NCPA Summary of RxTEC Supply Chain Security Proposal (5/23/12)

Background of RxTEC System

The RxTEC system currently under consideration is the result of a year-long collaborative process undertaken by a diverse group of industry stakeholders including representatives of manufacturer, distributor and pharmacy associations as well as numerous representatives of individual companies or entities. The RxTEC system is premised upon all manufacturers placing the RxTEC "code" or set of data elements in both machine and human readable form on each individual prescription drug unit. The RxTEC "code" consists of the standardized numerical identifier or "SNI," the lot number, and the expiration date of a product.

The RxTEC system requires each sector of the supply chain (manufacturers, distributors and dispensers) to keep track of certain transactional information about the products that they handle in their role in the current supply chain as well as the lot numbers of the products that they are handling.

System Attributes for Pharmacy

Dispensers under the proposed system will be required to:

- Receive product only from a licensed manufacturer, repackager, or wholesale distributor;
- Receive only products encoded with RxTEC (lot level) data from a manufacturer, repackager or wholesale distributor selling the drug product to the dispenser;
- Maintain RxTEC lot level data or allow the wholesale distributor to confidentially maintain and store RxTEC lot level data sufficient to identify the product provided to a dispenser from the immediate previous source where a change of ownership has occurred between non-affiliated entities (if such arrangement is mutually agreed to upon the dispenser and the wholesale distributor)
- Use the RxTEC lot level data maintained by the dispenser or maintained by the wholesale distributor on behalf of the dispenser (if such arrangement is mutually agreed upon by the dispenser and the wholesale distributor), as necessary to respond to a request from the Secretary in the event of a suspect product or recall;
- Maintain lot level data upon change of ownership between non-affiliated entities and for recalled product; and
- Upon request by the Secretary or other appropriate federal official, or state official for the purpose of investigating a suspect or recalled product, provide the RxTEC data by lot and the immediate previous source or subsequent receipt of the suspect or recalled product, as applicable.
- Not later than 7.5 years after enactment, a dispenser shall be required to conduct lot level verification of suspect product only.

- Not later than 7.5 years after enactment, a dispenser upon verifying that a product is a suspect product or a product otherwise unfit for distribution---shall notify the Secretary and impacted trading partners, as applicable and appropriate; and take steps to remove such product from the pharmaceutical distribution supply chain

    - "Nothing in this section shall require a dispenser to verify product at the unit level"
    - "Nothing in this section shall require a dispenser to adopt specific technologies or business systems for compliance with this section."

For the purposes of these provisions, the following terms are defined as:

"Suspect product"—a product, based on credible evidence—

(a) Is potentially counterfeit, diverted or stolen;

(b) Is reasonably likely to be intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; or

(c) Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans

"Verification"—means the process of determining whether a product has the standardized numerical identifier or lot number (for pharmacists) and expiration date assigned by the manufacturer and identifying whether a product has the appearance of being counterfeit, diverted or stolen product or a product otherwise unfit for distribution. Verification of the RxTEC data may occur by using either human readable, machine readable or other methods such as through purchase records or invoices

Finally, the last provision merely requires pharmacists to remove any product that appears to be suspect or unfit for distribution and notify the Secretary and trading partners as applicable.

Assessment and Probable Impact on Pharmacy

Essentially, pharmacists will have to buy only from licensed trading partners and make sure that products are imprinted with RxTEC data. Pharmacists will have to keep records of from whom they bought product from and the lot numbers that they receive and may do this through retention of purchase records or invoices or any other method they choose. However, most pharmacies will most likely opt to let their primary wholesalers to keep track of what lot numbers were sent or delivered to them on what day. Wholesalers will already have to be keeping track of what lot numbers are sent to which pharmacies on any specific date.

Practically speaking, If a recall is sent out for a specific lot number, a pharmacist will essentially be able to go to the shelf to look for the number, check with their wholesaler to see if they sent them that lot number or check their own internal records to see if they have ever received that number.

If supply chain participants are in receipt of a product that they believe may be counterfeit/stolen or the product itself looks as though it has been tampered with or seems otherwise unfit for distribution, the pharmacist should check the lot number on the product and then make certain that it matches the lot number in either their records or their wholesalers records.

Each individual unit will be marked with a unique serial number and each manufacturer will be able to confirm whether an individual serial number is in fact a valid number and whether it was in fact issued. Pharmacists may contact the manufacturer or request that their wholesaler check with the manufacturer—but are not required to do so.

Most notably, this proposed system does not require an individual pharmacy to purchase any new equipment, or scan every item that passes through the pharmacy. As noted, most pharmacies are likely to enter into a contractual agreement with their primary wholesaler who will keep track of the actual lot numbers that are being sent to their pharmacy on any particular day but may have to keep track of any other purchases that are made from other secondary wholesalers. It should be noted that of the supply chain sectors, the pharmacy sector requirements are significantly less rigorous than any other sector in light of their status as an actual health care provider and the unique patient care services that they provide.