Prescription Monitoring Program State Profiles - Utah

Research current through December 2014.

This project was supported by Grant No. G1399ONDCP03A, awarded by the Office of National Drug Control Policy. Points of view or opinions in this document are those of the author and do not necessarily represent the official position or policies of the Office of National Drug Control Policy or the United States Government.

UTAH

http://www.dopl.utah.gov/programs/csdb/index.html
Marvin Sims, Administrator
(801) 530-6232
csdb@utah.gov

- Status of Program – operational
- Housing Entity – Division of Occupational and Professional Licensing
- Advisory Commission – no
- Funding – database registration fee
- Drugs Monitored – Schedules II – V
- Who's Required to Report Dispensing Information – pharmacy or pharmacy group; dispensing medical practitioner
- Exemptions from Reporting – drugs dispensed to a hospital inpatient
- Nonresident Pharmacies Required to Report – yes
- Veterinarians Required to Report – no
- Data Collection Interval – weekly/7 days; for those participating in the statewide pilot program, submission is required daily
- Notice to Consumers – yes
- Interstate Sharing – with other PMPs
- Persons Authorized to Receive Information – Department of Health; law enforcement and judicial/prosecutorial officials; licensing/regulatory boards; employees of the Office of Internal Audit and Program Integrity for Medicaid participants; substance abuse or mental health professionals; patient or parent of minor child; health care agent; third party with signed consent form; prescribers; dispensers; worker's compensation specialists
- Delegates Allowed – yes
- De-identified Data Provided – yes
- Unsolicited Reports – to prescribers, pharmacists, and law enforcement
- Training Required – yes
- Mandatory Enrollment – yes; all prescribers except veterinarians
- Mandatory Access – no

West's Utah Code Annotated (2014)
Title 26. Utah Health Code
Chapter 1. Department of Health Organization

§ 26-1-36. Duty to establish program to reduce deaths and other harm from prescription opiates used for chronic noncancer pain

(1) As used in this section, "opiate" means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability.

(2) In addition to the duties listed in Section 26-1-30, the department shall develop and implement a two-year program in coordination with the Division of Professional Licensing, the Utah Labor Commission, and the Utah attorney general, to:

(a) investigate the causes of and risk factors for death and nonfatal complications of prescription opiate use and misuse in Utah for chronic pain by utilizing the Utah Controlled Substance Database created in Section 58-37f-201;

(b) study the risks, warning signs, and solutions to the risks associated with prescription opiate medications for chronic pain, including risks and prevention of misuse and diversion of those medications;

(c) provide education to health care providers, patients, insurers, and the general public on the appropriate management of chronic pain, including the effective use of medical treatment and quality care guidelines that are scientifically based and peer reviewed; and

(d) educate the public regarding:

(i) the purpose of the Controlled Substance Database established in Section 58-37f-201; and

(ii) the requirement that a person's name and prescription information be recorded on the database when the person fills a prescription for a schedule II, III, IV, or V controlled substance.

West's Utah Code Annotated (2014)
Title 58. Occupations and Professions
Chapter 17b. Pharmacy Practice Act
Part 8. Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy

§ 58-17b-803. Qualifications for licensure as a dispensing medical practitioner – Scope of practice.

(1) An applicant for a license as a dispensing medical practitioner shall:

(a) be licensed in good standing under at least one of the chapters listed in Subsection 58-17b-102(23)(a); and

(b) submit an application for a license as a dispensing medical practitioner in a form prescribed by the division and pay a fee established by the division.

(2) The division shall accept the licensing in good standing under Subsection (1) in lieu of requiring an applicant for a license under this part to comply with Sections 58-17b-303 and 58-17b-307.

(3) A dispensing medical practitioner may dispense, in accordance with this part:

(a) a cosmetic drug and an injectable weight loss drug if:

(i) the drug was prescribed by the dispensing medical practitioner to the dispensing medical practitioner's patient; and

(ii) the dispensing medical practitioner complies with administrative rules adopted by the division under Subsection 58-17b-802(1);

(b) a cancer drug treatment regimen if the dispensing medical practitioner complies with Section 58-17b-805; and

(c) a pre-packaged drug to an employee or a dependent of an employee at an employer sponsored clinic if the dispensing medical practitioner:

(i) treats an employee, or the dependent of an employee, of one of an exclusive group of employers at an employer sponsored clinic;

(ii) prescribes a prepackaged drug to the employee or the employee's dependent;

(iii) dispenses the prepackaged drug at the employer sponsored clinic; and

(iv) complies with administrative rules adopted by the division in consultation with the Board of Pharmacy that establish labeling, record keeping, patient counseling, purchasing and distribution, operating, treatment, quality of care, and storage requirements.

(4) A dispensing medical practitioner:

(a) shall inform the patient:

(i) that the drug dispensed by the practitioner may be obtained from a pharmacy unaffiliated with the practitioner;

(ii) of the directions for appropriate use of the dispensed drug;

(iii) of potential side effects to the use of the dispensed drug; and

(iv) how to contact the dispensing medical practitioner if the patient has questions or concerns regarding the drug;

(b) shall report to the controlled substance database in the same manner as required in Section 58-37f-203; and

(c) may delegate the dispensing of the drug if the individual to whom the dispensing was delegated is:

(i) employed by the dispensing medical practitioner or the outpatient clinic setting in which the dispensing medical practitioner works; and

(ii) acting under the direction of a dispensing medical practitioner who is immediately available on site for any necessary consultation.

(5) If the chapter that governs the license of a dispensing medical practitioner, as listed in Subsection 58-17b-102(23), requires physician supervision in its scope of practice requirements, the dispensing medical practitioner shall only dispense a drug under the supervision of an individual licensed under Chapter 67, Utah Medical Practice Act, or Chapter 69, Utah Osteopathic Medical Practice Act.

