
Members Present:
Howard C. Anderson, Jr (ND), chair; Wendy L. Anderson (CO); Jack William “Jay” Campbell IV (NC); Edith G. Goodmaster (CT); Edward G. McGinley (NJ); Peter J. Orzali, Jr (KY); Frank A. Whitchurch (KS).

Members Not Present:
John R. Dorvee, Jr (VT).

Others Present:
Lloyd K. Jessen, executive committee liaison (telephonically); Carmen A. Catizone, Robert Cowan, Melissa Madigan, Eileen Lewalski, Dana Oberman, NABP staff.

Guest Participants/Stakeholders:
Paul Arnold, Steve Hutter, United Parcel Service of America (UPS); Demetra Ashley, Drug Enforcement Administration (DEA); Dan Bellingham, Brian Cherico, Healthcare Distribution Management Association; Barry Boudreaux, Medco Health Solutions, Inc; Frank Devlin, CVS Caremark Corporation; Robert P. Giacalone, Carolyn McPherson, Cardinal Health; Bruce Gundy, AmerisourceBergen Corporation; Connie T. Jung, Food and Drug Administration (FDA); Ronald Koziol, Federal Bureau of Investigation (FBI).

Introduction:
The Task Force on Prescription Drug Diversion from Common Carriers met April 21-22, 2008 at Hilton Northbrook Hotel, Northbrook, IL.

This task force was established in response to Resolution 103-4-07, Prescription Drug Diversion from Common Carriers, which was approved by the NABP membership at the Association’s 103rd Annual Meeting in May 2007. The task force first met on November 8-9, 2007, and, as part of its recommendations, requested a second meeting. This request was subsequently approved by the Executive Committee:

Review of the Task Force Charge
Task force members reviewed their charge and accepted it as follows:
1. Solicit input from entities potentially affected by any action by NABP to address the issue and propose regulations, including the possible recommendation to license common carriers and other areas;
2. Review and suggest revisions, where appropriate, to the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) to reflect the recommended actions to assist in preventing prescription drug diversion from common carriers;
3. Review and suggest revisions, where appropriate, to the NABP Verified-Accredited Wholesale Distributors (VAWD) program criteria to reflect any approved revisions to the Model Act.
**Recommendation 1: Amend Model Act**

The task force recommends the following changes to the *Model Act*, including changes to the *Model Rules for the Practice of Pharmacy* and *Model Rules for the Licensure of Wholesale Distributors*.

**Model State Pharmacy Act**

**Article I Title, Purpose, and Definitions**

---

**Section 105. Definitions.**

---

(y) “Common Carrier” means any person or entity who undertakes, whether directly or by any other arrangement, to transport property including Prescription Drugs, for compensation.

---

(kkkkkk) “Significant Loss” means any loss of a Prescription Drug that exceeds a reasonable level established by like persons, which requires that loss to be reported to the Board or as required by DEA or other state and/or federal agencies for Prescription Drugs and controlled substances.

---

**Section 105(y). Comment.**

The definition of “Common Carrier” specifically excludes Wholesale Distributors which are defined separately.

**Section 105(kkkkkk). Comment.**

Some factors to consider in determining a Significant Loss include:

1. the actual quantity of Prescription Drugs or controlled substances lost in relation to the type of business;
2. the specific Prescription Drugs or controlled substances lost;
3. whether the loss of the Prescription Drugs or controlled substances can be associated with access to those Prescription Drugs or controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the Prescription Drugs or controlled substances;
4. a pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses;
5. whether the specific Prescription Drugs or controlled substances are likely candidates for diversion;
6. local trends and other indicators of the diversion potential of the missing Prescription Drug or controlled substance.
If is determined that the loss is not significant, a record of the occurrence should be kept for future reference. When a Significant Loss occurs in a Pharmacy that is registered in multiple states, all applicable Boards should be notified.

---

**Model Rules for the Practice of Pharmacy**

---

**Section 2. Personnel.**

A. Duties and Responsibilities of the Pharmacist-in-Charge

---

(2) The Pharmacist-in-Charge has the following responsibilities:

(e) Reporting any theft, suspected theft, diversion, or other Significant Loss of any Prescription Drug within one business day of discovery to the Board of Pharmacy or as required by DEA or other state or federal agencies for Prescription Drugs and controlled substances.

---

**Model Rules for the Licensure of Wholesale Distributors**

---

**Definitions**

---

“Common Carrier” means any person or entity who undertakes, whether directly or by any other arrangement, to transport property including Prescription Drugs, for compensation.

