Advisory

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Proper Prescription and Controlled Substance Practices: A Review of Federal and State Requirements

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Federal and state laws govern the distribution and dispensing of controlled substances. The Controlled Substances Act (the ***"CSA"***) is the federal law that regulates individuals and entities, including health care practitioners and pharmacies throughout the chain of distribution of controlled substances.[1] For practitioners licensed to prescribe controlled substances, the CSA details the requirements for valid prescription of controlled substances in the United States. Connecticut laws governing practitioners and pharmacies generally mirror the federal laws regarding controlled substances, but are more restrictive in some instances.

Controlled substances are organized into five schedules according to the characteristics of each substance. Schedule I drugs have the greatest potential for abuse, and Schedule V drugs have the least potential. Schedule I substances, including compounds such as LSD and Mescaline, are designated as having no legitimate medical use, and therefore no one may legally prescribe or use these drugs.[2] Schedule II substances are significantly regulated because of their high potential for abuse. There are fewer restrictions on the use of controlled substances on Schedules III–V.

In this Advisory, we first summarize the general prescription requirements for all controlled substances. We then discuss the additional requirements for a valid prescription for a Schedule II substance. Finally, we address record-keeping as well as disposal of controlled substances.

WHO MAY PRESCRIBE CONTROLLED SUBSTANCES?

Federal and Connecticut laws require that controlled substances may only be prescribed in the usual course of professional practice and for legitimate medical purposes. This means that there must be a bona fide physician/practitioner patient relationship when a practitioner prescribes controlled substances. Connecticut regulations specifically state that a failure to medically evaluate a patient to determine his or her need for a controlled substance prior to prescribing the controlled substance violates this requirement because the prescribing professional is not prescribing in the usual course of professional practice under these circumstances. Connecticut further requires that patients undergoing long-term treatment with controlled substances be monitored periodically, although the time between examinations is not specified.

Under federal law, a prescription for a controlled substance may only be issued by a physician, dentist, podiatrist, veterinarian, mid-level practitioner or other registered practitioner who is (1) authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice, and (2) registered with the DEA or exempted from registration (that

CONTINUED ON NEXT PAGE

Proper Prescription and Controlled Substance Practices: A Review of Federal and State Requirements CONTINUED

is, Public Health Service, Federal Bureau of Prisons or military practitioners). An agent or employee of a hospital or other institution acting in the normal course of business or employment may prescribe under the DEA registration of the hospital or other institution, provided that certain additional requirements are met.

In Connecticut, mid-level providers who may seek controlled substance licensure include optometrists, physician assistants, advanced practice registered nurses and nurse mid-wives. Once properly licensed, these practitioners may prescribe Schedules II, III, IV and V controlled substances in the normal course and scope of each practitioner's professional practice.

WHAT CONSTITUTES A VALID PRESCRIPTION FOR CONTROLLED SUBSTANCES?

A prescription for a controlled substance issued by an authorized practitioner must be written in ink or indelible pencil or typewritten and must be dated and signed on the date it is issued. An individual (*e.g.*, secretary or nurse) may be designated by the practitioner to prepare prescriptions for the practitioner's signature. In other words, these individuals may type or write out the actual prescription order. However, they may not sign the prescription. The prescribing practitioner must sign the prescription and is responsible for making sure it is accurate.

Based on federal and Connecticut requirements, in order to be valid prescriptions for controlled substances issued in Connecticut must include each of the following:

- patient's full name and address;
- patient's age or, alternatively, a note indicating whether the patient is an adult or a child;
- practitioner's full name, address and DEA registration number;
- drug name;
- strength;
- dosage form;
- quantity prescribed;
- directions for use; and
- number of refills authorized (if any) [3]

Connecticut further specifies that no duplicate, carbon or photographic copies and no printed or rubber-stamped orders shall be considered valid prescriptions. [4]

WHAT ARE THE PERMITTED METHODS OF TRANSMITTING PRESCRIPTIONS FOR SCHEDULES III-V CONTROLLED SUBSTANCES?

Generally, a practitioner may transmit a prescription for Schedules III–V controlled substances to the pharmacist either orally, in writing or by facsimile. The patient may refill the prescription if so authorized on the prescription, or the physician may call in the refill. The practitioner or an employee or agent of the practitioner may transmit prescriptions for Schedules III–V controlled substances by facsimile to the dispensing pharmacy. The facsimile is considered to be equivalent to an original prescription. A computer-generated prescription that is printed out or faxed by the practitioner must be manually signed. It is also permissible to transmit prescriptions electronically to a pharmacy and for the physician to affix an electronic signature to the prescription.