West's Utah Code Annotated (2014)
Title 58. Occupations and Professions
Chapter 37F. Controlled Substance Database Act
Part 2. Controlled Substance Database

§ 58-37f-203. Submission, collection, and maintenance of data

(1)(a) The pharmacist in charge of the drug outlet where a controlled substance is dispensed shall submit the data described in this section to the division:

(i) in accordance with the requirements of this section;

(ii) in accordance with the procedures established by the division; and

(iii) in the format established by the division.

(b) A dispensing medical practitioner licensed under Chapter 17b, Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, shall comply with the provisions of this section and the dispensing medical practitioner shall assume the duties of the pharmacist under this chapter.

(2) The pharmacist described in Subsection (1) shall, for each controlled substance dispensed by a pharmacist under the pharmacist's supervision other than those dispensed for an inpatient at a health care facility, submit to the division the following information:

(a) the name of the prescribing practitioner;

(b) the date of the prescription;

(c) the date the prescription was filled;

(d) the name of the individual for whom the prescription was written;

(e) positive identification of the individual receiving the prescription, including the type of identification and any identifying numbers on the identification;

(f) the name of the controlled substance;

(g) the quantity of the controlled substance prescribed;

(h) the strength of the controlled substance;

(i) the quantity of the controlled substance dispensed;

(j) the dosage quantity and frequency as prescribed;

(k) the name of the drug outlet dispensing the controlled substance;

(l) the name of the pharmacist dispensing the controlled substance; and

(m) other relevant information as required by division rule.

(3)(a) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to establish the electronic format in which the information required under this section shall be submitted to the division.

(b) The division shall ensure that the database system records and maintains for reference:

(i) the identification of each individual who requests or receives information from the database;

(ii) the information provided to each individual; and

(iii) the date and time that the information is requested or provided.

West's Utah Code Annotated (2014)
Title 58. Occupations and Professions
Chapter 37F. Controlled Substance Database Act
Part 3. Access

§ 58-37f-301. Access to database

(1) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to:

(a) effectively enforce the limitations on access to the database as described in this part; and

(b) establish standards and procedures to ensure accurate identification of individuals requesting information or receiving information without request from the database.

(2) The division shall make information in the database and information obtained from other state or federal prescription monitoring programs by means of the database available only to the following individuals, in accordance with the requirements of this chapter and division rules:

(a) personnel of the division specifically assigned to conduct investigations related to controlled substance laws under the jurisdiction of the division;

(b) authorized division personnel engaged in analysis of controlled substance prescription information as a part of the assigned duties and responsibilities of their employment;

(c) in accordance with a written agreement entered into with the department, employees of the Department of Health:

(i) whom the director of the Department of Health assigns to conduct scientific studies regarding the use or abuse of controlled substances, if the identity of the individuals and pharmacies in the database are confidential and are not disclosed in any manner to any individual who is not directly involved in the scientific studies; or

(ii) when the information is requested by the Department of Health in relation to a person or provider whom the Department of Health suspects may be improperly obtaining or providing a controlled substance;

(d) in accordance with a written agreement entered into with the department, a designee of the director of the Department of Health, who is not an employee of the Department of Health, whom the director of the Department of Health assigns to conduct scientific studies regarding the use or abuse of controlled substances pursuant to an application process established in rule by the Department of Health, if:

(i) the designee provides explicit information to the Department of Health regarding the purpose of the scientific studies;

(ii) the scientific studies to be conducted by the designee:

(A) fit within the responsibilities of the Department of Health for health and welfare;

(B) are reviewed and approved by an Institutional Review Board that is approved for human subject research by the United States Department of Health and Human Services; and

(C) are not conducted for profit or commercial gain; and

(D) are conducted in a research facility, as defined by division rule, that is associated with a university or college in the state accredited by the Northwest Commission on Colleges and Universities;

(iii) the designee protects the information as a business associate of the Department of Health; and

(iv) the identity of the prescribers, patients, and pharmacies in the database are de-identified, confidential, not disclosed in any manner to the designee or to any individual who is not directly involved in the scientific studies;

(e) in accordance with the written agreement entered into with the department and the Department of Health, authorized employees of a managed care organization, as defined in 42 C.F.R. Sec. 438, if:

(i) the managed care organization contracts with the Department of Health under the provisions of Section 26-18-405 and the contract includes provisions that:

(A) require a managed care organization employee who will have access to information from the database to submit to a criminal background check; and

(B) limit the authorized employee of the managed care organization to requesting either the division or the Department of Health to conduct a search of the database regarding a specific Medicaid enrollee and to report the results of the search to the authorized employee; and

(ii) the information is requested by an authorized employee of the managed care organization in relation to a person who is enrolled in the Medicaid program with the managed care organization, and the managed care organization suspects the person may be improperly obtaining or providing a controlled substance;

(f) a licensed practitioner having authority to prescribe controlled substances, to the extent the information:

(i)(A) relates specifically to a current or prospective patient of the practitioner; and

(B) is provided to or sought by the practitioner for the purpose of:

(I) prescribing or considering prescribing any controlled substance to the current or prospective patient;

(II) diagnosing the current or prospective patient;

(III) providing medical treatment or medical advice to the current or prospective patient; or

(IV) determining whether the current or prospective patient:

(Aa) is attempting to fraudulently obtain a controlled substance from the practitioner; or

(Bb) has fraudulently obtained, or attempted to fraudulently obtain, a controlled substance from the practitioner;

(ii)(A) relates specifically to a former patient of the practitioner; and

(B) is provided to or sought by the practitioner for the purpose of determining whether the former patient has fraudulently obtained, or has attempted to fraudulently obtain, a controlled substance from the practitioner;

