

Wisconsin Department of Safety and Professional Services

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PHARMACY EXAMINING BOARD

PHARMACY SELF-INSPECTION INFORMATIONAL SHEET

The Board no longer requires the Department of Safety and Professional Services to send inspectors to conduct on-site inspections prior to licensure.

In lieu of the above, the Board requires the Managing Pharmacist to complete the attached "Pharmacy Self-Inspection Report" (Form 923). Please complete each line indicating the date of compliance, either actual or anticipated, but in no event later than the proposed opening date indicated on the cover page of Form #923. Sign and notarize the affidavit. If the Pharmacy is in non-compliance with any portions of the "Pharmacy Self-Inspection Report" please indicate why the pharmacy is in non-compliance and when the pharmacy will be in compliance. Return the entire "Pharmacy Self-Inspection Report" to the Board office when completed. Please make a copy for your files.

After the "Pharmacy Self-Inspection Report" has been reviewed and is found to be in order, a license number will be issued if all other requirements have been satisfied.

The Department on behalf of the Board will conduct an unannounced audit of the pharmacy location within one year after the date the license was issued to verify that the pharmacy is in compliance with the "Pharmacy Self-Inspection Report" as well as the "Wisconsin Statutes and Administrative Code Relating to the Practice of Pharmacy."

This procedure will also be used for remodeling.

If you have any questions regarding this procedure or the "Pharmacy Self-Inspection Report" please feel free to contact the Bureau of Health Professions at the Department of Safety and Professional Services.

NOTICE TO CREDENTIAL HOLDERS CONDUCTING SELF-INSPECTIONS

The Division of Legal Services and Compliance in the Department of Safety and Professional Services conducts a follow-up inspection to the self-inspection done by new Pharmacies prior to their opening for business.

Below is a list of the most frequently occurring problems we found during our follow-up inspections. The reference is to the Pharmacy Board Rule or Statute. This list is being provided to assist new businesses in conducting their self-inspections.

Pharmacies:

- Prescription labels – Not having the correct address of the facility or using the name of the previous pharmacy (Phar 7.02).
- Records – Inadequate recordkeeping of Schedule V substances (Phar 8.02(3)(e)(2)).
- Alarm systems – All facilities must have a functioning alarm system or alternate board approved security system at all times to detect entry after hours. Some facilities were found to have opened without an alarm system in place or the alarm system was not working at various times (Phar 13.10(4)).
- Display of license – License is not displayed in a conspicuous place (Wis. Stats. 450.09(5)).

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PROCEDURE FOR REPORTING THEFT OR LOSS OF CONTROLLED SUBSTANCES

The Managing Pharmacist is responsible for reporting any theft or significant loss of controlled substances to the U.S. Department of Justice, DEA Kluczynski Building, Ste. 1200, 230 S. Dearborn Street, Chicago, IL 60604 (312-353-1236, or 1-800-478-7642 toll free 24 hours). Report the theft or loss on DEA Form #106 (Report of Theft or Loss of Controlled Substances), obtainable from DEA at www.deadiversion.usdoj.gov. In any instance that a pharmacy, practitioner or other DEA registrant authorized to possess controlled substances is required to file with the DEA a report of theft or loss of controlled substances, the pharmacy, practitioner or other DEA registrant shall also send a copy to the board within 2 weeks of filing with the DEA.

PROCEDURE FOR DESTROYING CONTROLLED SUBSTANCES

Contact the US Department of Justice, 1000 N. Water Street, Room 1010, Milwaukee, WI 53202 or www.deadiversion.usdoj.gov for the proper forms.

WISCONSIN STATUTES AND ADMINISTRATIVE CODES

This book can be viewed online at dsps.wi.gov/boards/phm/code/codebook.htm or purchased through DOA at dsps.wi.gov/includes/catalog.htm.

APPROVED PRESCRIPTION DRUG PRODUCTS AND CODE OF FEDERAL REGULATIONS

These publications are obtainable from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20401.