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Legal Brief

SOUTH DAKOTA STATE MEDICAL ASSOCIATION
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Providing General Legal Guidance and Regulatory Compliance Information to SDSMA Members

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Controlled Substances

This Legal Brief was drafted for general informational purposes only. It is not meant to be a comprehensive guide, nor should it be construed as legal advice. The information in this brief is current as of July 1, 2016; readers should consult the most recent versions of referenced statutes, regulations, and cases to ensure there have been no material changes.

Summary

Drug use for medicinal purposes is controlled by state law. State law categorizes these controlled substances based on their characteristics and effect on the patient. The prescription of a controlled substance requires a license and compliance with all applicable state and federal laws and rules. Regulations differ depending on the category of controlled substance within which a drug falls. In addition to prescription regulations, physicians must follow record-keeping and handling requirements.

Discussion

For the purposes of regulation under South Dakota law, drugs and other substances are categorized as follows:

1. Schedule I. These substances have a high potential for abuse, have no accepted medical use in the United States, and lack accepted safety for use under medical supervision.
2. Schedule II. These substances have a high potential for abuse, have a currently accepted medical use in the United States, or currently accepted medical use with severe restrictions and abuse may lead to severe psychic or physical dependence.
3. Schedule III. These substances have a potential for abuse less than the substances listed in Schedules I and II, have a well documented and approved medical use in the United States, and abuse may lead to moderate or low physical dependence or high psychological dependence.
4. Schedule IV. These substances have a low potential for abuse relative to the substances listed in Schedule III, have a currently accepted medical use in the United States, and use may result in limited physical dependence or psychological dependence, or both, relative to substances listed in Schedule III.

The following combinations of medicinal ingredients and Schedule III substances are exempt from control:

1. Analgesic agents which are not controlled substances, combined with a barbiturate;
2. Antiangina agents, combined with a barbiturate or meprobamate;
3. Anticholinerigic agents, combined with a barbiturate, a benzodiazepine, or meprobamate;
4. Antiasthmatic agents, combined with a barbiturate;
5. Hormone replacement agents, combined with a benzodiazepine or meprobamate;
6. Anabolic steroid and estrogen combinations; and

7. Products that contain ephedrine in quantities at or less than:
   a. 25 milligrams in combination with 400 milligrams of quaifenesin, packaged in blister packs of not more than two tablets per blister; and
   b. Five percent by weight in an anorectal preparation in combination with other active medicinal ingredients. ARSD 44:58:13.

State law lists specific substances in each category; those substances are listed in the appendix to this Legal Brief. See SDCL 34-20B.

Schedule I Drugs and Other Substances

It is a crime under state law, and in most cases under federal law as well, to possess or distribute any Schedule I drug or other substance. The penalty for possession or distribution depends on the drug or substance, but in most cases, they are felony offenses, punishable by a prison term.

Prescriptions Generally - ARSD 44:58:08

Physicians must have a license from the South Dakota Department of Health to prescribe any controlled drug. SDCL 34-20B-29.

A prescription may not be issued by an individual practitioner to obtain controlled substances for general dispensing to patients; the prescription must be for a specific patient. A prescription may not be issued for a controlled substance, nor may a controlled substance be dispensed or administered to a drug dependent person, for the purpose of continuing the person's dependency. An individual practitioner, in the course of professional practice only, may directly administer or dispense a controlled substance without a prescription. An individual practitioner or institutional practitioner may not order a controlled substance for direct administration or dispense a controlled substance, including any controlled substance sample, for his own use.

Prescriptions for controlled substances must be dated and signed on the day when issued and must bear the full name and address of the patient; the drug name, strength, dosage form, quantity prescribed, and directions for use; and the name, address, and registration number of the practitioner. A practitioner shall sign a prescription in the same manner as the practitioner would sign a legal document.

If an oral order is not permitted, prescriptions must be written with ink, indelible pencil, or mechanically, and must be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible and liable if the prescription does not conform in all essential respects to applicable law.