(iii) relates specifically to an individual who has access to the practitioner's Drug Enforcement Administration identification number, and the practitioner suspects that the individual may have used the practitioner's Drug Enforcement Administration identification number to fraudulently acquire or prescribe a controlled substance;

(iv) relates to the practitioner's own prescribing practices, except when specifically prohibited by the division by administrative rule;

(v) relates to the use of the controlled substance database by an employee of the practitioner, described in Subsection (2)(g); or

(vi) relates to any use of the practitioner's Drug Enforcement Administration identification number to obtain, attempt to obtain, prescribe, or attempt to prescribe, a controlled substance;

(g) in accordance with Subsection (3)(a), an employee of a practitioner described in Subsection (2)(f), for a purpose described in Subsection (2)(f)(i) or (ii), if:

(i) the employee is designated by the practitioner as an individual authorized to access the information on behalf of the practitioner;

(ii) the practitioner provides written notice to the division of the identity of the employee; and

(iii) the division:

(A) grants the employee access to the database; and

(B) provides the employee with a password that is unique to that employee to access the database in order to permit the division to comply with the requirements of Subsection 58-37f-203(3)(b) with respect to the employee;

(h) an employee of the same business that employs a licensed practitioner under Subsection (2)(f) if:

(i) the employee is designated by the practitioner as an individual authorized to access the information on behalf of the practitioner;

(ii) the practitioner and the employing business provide written notice to the division of the identity of the designated employee; and

(iii) the division:

(A) grants the employee access to the database; and

(B) provides the employee with a password that is unique to that employee to access the database in order to permit the division to comply with the requirements of Subsection 58-37f-203(3)(b) with respect to the employee;

(i) a licensed pharmacist having authority to dispense a controlled substance to the extent the information is provided or sought for the purpose of:

(i) dispensing or considering dispensing any controlled substance; or

(ii) determining whether a person:

(A) is attempting to fraudulently obtain a controlled substance from the pharmacist; or

(B) has fraudulently obtained, or attempted to fraudulently obtain, a controlled substance from the pharmacist;

(j) in accordance with Subsection (3)(a), a licensed pharmacy technician who is an employee of a pharmacy as defined in Section 58-17b-102, for the purposes described in Subsection (2)(i)(i) or (ii), if:

(i) the employee is designated by the pharmacist-in-charge as an individual authorized to access the information on behalf of a licensed pharmacist employed by the pharmacy;

(ii) the pharmacist-in-charge provides written notice to the division of the identity of the employee; and

(iii) the division:

(A) grants the employee access to the database; and

(B) provides the employee with a password that is unique to that employee to access the database in order to permit the division to comply with the requirements of Subsection 58-37f-203(3)(b) with respect to the employee;

(k) federal, state, and local law enforcement authorities, and state and local prosecutors, engaged as a specified duty of their employment in enforcing laws:

(i) regulating controlled substances;

(ii) investigating insurance fraud, Medicaid fraud, or Medicare fraud; or

(iii) providing information about a criminal defendant to defense counsel, upon request during the discovery process, for the purpose of establishing a defense in a criminal case;

(l) employees of the Office of Internal Audit and Program Integrity within the Department of Health who are engaged in their specified duty of ensuring Medicaid program integrity under Section 26-18-2.3;

(m) a mental health therapist, if:

(i) the information relates to a patient who is:

(A) enrolled in a licensed substance abuse treatment program; and

(B) receiving treatment from, or under the direction of, the mental health therapist as part of the patient's participation in the licensed substance abuse treatment program described in Subsection (2)(l)(i)(A);

(ii) the information is sought for the purpose of determining whether the patient is using a controlled substance while the patient is enrolled in the licensed substance abuse treatment program described in Subsection (2)(l)(i)(A); and

(iii) the licensed substance abuse treatment program described in Subsection (2)(l)(i)(A) is associated with a practitioner who:

(A) is a physician, a physician assistant, an advance practice registered nurse, or a pharmacist; and

(B) is available to consult with the mental health therapist regarding the information obtained by the mental health therapist, under this Subsection (2)(l), from the database;

(n) an individual who is the recipient of a controlled substance prescription entered into the database, upon providing evidence satisfactory to the division that the individual requesting the information is in fact the individual about whom the data entry was made;

(o) the inspector general, or a designee of the inspector general, of the Office of Inspector General of Medicaid Services, for the purpose of fulfilling the duties described in Title 63A, Chapter 13, Part 2, Office and Powers; and

(p) the following licensed physicians for the purpose of reviewing and offering an opinion on an individual's request for workers' compensation benefits under Title 34A, Chapter 2, Workers' Compensation Act, or Title 34A, Chapter 3, Utah Occupational Disease Act:

(i) a member of the medical panel described in Section 34A-2-601; or

(ii) a physician offering a second opinion regarding treatment.

(3)(a)(i) A practitioner described in Subsection (2)(f) may designate up to three employees to access information from the database under Subsection (2)(g), (2)(h), or (4)(c).

(ii) A pharmacist described in Subsection (2)(i) who is a pharmacist-in-charge may designate up to three employees to access information from the database under Subsection (2)(j).

(b) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to:

(i) establish background check procedures to determine whether an employee designated under Subsection (2)(g), (2)(h), or (4)(c) should be granted access to the database; and

(ii) establish the information to be provided by an emergency room employee under Subsection (4).

(c) The division shall grant an employee designated under Subsection (2)(f), (2)(g), or (4)(c) access to the database, unless the division determines, based on a background check, that the employee poses a security risk to the information contained in the database.

(4)(a) An individual who is employed in the emergency room of a hospital may exercise access to the database under this Subsection (4) on behalf of a licensed practitioner if the individual is designated under Subsection (4)(c) and the licensed practitioner:

(i) is employed in the emergency room;

(ii) is treating an emergency room patient for an emergency medical condition; and

(iii) requests that an individual employed in the emergency room and designated under Subsection (4)(c) obtain information regarding the patient from the database as needed in the course of treatment.

