REFERENCE