North Carolina Board of Pharmacy

Controlled Substance Rules & Regulations Pocket Card

A brief summary of pertinent rules and regulations impacting the practice of pharmacy

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Controlled II Substance Rules & Regulations

Manner of Issuance of Prescriptions:
All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.
21 CFR §1306.05 (a)

Requirements of a Prescription:
A prescription for a CII may be transmitted by the practitioner via facsimile provided that the original written Rx is presented to the pharmacist for review prior to the actual dispensing of the controlled substance.
21 CFR §1306.11 (a)

Refilling CII Prescriptions:
The refilling of a Schedule II prescription is prohibited.
21 CFR §1306.12 (a)

Expiration date of CII Prescriptions:
North Carolina state law (that went into effect on October 1, 2013) provides that "No Schedule II substance shall be dispensed pursuant to a written prescription more than six months after the date it was prescribed." The new six-month limitation applies to all prescriptions issued on or after October 1, 2013.
NCGS §90-106 (b)

Sequential "Do Not Fill Until" prescriptions for CII medications are permissible so long as: (a) each prescription is dated with the day of issuance along with a "*do not fill until*" date; and (b) the sequential prescriptions authorize no more than a total 90-day supply.
21 CFR §1306.12

Emergency CII Prescriptions:
In an **emergency situation**, a pharmacist may dispense a CII upon receiving an oral authorization of a prescribing practitioner provided that the quantity prescribed and dispensed is **limited** to the **amount** adequate to treat the patient during the emergency period.

The prescribing practitioner shall within **7 days** of authorizing the emergency Rx, mail or deliver a written Rx for the emergency quantity prescribed. In addition, the written Rx shall have "Authorization for Emergency Dispensing" printed on the face of the script along with the date of the oral order.

Upon receipt, the original script shall be attached to the oral emergency script. The pharmacist shall notify the Drug Enforcement Agency (DEA) if the prescribing practitioner fails to deliver a written Rx.
21 CFR §1306.11 (d)

Clarification of CII prescriptions:
Scheduled CII prescriptions may be clarified by the pharmacist by consulting with the prescriber. Permissible changes after consultation are documented at http://www.ncbop.org/faqs/Pharmacist/faq_ChangestoSchIICS.htm. Such changes do not require a new Rx hardcopy from the prescriber.

Controlled II Substance Rules & Regulations

Facsimile Prescriptions for CII medications:
CII prescriptions that are to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted via facsimile by the prescribing practitioner. The facsimile will act as the original Rx. **21 CFR §1306.11 (e)**

CII prescriptions for a resident of a Long-Term Care Facility may be transmitted via facsimile by the prescribing practitioner. The facsimile will act as the original Rx. No written copy is necessary. **21 CFR §1306.11 (f)**

CII prescriptions for patients under hospice care may be transmitted via facsimile by the prescribing practitioner. The facsimile will act as the original Rx. **21 CFR §1306.11 (g)**

Transmission of Prescription Orders:
Prescription orders may be transmitted by using a facsimile machine ("FAX") or by other electronic transmission from a prescriber to a pharmacy. "Electronic transmission" means transmission of the digital representation of information by way of electronic equipment. All prescription drug orders transmitted by FAX or by electronic transmission shall:
(1) be transmitted directly to a pharmacist or certified technician in a pharmacy of the patient's choice with no intervening person altering the content of the prescription drug order;
(2) identify the transmitter's phone number for verbal confirmation, the time and date of transmission, and the identity of the pharmacy intended to receive the transmission;
(3) be transmitted by an authorized practitioner or his designated agent and contain either a written signature or an electronic signature unique to the practitioner;
(4) be deemed the original prescription drug order, provided it meets all requirements of federal and state laws and regulations; and
(5) if a refill order, contain all information required for original prescription orders except for the prescriber's signature.
21 NCAC 46 .1813 (a) (b) (1-5)

Controlled II Substance Rules & Regulations

Partial Filling of a Schedule II Controlled Substance

The Comprehensive Addiction and Recovery Act of 2016 (CARA) allows a pharmacy to partially fill a Schedule II controlled substance if:

(1) state law does not prohibit partial fills of Schedule II prescriptions;

(2) the prescription is written and filled in compliance with federal and state law;

(3) partial fill is requested by the patient or prescriber;

(4) total quantity dispensed in all partial fills does not exceed the total quantity prescribed.

The total amount of a Schedule II prescription may be filled no later than thirty (30) days from the date the prescription was written.

DEA still allows partial fills of a Schedule II prescription for a Long-Term Care patient for up to sixty (60) days from the date of the prescription.

A verbal emergency order for a Schedule II controlled substance may be partially filled, but the remained must be filled within seventy-two (72) hours. After this period, no further partial fills are allowed. **[See 21 CFR 1306.13(a)(b)]**

Prior to CARA's enactment in October 2016, DEA regulations allowed partial fills of a Schedule II prescription if the pharmacy was unable to supply the full quantity. CARA superseded DEA's rules on this matter.

Controlled III, IV, & V Substance Rules & Regulations

Requirements of a prescription:
A pharmacist may dispense a controlled substance (Schedule III, IV, & V) only pursuant to: a **written prescription** signed by a practitioner, **facsimile** of a written, signed Rx, an electronic Rx that meets requirements, **or** an **oral** Rx made by an individual practitioner.
21 CFR §1306.21 (a)

Refilling of a prescription:
No Rx for CIII-IV medications shall be filled or refilled more than **6 months** after the written date **or** refilled more than **five times**. Schedule V controlled substances may be refilled as authorized. **21 CFR §1306.22 (a-b)**

Schedule V medications are **not** subject to the 6-month, 5 refill limit.

Dispensing in excess of the prescribed quantity is prohibited for all controlled substances and psychotherapeutic drugs without authorization from the prescriber.
21 NCAC 46.1802 (b)

Partial filling of a prescription:
Partial dispensing of Schedule CIII-IV prescriptions is **permissible** provided that each partial filling is recorded, the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed and no dispensing occurs after **6 months** from the date the prescription is issued.
21 CFR §1306.23

Controlled Substance Inventory & Recordkeeping:
Pharmacies with automatic data processing systems are permitted to file Schedules III, IV, & V prescriptions **without** stamping them in the lower right corner with a one-inch high letter "C". **21 CFR §1304.04 (h) (4)**

Whenever a change in ownership or change of pharmacist-manager occurs, the successor shall complete an inventory of **all** controlled substances in the pharmacy **within 10 days**. A record of this inventory must be signed by the pharmacist-manager, dated and maintained on file with other controlled substance records for a three-year period.
21 NCAC 46.2502 (c)

Controlled III, IV, & V Substance Rules & Regulations

(Controlled Substance Inventory & Recordkeeping, continued):

Biennial inventory is to be performed on any date within two years of the previous biennial inventory. **21 CFR §1304.11 (c)**

When performing a biennial inventory, an **exact count** is required of all CII medications on hand. If the drug is listed as a Schedule III-V, an estimated count is sufficient, **unless** the drug container holds more than **1,000** tablets or capsules in which an **exact count is warranted. 21 CFR §1304.11 (3) (i) (ii)**

Hard-copy printouts of the day's controlled substance Rx orders and refills shall be verified, dated, and signed by the pharmacist who filled these orders. This document must be maintained in the pharmacy for three years from the dispensing date. **21 CFR §1306.22 (3)**

Transfer of CIII-V Prescriptions between pharmacies:
The transfer of CIII-V prescriptions is permissible for refilling only **once**. However, pharmacies electronically sharing a real-time, on-line database may transfer the maximum allowable refills as permitted by law. **21 CFR §1306.25 (a)**

The transfer of such prescriptions **must be communicated directly** between two licensed pharmacists.

The name, address, date, DEA number of the pharmacy to which it is being transferred along with the pharmacist's name must be recorded. **21 CFR §1306.25 (1) (ii)**

The transferred Rx hardcopy shall be noted by the word "VOID" on the face of the Rx. Also, the date must be noted. The following information must also be provided:

- Date prescription originally written
- Original number of refills
- Date of original dispensing and last refill, if any
- Number of authorized refills
- Number of valid refills remaining
- Pharmacy name, address, DEA number of transferring pharmacy, and the Rx number
- Pharmacist name transferring Rx

21 CFR §1306.25 (b)

The original and transferred prescription(s) must be maintained for a three-year period from the date of last refill. **21 NCAC 46.1806 (c)**

Electronic Prescriptions for Controlled Substances
DEA rule allows for the transmission and receipt of ECSRx for all schedules if both the transmitting and receiving systems are certified as meeting DEA security requirements.
21 CFR §1311.100, et seq.

Prescription and Labeling of Controlled Substances:
The label of **CII-IV** controlled substances **shall contain** the following warning statement: "***Caution: Federal Law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."*** **21 CFR §290.5**

The patient's name and physical street address for all controlled substance prescriptions must be readily retrievable, but is **not** required to be handwritten on the face of the Rx hard-copy. **21 CFR §1306.05 (a)**

The preprinting of or use of preprinted prescription blanks with the name of scheduled substances is prohibited. Prescription blanks that are individually generated (aka: computer generated prescriptions) are permissible. **45.G NCAC .0307**

Proper Disposal of Controlled Substances:
A written request for disposal of controlled substances must be made to the Board. The Board will, at that point, provide authority and instructions for disposal. After authority has been granted, two licensed pharmacists approved by the Board must witness the destruction of the substance, if it occurs on the permit holder's premises. All destruction must be documented and such records should be maintained on file for a three-year period. Copies of such documentation should also be forwarded to the Drug Enforcement Administration. **21 NCAC 46.3001 (c)**

Right to Refuse a Prescription:
A pharmacist has the right and responsibility to **refuse** to fill or refill an Rx order **if**, in his judgment:

- it would be harmful to the patient
- it is not in the patient's best interests **or**
- there is question as to its validity.

21 NCAC 46.1801

Patient Counseling:
An offer to counsel shall be made on all new or transfer prescriptions at the time the prescription is dispensed or delivered to the patient. Ancillary personnel (i.e: pharmacy technicians) may make the offer to counsel, but the pharmacist must personally conduct counseling if the offer is accepted. Professional judgment should be used in determining whether or not to offer counseling for prescriptions refills. **21 NCAC 46.2504**

Records of counseling compliance, including documentation of refusals to receive counseling, shall be maintained on file for three years. **21 NCAC 46.2504 (g)**

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Other information may be obtained from the following:

Drug Enforcement Agency
Greensboro, North Carolina
336.547.4219
Controlled Substance Information

North Carolina Department of Agriculture
Jeremy Evans, Drug Administrator
Food and Drug Protection Division
919.733.7366
jeremy.evans@ncagr.gov
NC Food, Drug & Cosmetic Act and Wholesaler Information

National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056
847.391.4406
https://nabp.pharmacy
Foreign Pharmacy Graduate Equivalency Examination & Reciprocity Issues

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North Carolina Association of Pharmacists
Brighton Hall, 1101 Slater Road, Suite 110
Durham, NC 27703
984.439.1646
http://www.ncpharmacists.org/
Association & Continuing Education information

North Carolina Medicaid
Division of Medical Assistance
2501 Mail Service Center
Raleigh, NC 27699-2501
Angela Smith, Pharmacy Director
919.855.4700
angela.smith@dhhs.nc.gov
Medicaid pharmacy policy information

NCDHHS - Drug Control Unit
Kristen Weisberg
919-733-1765
984-236-5100
Kristen.Weisberg@dhhs.nc.gov
306 N. Wilmington Street
Raleigh, NC 27601
Controlled Substance Reporting System (CSRS)

North Carolina Board of Pharmacy
6015 Farrington Road, Suite 201
Chapel Hill, North Carolina 27517

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