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Division of
Professional Regulation

Frequently Asked Questions

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For additional questions, see Pharmacy FAQ's (/boards/pharmacy/faqs/).

Answers

How do I register to prescribe controlled substances?

Answer: You must have all of the following to apply for a Delaware controlled substance registration (CSR):

- Delaware office or resident location
- Delaware professional license to practice your profession (e.g., Physician M.D. license)
- Prescriptive authority if you are an Advanced Practice Registered Nurse (APRN) or Physician Assistant (PA)
- Supervising physician (if you are a PA) for *each* individual business/practice where you will practice in Delaware

If you meet the above requirements, refer to these pages for instructions on applying for Delaware CSR registration:

- Physician, Dentist, Veterinarian, Podiatrist – Controlled Substances Registration – Practitioners (/boards/controlledsubstances/practitioner_CSR/)
- PA – Controlled Substances Registration – Physicians Assistant (/boards/controlledsubstances/PA_CSR/)
- APRN – Controlled Substances Registration – Advanced Practice Registered Nurse (/boards/controlledsubstances/APN_CSR/)
- Optometrist – Application for Controlled Substance Registration – Optometrists (https://dpr.delaware.gov/boards/controlledsubstances/Opt_CSR/)

When you receive your Delaware CSR, you must apply for a federal DEA registration for Delaware (a DEA registration in another jurisdiction is not sufficient). For instructions on applying, see DEA New Registration Applications (https://www.deadiversion.usdoj.gov/webforms/jsp/regapps/common/newAppLogin.jsp).

How long does it take to process my application?

Answer: The time period for the processing your controlled substance application is 4-6 weeks *after* your permanent professional license (e.g., as a physician, APRN, dentist, veterinarian, etc.) is issued.

Do I need two separate registrations for two different offices?

Answer: You need only one Delaware CSR to ***prescribe*** controlled substances in Delaware even if you prescribe controlled substances at more than one Delaware business/practice or more than one location of a business/practice. However, every Delaware location where controlled substances are dispensed/stored must be covered by a CSR. If no other practitioner (e.g., physician), physician assistant or APRN holds a Delaware CSR for a location where you will ***store/dispense***, as well as prescribe, controlled substances, you must file for an additional CSR for the location.

What does the law say about verbally communicated prescriptions?

Answer: According to the *Uniform Controlled Substances Act Regulations*, only the **prescriber** may communicate a verbal prescription for a controlled substance to a pharmacist. Prescriptions for controlled substances communicated by the prescriber's employee or agent are not valid. However, an employee or agent of the prescriber is allowed to verbally communicate prescriptions for *non-controlled* substances.

Does Delaware law allow electronically originated controlled substance prescriptions?

Answer: A prescriber or the prescriber's authorized agent may send written prescriptions for controlled substances by fax to a pharmacy when the transmission complies with 21 CFR 1306.11, 1306.21 and 1306.31 and Delaware Controlled Substance and Pharmacy Rules and Regulations. The prescriber must ***hand-sign*** prescriptions for controlled substances transmitted by fax (Section 4.4 of the Controlled Substance Regulations (http://regulations.delaware.gov/AdminCode/title24/Uniform%20Controlled%20Substances%20Act%20Regulations.shtml)).

In addition, all other state and federal requirements must be followed when receiving and transmitting faxed prescriptions. See Section 5.0 of the Pharmacy Regulations (http://regulations.delaware.gov/AdminCode/title24/Uniform%20Controlled%20Substances%20Act%20Regulations.shtml).

For information about the implementation of electronically originated controlled substance prescriptions, see e-Prescriptions for Controlled Substances (https://dprfiles.delaware.gov/controlledsubstances/e-Prescribing_Update_1-2013.pdf).

When am I allowed to issue a controlled substance prescription?

Answer: A practitioner acting in the usual course of his or her professional practice may issue a controlled substance prescription for a legitimate medical purpose (21 CFR 1306.04). Responsibility for properly prescribing and dispensing controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order that is not issued in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the law (**21 U.S.C. 829** (http://www.deadiversion.usdoj.gov/21cfr/21usc/829.htm)). A person who knowingly fills such a purported prescription, as well as the person issuing it, will be subject to the penalties for violations of the provisions of controlled substances law.

A prescription may **not** be issued for*:*

- an individual practitioner to obtain controlled substances for general dispensing to patients
- dispensing narcotic drugs listed in any schedule for “detoxification treatment” or “maintenance treatment” unless the prescription is for a Schedule III, IV, or V narcotic drug that the Food and Drug Administration has approved specifically for use in maintenance or detoxification treatment and the practitioner complies with requirements in **§1301.28**. (http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_28.htm)

What is the expiration for a controlled substance prescription?

Answer: Prescriptions for Schedule II and III controlled substances become void if not dispensed within seven days of the original date of the prescription unless the original prescriber authorizes the prescription past the seven-day period.

Exception:

Schedule II prescriptions for terminally ill or Long-Term Care Facility patients are valid for up to 60 days from the issue date unless terminated by the discontinuance of the medication.

How much can I prescribe and dispense?

Answer: You cannot write prescriptions or dispense Schedule II and III controlled substances for more than 100 dosage units *or* a 31-day supply, whichever is greater, at a time.