---

“Significant Loss” means any loss of a Prescription Drug that exceeds a reasonable level established by like persons, which requires that loss to be reported to the Board or as required by DEA or other state and/or federal agencies for Prescription Drugs and controlled substances.

---

**Definition of “Common Carrier.” Comment.**

The definition of “Common Carrier” specifically excludes wholesale distributors which are defined separately.
Section 5. Security and Anti-Counterfeiting.

(d) All common carriers used by a Wholesale Distributor shall ensure security via one of the following:
   (1) a verifiable security system; or
   (2) a Board-approved accreditation or certification program.

(e) At a date at which such technology is required to be maintained, Wholesale Distributors shall possess and maintain in good working order technology and equipment that allows the Wholesale Distributor to Authenticate, track, and trace Prescription Drugs. The technology and equipment shall satisfy standards set by the Board for such technology and equipment. The technology and equipment shall be used, as required by the Board, to conduct tracking, tracing, and Authentication of Prescription Drugs. Wholesale Distributors shall employ, train, and document the training of personnel in the proper use of such technology and equipment.

(f) All facilities shall be equipped with security systems to protect the integrity and confidentiality of data and documents and make such data and documents readily available to the Board and other state and federal law enforcement officials.

(g) Authentication of Pedigrees:

Section 9. Due Diligence.

If a Wholesale Distributor is licensed in accordance with these Rules or provides documentation that the Due Diligence procedures are in place and monitored by the Board or a third party recognized by the Board, then the following Due Diligence requirements may be waived by the Board:

(a) Prior to the initial Wholesale Distribution or acquisition of Prescription Drugs to or from any Wholesale Distributor (or prior to any Wholesale Distribution to a Wholesale Distributor by a Manufacturer), the Distributing Wholesale Distributor (or Manufacturer) shall provide the following information to the acquiring Wholesale Distributor:
   (1) a list of states in which the Wholesale Distributor is licensed, and into which it ships Prescription Drugs;
   (2) copies of all State and federal regulatory licenses and registrations;
   (3) the Wholesale Distributor’s most recent facility inspection reports;
   (4) information regarding general and product liability insurance, including copies of relevant policies;
   (5) a list of other names under which the Wholesale Distributor is doing business, or was formerly known;
   (6) a list of corporate officers;
   (7) a list of managerial employees directly involved in the day-to-day operations of Wholesale Distribution;
   (8) a list of all owners of the Wholesale Distributor that own more than ten percent (10%) of the Wholesale Distributor, unless the Wholesale Distributor is publicly traded;
(9) a list of all secured common carriers approved by the Wholesale Distributor; 
(10) a list of all disciplinary actions by State and federal agencies; 
(11) a description, including the address, dimensions, and other relevant information, of each facility or warehouse used for Prescription Drug storage and Wholesale Distribution; 
(12) a description of Prescription Drug import and export activities of the Wholesale Distributor; and 
(13) a description of the Wholesale Distributor’s policies and procedures to comply with this Act.

(b) Prior to the initial Wholesale Distribution or acquisition of Prescription Drugs to or from any Wholesale Distributor, the Distributing or acquiring Wholesale Distributor shall:

(1) Conduct a criminal background check of all of the Wholesale Distributor’s personnel, shareholders, and owners involved in operations and management as specified in Section 2 (Minimum Qualifications), and require that all Common Carriers contracted with or utilized by the Wholesale Distributor conduct criminal background checks of the employees whose responsibilities include the handling of Prescription Drugs; or 

(2) Verify that the Wholesale Distributor has been accredited by a third party recognized by the Board;

---

Section 10. Recordkeeping.

---

(f) Wholesale Distributors shall maintain a system for the mandatory reporting of any theft, suspected theft, diversion, or other significant loss of any Prescription Drug or Device significant shortages or losses of Prescription Drugs and Devices where it is known or suspected that diversion is occurring to the Board and FDA, and, where applicable, to DEA.

Section 10(g). Comment.

This information should be reported to NABP, if serving as a data collection repository, in addition to the other relevant authorities.

---


Wholesale Distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, and shipping and Wholesale Distribution of Prescription Drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesale Distributors shall include in their written policies and procedures the following:
(f) A procedure for identifying, investigating and reporting significant Prescription Drug inventory discrepancies involving Counterfeit, suspect of being Counterfeit, Contraband, or suspect of being Contraband, in the inventory and reporting of such discrepancies within 10 business days to the Board and/or appropriate federal or State agency upon discovery of such discrepancies.

