

Wisconsin Phar 8 Updates

WISCONSIN PHAR 8 UPDATES

Effective 10/1/2022

The Wisconsin Pharmacy Examining Board updated and wrote Phar 8 – Requirements for Controlled Substances to comprehensively update the chapter for modern pharmacy practice and alignment with federal regulations. The updated version of this rule is effective October 1, 2022.

The Pharmacy Society of Wisconsin has created this toolkit as a resource for pharmacies and pharmacists practicing in Wisconsin. While every effort has been made to ensure the accuracy of this information, pharmacies and pharmacists should always ensure compliance with all state and federal laws, administrative rules, and regulations. All pharmacies and pharmacists practicing in Wisconsin are responsible for complying with the laws and regulations as they are written.

A copy of Phar 8 can be found online here.

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Please Note:

The new Phar 8 is significantly shorter than the previous version. Many previous Phar 8 regulations that are also federal requirements have been removed. Pharmacies are still required to meet these requirements as a condition of DEA registration and state licensure (e.g., requirements of a prescription, prescription labels, emergency dispensing, etc.). If a requirement was removed from Phar 8 but is still a federal requirement, it is not listed in this guide. The <u>DEA Pharmacist's Manual</u> is a good source of information on federal requirements.

Changes to Phar 8

Recordkeeping

- The pharmacy must maintain a perpetual inventory of all schedule II medications.
- Quarterly, the pharmacy shall complete an inspection of and reconcile all controlled substances (including non-prescription schedule V substances). The regulation does not specify how reconciliation is to occur.
- Controlled substance inventory records, invoices, and DEA official order forms (Forms 222) must be maintained for 2 years (previously, Wisconsin required all records to be kept for 5 years). Controlled substance prescriptions must still be maintained for 5 years.

Valid Prescription

• A pharmacist may not dispense a prescription for a controlled substance that the pharmacist knows, or reasonably should know, is not a valid prescription.

Changing Prescription Orders

- Phar 8 removes the allowance for pharmacists to change information on a controlled substance prescription order (e.g., strength, dosage form, quantity prescribed) pending DEA clarification of this allowance.
- The new Phar 8 eliminates state-level regulations on the information a pharmacist may not change on a controlled substance prescription and how a pharmacist may clarify information when needed. No federal law or regulations exist on which components of a controlled substance prescription may or may not be changed by the pharmacist. Until DEA or PEB provides further clarification:
 - » Schedule III-V prescription information could be clarified through consultation with the prescriber or obtaining a new prescription.
 - » Schedule II prescription information should be changed through a new prescription from the prescriber if any changes need to be made.

Dispensing

- For schedule II prescriptions delivered to a patient not personally known to the pharmacist, the printed name, signature, and address of the person are no longer required to be written on the back of the prescription order.
- Prescriptions for schedule II medications no longer expire 60 days after the date of issue on the prescription order. This change does not apply to partially filled prescriptions for long-term care or hospice patients, which still expire after 60 days.

Partial Dispensing

- One-time partial dispensing is now allowed for schedule II controlled substances if one of the following conditions applies:
 - » The pharmacist is unable to supply the total quantity called for in the prescription;
 - » The patient requests partial dispensing; or
 - » The prescribing practitioner requests partial dispensing.

• The remaining portion of a partially filled schedule II prescription must be dispensed within 72 hours of the first partial dispensing. The pharmacist must notify the prescribing practitioner if the remaining portion is not dispensed within 72 hours.

Identification Cards

• While state law typically requires an identification card of the person receiving a schedule II and III prescription, this requirement does not apply when a drug is lawfully delivered to the location of a patient's choice (via mail, common carrier, or delivery service). In this case, a valid signature is required.

Suspicious Orders and Theft/Loss

• Manufacturers and distributors must report "suspicious orders" of controlled substances to the DEA. Phar 8 now requires that pharmacies that receive suspicious orders (for distribution, not dispensing) or experience theft or loss of controlled substances report this to the PEB on the same day that it is reported to the DEA (previously 2 weeks).