(b) The emergency room employee obtaining information from the database shall, when gaining access to the database, provide to the database the name and any additional identifiers regarding the requesting practitioner as required by division administrative rule established under Subsection (3)(b).

(c) An individual employed in the emergency room under this Subsection (4) may obtain information from the database as provided in Subsection (4)(a) if:

(i) the employee is designated by the practitioner as an individual authorized to access the information on behalf of the practitioner;

(ii) the practitioner and the hospital operating the emergency room provide written notice to the division of the identity of the designated employee; and

(iii) the division:

(A) grants the employee access to the database; and

(B) provides the employee with a password that is unique to that employee to access the database in order to permit the division to comply with the requirements of Subsection 58-37f-203(3)(b) with respect to the employee.

(d) The division may impose a fee, in accordance with Section 63J-1-504, on a practitioner who designates an employee under Subsection (2)(g), (2)(h), or (4)(c) to pay for the costs incurred by the division to conduct the background check and make the determination described in Subsection (3)(b).

(5)(a) An individual who is granted access to the database based on the fact that the individual is a licensed practitioner or a mental health therapist shall be denied access to the database when the individual is no longer licensed.

(b) An individual who is granted access to the database based on the fact that the individual is a designated employee of a licensed practitioner shall be denied access to the database when the practitioner is no longer licensed.

West's Utah Code Annotated (2014)
Title 58. Occupations and Professions
Chapter 37F. Controlled Substance Database Act
Part 3. Access

§ 58-37f-302. Other restrictions on access to database

(1) A person who is a relative of a deceased individual is not entitled to access information from the database relating to the deceased individual based on the fact or claim that the person is:

(a) related to the deceased individual; or

(b) subrogated to the rights of the deceased individual.

(2) Except as provided in Subsection (3), data provided to, maintained in, or accessed from the database that may be identified to, or with, a particular person is not subject to discovery, subpoena, or similar compulsory process in any civil, judicial, administrative, or legislative proceeding, nor shall any individual or organization with lawful access to the data be compelled to testify with regard to the data.

(3) The restrictions described in Subsection (2) do not apply to a civil, judicial, or administrative action brought to enforce the provisions of this chapter.

West's Utah Code Annotated (2014)
Title 58. Occupations and Professions
Chapter 37F. Controlled Substance Database Act
Part 4. Registration and Training

§ 58-37f-401. Database registration required--Penalties for failure to register

(1) Each individual, other than a veterinarian, who, on June 30, 2010, has a license to prescribe a controlled substance under Chapter 37, Utah Controlled Substances Act, but is not registered with the division to use the database shall, on or before September 30, 2010, register with the division to use the database.

(2) Each individual who, on November 1, 2012, is registered with the division to use the database shall, on or before January 1, 2013, participate in the online tutorial and pass the online test described in Section 58-37f-402.

(3)(a) An individual who is not a veterinarian, who obtains a new license to prescribe a controlled substance under Chapter 37, Utah Controlled Substances Act, shall, within 30 days after the day on which the individual obtains a license to prescribe a controlled substance from the Drug Enforcement Administration, register with the division to use the database.

(b) An individual who is not a veterinarian may not renew a license to prescribe a controlled substance under Chapter 37, Utah Controlled Substances Act, unless the individual registers with the division to use the database.

(4) Beginning on November 2, 2012, in order to register to use the database, the individual registering must participate in the online tutorial and pass the online test described in Section 58-37f-402.

(5) Failure by an individual to comply with the requirements of this section is grounds for the division to take the following actions in accordance with Section 58-1-401:

(a) refuse to issue a license to the individual;

(b) refuse to renew the individual's license; or

(c) revoke, suspend, restrict, or place on probation the license.

(6) Beginning on July 1, 2010, the division shall, in accordance with Section 63J-1-504, impose an annual database registration fee on an individual who registers to use the database, to pay the startup and ongoing costs of the division for complying with the requirements of this section and Section 58-37f-402.

West's Utah Code Annotated (2014)
Title 58. Occupations and Professions
Chapter 37F. Controlled Substance Database Act
Part 4. Registration and Training

§ 58-37f-402. Online tutorial and test relating to the database--Fees--Rulemaking authority--Continuing professional education credit

(1) The division shall develop an online tutorial and an online test for registration to use the database that provides instruction regarding, and tests, the following:

(a) the purpose of the database;

(b) how to access and use the database;

(c) the law relating to:

(i) the use of the database; and

(ii) the information submitted to, and obtained from, the database; and

(d) basic knowledge that is important for all people who prescribe controlled substances to know in order to help ensure the health and safety of an individual to whom a controlled substance is prescribed.

(2) The division shall design the test described in this section as follows:

(a) an individual shall answer all of the questions correctly in order to pass the test;

(b) an individual shall be permitted to immediately retake the portion of the test that the individual answers incorrectly as many times as necessary for the individual to pass the test; and

(c) after an individual takes the test, the test software shall:

(i) immediately inform the individual of the number of questions that were answered incorrectly;

(ii) provide the correct answers;

(iii) replay the portion of the tutorial that relates to the incorrectly answered questions; and

(iv) ask the individual the incorrectly answered questions again.

(3) The division shall design the tutorial and test so that it is possible to take the tutorial and complete the test in 20 minutes or less, if the individual answers all of the questions correctly on the first attempt.

(4) The division shall ensure that the tutorial and test described in this section are fully functional and available for use online on or before November 1, 2010.

(5) The division shall impose a fee, in accordance with Section 63J-1-504, on an individual who takes the test described in this section, to pay the costs incurred by the division to:

(a) develop, implement, and administer the tutorial and test described in this section; and

(b) fulfill the other duties imposed on the division under this part.

