

# Legal Brief

## Dispensing Controlled Substances and Drug Packaging Requirements

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 December 31, 2013; readers should consult the most recent versions of referenced statutes, regulations, and cases to ensure there have been no material changes.

### Summary

*The Prescription Drug Monitoring law (SDCL 34:20E) requires, with few exceptions, any person who delivers a controlled substance to the ultimate user must submit particular patient, prescriber, and prescription related information to a central data repository at least once each week. Additionally, the Federal Poison Prevention Packaging Act (15 U.S.C. §§1471, et. seq.) requires physicians dispensing drugs and other medically related substances to package them in child-proof containers.*

### Discussion

#### Dispensing of Controlled Substances

The South Dakota Board of Pharmacy (“BOP”) administers a prescription drug monitoring program for the purposes of improving patient care and reducing the diversion and illicit use of prescription controlled substances. “Controlled substances” are defined as any Schedule II through IV drug, substance, or immediate precursor thereof. SDCL 34-20B-11 to 34-20B-26. See attached Addendum A.

The drug monitoring program “utilizes a central repository, to which each dispenser shall submit, by electronic means, information regarding each prescription dispensed for a controlled substance. The information submitted for each prescription shall include specifically identified data elements adopted by the board and 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.” SDCL 34-20E-2.

A “dispenser” must submit the information required by the BOP at least weekly. A “dispenser” is any person who delivers a controlled substance to the ultimate user. However, the following categories are excluded: a licensed hospital pharmacy that provides a controlled substance for the purpose of inpatient hospital care; a licensed health care provider or other authorized individual in those instances when the practitioner administers a controlled substance to a patient; or a licensed veterinarian. The weekly submission requirement may be waived for good cause. In addition, an extension of time may be granted if equipment problems prohibit submission, or for other good cause.

Any dispenser who knowingly fails to submit prescription monitoring information to the BOP as required or knowingly submits incorrect prescription information may be reported by the BOP to the dispenser's licensing board.

Nothing in South Dakota law requires a prescriber or dispenser 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.

Furthermore, absent a lack of good faith, the BOP, a prescriber, dispenser, or any other person in proper possession of information provided through the prescription drug monitoring program is not subject to any civil liability by reason of:

1. The furnishing of information under the requirements of SDCL 34-20E;
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 BOP to the wrong person or entity.

Any patient, dispenser, or prescriber may request that erroneous information contained in the central repository be corrected or deleted. The BOP must review the request to determine if the information is erroneous with respect to the patient, prescriber, or dispenser and correct any erroneous information discovered due to the request for review by a patient, prescriber, or dispenser.

Information submitted to the central repository is confidential and may not be disclosed except by:

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;
4. 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. The official must include the reason for the request at the time it is made;
5. The Department of Social Services for purposes regarding the utilization of controlled substances by a Medicaid recipient;
6. Any insurer for purposes relating to the utilization of controlled substances by a claimant;
7. Any judicial authority under grand jury subpoena or court order or equivalent judicial process for investigation of criminal violations of controlled substances laws;
8. 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
9. Any peer review committee, which means any committee of a health care organization, composed of health care providers, employees, administrators, consultants, agents, or members of the health care organization's governing body, which conducts professional peer review.

Any person authorized to have prescription monitoring information and who knowingly discloses such information in violation of the law is subject to prosecution for a Class 6 felony.

Persons authorized to request information from the central repository may do so by written request. ARSD 20:51:32:05. Each request for information must be submitted on a form provided by the BOP and must be mailed, faxed, or submitted electronically. In addition, healthcare practitioners authorized to prescribe or dispense controlled substances may request on-line access to the data for the purpose of providing patient health care. ARSD 20:51:32:04. However, prior to being granted access to program information, the practitioner must submit a request for registration and program access.

The BOP will verify the licensure status of the practitioner with the appropriate licensing authority before granting access. BOP safeguards to protect the privacy of the data include a secure login and password for practitioners authorized to access the data online.