Correspondingly, a pharmacist may dispense a controlled substance listed in Schedules III–V pursuant to an oral prescription made by an individual practitioner. The pharmacist must promptly reduce the oral prescription into a writing that must contain all information required for a valid prescription, except for the signature of the practitioner.

In the hospital setting, Schedules III–V substances may be administered upon an oral order of a prescribing practitioner, provided the prescribing practitioner confirms the oral order with a written order within seventy-two hours of giving the oral order. Further, original and continuing orders for Schedule III–V medications cannot be effective for more than thirty days, after which time a new prescription is required.

WHAT ADDITIONAL REQUIREMENTS APPLY FOR PRESCRIPTIONS OF SCHEDULE II SUBSTANCES

Because of the highly addictive properties of Schedule II medications, additional restrictions regulate the way in which these pharmaceuticals are prescribed:

- Unlike medications on Schedules III–V, Schedule II controlled substances may only be prescribed pursuant to an oral prescription in an emergency situation. An emergency situation is one in which the practitioner determines that immediate administration of a controlled substance is necessary for proper

CONTINUED ON NEXT PAGE

Proper Prescription and Controlled Substance Practices: A Review of Federal and State Requirements CONTINUED

treatment, and there are no appropriate alternative treatments available. In order for a Schedule II prescription to qualify as a valid oral emergency prescription, the following conditions must be met: (1) the prescribing practitioner must speak directly to the dispensing pharmacist; (2) the quantity prescribed must be limited to the amount adequate to treat the patient only during the emergency period; (3) the pharmacist must immediately reduce the prescription to a writing that meets all of the requirements of a valid controlled substance prescription with the exception of the practitioner signature; and (4) the pharmacy must receive a written prescription from the prescribing practitioner within seventy-two hours of the oral prescription.[5] Practically, this means that prescriptions for Schedule II drugs are never valid without the prescribing practitioner's signature. Even emergency oral prescriptions must be backed up with the prescribing practitioner's signature within seventy-two hours of the oral prescription.

- In the hospital setting, a Schedule II substance may be administered upon an oral order of a prescribing practitioner, but only if the prescribing practitioner confirms the oral order with a written order within twenty-four hours of giving the oral order. Further, original and continuing orders for Schedule II controlled substances must be limited to a period of seven days, but a practitioner may extend this time period by re-signing or initialing the order. Note that this exception for hospital settings does not apply to nursing homes. In those settings, prescriptions for Schedule II controlled substances must be in writing and oral prescriptions are only permitted in the emergency situations described above.

- Finally, unlike medicines on Schedules III–V, Schedule II controlled substances may not be refilled. A new prescription is required. That being said, the law permits a practitioner to issue multiple prescriptions authorizing a patient to receive a ninety-day supply if the following conditions are met: (1) each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the normal course of business; (2) the individual practitioner provides written instructions on each prescription indicating the earliest date on which a pharmacy may fill each prescription; and (3) the individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse. It is critically important that the prescribing practitioner document his or her conclusion that there is no risk of abuse or diversion.

ARE PRESCRIBING PRACTITIONERS SUBJECT TO RECORD-KEEPING REQUIREMENTS?

Connecticut law governing record-keeping requirements is more restrictive than federal law.[6][7]

Under Connecticut law, as a condition to controlled substance licensure, a practitioner must keep records of medical evaluations of patients and all controlled substances that the practitioner dispensed, administered or prescribed. Connecticut law does not provide guidance on the length of time the records must be maintained, but practitioners should follow medical record retention requirements. In office settings or outpatient clinics, for example, medical records are kept for seven years after last seeing a patient or for three years after a patient's death. The requirement to maintain a medical evaluation extends to any prescriptions the practitioner may write for him or herself. While most practitioners do not self-prescribe Schedule II medications, the requirement to keep records of medical evaluations extends to all Schedules of controlled substances. For example, if a practitioner were to self-prescribe Ambien, a Schedule IV drug, or Lomotil, a Schedule V drug, or Robitussin with codeine, a Schedule V drug, that practitioner would be expected to maintain a medical evaluation of himself or herself.

