Virginia Board of Pharmacy
Theft or Loss of Drugs

Virginia law requires the reporting of any theft or unusual loss of any Schedule I – V controlled substances to the Board of Pharmacy, as follows:

from Code of Virginia, Drug Control Act
§54.1-3404

…

E. Whenever any registrant or licensee discovers a theft or any other unusual loss of any controlled substance, he shall immediately report such theft or loss to the Board. If the registrant or licensee is unable to determine the exact kind and quantity of the drug loss, he shall immediately make a complete inventory of all Schedule I through V drugs. Within thirty days after the discovery of a loss of drugs, the registrant or licensee shall furnish the Board with a listing of the kind, quantity and strength of such drugs lost.

…

Board guidance on reporting theft or unusual loss

The Drug Control Act in §54.1-3404 requires a registrant or licensee who discovers a theft or any other unusual loss of a drug in Schedules II, III, IV, or V to immediately report the theft or loss to the Board. Similarly, Title 21 Code of Federal Regulations (CFR) §1301.74 states, "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss." In addition to the notification requirement, a registrant or licensee must furnish the Board with a listing of the kind, quantity, and strength of such drugs lost within 30 days after the discovery of the loss. Submission of a copy of Drug Enforcement Administration (DEA) Form 106 is acceptable for complying with the Board's reporting requirement.

While it is clear that a "theft" of any quantity of drug in Schedules II-V must be reported to the Board and DEA, there is occasionally confusion regarding the reporting requirements for a loss when it is unclear whether the loss constitutes an "unusual" or "significant" loss. While the terms "unusual loss" as used in the Drug Control Act and "significant loss" as used in the federal regulation are not defined in state or federal rules, DEA does offer guidance in rule and the *Pharmacist's Manual* for determining if a loss constitutes a "significant loss." It is suggested that pharmacists and pharmacy technicians follow DEA's guidance for satisfying the state and federal reporting requirements for both unusual and significant drug losses. To determine whether a loss is "significant," Title 21 CFR §1301.74 states:

. . . a registrant should consider, among others, the following factors:

1. The actual quantity of controlled substances lost in relation to the type of business;
2. The specific controlled substances lost;
3. Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the 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; and, if known,
5. Whether the specific controlled substances are likely candidates for diversion;
6. Local trends and other indicators of the diversion potential of the missing controlled substance.

Furthermore, DEA's 2010 edition of the *Pharmacist's Manual* states:

> Although the [Controlled Substances Act] regulations do not define the term "significant loss," it is the responsibility of the registrant to use his/her best judgment to take appropriate action. Whether a "significant loss" has occurred depends, in large part, on the business of the pharmacy and the likelihood of a rational explanation for a particular occurrence. What would constitute a significant loss for a pharmacy may be viewed as comparatively insignificant for a hospital or manufacturer. Further, the loss of a small quantity of controlled substances, repeated over a period of time, may indicate a significant problem for a registrant, which must be reported. The burden of responsibility is on the registrant to identify what is a significant loss and make the required report to DEA.

In accordance with §54.1-3404 of the Drug Control Act, if the registrant or licensee is unable to determine the exact kind and quantity of the drug loss, he or she shall immediately make a complete inventory of all Schedule II-V drugs. Also, if after the initial notification of a theft or loss to the Board or DEA the investigation of the theft or loss determines no such theft or loss of controlled substances occurred, then a complete listing and the DEA Form 106 is not required to be filed. However, the licensee or registrant should notify the Board and DEA in writing of this fact in order to resolve the initial report.

If it is determined that a loss occurred, but it is not significant, DEA indicates in the *Pharmacist's Manual* that " . . . the registrant should place a record of the occurrence in a theft and loss file for future reference. Miscounts or adjustments to inventory involving clerical errors on the part of the pharmacy should not be reported on a DEA Form 106, but rather should be noted in a separate log at the pharmacy management's discretion." Lastly, as indicated in the *Pharmacist's Manual* and supported by the Board, if there is a question as to whether a theft has occurred or a loss is significant, a licensee or registrant should err on the side of caution and report it to DEA and the Board.

Procedure for reporting a theft or loss

Please use DEA 106 form for the complete reporting of theft or loss of drugs. The form may be found on DEA's website as follows:
http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html

If, after a breaking or suspected loss of drugs, it is determined that no drugs were taken, the above form does not need to be completed.

Distribute copies and keep a copy as follows:

1 Copy: Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Richmond, VA 23233
804/367-4456

2 Copies: Drug Enforcement Administration*
Techworld Plaza
ATTN: Drug Diversion
800 K Street, N.W., Suite 500
Washington, DC 20001

202/305-8888

1 Copy: To be maintained at location of drug stock for your records

***You may submit your DEA form via the online submission process on DEA's website. You will need to print a copy for your records and the Board of Pharmacy**