The BOP is required to conduct regular reviews of data access by practitioners to identify possible violations of law or breach of professional standards that may have occurred. Whenever such violations are identified, the board will notify the appropriate professional licensing, certification, or regulatory agency or entity, and provide information necessary for an investigation. SDCL 24-20E-12.

### **Drug Packaging**

The U.S. Consumer Product Safety Commission (“CPSC”) administers the Poison Prevention Packaging Act (“PPPA”) of 1970, 15 U.S.C. §§1471-1476, which requires special (child-resistant and adult-friendly) packaging of a wide range of hazardous household products including oral prescription drugs and other medically related substances. The CPSC determined “that the degree or nature of the hazard to children...by reason of their packaging, is such that special packaging...is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances, and the special packaging herein required is technically feasible, practicable, and appropriate for these substances” 16 CFR § 1700.14.

“Special Packaging” is defined as “packaging that is designed or constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly...” 16 CFR §1700.1. The medically-related substances regulated at 16 CFR § 1700.14 which require special packaging are as follows:

1. Aspirin: Any aspirin-containing preparation for human use in oral dosage form.
2. Methyl Salicylate (oil of wintergreen): Liquid preparations containing more than 5 percent by weight, unless packaged in pressurized spray containers.
3. Controlled Drugs: Preparations intended for oral human use, which are subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970. See attached Addendum B.
4. Prescription Drugs: Any drug for human use in oral dosage form and which is required by federal law to be dispensed only by or upon an oral or written prescription of a practitioner licensed to administer such drug. However, the regulation regarding special packaging for prescription drugs contains particular exemptions which include:
  - a. Sublingual dosage forms of nitroglycerin,
  - b. Sublingual and chewable forms of isosorbide dinitrate in dosage strengths of 10 milligrams or less.
  - c. Erythromycin ethylsuccinate granules for oral suspension and oral suspensions in packages containing not more than 8 grams or the equivalent of erythromycin.
  - d. Erythromycin ethylsuccinate tablets in packages containing no more than the equivalent of 16 grams erythromycin.
  - e. Anhydrous cholestyramine in powder form.
  - f. Potassium supplements in unit dose forms, including individually wrapped effervescent tablets, unit dose vials of liquid potassium, and powdered potassium in unit dose packets, containing not more than 50 milliequivalents per unit dose.
  - g. Sodium fluoride drug preparations, including liquid and tablet forms, containing no more than 110 milligrams of sodium fluoride per package or not more than the concentration of 0.5 percent elemental fluoride on a weight-to-volume basis for liquids or a weight-to-weight basis for non-liquids and containing no other substances subject to packaging regulations.
  - h. Betamethasone tablets packaged in manufacturers' dispenser packages containing no more than 12.6 milligrams betamethasone.
  - i. Mebendazole in tablet form in packages containing not more than 600 milligrams of the drug.