Prescriptions for Schedule III and IV controlled substances may be transmitted directly from the individual practitioner to the pharmacy by facsimile equipment or by computer interface. In the case of transmission by computer interface, both the prescriber’s and the pharmacy’s computer must be approved to do so by the U.S. Drug Enforcement Administration.

A prescription for a Schedule III or IV drug or substance may be refilled up to five (5) times within a six (6) month period if the refills are authorized by the practitioner on the original prescription. Each refill dispensed shall be entered on the prescription or on a patient medication record which indicates the date, quantity dispensed, and initials or name of the dispensing pharmacist. If the pharmacist merely initials and dates the prescription, the pharmacist is assumed to have dispensed a refill for the full face amount of the prescription. Additional quantities of controlled substances listed in Schedule III or IV may only be authorized by a practitioner through issuance of a new prescription.

Any person who knowingly obtains a controlled substance from a medical practitioner and who knowingly withholds information from that medical practitioner that he has obtained a controlled substance of similar therapeutic use in a concurrent time period from another medical practitioner is guilty of a Class 1 misdemeanor. For information regarding drug diversion, *see* the SDSMA Legal Brief on Patient Drug Use or Diversion.

Prescriptions: Schedule II Drugs

No person, other than a practitioner (i.e., M.D., physician's assistant, osteopath, podiatrist, optometrist, dentist, or D.V.M.) who is not a pharmacist, may dispense a controlled drug or substance included in Schedule II to an ultimate user without the written prescription of a practitioner other than a pharmacist.

In an emergency situation, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization from an authorized practitioner. Oral authorization is only acceptable if immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user; no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II; and it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance prior to the dispensing, and the pharmacist reduces the prescription and the information described above to writing.

If oral authorization is permitted, the quantity prescribed and dispensed must be limited to the amount adequate to treat the patient during the emergency period; the prescription must be immediately reduced to writing by the pharmacist and must contain all information otherwise required except for the signature of the prescribing individual practitioner; and within seven (7) days after authorizing an emergency oral prescription, the individual practitioner shall supply the pharmacy with a written prescription for the emergency quantity prescribed. The prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. If the emergency prescription is sent by mail, the carrier envelope must be postmarked within the seven (7) days. The pharmacist must notify the Department of Health if the prescribing practitioner fails to deliver a written prescription within seven (7) days. Failure to notify the Department voids the authority to dispense the controlled substance without a written prescription. ARSD 44:58:08:13.

No prescription for a Schedule II drug or substance may be refilled. 44:58:08:17.01

A written prescription for a Schedule II controlled substance may be transmitted from the individual prescribing practitioner to a pharmacy by facsimile equipment, if the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance. ARSD 44:58:08:18.03. In an emergency, the pharmacist may fill the prescription without first seeing the original written prescription, but the practitioner must send the original prescription to the pharmacist within seven (7) days; if the practitioner doesn't do so, the pharmacist is required to report that fact to the U.S. Drug Enforcement Administration.

Schedule II controlled substance prescriptions intended for direct administration to a patient by parenteral, intravenous, subcutaneous, or intraspinal infusion may be transmitted by facsimile. The facsimile prescription serves as the original prescription. Schedule II controlled substance prescriptions for residents of long-term care facilities or patients residing in a Medicare-certified hospice may be transmitted directly from the prescribing practitioner to the pharmacy by facsimile equipment. The facsimile prescription serves as the original prescription. The facsimile prescription must be marked on the face with the notation "long-term care resident" or "hospice patient." ARSD 44:58:08:18.02.

Records

Practitioners must be registered with the state Department of Health, Division of Health Systems Development and Regulation, to dispense substances in Schedules II through IV if they are authorized to dispense under the law of South Dakota. Registrants dispensing controlled drugs and substances must maintain complete and accurate records of all stocks

of such drugs and substances on hand. The records must contain such information as shall be provided by rules and regulations promulgated by the Department. All required records must be kept for a period of at least two (2) years. The provision relating to records does not apply to practitioners who lawfully prescribe or administer, but do not otherwise dispense, controlled drugs and substances. SDCL 34-20B-39.

Opioid Antagonists

In 2016, the state of South Dakota passed legislation permitting the prescription and possession of opioid antagonists in certain instances.

A licensed health care professional may, directly or by standing order, prescribe an opioid antagonist to a person at risk or experiencing an opioid-related overdose, or prescribe to a family member, friend, or other close third party person the provider reasonably believes to be in a position to assist a person at risk of experiencing an opioid-related overdose.

The South Dakota codified law, the authority to prescribe an opioid antagonist does not establish a duty or standard of care with respect of whether to prescribe, dispense, or administer an opioid antagonist. Furthermore, a provider is not subject to any disciplinary action or civil or criminal liability for the prescribing or dispensing of an opioid antagonist to a person whom the health care professional reasonably believes may be in a position to assist or administer the opioid antagonist to a person at risk of an opioid-related drug overdose.

The South Dakota Prescription Drug Monitoring Program: SDCL 34-20E

In 2010, the state of South Dakota passed legislation calling for the establishment of a program to monitor the prescribing and dispensing of all controlled substances. The program utilizes a central repository, to which each dispenser must submit information regarding each prescription dispensed for a controlled substance. The information submitted for each prescription includes specifically-identified data elements contained in the 2005 version of the electronic reporting standard for prescription monitoring programs, Version 003, Release 000, of the American Society for Automation in Pharmacy.

For the purposes of this program, a “dispenser” is defined as any person who delivers a controlled substance to the ultimate user, but does not include:

1. A licensed hospital pharmacy that provides a controlled substance for the purpose of inpatient hospital care;
2. A licensed health care provider or other authorized individual in those instances when the practitioner administers a controlled substance to a patient; or
3. A licensed veterinarian.

A “prescriber” is defined as an individual licensed, registered, or otherwise authorized by the jurisdiction in which the individual is practicing to prescribe drugs in the course of professional practice. The term does not include a veterinarian.

Each dispenser must submit the required information to the central repository at least once each week unless the South Dakota Board of Pharmacy waives this requirement for good cause shown by the dispenser.

Unless disclosure is prohibited by law, the Board may provide data in the central repository to:

1. Any prescriber for the purpose of providing medical care to a patient, a dispenser for the purpose of filling a prescription or providing pharmaceutical care for a patient, a prescriber or dispenser inquiring about the prescriber's or dispenser's own prescribing activity, or a prescriber or dispenser in order to further the purposes of the program;
2. Any individual who requests the prescription information of the individual or the individual's minor child;
3. Any state board or regulatory agency that is responsible for the licensing of individuals authorized to prescribe or dispense controlled substances if the board or regulatory agency is seeking information from the central repository that is relevant to an investigation of an individual who holds a license issued by that board or regulatory agency;

1. Any local, state, and federal law enforcement or prosecutorial officials engaged in the enforcement of laws relating to controlled substances who seek information for the purpose of an investigation or prosecution of the drug-related activity or probation compliance of an individual;
2. The Department of Social Services for purposes regarding the utilization of controlled substances by a Medicaid recipient;
3. Any insurer for purposes regarding the utilization of controlled substances by a claimant;
4. Any judicial authority under grand jury subpoena or court order or equivalent judicial process for investigation of criminal violations of controlled substances laws;
5. Any public or private entity for statistical, research, or educational purposes after the information is de-identified with respect to any prescriber, dispenser, or patient who received a prescription for a controlled substance; or
6. Any peer review committee.

A prescriber or dispenser is not required to obtain information about a patient from the central repository prior to prescribing or dispensing a controlled substance. A prescriber, dispenser, or other health care provider may not be held liable in damages to any person in any civil action on the basis that the prescriber, dispenser, or other health care provider did or did not seek to obtain information from the central repository. Unless a lack of good faith is shown, the Board of Pharmacy, a prescriber dispenser, or any other person in proper possession of information provided under the program is not subject to any civil liability by reason of:

1. The furnishing of information in compliance with the program's rules;
2. The receipt and use of, or reliance on, such information;
3. The fact that any such information was not furnished; or
4. The fact that such information was factually incorrect or was released by the Board of Pharmacy to the wrong person or entity.