(6) The division may make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to:

(a) develop, implement, and administer the tutorial and test described in this section; and

(b) fulfill the other duties imposed on the division under this part.

(7) The Department of Health shall assist the division in developing the portion of the test described in Subsection (1)(d).

(8) Completing the online tutorial and passing the online test described in this section shall count as 1/2 hour of continuing professional education under Subsection 58-37-6.5(2).

West's Utah Code Annotated (2014)
Title 58. Occupations and Professions
Chapter 37F. Controlled Substance Database Act
Part 5. Costs and Funding

§ 58-37f-501. Costs of operating database and recording and submitting data

(1) All department and division costs necessary to establish and operate the database shall be funded by appropriations from:

(a) the Commerce Service Account; and

(b) the General Fund.

(2) All costs associated with recording and submitting data as required in this chapter shall be assumed by the submitting pharmacy.

West's Utah Code Annotated (2014)
Title 58. Occupations and Professions
Chapter 37F. Controlled Substance Database Act
Part 5. Costs and Funding

§ 58-37f-502. Use of dedicated credits--Controlled Substance Database--Collection of penalties

(1) The director may use the money deposited in the General Fund as a dedicated credit under Subsections 58-37-6(8)(a), 58-37f-601(3)(d), and 58-37f-602(2) for the following purposes:

(a) maintenance and replacement of the database equipment, including hardware and software;

(b) training of staff; and

(c) pursuit of external grants and matching funds.

(2) The director of the division may collect any penalty imposed under Subsections 58-37-6(8)(a), 58-37f-601(3)(d), and 58-37f-602(2) and which is not paid by:

(a) referring the matter to the Office of State Debt Collection or a collection agency; or

(b) bringing an action in the district court of the county in which the person owing the debt resides or in the county where the office of the director is located.

(3) The director may seek legal assistance from the attorney general or the county or district attorney of the district in which the action is brought to collect the fine.

(4) The court shall award reasonable attorney fees and costs to the division for successful collection actions under Subsection (2)(b).

West's Utah Code Annotated (2014)
Title 58. Occupations and Professions
Chapter 37F. Controlled Substance Database Act
Part 8. Pilot Program

§ 58-37f-801. Pilot program for real-time reporting for controlled substance database--Statewide implementation

(1) As used in this section:

(a) “Pilot area” means the areas of the state that the division determines to operate the pilot program in, under Subsection (3), which may include:

(i) the entire state; or

(ii) geographical areas within the state.

(b) “Pilot program” means the pilot program described in this section.

(2) There is established a pilot program for real-time reporting of data to, and access to data from, the database by a pharmacy, a pharmaceutical facility, or a prescribing practitioner beginning on July 1, 2010, and ending on July 1, 2012.

(3) In addition to fulfilling the requirements relating to the database on a statewide basis, the division shall, in accordance with Subsection (4), upgrade, administer, and direct the functioning of the database in geographical areas specified by the division, or on a statewide basis, in a manner that provides for real-time reporting of information entered into, and accessed from, the database by a pharmacy or pharmaceutical facility.

(4) The division shall, under state procurement laws, and with the technical assistance of the Department of Technology Services, contract with a private entity to upgrade, operate, and maintain the database in the pilot area.

(5)(a) All provisions and requirements of the statewide database, described in the other parts of this chapter, are applicable to the database in the pilot area, to the extent that they do not conflict with the requirements of this section.

(b) For purposes of the other parts of this chapter, and this section, the database in the pilot area is considered part of the statewide database.

(6) A pharmacy or pharmaceutical facility shall cooperate with the division, or the division's designee, to provide real-time submission of, and access to, information for the database:

(a) in the pilot area; and

(b) when the division implements the pilot program as a permanent program under Subsection (9), on a statewide basis.

(7) The penalties and enforcement provisions described in the other parts of this chapter apply to enforce the provisions of this section in relation to a pharmacy or pharmaceutical facility that is located in, or operates in, the pilot area.

(8) The division may make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to provide for the real-time reporting of, and access to, information in accordance with the requirements of this section.

(9) The division shall, on or before July 1, 2012, implement the pilot program as a permanent program on a statewide basis.

(10)(a) The division shall, through the private entity contracted with under Subsection (4), provide, free of charge, to a pharmacy or pharmaceutical facility that is required to comply with Subsection (6), software, software installation assistance, and training, that will enable the pharmacy or pharmaceutical facility to comply with Subsection (6).

(b) Notwithstanding Subsection (10)(a), a pharmacy or pharmaceutical facility required to comply with Subsection (6) may, instead of accepting installation of the software provided by the division under Subsection (10)(a), modify its own software in order to comply with the requirements of Subsection (6), if the modification is made:

(i) except as provided in Subsection (10)(d), at the expense of the pharmacy or pharmaceutical facility;

(ii) in consultation with the division; and

(iii) within six months after the division notifies the pharmacy or pharmaceutical facility, in writing, of the division's intention to install the software described in Subsection (10)(a).

(c) The division shall, through the private entity contracted with under Subsection (4), cooperate with a pharmacy or pharmaceutical facility that is required to comply with Subsection (6), to ensure that the installation and operation of the software described in Subsection (10)(a), or the provision of information from the pharmacy or pharmaceutical facility to the database:

(i) complies with the security standards described in 45 C.F.R. Parts 160, 162, and 164, Health Insurance Reform: Security Standards;

(ii) does not interfere with the proper functioning of the pharmacy's or pharmaceutical facility's software or computer system; and

(iii) in order to minimize changes in existing protocols, provides, to the extent practicable, for the transmission of data in the same manner that pharmacies currently transmit information to insurance companies.

