April 26. 2013

To: Senate Health, Education, Labor and Pensions Committee

From: International Warehouse Logistics Association
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Re: Comments on the April 19, 2013, Draft Proposal to Improve Drug Distribution Security

The International Warehouse Logistics Association (IWLA) appreciates this opportunity to comment on the Draft Proposal to Improve Drug Distribution Security. We thank the Committee for its continued efforts to reach a consensus on supply chain security. Our comments are intended to keep the process moving forward.

We very much appreciate that the draft recognizes and defines the role of the third-party logistics provider in the prescription drug supply chain. The warehouse 3PL has a very specific role in the supply chain. The 3PL receives, stores and ships product at the direction of the customer – typically the manufacturer, wholesaler or chain drug store. Under recognized commercial law, the 3PL is responsible for the proper care of the product while it is under our physical custody and control. Significantly, however, the 3PL *never* takes title to the product, nor does the 3PL arrange for the purchase or sale of the product held and shipped on behalf of the customer.

Comments

1. "Third-Party Logistics Provider Requirements" (beginning on page 60)

   This section requires a 3PL to not accept possession of a product unless the owner of the product provides the transaction history, transaction information, and a transaction statement for the product. Within 6 years of the date of enactment, the 3PL may accept possession of a product if it is encoded with a product identifier. In addition, not later than 1 year after the date of enactment, the 3PL must have systems in place to alert the owner in the case of a suspect or illegitimate product.

   Comment: A transaction is defined as a transfer of product in which a change of ownership occurs. Because a change of ownership does not occur when the 3PL takes possession of a product, it is unclear what transaction information is to be provided to and maintained by the 3PL, as by definition no "transaction" has occurred. The 3PL, however, does routinely receive and maintain certain information, including lot number. We recommend that (f) (1) be replaced (page 60, lines 21-24, and page 61, lines 1-7) with language that more accurately

reflects the type of information a 3PL routinely receives and maintains. We will suggest such language in follow-up comments.

2. Section 5. National Licensure Standards for Third-Party Logistics Providers (beginning on page 97)

This section requires the FDA to set minimum national standards for licensing third-party logistics providers. The draft sets the national standards as the floor or starting point for States to license 3PLs. States are allowed to set 3PL licensing requirements that go beyond the national standards.

Comments: Today only one state, Florida, specifically licenses a 3PL. The 3PL sector has advocated for a uniform federal licensing process for 3PLs to provide the needed visibility and shared understanding among regulatory and law enforcement resources. In short, a uniform standard of rules, requirements, and regulations applicable to 3PLs allows reduced cost and enhanced enforcement throughout all 50 states, D.C. and Puerto Rico.

As part of this process, the 3PL sector has consistently supported strong, consistent licensing standards that would apply throughout the country. We have done so with the understanding that these federal standards would constitute the requirements for 3PL licensure. This is the only way to ensure the uniformity from state to state that is so important to us and is essential to effective regulation of the pharmaceutical supply chain.

Now, under the Senate draft, 3PLs face the prospect that states will use the federal standard as a jumping off point, creating the same excessive, inconsistent and duplicative regulation that exists today. The draft advises the states that the federal licensing standards are the "minimum," implying that the States adopt stricter licensing requirements for 3PL (page 99, line 17-19, "the Secretary shall issue regulations regarding the minimum issuance and eligibility requirements for licensing"). The Senate draft encourages states to use the national standards as the starting point for 3PL licensing by allowing states to collect fees for licensing 3PLs and prohibiting fees if the state chooses not to license 3PLs.

We appreciate, but do not agree, with the concern voiced by some that States should have the prerogative to set more stringent standards for 3PL licensing. A state that has a legitimate concern with licensing standards can present those concerns during the rulemaking process outlined on page 103 of the draft – a notice of proposed rulemaking with a public comment period.

Further, the 3PL should be licensed in accordance with national standards by the state *where the facility is located*, not by each and every state into which it ships product on behalf of its customers. The requirement that a 3PL also be licensed by the state into which product is shipped is unnecessary and duplicative in view of the national standards in the draft.

An example illustrates the issue. A 3PL company based in Denver ships prescription drugs on behalf of a customer into thirty-two different states and, thus, has to be licensed in each of the thirty-two states. Under the Committee draft, this 3PL could become subject to expanded requirements in each of these 32 states (for example, the Florida 3PL license currently does not require a background check.) The final result will be that this Denver company could become subject to thirty-two different and varying background checks. A single license by the State of Colorado, where the 3PL is physically located, should suffice, with other states able to require registration, but not licensing, of an out-of-state 3PL.

We recommend that the licensure standards for 3PLs be modified as follows:

- Regulations issued by the Secretary for licensing of 3PLs are the basis for state licensing, rather than being described as "minimum standards" and that state licensing requirements be "consistent" with the federal standards.
- No facility may engage in the activities of a third-party logistics provider in any State unless such facility is licensed by the State in which it is physically located; or if the State in which the third-party logistics provider is located has not established a licensure requirement, is licensed by the Secretary.
- Any State that licenses a facility located in its state may collect a licensing fee.
- Any State into which a 3PL distributes a drug may require the out-of-state 3PL to register with the State and the State may collect a registration fee.

3. Sec. 7. Uniform National Policy

This section provides that no state may set licensing standards for wholesalers or 3PLs that are **less** stringent than the national standards. States may not license a 3PL as a wholesaler.

Comments: We very much appreciate the recognition that the 3PL is a different business model from a wholesaler and the directive to the States not to license a 3PL as a wholesaler. Consistent with our comments above, we request that this section be revised to read that no State shall regulate third-party logistics providers as wholesale distributors or establish or continue any standards, requirements, or regulations with respect to a third-party logistics provider licensure which are not consistent with the standards and requirements under this Act.