

LEGEND DRUGS

What are legend drugs?

Legend drugs are drugs which may only be dispensed by prescription or are restricted for use by practitioners only.¹ A prescription for legend drugs is valid only if issued for a legitimate medical purpose.²

Is the substitution of prescription drugs permitted?

Yes. Every written or oral prescription must contain an instruction as to whether or not a generic drug may be substituted in its place. Every prescription must have two signature lines at opposite ends on the bottom of the form with the words “dispense as written” under the right line and “substitution permitted” under the left line³ See **DRUG SUBSTITUTION**.

Is the prescription of steroids restricted?

Yes. A physician may not prescribe, administer or dispense steroids for the purpose of manipulating hormones to increase muscle mass, strength, weight, or for the purpose of enhancing athletic ability, without a medical necessity to do so.⁴

Are there requirements for legibility of prescriptions?

Yes. Prescriptions must be legible under the law.⁵ In order to be legible the prescription must be capable of being read and understood by the pharmacist.⁶ A prescription may be hand printed, typewritten, or electronically generated.⁷

Are there any specific requirements for the paper on which a prescription is written?

Yes. Effective July 1, 2010, every prescription written in Washington by a licensed practitioner must be written on a tamper-resistant prescription pad or paper approved by the Board of Pharmacy (BOP).⁸ A pharmacist may not fill a prescription not written on a tamper-resistant pad or paper (except to provide an emergency supply to the patient as allowed by the BOP and insurance contract requirements.⁹ Hard copies of electronic prescriptions must also be on tamper-resistant paper.¹⁰ Tamper-resistant prescription pads or paper does not have to be

¹ RCW 69.41.010(12).

² RCW 69.41.040(1).

³ RCW 69.41.120.

⁴ RCW 69.41.320.

⁵ RCW 69.41.120.

⁶ RCW 69.41.010(13).

⁷ *Id.*

⁸ RCW 18.64.500(1).

⁹ RCW 18.64.500(2).

¹⁰ RCW 18.64.500(3).

used for prescriptions transmitted to the pharmacy by telephone, facsimile, or electronic means.¹¹ Physicians must employ reasonable safeguards to prevent to assure against theft or unauthorized use of the prescriptions.¹²

Tamper-resistant prescription pads or paper must contain one or more industry-recognized features designed to prevent:¹³

- Unauthorized copying of a completely blank form;
- The erasure or modification of information written on the prescription for by the physician; and
- The use of counterfeit prescription forms.

For more information about tamper-resistant prescription pads and paper, visit the BOP website:

<http://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/Pharmacy/TamperResistantPrescriptions.aspx>.

What are the rules governing electronic communication of prescriptions?

Over-the-counter, legend drug and controlled substance prescriptions may be transmitted electronically.¹⁴ Electronic transmission of prescription information means the communication from a prescriber to a pharmacy (or between pharmacies) by computer, facsimile, or other electronic means (not voice communication) of original prescription or prescription refill information for a legend drug or controlled substance.¹⁵ Both the system used for transmitting and the system used for receiving electronically communicated prescription information must be approved by the Board of Pharmacy.¹⁶ The system must have adequate security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of the records.¹⁷ Policies and procedures to ensure the integrity and confidentiality of the electronically transmitted information¹⁸ and that do not restrict patients' access to the pharmacy of their choice must also be in place.¹⁹

Transmission of original prescriptions must include all of the following:²⁰

- Prescriber's name and address.

¹¹ RCW 18.64.500(9).

¹² RCW 18.64.500(5).

¹³ RCW 18.64.500(4).

¹⁴ WAC 246-870-040.

¹⁵ WAC 246-870-020(1).

¹⁶ RCW 69.41.055(1)(b).

¹⁷ RCW 69.41.055(e).

¹⁸ *Id.*

¹⁹ WAC 246-870-060(3)(a).

²⁰ WAC 246-870-030.

- Prescriber's DEA number, when required for controlled substances.
- Date of the prescription.
- Patient's name and address.
- Drug name, dose, route, form, directions for use, and quantity.
- Electronic, digital, or manual signature of the prescriber.
- Refills or renewals authorized, if any.
- A place to note allergies and a notation for the purpose of the drug.
- Indication of preference for a generic equivalent drug substitution.
- Any other requirements consistent with state and federal laws related to prescription form and content.
- Identification of the electronic system easily retrievable in case of Board of Pharmacy inspection.

Information concerning electronic prescriptions and electronic communication systems approved by the Board of Pharmacy may be found at: <http://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/Pharmacy/ElectronicPrescriptions.aspx>.

E-mail may be used to transmit prescription information if the system meets requirements for security and confidentiality.²¹ Email systems must meet requirements for security, which include having documented formal procedures for selecting and executing security measures, physical safeguards to protect computer systems from intrusion, processes to protect, control, and audit access to confidential patient information, and processes to prevent unauthorized access to the data when it's transmitted over a network or when data is physically moved from one location to another using media such as removable drives or data disks.²²

Are there special rules related to use of facsimile machines to transmit prescription information?

Yes. Prescriptions orders transmitted via facsimile from a prescriber to a pharmacist must meet the following requirements:²³

²¹ WAC 246-870-090.

²² WAC 246-870-090; 246-870-020(5).

²³ WAC 246-870-050.