(d) The division may, within funds appropriated by the Legislature for this purpose, reimburse a pharmacy for all or part of the costs of the in-house programing described in Subsection (10)(b), if:

(i) the pharmacy requests the reimbursement, in writing;

(ii) the pharmacy provides proof of the costs for the in-house programming to the division;

(iii) the pharmacy requests the reimbursement prior to a deadline established by the division; and

(iv) except as provided in Subsection (10)(e), the division pays an equal reimbursement amount to each pharmacy that complies with Subsections (10)(d)(i) through (iii).

(e) The division may reimburse a pharmacy described in Subsection (10)(d)(iv) for an amount that is less than the reimbursement paid to other pharmacies described in Subsection (10)(d)(iv), if:

(i) the proof of costs for in-house programming provided by the pharmacy establishes a cost less than the amount reimbursed to the other pharmacies; and

(ii) the amount reimbursed to the pharmacy is equal to the amount established by the proof of costs for in-house programming submitted by the pharmacy.

(f) Notwithstanding any other provision of this section, the division may, by rule, allow up to 24 hours for the reporting of data to the database by a non-resident pharmacy, as defined in Section 58-17b-102.

Utah Administrative Code (2014)
Commerce
R156. Occupational and Professional Licensing.

R156-37f. Controlled Substance Database Act Rule.

R156-37f-101. Title.

This rule shall be known as the "Controlled Substance Database Act Rule".

R156-37f-102. Definitions.

In addition to the definitions in Sections 58-17b-102, 58-37-2 and 58-37f-102, as used in this chapter:

(1) "ASAP" means the American Society for Automation in Pharmacy system.

(2) "DEA" means Drug Enforcement Administration.

(3) "NABP" means the National Association of Boards of Pharmacy.

(4) "NCPDP" means National Council for Prescription Drug Programs.

(5) "NDC" means National Drug Code.

(6) "Research facility" means a facility in which research takes place that has policies and procedures describing such research.

(7) "Rx" means a prescription.

R156-37f-103. Authority—Purpose.

This rule is adopted by the Division under the authority of Subsection 58-1-106(1)(a) to enable the Division to administer Title 58, Chapter 37f.

R156-37f-104. Organization—Relationship to Rule R156-1.

The organization of this rule and its relationship to Rule R156-1 is as described in Section R156-1-107.

R156-37f-203. Submission, Collection, and Maintenance of Data.

(1) The format for submission to the Database shall be in accordance with the ASAP Telecommunications Format for Controlled Substances published by the American Society for Automation in Pharmacy, revised May 1995 (ASAP Format), which is hereby incorporated by

reference. The Division may approve alternative formats substantially similar to this standard. This standard is further classified by the Database as follows:

(a) Mandatory Data. The following Database data fields are mandatory:

(i) pharmacy NABP or NCPDP number;

(ii) patient birth date;

(iii) patient gender code;

(iv) date filled;

(v) Rx number;

(vi) new-refill code;

(vii) metric quantity;

(viii) days supply;

(ix) NDC number;

(x) prescriber identification number;

(xi) date Rx written;

(xii) number refills authorized;

(xiii) patient last name;

(xiv) patient first name; and

(xv) patient street address, including zip code (extended).

(b) Preferred Data. The following Database data fields are strongly suggested:

(i) customer identification number;

(ii) compound code;

(iii) DEA suffix;

(iv) Rx origin code;

(v) customer location;

(vi) alternate prescriber number; and

(vii) state in which the prescription is filled.

(c) Optional Data. All other data fields in the ASAP Format not included in Subsections (a) and (b) are optional.

(2) Upon request, the Division will consider approving alternative formats, or adjustments to the ASAP Format, as might be necessary due to the capability or functionality of Database collection instruments. A proposed alternative format shall contain all mandatory data elements.

(3) In accordance with Subsection 58-37f-203(1)(c), the data required in Subsection (1) shall be submitted to the Database through one of the following methods:

(a) electronic data sent via telephone modem;

(b) electronic data submitted on floppy disk or compact disc (CD);

(c) if approved by the Database staff prior to submission, electronic data sent via encrypted electronic mail (e-mail);

(d) electronic data sent via a secured internet transfer method, including but not limited to sFTP site transfer and HyperSend; or

(e) any other electronic method approved by the Database manager prior to submission.

(4) The required information may be submitted on paper if:

(a) the pharmacy or pharmacy group submits a written request to the Division and receives prior approval for a paper submission; and

(b)(i) the pharmacy or pharmacy group has no computerized record keeping system upon which the data can be electronically recorded; or

(ii) The pharmacy or pharmacy group is unable to conform its submission(s) to an electronic format without incurring undue financial hardship.

(5)(a) Each pharmacy or pharmacy group shall submit all data collected at least once every seven days on a weekly reporting cycle established by the pharmacy.

(i) If the data is submitted by a single pharmacy entity, the data shall be submitted in chronological order according to the date each prescription was filled.

(ii) If the data is submitted by a pharmacy group, the data is required to be sorted by individual pharmacy within the group, and the data of each individual pharmacy within the group is required to be submitted in chronological order according to the date each prescription was filled.

(b)(i) A Class A, B, or D pharmacy or pharmacy group that has a controlled substance license but has not dispensed a controlled substance during the preceding seven days shall:

(A) submit a null report stating that no controlled substance was dispensed during the preceding seven days; or

(B) comply with this Subsection (5)(c).

(ii) A null report may be submitted on paper without prior approval of the Division. The Division shall facilitate electronic null reporting as resources permit.

(c)(i) A Class A, B, or D pharmacy or pharmacy group that has a controlled substance license but is not dispensing controlled substances and does not anticipate doing so in the immediate future may submit a certification of such, in a form preapproved by the Division, in lieu of weekly null reporting.

(ii) The certification must be resubmitted at the end of each calendar year.