For more information, navigate to http://doh.sd.gov/Boards/pharmacy/PDMP-FAQ.aspx.

Determination of Expiration Dates

It is the responsibility of the practitioner to see that outdated products and near out-dated products are removed from stock. The United States Pharmacopeia directs that unless specified by an actual date, it is assumed that the product will be out-dated on the last day of the month shown on the package. Good practice dictates that careful consideration be given by the practitioner to expiration dates of the product before dispensing. If the directions for use and the quantity dispensed would mean that the patient would be taking the medication beyond the expiration date, the product must be removed from stock.

Because of differences in packaging and handling, samples carry shorter expiration dates than conventionally- packaged drugs. Any drug retained in stock beyond its expiration date is considered by law to be adulterated and misbranded.

Destruction of Drugs

Medical practitioners and clinics often must destroy out-dated, damaged, returned, or unneeded office drugs or samples. Except for controlled substances and hazardous materials, a medical practitioner may destroy such undesired items in any safe and prudent manner. Destruction may occur by dissolution through the sewer system, incineration, or compaction and direct burial at a landfill. Great care must be taken to insure that all drugs, including samples, are rendered unfit for consumption. Very special care must be given to injectable items to insure that all needles are properly disposed.

Practitioners are not authorized to destroy any controlled substances, including controlled samples, without authorization from the United States Drug Enforcement Agency (DEA). Controlled substances may be destroyed by an agent from the DEA, authorized South Dakota Department of Health personnel or an inspector from the South Dakota Board of Pharmacy. This procedure applies to all controlled substances in Schedules II, III, IV, and V.

Before destruction, all controlled substance drugs to be destroyed must be listed on DEA form 41. Form 41 is available from the DEA, authorized Department of Health personnel, the Board of Pharmacy, or the Board of Pharmacy Inspector. Schedule II drugs must be counted and listed. Schedule III, IV, or V may be estimated. It is the responsibility of the practitioner and not the agent or inspector to count and list the items on the form.

The destruction must be witnessed and signed for by the practitioner and the DEA agent, authorized Department of Health personnel or the inspector from the Board of Pharmacy. A copy of the DEA form is retained at the site, and others are forwarded to the DEA. The form must be retained by the practitioner for a minimum of two (2) years.

In the past, DEA offices would, following certain procedures, accept controlled substances and destroy them at the DEA office. This practice is no longer followed.

Instead, DEA encourages the use of licensed "reverse distributions" (see below). Questions about destruction of controlled substances can be addressed to:

1. Des Moines DEA Office: 515.284.4700;
2. South Dakota Department of Health: 605.773.4520; or
3. South Dakota Board of Pharmacy: 605.362.2737

Because of the increasing complexity of regulations regarding destruction of controlled substances and disposal of hazardous materials, a number of companies have been formed to handle the return and disposal of out-dated drugs. Many of these companies have obtained DEA permits to handle controlled substances. These companies may offer a lawful and effective method of disposing of unneeded drug products.

Hazardous Materials

Certain drugs - primarily chemotherapy agents and materials used in handling such drugs - may be considered to be hazardous materials by state and federal regulation. These materials should not be disposed of through conventional methods. Arrangements should be made with other facilities that dispose of hazardous materials to insure proper disposal.

Conclusion

The use, prescription, and disposal of controlled substances is subject to substantial regulation by both the state and the United States. Physicians must take care to comply with state and federal law relating to the procedures for prescribing medication, including those related to use by the prescriber. South Dakota law also provides for a drug monitoring program that requires "dispensers" (the person or entity who delivers the drug to the end user) to file certain reports, and allows for access by physicians for the purpose, among others, of determining if a patient is "doctor shopping" to obtain multiple subscriptions for the same drug.

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