

Concerns for Retail Community Pharmacy re: S164

“Drug Supply Chain Security Act”

Title 21-FOOD AND DRUGS

CHAPTER 9-FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER V-DRUGS AND DEVICES

Part H-Pharmaceutical Distribution Supply Chain

§360eee-1. Requirements

(d) Dispenser requirements

(1) Product tracing

(A) In general

Beginning July 1, 2015, a dispenser-

(i) shall not accept ownership of a product, unless the previous owner prior to, or at the time of, the transaction, provides transaction history, transaction information, and a transaction statement;

(ii) prior to, or at the time of, each transaction in which the dispenser transfers ownership of a product (but not including dispensing to a patient or returns) shall provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product, except that the requirements of this clause shall not apply to sales by a dispenser to another dispenser to fulfill a specific patient need; and

(iii) shall capture transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintain such information, history, and statements for not less than 6 years after the transaction.

The task of maintaining product pedigree information from donated materials would be near impossible for retail community pharmacist

Secondly, retail pharmacists do not have the ability to “test” the quality of any returned products and therefore are not able to appropriately validate the integrity of such product.

Lastly, the act of taking back drug products for reuse may be misconstrued in the eyes of the public which may negatively affect public trust in the community pharmacists.

Recommendation

This program be limited to institutional settings and not involve publicly distributed product such as that dispensed from a retail pharmacy setting.

If public donations are requested to be accepted in the retail setting, then a mechanism such as a secure drop box be made available to pharmacies to effectively separate the donation process from the pharmacy’s normal business.

Resources:

State Programs for Reuse

<http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx>

Drug Supply Chain Security Act

<https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm>