Report of the Task Force on Prescription Drug Diversion from Common Carriers

Members Present:
Howard C. Anderson, Jr (ND), chair; Wendy L. Anderson (CO); John R. Dorvee, Jr (VT); Edith G. Goodmaster (CT); Edward G. McGinley (NJ); Peter J. Orzali, Jr (KY); Frank A. Whitchurch (KS).

Members Not Present:
Jack William “Jay” Campbell IV (NC).

Others Present:
Lloyd K. Jessen, executive committee liaison; Carmen A. Catizone, Eileen Lewalski, Christine Siwik, NABP staff.

Introduction:
The Task Force on Prescription Drug Diversion from Common Carriers met November 8-9, 2007 at NABP headquarters.

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.

Review of the Task Force Charge
Task Force members reviewed their charge and accepted it as follows:
1. Identify the scope and breadth of the problem;
2. Recommend ways in which the boards of pharmacy and NABP can collaborate with government, industry, and other stakeholders in preventing prescription drug diversion from common carriers; and
3. Review and revise, where appropriate, the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) to reflect the recommended actions and assist in preventing prescription drug diversion from common carriers.

Recommendation 1: Loss/Theft Data Must Be Compiled and Shared; NABP Should Seek Assistance from Other State and Federal Agencies

The Task Force recommends that NABP contact the state boards of pharmacy to collect data on the diversion of prescription drugs from common carriers for the past five years in order to document the scope of the problem. Additionally, NABP should contact other state and federal agencies, such as Drug Enforcement Administration (DEA) and Food and Drug Administration (FDA), in an effort to coordinate efforts between the state boards of pharmacy and federal agencies.

Background:
Task Force members were alerted to the problem of the diversion of prescription drugs by common carriers by ex-officio Task Force member, William Harvey, executive director of the New Mexico Board of Pharmacy. Task Force members concurred with the findings of Mr
Harvey and agreed that the theft and diversion and subsequent illegal distribution of prescription drugs are a significant public health concern. Task Force members also shared diversion issues and incidents occurring within their various states, noting of particular concern the lack of security maintained by common carriers during deliveries from drug wholesalers to pharmacies. Members stated that deliveries are routinely made by vans, albeit with no markings, but also lacking alarms, other additional anti-theft devices and the fact that background checks are not performed on common carrier drivers. Beyond the actual delivery vehicle, concerns were also raised by Task Force members about the absence of security cameras in delivery parking lots or entrances. Task Force members also noted that suspects in these diversion activities frequently include acquaintances or family members of common carrier employees.

A major concern expressed by Task Force members was that many prescription drug and controlled substance thefts go unreported. Even though DEA requires the reporting of all significant losses of controlled substances via DEA Form 106, many losses remain unreported due to the ambiguity of the term “significant loss.” Task Force members discussed that in the event that a report is made, DEA field offices may not be in a position to share this information with the applicable state boards of pharmacy. Additionally, not all state boards of pharmacy require registrants to provide a copy of the DEA Form 106 to the board and also do not have in place any other reporting regulations pertaining to losses.

Task Force members proposed the following as reasons for not reporting:

- Fear of punitive action;
- Confusion as to which party in the wholesale chain of custody actually sustained the loss and at what point, as well as which party is then responsible for reporting;
- Considering the loss a non-loss if it is covered by insurance, thus not realizing it should be reported.

Regardless of the reason, losses and thefts appear to be on the rise among common carriers and Task Force members believe it is necessary for NABP to obtain baseline data and defining data from all available sources in order to determine the scope of the problem and to formulate recommendation on how to address the problem.

**Recommendation 2: NABP Research Additional Data Sources to Discover the Scope and Nature of Prescription Drug Theft**

The Task Force recommends that NABP research additional, available data sources, for example, insurance data sources, that may reveal the scope and nature of prescription drug thefts by and from common carriers.

**Background:**

Task Force members discussed the process and action steps that may be involved when prescription drugs are diverted by and/or from common carriers. As previously mentioned, one of the reasons advanced for the lack of substantive data on the incidence and scope of the problem is the reporting of such losses to insurance companies for coverage reimbursement. The reporting to insurance entities may mislead the responsible Person (pharmacists, pharmacies,
wholesalers, or manufacturers) from recognizing the legal responsibility to report losses, when applicable, to the state boards of pharmacy, DEA, or other federal/state law agency.

Task Force members agreed that data collected by insurance companies would help further to define the scope of the problem as well as provide valuable insight into these occurrences that may never be known to state boards of pharmacy or other state/federal enforcement agencies.

**Recommendation 3: 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.**

(cccc) “Loss Threshold” means the level established by a pharmacy whereby any loss of a prescription drug that exceeds that level must be reported to the Board and the responsible state and federal authority.

---

(kkkkkk) “Significant Loss” means any loss of a prescription drug that exceeds the loss threshold and which requires a pharmacy to report the loss to the Board and the responsible state and federal authority.

**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 to the Board of Pharmacy and as required by DEA or other state/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, by motor vehicle, for compensation.

“Loss Threshold” means the level established by a wholesale distributor whereby any loss of a prescription drug that exceeds that level must be reported to the Board and the responsible state and federal authorities.

“Significant Loss” means any loss of a prescription drug that exceeds the loss threshold and which requires a company to report the loss to the Board and the responsible state and federal authorities.

Section 10. Recordkeeping.

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.

Background:

Members reviewed the Model Act and the Model Rules for the Licensure of Wholesale Distributors and concluded that definitions for “common carrier,” “loss threshold,” and “significant loss” were required. Members specifically felt it necessary to add the term “loss threshold” recognizing that the term “significant loss,” as it is currently used in federal and state laws and regulations, is a relative term. A “significant loss” to one pharmacy may not be deemed a “significant loss” to another pharmacy. A “loss threshold” establishes an individually determined benchmark for each pharmacy to determine a “significant loss.”

It was also agreed that the Model Act should be amended in one of two manners 1) to require reporting by manufacturers, wholesale distributors and pharmacies of any theft, suspected theft,
diversion, or other significant loss of any prescription drug or 2) require the licensure/registration of common carriers. Before formulating a final recommendation on which course to take, the Task Force members agreed that additional information and input from interested stakeholders was required. At this point, the Task Force agreed that modifying the requirements for wholesale distributors was an appropriate first step and would facilitate further discussion.

Recommendation 4: NABP Should Serve as a Clearinghouse for the Reporting of Prescription Drug Losses

The Task Force recommends that NABP partner with appropriate stakeholders to serve as a clearinghouse for reports of any theft, suspected theft, diversion, or significant loss of any prescription drug and that NABP develop a process that encourages the reporting of such incidents. 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 previously mentioned, members were very concerned that information about diversion by and from common carriers is not being shared among the boards of pharmacy and law enforcement entities. Members discussed RxPATROL (Pattern Analysis Tracking Robberies and Other Losses), a clearinghouse for data on pharmacy robberies, burglaries, and theft involving the loss of controlled substances. Sponsored by Purdue Pharma LP, RxPATROL collects, analyzes, and disseminates pharmacy theft information to law enforcement agencies nationally. Task Force members felt that NABP would be an excellent resource to serve as a national clearinghouse for this type of data, which could then be made available to the appropriate entities to better protect the public. Members conveyed the importance of ensuring some protection for those reporting based on concerns that, if reporting resulted in punitive action, individuals would be reluctant to provide the information.

Recommendation 5: Consider Additional Model Act Amendments; Consult with Stakeholders; Request Second Task Force Meeting

NABP should consider amending the Model Act to require licensure of common carriers after consultation with industry stakeholders at a second meeting of this Task Force.

Background:

The Task Force discussed in depth as to whether common carriers should be licensed due to the integral part they play in the chain of custody of prescription drugs. The major concern was with the current lack of jurisdiction over common carriers, especially pertaining to security issues (e.g., vehicular security, employee background checks), recognizing that this is where a large number of diversions occur. Members, however, were reluctant to recommend amending the Model Act to such a degree without further discussion with other stakeholders.

Task Force members requested that the Executive Committee approve funding for a second meeting to 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.

**Recommendation 6: Strengthen Wholesale Drug Distributor and Pharmacy Regulations In the Model Act or VAWD Program**

The Task Force agreed that if the licensure/registration of common carriers is not feasible or viable then the *Model Act* should be amended and/or standards for the accreditation of wholesale distributors through the NABP Verified-Accredited Wholesale Distributors (VAWD) Program amended to strengthen the requirements currently in place for manufacturers, wholesale distributors, and pharmacies.