- j. Methylprednisolone in tablet form in packages containing not more than 84 milligrams of the drug.
  - k. Colestipol in powder form in packages containing not more than 5 grams of the drug.
  - l. Pancrelipase preparations in tablet, capsule, or powder form.
  - m. Cyclically administered oral contraceptives in mnemonic (memory-aid) dispenser packages which rely solely upon the activity of one or more progestogen or estrogen substances.
  - n. Prednisone in tablet form when dispensed in packages containing no more than 105 milligrams of the drug.
  - o. Conjugated estrogen tablets when dispensed in mnemonic dispenser packages containing not more than 32.0 milligrams of the drug.
  - p. Norethindrone acetate tablets in mnemonic dispenser packages containing not more than 50 milligrams of the drug.
  - q. Medroxyprogesterone acetate tablets.
  - r. Sacrosidase (sucrase) preparations in a solution of glycerol and water.
  - s. Hormone Replacement Therapy Products that rely solely upon the activity of one or more progestogen or estrogen substances.
  - t. Colesevelam hydrochloride in powder form in packages containing not more than 3.75 grams of the drug.
  - u. Sevelamer carbonate in powder form in packages containing not more than 2.4 grams of the drug.
5. Iron-Containing Drugs, with the exception of (i) animal feeds used as the vehicle for the administration of drugs and (ii) those preparations in which iron is present solely as a colorant, non-injectable animal and human drugs providing iron for therapeutic or prophylactic purposes which contain a total amount of elemental iron equivalent to 250 milligrams or more in a concentration of 0.025 percent or more on a weight to volume basis for liquids and a 0.05 percent or more on a weight-to-weight basis for non-liquids.
  6. Iron-Containing Dietary Supplements: Most dietary supplements that contain an equivalent of 250 milligrams or more of elemental iron per package in a concentration of 0.025 percent or more on a weight to volume basis for liquids and a 0.05 percent or more on a weight-to-weight basis for non-liquids.
  7. Acetaminophen: With few exceptions, preparations for human use in oral dosage forms containing more than 1 gram of acetaminophen in a single package.
  8. Diphenhydramine: Preparations for human use in oral dosage forms containing more than the equivalent of 66 milligrams of diphenhydramine base in a single package.
  9. Ibuprofen: Preparations for human use in oral dosage forms containing 1 gram or more of ibuprofen in a single package.
  10. Loperamide: Preparations for human use in oral dosage forms containing more than 0.045 milligrams of loperamide in a single package.
  11. Mouthwash: Most mouthwash containing 3 grams or more of ethanol in a single package.
  12. Lidocaine: Products containing more than 5 milligrams of lidocaine in a single package.
  13. Dibucaine: Products containing more than 0.5 milligrams of dibucaine in a single package.
  14. Naproxen: Preparations for human use in oral dosage forms containing 250 milligrams or more of naproxen in a single package.
  15. Ketoprofen: Preparations for human use in oral dosage forms containing more than 50 milligrams of ketoprofen in a single package.
  16. Fluoride: Products containing more than 50 milligrams of elemental fluoride and more than 0.5 percent elemental fluoride on a weight-to-volume basis for liquids or a weight-to-weight basis for non-liquids.
  17. Minoxidil: Preparations for human use containing more than 14 milligrams of minoxidil in a single package.
  18. Over-the-Counter Drug Products: Preparations in oral dosage forms that contain any active ingredient that was previously available for oral administration only by prescription.
  19. Drugs and cosmetics containing low viscosity hydrocarbons: Products containing 10 percent or more hydrocarbon by weight with a viscosity of less than 100 SUS at 100°F.

All dispensers are required to dispense the substances listed above in “special packaging.” However, exceptions exist if the substance is unlikely to enter a home (when dispensed by professionals at an institution), or the patient requests non-special packaging. In cases where an accidental poisoning occurs, a physician may be liable for failure to provide child-proof packaging of drugs dispensed in the physician’s office; accordingly, if non-special packaging is requested, it is prudent to obtain such request in writing.

### Conclusion

*Unless a waiver is granted, any person who delivers a controlled substance to the ultimate user must submit information concerning the substance and person to the South Dakota Board of Pharmacy at least weekly. However, the following categories of dispensers are exempt from said requirement: a licensed hospital pharmacy that provides a controlled substance for the purpose of inpatient hospital care; a licensed health care provider or other authorized individual in those instances when the practitioner administers a controlled substance to a patient; or a licensed veterinarian.*

*In addition, as dispensers of controlled substances, physicians must be aware of the Poison Prevention Packaging Act (PPPA) of 1970, 15 U.S.C. §§1471-1476. The Act requires special (child-resistant and adult-friendly) packaging of a wide range of hazardous household products including oral prescription drugs and other substances related to medical treatment. If accidental poisoning occurs, a physician may be liable for failure to provide child-proof packaging of drugs dispensed in the physician’s office.*



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