

CONTROLLED SUBSTANCES

What is a controlled substance?

A controlled substance is a drug, substance, or immediate precursor to a drug included in Schedules I through V under federal and state law.¹

What are the characteristics of controlled substances?

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| <i>Schedule I:</i> | Substances having no currently accepted medical uses in treatment in the U.S.; lacking accepted safety for use in treatment under medical supervision; and having a high potential for abuse. ² |
| <i>Schedule II:</i> | Substances having currently accepted medical uses in treatment in the U.S. (possibly with severe restrictions); having a high potential for abuse; and, if abused, leading potentially to severe psychological or physical dependence. ³ |
| <i>Schedule III:</i> | Substances having currently accepted medical uses in treatment in the U.S.; having a potential for abuse less than substances listed in Schedules I and II; and, if abused, leading potentially to moderate or low physical dependence or high psychological dependence. ⁴ |
| <i>Schedule IV:</i> | Substances having currently accepted medical uses in treatment in the U.S.; having a low potential for abuse relative to substances listed in Schedule III; and, if abused, leading potentially to limited physical dependence or psychological dependence relative to the substances in Schedule III. ⁵ |
| <i>Schedule V:</i> | Substances having currently accepted medical uses in treatment in the U.S.; having a low potential for abuse relative to substances listed in Schedule IV; and, if abused, leading potentially to limited physical dependence or psychological dependence relative to the controlled substances listed in Schedule IV. ⁶ |

¹ RCW 69.50.101(d); 21 U.S.C. § 802(6).

² RCW 69.50.203(a); 21 U.S.C. § 812(b)(1).

³ RCW 69.50.205(a); 21 U.S.C. § 812(b)(2).

⁴ RCW 69.50.207(a); 21 U.S.C. § 812(b)(3).

⁵ RCW 69.50.209(a); 21 U.S.C. § 812(b)(4).

⁶ RCW 69.50.211(a); 21 U.S.C. § 812(b)(5).

Must a physician be registered in order to prescribe, dispense, or administer controlled substances?

A physician must be registered with the federal Drug Enforcement Administration (DEA) before prescribing, dispensing, administering, or distributing controlled substances, unless exempted from registration by federal regulation.⁷ Physicians who prescribe or dispense narcotics to patients for maintenance treatment or detoxification treatment must obtain a separate registration for that purpose.⁸ Applications for registration may be obtained at any regional office of the DEA, or by writing to the Drug Enforcement Administration, Attn: Registration Section/ODR, P.O. Box 2639, Springfield, Virginia 22152-2639, or by calling the DEA at 1-800-882-9539 (or 206-553-5443 locally).⁹

Physicians licensed in the State of Washington are exempted from registering with the State,¹⁰ but this exemption may be revoked.¹¹

May a physician's controlled-substances registration be suspended or revoked?

Yes. A physician's federal registration may be suspended or revoked upon a finding that:¹²

- the physician materially falsified the registration application;
- the physician has been convicted of a felony relating to any controlled substance;
- the physician has had his or her state license or registration suspended, revoked, or denied by the state authority and is no longer authorized by the state to prescribe, dispense, or administer controlled substances or has had the suspension, revocation, or denial of the physician's registration recommended by a state authority;
- the physician has committed acts that, in the context of controlled substances, would render his or her registration inconsistent with the public interest; or
- the physician has been excluded (or has been directed to be excluded) from participation in a federal health care program.

A registration to dispense narcotics for maintenance treatment or detoxification treatment may be suspended or revoked if the physician fails to comply with the specific requirements of the registration.¹³

⁷ 21 C.F.R. § 1301.11(a); 21 U.S.C. § 822(a).

⁸ 21 U.S.C. § 823(g)(1).

⁹ See 21 C.F.R. §§ 1301.13(e), 1301.14(a), 1321.01.

¹⁰ RCW 69.50.302(d).

¹¹ See RCW 69.50.304(a).

¹² 21 U.S.C. § 824(a).

¹³ 21 U.S.C. § 824(a).

Under Washington law, a physician's exemption from state registration requirements may be suspended or revoked, precluding the physician from prescribing, dispensing, or administering controlled substances, upon a finding that:¹⁴

- the physician furnished false or fraudulent material information in a registration application;
- the physician has been convicted of a felony under any state or federal law relating to any controlled substance;
- the physician's federal registration has been suspended or revoked; or
- the physician committed acts that, in the context of controlled substances, are inconsistent with the public interest.¹⁵

What are the recognized purposes for prescribing controlled substances?

Federal regulations specify the legitimate purposes for prescribing controlled substances as follows:

- A prescription for a controlled substance is effective only if it is issued for a legitimate medical purpose by a physician acting in the usual course of his or her professional practice.¹⁶
- A prescription may not be issued in order for a physician to obtain controlled substances for general dispensing to patients.¹⁷ A physician must use DEA Form 222 or its electronic equivalent to obtain Schedule I or II controlled substances for office use through regular supply sources.¹⁸ A physician who orders controlled substances for use by all physicians in an office or clinic must register with the DEA as a distributor.¹⁹
- A physician may not issue prescriptions for detoxification or maintenance treatment unless the physician complies with certain other federal regulations²⁰ and the prescription is for a Schedule III, IV, or V narcotic drug approved by the federal Food and Drug Administration (FDA) specifically for this kind of use.²¹ A physician may administer or dispense directly (but not prescribe) a narcotic drug to a narcotic-dependent person for maintenance or detoxification treatment if the physician is separately registered with the DEA as a narcotic treatment program and the physician complies with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs.²²

¹⁴ RCW 69.50.304(a).

¹⁵ See also WAC 246-887-290.

¹⁶ 21 C.F.R. § 1306.04(a).

¹⁷ 21 C.F.R. § 1306.04(b).

¹⁸ See 21 C.F.R. §§ 1305.03, 1307.11(a).

¹⁹ See 21 U.S.C. § 822(a)(1).

²⁰ See 21 C.F.R. § 1301.28.

²¹ 21 C.F.R. §§ 1306.04(c), 1306.07(d).

²² 21 C.F.R. § 1306.07(a).

However, a physician not registered as a narcotic treatment program can administer (but not prescribe) narcotic drugs to a patient daily for up to three days to relieve acute withdrawal symptoms while arrangements are being made for referral to an existing narcotic treatment program.²³

Are there requirements for legibility of prescriptions?

Yes. Prescriptions must be hand-printed, typewritten, or electronically generated.²⁴

What are the rules governing electronic communication of prescriptions?

Electronic transmission of prescription information means the communication from an authorized prescriber to a pharmacy (or between pharmacies) by computer, facsimile, or other electronic means (but not voice communication) of original prescription or prescription refill information for a legend drug or controlled substance.²⁵ Over-the-counter, legend drug, and controlled substance prescriptions may be transmitted electronically, consistent with federal²⁶ and state laws.²⁷ Only exact visual images of Schedule II prescriptions, however, may be transferred electronically.²⁸ Both the system used for transmitting and the system used for receiving electronically communicated prescription information must be approved by the Washington State Board of Pharmacy.²⁹ The system must have adequate security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information.³⁰ Policies and procedures that ensure the integrity³¹ and confidentiality³² of the electronically transmitted information and that do not restrict patients' access to the pharmacy of their choice³³ must also be in place. These rules do not apply, however, to facsimile transmission of an exact visual image of the prescription.³⁴ Transmission of original prescriptions must include all of the following:³⁵

- Prescriber's name and address.
- Prescriber's DEA registration number where required for controlled substance prescriptions.
- Date the prescription was issued.

²³ 21 C.F.R. § 1306.07(b).

²⁴ RCW 69.41.010(13). See also 21 C.F.R. § 1306.05(d).

²⁵ WAC 246-870-020(1). See also RCW 69.50.101(n).

²⁶ See generally 21 C.F.R. §§ 1311 *et seq.*

²⁷ WAC 246-870-040. See also 21 C.F.R. § 1306.08.

²⁸ WAC 246-870-040.

²⁹ RCW 69.50.312(b).

³⁰ WAC 246-870-060(3)(b).

³¹ See WAC 246-870-060.

³² WAC 246-870-060(3)(d).

³³ WAC 246-870-060(3)(a).

³⁴ RCW 69.50.312(1)(b).

³⁵ WAC 246-870-030(1)–(11).

- 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 readily retrievable for Board of Pharmacy inspection.

Information concerning electronic systems approved by the Board of Pharmacy may be found at: <http://www.doh.wa.gov/Portals/1/Documents/2300/ElectronicPresc.pdf>.

Email may be used to transmit prescription information if the system meets requirements for security and confidentiality.³⁶

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

Yes. Prescription orders transmitted via fax from a prescriber to a pharmacist must meet the following requirements:³⁷

- The order contains the date, time, and telephone number and location of the transmitting device.
- Prescriptions for Schedule III, IV, and V drugs may be transmitted at any time.
- Prescriptions for Schedule II drugs may be transmitted only under the following conditions:
 - The order is for an injectable Schedule II narcotic 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.

³⁶ WAC 246-870-090.

³⁷ WAC 246-870-050(1)–(3). See also RCW 69.50.308(b)–(c) (Schedule II prescriptions).

- In a non-emergent 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 of this kind.
- The prescription is to a hospital for a patient admitted to or being discharged from the hospital.

Refill authorizations for prescriptions may be electronically transmitted.³⁸

Is there a limitation on the quantity of controlled substances that may be prescribed to a patient?

There is no statutory limitation. A physician is limited, however, by the exercise of sound medical judgment required by the applicable standard of care.

Is there a limitation on refills of controlled substances?