(iii) If a pharmacy or pharmacy group that has submitted a certification under this Subsection (5)(c) dispenses a controlled substance:

(A) the certification shall immediately and automatically terminate;

(B) the pharmacy or pharmacy group shall provide written notice of the certification termination to the Division within seven days of dispensing the controlled substance; and

(C) the Database reporting requirements shall be applicable to the pharmacy or pharmacy group immediately upon the dispensing of the controlled substance.

(6) The pharmacist-in-charge, or his or her designee, for each reporting pharmacy shall submit its report, regardless of the reporting method, on a data transmission form (DTF) substantially equivalent to the DTF approved by the Division. The DTF may be mailed, faxed, emailed, or electronically uploaded to the Database. A copy of the DTF is required to be kept at the pharmacy unless an alternate location has been designated by the reporting pharmacy and approved by the Division. The DTF shall include the following information:

(a) pharmacy name;

(b) pharmacy facsimile (fax) and voice phone numbers;

(c) pharmacy e-mail address;

(d) pharmacy NABP/NCPDP number;

(e) period of time covered by each submission of data;

(f) number of prescriptions in the submission;

(g) submitting pharmacist's signature attesting to the accuracy of the report; and

(h) date of the report submission.

R156-37f-301. Access to Database Information.

In accordance with Subsections 58-37f-301(1)(a) and (b):

(1) The Division Director shall designate in writing those individuals employed by the Division who shall have access to the information in the Database (Database staff).

(2)(a) A request for information from the Database may be made:

(i) directly to the Database by electronic submission, if the requester is registered to use the Database; or

(ii) by oral or written submission to the Database staff, if the requester is not registered to use the Database.

(b) An oral request may be submitted by telephone or in person.

(c) A written request may be submitted by facsimile, email, regular mail, or in person except as otherwise provided herein.

(d) The Division may in its discretion require a requestor to verify the requestor's identity.

(3) The following Database information may be disseminated to a verified requestor who is permitted to obtain the information:

(a) dispensing/reporting pharmacy ID number/name;

(b) subject's birth date;

(c) date prescription was filled;

(d) prescription (Rx) number;

(e) metric quantity;

(f) days supply;

(g) NDC code/drug name;

(h) prescriber ID/name;

(i) date prescription was written;

(j) subject's last name;

(k) subject's first name; and

(l) subject's street address;

(4) Federal, state and local law enforcement authorities and state and local prosecutors requesting information from the Database under Subsection 58-37f-301(2)(d) must provide a valid case number of the investigation or prosecution.

(5) An individual whose records are contained within the Database may not receive an accounting of persons or entities that have requested or received Database information about the individual.

(6) An individual whose records are contained within the Database may obtain his or her own information and records by:

(a) personally appearing before the Database staff with government-issued picture identification confirming the requester's identity; or

(b) submitting a signed and notarized request that includes the requester's:

(i) full name;

(ii) complete home address;

(iii) date of birth; and

(iv) driver license or state identification card number.

(7) A requester holding power of attorney for an individual whose records are contained within the Database may obtain the individual's information and records by:

(a) personally appearing before the Database staff with government-issued picture identification confirming the requester's identity; and

(b) providing:

(i) an original, properly executed power of attorney designation; and

(ii) a signed and notarized request, executed by the individual whose information is contained within the Database, and including the individual's:

(A) full name;

(B) complete home address;

(C) date of birth; and

(D) driver license or state identification card number verifying the individual's identity.

(8) A requestor who is the legal guardian of a minor or incapacitated individual whose records are contained within the Database may obtain the individual information and records by:

(a) personally appearing before the Database staff with government-issued picture identification confirming the requester's identity;

(b) submitting the minor or incapacitated individual's:

(i) full name;

(ii) complete home address;

(iii) date of birth; and

(iv) if applicable, state identification card number verifying the individual's identity; and

(c) submitting legal proof that the requestor is the guardian of the individual who is the subject of the request for information from the Database.

(9) A requestor who has a release-of-records from an individual whose records are contained within the Database may obtain the individual's information and records by:

(a) submitting a request in writing;

(b) submitting an original, signed and notarized release-of-records in a format acceptable to the Database staff, identifying the purpose of the release; and

(c) submitting the individual's:

(i) full name;

(ii) complete home address;

(iii) telephone number;

(iv) date of birth; and

(v) driver license or state identification card number verifying the identity of the person who is the subject of the request.

(10) An employee of a licensed practitioner who is authorized to prescribe controlled substances may obtain Database information to the extent permissible under Subsection 58-37f-301(2)(d)if, prior to making the request:

(a) the licensed practitioner has provided to the Division a written designation that includes the designating practitioner's DEA number and the designated employee's:

(i) full name;

(ii) complete home address;

(iii) e-mail address;

(iv) date of birth; and

(v) driver license number or state identification card number;

(b) the designated employee has registered for an account for access to the Database and provided a unique user identification and password;

(c) the designated employee has passed a Database background check of available criminal court and Database records; and

(d) the Database has issued the designated employee a user personal identification number (PIN) and activated the employee's Database account. (11) An employee of a business that employs a licensed practitioner who is authorized to prescribe controlled substances may obtain Database information to the extent permissible under Subsection 58-37f-301(2)(d) if, prior to making the request:

(a) the licensed practitioner and employing business have provided to the Division a written designation that includes:

(i) the designating practitioner's DEA number;

(ii) the name of the employing business; and

(iii) the designated employee's:

(A) full name;

(B) complete home address;

(C) e-mail address;

(D) date of birth; and

(E) driver license number or state identification card number;

(b) the designated employee has registered for an account for access to the Database and provided a unique user identification and password;

(c) the designated employee has passed a Database background check of available criminal court and Database records; and

(d) the Database has issued the designated employee a user personal identification number (PIN) and activated the employee's Database account.