WHAT REQUIREMENTS GOVERN CONTROLLED SUBSTANCE DISPOSAL?

Currently, only a DEA agent may destroy a controlled substance after the drug has been dispensed by a pharmacist to a patient. A practitioner is not allowed to take back medication from a patient without contacting the DEA and having the DEA present to witness destruction of the medication. Doing so would technically mean that the practitioner is in possession of a controlled substance prescribed to someone other than himself or herself, which is illegal for any individual.

This requirement creates challenges for practitioners when patients suffering from addiction bring them prescriptions for

CONTINUED ON NEXT PAGE

Proper Prescription and Controlled Substance Practices: A Review of Federal and State Requirements CONTINUED

disposal. Most practitioners would agree from a treatment perspective that when a patient struggling with addiction comes to the physician's office wanting to dispose of a controlled substance, the practitioner should accept and destroy the controlled substance. However, the practitioner cannot do so. Short of contacting the DEA, the available options are to instruct the patient to dispose of the medication at an Rx Drop Box or a take back program, or purchase a disposal envelope from a local pharmacy. Local towns are increasingly providing opportunities to dispose of unwanted or expired medication by providing drop boxes or special collection days.

Both federal and Connecticut agencies for environmental protection recommend against disposing of medication down the toilet or the sink and suggest that the pharmaceuticals be altered (*e.g.*, mixed with kitty litter or other undesirable substances) to discourage diversion and then thrown in the trash because most trash is incinerated at very high temperatures. Additional information on proper disposal of unwanted medication is available in the resource section below. Helping a patient alter medication brought into the office and dispose of it in the office may be an option to ensure patients with addiction concerns safely dispose of unwanted medication.

RESOURCES

DEA Practitioner's Manual

- http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf

Recommendations for Disposal of Medications

- http://water.epa.gov/scitech/swguidance/ppcp/upload/ppcpflyer.pdf
- http://www.ct.gov/deep/lib/deep/p2/individual/consumerpharmdisposalfactsheet.pdf

Other Resources for the Proper Use of Controlled Substances

- Statement from the Connecticut Medical Examining Board on the Use of Controlled Substances for the Treatment of Pain (included in the provided materials).

For more information, contact Maureen Weaver at mweaver@wiggin.com or Elisabeth Pimentel at epimentel@wiggin.com.

[1] In everyday conversation the terms "administer," "dispense," and "prescribe" are often used interchangeably. However, these terms have unique definitions and it is important to understand them in connection with the various requirements. "Administer" refers to the direct application of a controlled substance to the body of a patient by a practitioner (or, in his presence, by his authorized agent) or by the patient at the direction and in the presence of the practitioner. "Dispense" means to deliver controlled substances to a patient pursuant to a lawful order of a practitioner. "Prescribe" means to order or designate a remedy or any prescription containing controlled substances.

[2] There are instances when these substances may be used in research.

[3] The prescription may only be refilled up to five times within six months after the date on which the prescription was issued. After five refills or after six months, whichever occurs first, a new prescription is required.

[4] We note that Connecticut law also provides that no prescription or order for any controlled substance issued by a practitioner to an inanimate object or thing shall be considered a valid prescription.

[5] Federal law requires the pharmacy to receive a written prescription from the prescribing practitioner within seven days. Connecticut law shortens that timeframe to seventy-two hours, and therefore Connecticut licensed practitioners must comply with the seventy-two hour requirement.

[6] Under federal law, a registered practitioner is not required to keep records of controlled substances that are administered in the lawful course of professional practice unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges patients, either separately or together with charges for other professional services, for substances dispensed or administered.

[7] This Advisory does not discuss the extensive record-keeping requirements for practitioners who dispense or administer controlled substances. Minimally, if a practitioner is subject to record-keeping requirements, generally, inventories and records for controlled substances in Schedules III–V must be maintained separately from the ordinary business records of the practitioner. Additionally, inventories and records for Schedules I and II controlled substances must be maintained separately from the ordinary business records and separately from the inventories and records for controlled substances in Schedules III–V. Under federal law, all records related to controlled substances must be maintained and be available for inspection for a minimum of two years. Connecticut law specifies that the record be made of all stocks of controlled substances by May 1st biennially and lengthens the time the records must be maintained from the two years required under federal law, to three years. Conn. Gen. Stat. § 21-a-254(h).