RxLegal

Federal Controlled Substances Act: Dispensing Requirements, Electronic Prescriptions, and Fraudulent Prescriptions

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In this final column of a 4-part series on key components of the Federal Controlled Substances Act, dispensing requirements, electronic controlled substances prescriptions, and fraudulent controlled substances prescriptions will be discussed. Similar to other medications, prescription labels for controlled substances are required to contain all of the following elements prior to dispensing to the patient¹:

- Pharmacy name and address
- Prescription number
- Patient name
- Initial dispensing date
- Name of the prescriber
- Directions for use
- Cautionary statements, if applicable

Labels for Schedule II to IV medications are also required by the US Food and Drug Administration (FDA) to contain the following statement: “CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.”¹

In general, prescriptions for Schedule II medications must be presented to the pharmacy in written form prior to dispensing to the patient. However, the Drug Enforcement Administration (DEA) acknowledges that there may be certain emergent situations that require dispensing of a Schedule II medication without a written prescription. In emergencies, an authorized prescriber may phone in a prescription for a Schedule II medication and the pharmacist may dispense the controlled substance to the patient provided that all of the following conditions are met¹:

- The amount of Schedule II medication prescribed and dispensed must be limited to the quantity needed to treat the patient during the duration of the emergency only.
- The pharmacist immediately reduces the verbal emergency prescription to writing with all necessary information except for the prescriber’s signature.
- The pharmacist makes a good faith effort to verify that the verbal order is coming from an authorized prescriber if the order is from an unknown health care provider.

The prescriber must present a written, signed prescription for the emergency Schedule II verbal order within 7 days.¹ This prescription must contain the words “Authorization for Emergency Dispensing” on its face. The pharmacist must attach the written, signed prescription to the one that was reduced to writing previously. If the prescriber fails to present a written, signed prescription for the Schedule II medication to the pharmacy within the 7-day period, the pharmacist must report this infraction to the nearest DEA Diversion Field Office. Failure to report the infraction can result in revocation of the pharmacist’s authority to dispense without a written prescription.

Partial dispensing of a Schedule II controlled substance is allowed; however, the pharmacist must note the partial quantity dispensed on the front of the prescription and dispense the remaining portion of the prescription within 72 hours of the initial dispensing.¹ If the rest of the prescription is not dispensed within the 72-hour period, the pharmacist must notify the prescriber and a new prescription is warranted. Schedule III to V controlled substances may also be partially dispensed; however, each partial fill must be recorded in the same manner as a refill,

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the total quantity dispensed in all partial fillings must not exceed the total amount prescribed, and no partial dispensing can occur beyond 6 months from the original issue date for the prescription.

The DEA only began to officially address the issue of electronic controlled substances prescriptions in 2010. On March 31, the DEA published a final rule on electronic prescriptions for controlled substances with request for comment in the *Federal Register*.² This rule became effective on June 1, 2010, and provided health care practitioners with the option of writing prescriptions for controlled substances electronically.³ Under this new rule, pharmacies are not required to accept electronic prescriptions for controlled substances; acceptance in this manner is purely at the discretion of the pharmacy.⁴

If a pharmacy chooses to accept electronic controlled substances prescriptions, the pharmacy may archive the prescriptions in an electronic format; however, this archiving is subject to provisions within the rule regarding security and retrievability.³ Basic required components of the technology application for electronic controlled substances prescriptions are summarized in the box, Required Components of the Technology Application for Electronic Controlled Substances Prescriptions.³ It is the responsibility of

the DEA-registered pharmacy to ensure that any technology application meets the standards within the rule prior to the pharmacy accepting electronic controlled substances prescriptions.

The contents of an electronic controlled substance prescription cannot be altered during electronic transmission between the health care provider and the pharmacy.³ Content changes may be made to a prescription upon pharmacy receipt. More information regarding electronic controlled substance prescriptions may be found in the *Pharmacist's Manual*.¹

Under the Controlled Substances Act, pharmacists play a key role in preventing fraud and identifying prescriptions that are illegitimate. Patients may go to great lengths to fraudulently obtain a controlled substance including the following¹:

- Altering a legitimately prescribed prescription
- Printing prescription pads with a legitimate health care provider's name, but with an accomplice's call-back number that is answered when the pharmacy calls to verify the prescription
- Calling in their own prescription with their own telephone number as the call-back number for verification
- Stealing legitimate prescription pads from a health care provider's office or hospital
- Going to an emergency room department with complaints of pain simply to receive a prescription for a controlled substance

Required Components of the Technology Application for Electronic Controlled Substances Prescriptions³

- Ability to digitally sign and archive the prescription or import and archive the record digitally signed by the last intermediary (ie, a vendor that receives and transmits an electronic prescription between the health care provider and the pharmacy)
- Ability to electronically accept and store all information required by the DEA regarding dispensing of the prescription
- Allows the pharmacy to limit access to controlled substance prescription information to specific individuals or roles (ie, pharmacy technician, pharmacist)
- Provides an internal audit trail mechanism that documents whenever a controlled substance prescription has been received, altered, or deleted
- Conducts a daily internal security audit that can not only identify security concerns, but also generates a report for pharmacy review once a concern has been identified

Patients have become more inventive with ways to obtain controlled substances illegally. Therefore, pharmacists need to be aware of criteria that may aid them in identifying both controlled substances prescriptions that are issued for illegitimate medical purposes as well as criteria for identifying forged prescriptions (box, Criteria for Identifying Illegitimate and Forged Controlled Substances Prescriptions¹).

In addition to these criteria, pharmacists can use simple prevention techniques that may significantly reduce controlled substance prescription fraud. These include knowing the prescriber and his/her signature, being familiar with a prescriber's DEA registration number, knowing the patients who come to the pharmacy, and checking the date on the controlled substance prescription to assess whether or not it has been presented to the pharmacy for filling in a reasonable time frame.¹ If there is any doubt regarding the validity of a controlled substance prescription, the pharmacist should make every effort to contact the prescriber for verification.

Criteria for Identifying Illegitimate and Forged Controlled Substances Prescriptions ¹	
Criteria for identifying prescriptions not issued for a legitimate medical purpose	Criteria for identifying a forged prescription
<ul style="list-style-type: none"> • Health care provider writes significantly more controlled substance prescriptions (or writes for larger quantities) than other prescribers in the area. • Patients return to the pharmacy too frequently (ie, a prescription that should last a month for a legitimate medical purpose is being refilled weekly or daily). • Health care provider writes for drugs with “antagonistic” effects (ie, drug abusers often request prescriptions for “uppers and downers” at the same time). • Patient presents prescriptions to the pharmacy written for other individuals other than the patient. • Similar prescriptions from the same health care provider are presented to the pharmacy by a variety of individuals at the same time. • Patients who are not regular customers, or who do not live in the area, present prescriptions to the pharmacy from the same health care provider. 	<ul style="list-style-type: none"> • Prescription looks “too good” (ie, the handwriting of the prescriber is too legible). • Medication quantity, directions for use, or dosages vary from usual medical usage. • Prescription does not contain acceptable standard abbreviations or appears too “textbook.” • Prescription appears to be a photocopy and not an original. • Directions for use are written out in full with no standard abbreviations. • Different color ink or different handwriting is used on the prescription.

REFERENCES

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