- The order must contain the date, time, and telephone number and location of the transmitting device.
- Prescriptions for Schedule III, IV, and V drugs may be transmitted without condition.
- Refill authorizations for prescriptions may be electronically transmitted.
- Prescriptions for Schedule II drugs may be transmitted only under the following conditions:
 - The order is for an injectable Schedule II controlled substance that is to be compounded by the pharmacist for patient use or the prescription is written for patients in a long-term care facility or a hospice program.
 - The prescription must be signed by the prescriber.
 - In a nonemergent situation, an order for Schedule II controlled substances may be prepared for delivery to a patient pursuant to a facsimile transmission but may not be dispensed to the patient except upon presentation of a written order.
 - In an emergent situation, an order for Schedule II controlled substances may be dispensed to the patient upon the verbal orders of a prescriber, provided that the prescription is promptly transmitted in written form. The pharmacy has seven days to obtain a written prescription that covers an emergency prescription.
 - When the prescription is transmitted to a hospital for a patient admitted to or being discharged from the hospital.

Should a physician report the theft or loss of a legend drug?

Although federal law requires that a physician, upon discovery, notify the DEA field office of the theft or loss of any controlled substance,²⁴ **see CONTROLLED SUBSTANCES**, there is no specific requirement under Washington law for reporting the theft or loss of a legend drug.

Because theft is a crime, however, when a physician in good faith believes that there has been a theft of legend drugs, the physician may report the theft to the local law enforcement agency. A person who in good faith communicates a complaint or information to any federal, state or local government agency regarding any matter reasonably of concern to that agency is immune from civil liability for claims based on the communication to the agency.

²⁴ 21 C.F.R. § 1301.76(b).

May a physician prescribe a legend drug for personal use?

Washington law does not specifically prohibit a physician from self-prescribing a legend drug. It is unprofessional conduct, however, for a physician to self-prescribe a controlled substance.²⁵ See **CONTROLLED SUBSTANCES**. Because a legend drug may only be prescribed for a legitimate medical purpose and because misuse of a legend drug by a physician can result in disciplinary action, caution should be exercised in self-prescribing legend drugs.

May a physician prescribe a legend drug to a family member?

Washington law does not specifically prohibit a physician from prescribing legend drugs for family members. A legend drug, however, may be prescribed only for a legitimate medical purpose. Thus, it is advisable to exercise caution before prescribing legend drugs to family members and to keep thorough medical records and to avoid manipulation by family members.

May a physician obtain drug samples from a manufacturer without signing for them?

No. Samples can only be secured with a written request that is signed and dated by the physician (or other individual authorized to prescribe drugs, such as an Advanced Registered Nurse Practitioner).²⁶ The request must contain:

- The recipient's name, address, and professional designation;
- The name, strength, and quantity of the drug samples delivered;
- The name or identification of the manufacturer and of the individual distributing the drug samples; and
- The dated signature of the practitioner requesting the drug sample.

How must drug samples be stored?

In addition to storing drug samples in compliance with any other requirements of federal and state laws, rules, and regulations, drug samples must be stored:²⁷

- In a locked area to which access is limited to persons authorized by the manufacturer.
- In a manner as to be free from contamination, deterioration, and adulteration.
- Under conditions of temperature, light, moisture, and ventilation so as to meet the label instructions for each drug.

²⁵ RCW 18.130.180(6).

²⁶ RCW 69.45.050.

²⁷ RCW 69.45.040.

Drug samples which have exceeded their expiration date must be physically separated from other drug samples until disposed of or returned to the manufacturer.²⁸

What records must a physician maintain with respect to legend drug samples?

A physician who purchases, dispenses, or distributes legend drugs (including samples) must maintain invoices or such other records as are necessary to account for the receipt and disposition of the legend drugs. In other words, all drug samples must be logged in and out of a medical practice. Such records must be maintained for two years.²⁹

How must legend drug samples and legend drugs be labeled when dispensed to a patient?

Legend drugs dispensed as a trial sample in its original package, and which is labeled in accordance with federal law or regulation must have the name of the issuing practitioner and the name of the patient.³⁰ Otherwise every container of a legend drug which is dispensed by a physician must have a label bearing the name of the prescriber, complete directions for use, the name of the drug, strength per unit dose, and the name of the patient (unless the physician determines the patient should not be informed of the name and dosage of the medication).³¹

How should a physician dispose of drug samples?

Surplus, outdated or damaged drug samples must be either returned to the manufacturer or destroyed before a witness by means which assure that the drug cannot be retrieved.³² However, specific rules apply to the disposition of controlled substances. See **CONTROLLED SUBSTANCES**.

May a physician be disciplined for conduct related to legend drugs?

Yes. A physician may be disciplined for:³³

- The possession, use, prescription for use, or distribution of legend drugs in any way other than for legitimate or therapeutic purposes.
- Diversion of legend drugs.
- Violation of any drug law.
- Misuse of legend drugs by oneself.

The sale, delivery or possession of legend drugs except by prescription is a crime.³⁴

²⁸ *Id.*

²⁹ RCW 69.41.042.

³⁰ RCW 69.41.050.

³¹ *Id.*

³² RCW 69.45.060.

³³ RCW 18.130.180(6)_.

May an Advanced Registered Nurse Practitioner (ARNP) prescribe legend drugs?

Yes. Upon approval of the Nursing Care Quality Assurance Commission (NCQAC), an ARNP may prescribe legend drugs.³⁵ See **NURSES**.

May a Physician Assistant (PA) prescribe legend drugs?

Yes. A certified physician assistant may prescribe legend drugs.³⁶ A PA may prescribe legend drugs, when approved by the Medical Quality Assurance Commission (MQAC) and assigned by the supervising physician, for a patient who is under the care of the supervising physician.³⁷ See **PHYSICIAN ASSISTANTS**; see also **OSTEOPATHIC PHYSICIAN ASSISTANTS**.

³⁴ RCW 69.41.030.

³⁵ WAC 246-840-400.

³⁶ WAC 246-918-035.

³⁷ WAC 246-918-030.