Yes. A prescription for a Schedule II substance may not be refilled.³⁹ A prescription for a Schedule III or IV substance may not be refilled more than six months after the prescription's date and may not be refilled more than five times, unless the physician renews the prescription.⁴⁰

May a physician prescribe controlled substances for himself or herself?

No. It is unprofessional conduct to self-prescribe controlled substances.⁴¹ See **UNPROFESSIONAL CONDUCT.**

May a physician prescribe controlled substances for family members?

Washington law does not specifically prohibit it. However, a physician may prescribe a controlled substance only for a legitimate medical purpose while acting in the usual course of his or her professional practice.⁴² Furthermore, a physician may not issue a prescription to dispense narcotic drugs for detoxification or maintenance treatment of a person who is dependent on narcotic drugs unless the FDA has approved those drugs for such a purpose and the physician

³⁸ WAC 246-870-050(5).

³⁹ 21 U.S.C. § 829(a).

⁴⁰ 21 U.S.C. § 829(b).

⁴¹ RCW 18.130.180(6). See also RCW 69.50.308(i).

⁴² 21 C.F.R. § 1306.04(a). See also RCW 69.50.308(e).

complies with certain federal regulations.⁴³ Thus, a physician should exercise great caution before prescribing controlled substances for family members, should keep thorough medical records, and should avoid manipulation by family members.

May a physician be subject to criminal prosecution for violating the controlled substances laws?

Yes. A physician's violation of the laws governing controlled substances may result in criminal prosecution.⁴⁴ Furthermore, the physician's medical license will be suspended for the term of a sentence resulting from violation of the laws related to controlled substances.⁴⁵

May a physician be disciplined for conduct related to controlled substances?

Yes. A physician's violation of the laws governing controlled substances may result in disciplinary action. In particular, a physician may be disciplined for:⁴⁶

- The possession, use, prescription for use, or distribution of controlled substances in any way other than for legitimate or therapeutic purposes.
- Diversion of controlled substances.
- Violation of any drug law.
- Prescribing controlled substances for oneself.
- Personal misuse of controlled substances.⁴⁷

How should controlled substances be stored?

Physicians must store controlled substances in their offices or clinics in a securely locked, substantially constructed cabinet or safe. Access to the storage area should be kept to a minimum. A sufficiently detailed record of the receipt, use, and disposition of all controlled substances must be maintained. An inventory of all controlled substances in the physician's possession must be completed every two years and the inventory records kept for two years.⁴⁸

See also **LEGEND DRUGS.**

⁴³ See 21 C.F.R. §§ 1306.04(c), 1306.07(d), 1301.28.

⁴⁴ See generally RCW 69.50.401–440 (Article IV of Uniform Controlled Substances Act—Offenses and Penalties); 21 U.S.C. §§ 841–65 (Offenses and Penalties).

⁴⁵ RCW 69.50.413.

⁴⁶ RCW 18.130.180(6).

⁴⁷ RCW 18.130.180(23)(b).

⁴⁸ WAC 246-887-200(4). See also WAC 246-887-020(3).

How should physicians dispose of controlled substances?

Physicians should contact the local DEA office for specific instructions on the disposal of controlled substances. The local DEA office will instruct the physician to either transfer the controlled substances to the local DEA office (or such other person or entity as arranged by the DEA) or to destroy the substances in the presence of a DEA agent.⁴⁹

Must a physician report the theft or loss of a controlled substance?

Yes. Any loss or theft of controlled substances must be reported to a DEA field office using DEA Form 106, with a copy sent to the Washington State Board of Pharmacy.⁵⁰ DEA Form 106 is available at: http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html.

Washington law further requires that the theft or loss of a precursor drug be reported to the state Board of Pharmacy within seven days of discovery.⁵¹ Knowingly providing false information constitutes a Class C felony.⁵²

May an Advanced Registered Nurse Practitioner (ARNP) prescribe controlled substances?

Upon approval from the Nursing Care Quality Assurance Commission (NCQAC), an ARNP may prescribe Schedule V controlled substances and, subject to statutory guidelines, controlled substances contained in Schedules II through IV.⁵³ See **NURSES**.

May a Physician Assistant (PA) prescribe controlled substances?

A physician assistant may prescribe controlled substances only if specifically approved by the Medical Quality Assurance Commission (MQAC).⁵⁴ A certified physician assistant may prescribe controlled substances, subject to certain conditions.⁵⁵ See **PHYSICIAN ASSISTANTS**.

⁴⁹ 21 C.F.R. § 1307.21. See also WAC 246-887-200(4), -270(6).

⁵⁰ 21 C.F.R. § 1301.76(b); WAC 246-887-020(3)(c).

⁵¹ RCW 69.43.060(1).

⁵² RCW 69.43.080.

⁵³ RCW 18.79.050; RCW 18.79.240(1)(r)–(s).

⁵⁴ WAC 246-918-130(2).

⁵⁵ See WAC 246-918-035.