(12) An individual who is employed in the emergency room of a hospital that employs a licensed practitioner who is authorized to prescribe controlled substances may obtain Database information to the extent permissible under Subsection 58-37f-301(2)(d) if, prior to making the request:

(a) the practitioner and the hospital operating the emergency room have provided to the Division a written designation that includes:

(i) the designating practitioner's DEA number;

(ii) the name of the hospital;

(iii) the names of all emergency room practitioners employed at the hospital; and

(iv) the designated employee's:

(A) full name;

(B) complete home address;

(C) e-mail address;

(C) date of birth; and

(D) driver license number or state identification card number;

(b) the designated employee has registered for an account for access to the Database and provided a unique user identification and password;

(c) the designated employee has passed a Database background check of available criminal court and Database records; and

(d) the Database has issued the designated employee a user personal identification number (PIN) and activated the employee's Database account.

(13) The Utah Department of Health may access Database information for purposes of scientific study regarding public health. To access information, the scientific investigator shall:

(a) demonstrate to the satisfaction of the Division that the research is part of an approved project of the Utah Department of Health;

(b) provide a description of the research to be conducted, including:

(i) a research protocol for the project; and

(ii) a description of the data needed from the Database to conduct that research;

(c) provide assurances and a plan that demonstrates all Database information will be maintained securely, with access being strictly restricted to the requesting scientific investigator;

(d) provide for electronic data to be stored on a secure database computer system with access being strictly restricted to the requesting scientific investigator; and

(e) pay all relevant expenses for data transfer and manipulation.

(14) Database information that may be disseminated under Section 58-37f-301 may be disseminated by the Database staff either:

(a) verbally;

(b) by facsimile;

(c) by email;

(d) by U.S. mail; or

(e) where adequate technology is in place to ensure that a record will not be compromised, intercepted, or misdirected, by electronic access.

R156-37f-801a. Reporting of Information by Pharmacies Participating in the Pilot Program for Real-time Reporting.

(1) In accordance with Subsection 58-37f-801(1)(a), the pilot area is designated as the entire state of Utah. Any pharmacy or pharmacy group that submits information to the Database is eligible and may participate in the Real-time Pilot Program.

(2) In accordance with Subsection 58-37f-801(8), each licensed pharmacy participating in the pilot program for real-time reporting shall, in conjunction with controlled substance point of sale, submit from the pharmacy's database to the Controlled Substance Database, the information required by Section 58-37f-203 as implemented by Section R156-37f-203, through real-time interface and reporting software developed by the Division's contract provider.

R156-37f-801b. Access to Information in the Database Submitted by Pharmacies Participating in the Pilot Program for Real-time Reporting.

In accordance with Subsection 58-37f-801(8), access to information in the Database submitted by pharmacies participating in the pilot program for real-time reporting shall be the same as set forth in Section 58-37f-301 as implemented by Section R156-37f-301.

Utah Administrative Code (2014)
Health
R384. Health, Disease Control and Prevention, Health Promotion.

R384-203. Prescription Drug Database Access.

R384-203-1. Authority and Purpose.

This rule establishes procedures and application processes pursuant to Title 58-37f-301(2)(d) for Utah Department of Health Executive Director to allow access to the Prescription Drug database by a designated and assigned person to conduct scientific studies regarding the use or abuse of controlled substances, who is not an employee of the Department of Health.

R384-203-2. Definitions.

The following definitions apply to this rule:

(1) "Department" means the Utah Department of Health.

(2) "Director" means the Utah Department of Health Executive Director.

(3) "Prescription Drug Database" means the Utah Controlled Substance Database.

(4) "Research facility" means a research facility associated with a university or college in the state accredited by the Northwest Commission on Colleges and Universities.

(5) "Institutional Review Board" means a board that is approved for human subject research by the United States Department of Health and Human Services.

(6) "Designee" means a person designated and assigned by the Director to have access to the Prescription Drug database in order to conduct scientific studies regarding the use or abuse of controlled substances, who is not an employee of the Department.

(7) "Business associate" means a business associate as defined under the HIPAA privacy, security, and breach notification rules in 45 CFR 164.502(a), 164.504(e), and 164.532(d) and (e).

(8) "De-identified" means information as defined in 45 CFR 164.502(d) and 164.514(a), (b), and (c).

R384-203-3. Criteria for Application to Access Prescription Drug Database.

(1) The study must fit within the responsibilities of the Department for health and welfare.

(2) De-identified prescriber, patient and pharmacy data will meet the research needs.

(3) The research facility designee must provide:

(a) written assurances that the studies are not conducted for and will not be used for profit or commercial gain;

(b) written assurances that the designee shall protect the information as a business associate of the Department of Health; and

(c) documentation of an Institutional Review Board approval.

R384-203-4. Research Application Process.

(1) The research facility designee will prepare and submit for Department approval an application as designated by the Department detailing explicit information regarding the scientific studies to be conducted including the:

(a) purpose of the study;

(b) research protocol for the project;

(c) description of the data needed from the database to conduct that research;

(d) plan that demonstrates all database information will be maintained securely, with access being strictly restricted to the designee and research study staff; and

(e) provisions for electronic data to be stored on a secure database computer system with access being strictly restricted to the designee and research study staff.

(2) Application will be reviewed by the Department's Institutional Review Board and recommendation made to the director for or against approval.

(3) Director will determine approval status of the application.

(4) Designee will sign the Department's data sharing agreement if application is approved by the Director.

R384-203-5. Data Provision and Fees.

(1) Department will obtain, de-identify and provide the data set requested in the application.

(2) Research facility and designee shall pay all relevant expenses for data transfer and manipulation.

R384-203-6. Audit Provisions.

Research facility and designee shall submit, upon request, to a Department audit of the recipients' compliance with the terms of the data sharing agreement.