

STATE BOARD NEWS -- FEBRUARY 1997 ISSUE

LOSS OR THEFT - REQUIRED REPORTS

Controlled Substances

Both federal and state laws governing the legal distribution of controlled substances require that any theft or significant loss of controlled substances be reported. Federal regulations require that the theft or significant loss of controlled substances be reported to the Field Division office of the Drug Enforcement Administration "upon discovery of such loss or theft". The federal regulation (21 CFR 1301.76) also requires that the loss or theft be reported in writing by using DEA form 106.

Dangerous Drugs

Ohio Administrative Code Rule 4729-9-15 requires that anyone licensed to purchase or possess dangerous drugs in the course of business or their professional practice to immediately notify the Board of Pharmacy by telephone upon discovery of such loss or theft of dangerous drugs. A DEA Form 106 is automatically forwarded by the Board of Pharmacy office upon receiving notification by telephone of the theft or significant loss of controlled substances.

This rule also reiterates the federal regulation and requires that the significant loss or theft of dangerous drugs which are controlled substances be reported to the regional office of DEA. The Board rule also requires that a report of the theft or significant loss of any dangerous drug be filed with local law enforcement authorities. The theft of a dangerous drug is a felony of the fourth degree (ORC 2913.02). If the person has been previously convicted for the theft of a dangerous drug, the theft is a felony of the third degree.

A written report of the theft or significant loss of the dangerous drugs must be filed with the State Board of Pharmacy office within thirty days following the discovery of such loss or theft. If the dangerous drugs are controlled substances, the original copy of the DEA form 106 should be filed with the Board of Pharmacy office, a copy of the report forwarded to the DEA Field Division office, and a copy filed with your controlled substance records. The original copy is placed in the dangerous drug distributor file maintained by the Board office. This form may also be used to report the theft or significant loss of dangerous drugs which are not controlled substances. In these instances, it is not necessary to file a copy with the federal Drug Enforcement Administration.

It is important to note that all thefts of dangerous drugs must be reported while only significant losses must be reported. A frequently asked question is "What is a significant loss?" The answer to that question has to do with the circumstances regarding the loss of a dangerous drug. One dose of a dangerous drug may be significant if it continues to occur over a period of time under the same circumstances. Continuing loss of even one dose of a dangerous drug on a continuing basis indicates that the dangerous drug is being stolen. It is

especially significant if the dangerous drug is subject to abuse but has not been classified as a controlled substance (i.e., carisprodol, butorphone, etc.).

If doses of a dangerous drug continue to disappear on a regular basis, the Board office should be immediately notified in order to formulate a procedure for determining what is actually happening and identifying the responsible person if dangerous drugs are being stolen.

REVISED RULES EFFECTIVE JANUARY, 1997

The following rules have been revised and will be in effect by the time this newsletter arrives. Most of the changes were minor grammatical changes that did not affect the intent of the rule in any way. There are, however, several rules that may be of particular interest to practicing pharmacists.

The full text of these rules will be included in the next update to your lawbook. In the meantime, a copy of the rules may be obtained by sending a large self-addressed, stamped (55¢) envelope to the Board office with a note requesting a copy, or may be viewed on the Board's Home Page at <http://www.state.oh.us/pharmacy/>.

<u>RULE NO.</u>	<u>TITLE</u>	<u>COMMENTS</u>
4729-1-02	Notice of meetings.	Sunshine notice fee from \$15 to \$25
4729-3-01	Definitions (Internship)	Minimal grammatical changes
4729-3-03	Application for registration as a pharmacy intern.	Minimal grammatical changes
4729-3-04	Pharmacy intern identification card renewal.	Minimal grammatical changes
4729-3-05	Internship credit.	Eliminated 50 hour/week maximum
4729-5-01	Definitions(Pharmacy Practice)	Requires computer Rx to be hard copy.
4729-5-07	Recognized and approved colleges of pharmacy.	Revised TSE score to match 4729-5-34.
4729-5-17	Recordkeeping.	Deleted, see 5-27, 5-28, & 5-29
4729-5-19	Serial numbering of prescriptions.	See 4729-5-26 (new)
4729-5-24	Prescription copy.	Citation change to deal with 4729-5-17 deletion
4729-5-26	Partial dispensing of schedule II controlled substances.	Formerly paragraph (D) of 4729-5-19
4729-5-27	Recordkeeping.	First part of former 4729-5-17
4729-5-28	Computerized recordkeeping systems.	Second part of former 4729-5-17
4729-5-29	Confidentiality of patient records.	Third part of former 4729-5-17
4729-9-01	Definitions (Drug Distributors)	Minimal grammatical changes
4729-9-04	Returned drugs.	Minimal grammatical changes
4729-9-15	Report of theft or loss of dangerous drugs, controlled substances, and drug documents.	Minimal grammatical changes
4729-9-16	Minimum requirements for wholesalers.	Minimal grammatical changes

4729-27-01 solutions.	Definitions (Peritoneal Dialysis Solutions)	New chapter about sale of P.D.
4729-27-02 solutions.	Licensure.	New chapter about sale of P.D.
4729-27-03 solutions.	Security, storage, and sale.	New chapter about sale of P.D.
4729-27-04 solutions.	Records.	New chapter about sale of P.D.
4729-27-05 solutions.	Prescriber's order.	New chapter about sale of P.D.

Because the old recordkeeping rule (4729-5-17) was so long, pharmacists were having too much difficulty locating the answers to their questions. For that reason, this rule was divided into three separate rules dealing with general recordkeeping (4729-5-27), computer system recordkeeping (4729-5-28), and patient confidentiality issues (4729-5-29). The old recordkeeping rule (4729-5-17) has been deleted.

These three new rules bear much the same wording as was found in 4729-5-17. However, there have been several changes and additions that pharmacists need to be aware of in their daily practice. In the computer section, the security requirements have been clarified. The term "Positive Identification" is used throughout. This term was defined in rules effective September 1, 1996 and is included in the last update to the "Drug Laws of Ohio" on page F-15 in Rule 4729-5-01(N). If your computer system maintains positive identification of people entering orders, it requires more than initials or a password. "Positive Identification" requires some physical means of identifying a person such as a magnetic card, thumbprint, or some other means. In addition, the new rule clarifies the need for an audit trail for all changes that have been made to a prescription.

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