Exception:

You may fill prescriptions for Schedule II controlled substances in partial quantities, to include individual dosage units, for patients who either have a medically documented terminal illness or reside in Long-Term Care Facilities (21 CFR Section 1306.1(b)). The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. For each partial filling, the dispensing pharmacist must record the:

- date of the partial filling
- quantity dispensed
- remaining quantity authorized to be dispensed
- identification of the dispensing pharmacist.

This documentation may be on the back of the prescription or another appropriate record that is uniformly maintained and readily retrievable.

Does Delaware law permit multiple Schedule II prescriptions with different dates?

Answer: Multiple Schedule II prescriptions for the same patient but different dates are permitted. Each prescription must:

- show the issue date
- not exceed 90 days
- be prescribed for a legitimate purpose and written by a licensed, registered practitioner acting in the usual course of professional practice.

What is the policy for prescription pad security and storage?

Answer: The availability of prescriptions has led to controlled substance diversion on a number of occasions. Under Section 4.0 of the Delaware Controlled Substance Regulations (http://regulations.delaware.gov/AdminCode/title24/Uniform%20Controlled%20Substances%20Act%20Regulations.shtml), only a practitioner who is authorized to prescribe controlled substances is allowed to issue a prescription for controlled substances. Practitioners and licensed healthcare facilities are held accountable for any loss or theft of controlled substances that results from the loss or theft of blank prescriptions that are then used to criminally obtain substances of abuse.

For the reasons listed above, the Office of Controlled Substances recommends that you, as a practitioner, keep your prescription pads only on your person. If it is absolutely necessary to store blank prescriptions in your office or facility, store them separately and securely under lock and key. Do not allow prescription pads to be accessible to the public or to facility staff (e.g., pharmacists, nurses, etc.). Develop a policy to address this issue at each facility, and include the policy in the facility's policy/procedure manual. Make attending practitioners aware of the policy.

By complying with this policy, practitioners and facilities will be adhering to Delaware law and will lessen the likelihood of diversion due to prescription fraud.

What are the standards for securely storing controlled substances in a practitioner's office?

Answer: Schedule II controlled substances must be stored in a burglar-resistant safe or GSA Class 5 grade steel cabinet or equivalent. If the safe weighs less than 750 pounds, it must be bolted, cemented or secured to the wall or floor so that it cannot be readily removed. Other types of similarly constructed, securely locked cabinets or drawers are acceptable provided that the room or storage area has electronic intrusion detection equipment capable of detecting four-step movement in the area(s) where Schedule II controlled substances are stored. If excessive diversion of controlled substances occurs, additional security requirements may be deemed necessary. See Section 5.0 of the Delaware Controlled Substance Regulations (http://regulations.delaware.gov/AdminCode/title24/Uniform%20Controlled%20Substances%20Act%20Regulations.shtml) for more information.

What are the standards for storing controlled substances in a Delaware-licensed Pharmacy?

Answer: Pharmacies must store Schedule II controlled substances in a burglar-resistant safe or GSA Class 5 grade steel cabinet or equivalent. If the safe weighs less than 750 pounds, it must be bolted, cemented or secured to the wall or floor so that it cannot be readily removed. If excessive diversion of controlled substances occurs, additional security requirements may be deemed necessary.

What can a Pharmacist change on a controlled substance prescription?

Answer: A Pharmacist can change a controlled substance prescription *but only after* contacting the prescriber. After consulting with the prescriber, the pharmacist is permitted to change:

- patient's address
- drug strength
- drug quantity
- directions for use.

The pharmacist is also allowed to *add* the following but only after verifying it:

- information provided by the patient or bearer, such as the patient's address
- dosage form to the prescription order.

The pharmacist is *never* permitted to change:

- patient's name
- controlled substance prescribed (except for generic substitution permitted by state law)
- prescriber's signature.

These changes would challenge the need for the original prescription and require a new prescription from the prescribing practitioner.

What are the partial filling requirements for a Schedule II controlled substance?

Answer: Federal regulations allow for the partial filling of a Schedule II controlled substance when the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription (21 CFR 1306.13). The pharmacist must note the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling. However, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist must notify the prescriber. No further quantity may be supplied beyond the 72 hours without a new prescription.

How do we transfer controlled substances between Pharmacies?

Answer: Pharmacies are permitted to transfer original prescription information for a controlled substance listed in Schedules III, IV, or V to another pharmacy on a *one time basis only* (21 CFR 1306.25 (a)). Pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization. Transfers are subject to the following requirements:

- The transfer must be communicated directly between two licensed pharmacists
- The *transferring* pharmacist must:
    - write the word "VOID" on the face of the invalidated prescription
    - record the following on the reverse of the invalidated prescription:
        - name, address and DEA registration number of the pharmacy to which it was transferred
        - name of the pharmacist receiving the prescription information
    - record date of the transfer and the name of the pharmacist transferring the information
- The *receiving* pharmacist must:

- write the word “TRANSFER” on the face of the transferred prescription
- provide all information required by 21 CFR 1306.05 and include:
  - date of issuance of original prescription:
  - number of refills authorized on original prescription

Related Topics: Controlled Substances Frequently Asked Questions (https://dpr.delaware.gov/tag/controlled-substances-frequently-asked-questions/), Department of State (https://dpr.delaware.gov/tag/department-of-state/), Division of Professional Regulation (https://dpr.delaware.gov/tag/division-of-professional-regulation/), faqs (https://dpr.delaware.gov/tag/faqs/), State of Delaware (https://dpr.delaware.gov/tag/state-of-delaware/)

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