(g) A procedure for reporting criminal or suspected criminal activities involving the inventory of Prescription Drug(s) and Device(s) to the Board, FDA, and, if applicable, DEA, within the three business days.

(h) A procedure for conducting Authentication of Pedigrees in accordance with Section 5 (Security and Anti-Counterfeiting) and standards adopted by the Board.

(i) A procedure for verifying security provisions of Common Carriers.

---

Background:

Members reviewed the recommendations of the first task force and the Committee on Law Enforcement/Legislation and concluded that the definition for “common carrier” should remain the same, but agreed that the definition of “significant loss” required some revision. Members decided that changing “like pharmacies and practices” to “like persons” was not only clearer but all inclusive. After further discussion, it was also agreed that the comment clarifying what constitutes a “significant loss” should remain. The factors in the comment were adopted from DEA language and, as such, are currently the best indicators of determining whether a loss is significant.

It was also agreed that the Model Act should be amended in regard to the security provisions of common carriers. After the discussion with the guest participants, it became clear that any proposal to require the licensure/registration of common carriers was not viable; however, it was agreed that strengthening the security integrity of the actual persons delivering the product through contractual agreements between wholesale distributors and common carriers was a better approach. Stakeholders explained that background checks and safety/security training requirements are contained in the contracts and any failure to perform results in a breach of contract. Other stakeholders indicated that all of its distribution centers were Transported Asset Protection Association (TAPA) certified and that TAPA was considered the blueprint for proper security for warehouses. The TAPA security criteria were researched and the members agreed that the best method to ensure security was to allow wholesale distributors to utilize only common carriers that were certified or accredited. The background check provision was further implemented in the Due Diligence Section of the Model Act.

Recommendation 2: Revise VAWD criteria to reflect amendments made to the Model Act.

NABP will review and revise the standards for VAWD accreditation to incorporate the requirements for common carriers regarding contractually secure agreements with wholesale distributors. These agreements must contain requirements for common carrier employees who handle prescription drugs to undergo criminal background checks, initial and random toxicology screening, and security training.
Background:
Members discussed the fact that VAWD is operational and an increasing number of states are mandating its implementation. It was noted however, that some distributors continue to operate under the radar with insufficient security procedures. In light of the task force’s recommendation to not require the licensure/registration of common carriers, the task force agreed that it is critical to amend the VAWD criteria to address this concern.

Recommendation 3: Support Efforts to Identify the Scope of Diversion; Implement Requirements to Prevent and Monitor Diversion; Urge Congress and State Legislatures to Provide the Necessary Resources for State and Federal Enforcement Agencies to Address Diversion.

The task force recognizes that the theft, loss, and suspected loss of prescription products is a serious concern, the scope of which is unknown, and that the boards of pharmacy, state, local, and federal law enforcement agencies must continue to work together and share information to address this problem.

Background:
The members were told by federal enforcement agency representatives that since the tragedy of September 11, 2001, diversion has become a lower priority and resource supported activity in all the respective agencies. The members agreed that it is imperative for the boards of pharmacy to continue to request involvement by all law enforcement entities in making anti-diversion programs a priority.

Recommendation 4: NABP Examine the Feasibility of Serving as a Repository for the Collection of Theft and Loss Reports and Analyzing those Data to Provide Information to the Boards of Pharmacy and Appropriate State and Federal Agencies.

The task force recommends that, if feasible, NABP serve as a clearinghouse for reports of any theft, suspected theft, diversion, or significant loss of any prescription drug. The task force also recommends that, if the NABP Executive Committee approves the aforementioned recommendation, that NABP make the data available to the state boards of pharmacy and, when appropriate and applicable, to federal agencies and pharmacies in order to provide information and alerts on products that may be stolen or diverted and diversion/theft activities.

Background:
As stated in the initial meeting of the task force, members were very concerned that information about diversion by and from common carriers was not being shared among the boards of pharmacy and law enforcement entities. DEA indicated that the vast majority of diversion cases result from employee theft and that wholesale distributors and common carriers are involved in a smaller percentage of diversion cases than task force members had previously realized.

Stakeholders were not opposed to reporting controlled substances losses, but stated that it would be difficult and costly to report theft/losses of all prescription drugs. They indicated; however, that they would report to a national clearinghouse, if mandated by the states. Members agreed that a national clearinghouse for this type of data would assist in determining the scope of the overall
problem, and identification of data obtained may guide the boards of pharmacy in the development of rules and regulations to decrease diversion overall.