

# HB0395S01 compared with HB0395

~~{deleted text}~~ shows text that was in HB0395 but was deleted in HB0395S01.

inserted text shows text that was not in HB0395 but was inserted into HB0395S01.

**DISCLAIMER:** This document is provided to assist you in your comparison of the two bills. Sometimes this automated comparison will NOT be completely accurate. Therefore, you need to read the actual bills. This automatically generated document could contain inaccuracies caused by: limitations of the compare program; bad input data; or other causes.

Representative Edward H. Redd proposes the following substitute bill:

## CONTROLLED SUBSTANCE DATABASE AMENDMENTS

2015 GENERAL SESSION

STATE OF UTAH

**Chief Sponsor: Edward H. Redd**

Senate Sponsor: \_\_\_\_\_

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### LONG TITLE

#### General Description:

This bill modifies provisions of the Controlled Substance Database Act.

#### Highlighted Provisions:

This bill:

- ▶ requires the Division of Occupational and Professional Licensing to implement ~~{a program}~~options for:
  - real-time submission of data into the controlled substance database; and
  - 24-hour daily or next business day batch submission of data;
- ▶ requires a pharmacist to comply with the real-time or 24-hour submission requirements on and after January 1, 2016;
- ▶ authorizes additional rulemaking authority;

~~{ provides that those accessing data from the database are responsible for costs~~

## HB0395S01 compared with HB0395

~~associated with accessing the data;~~

- ‡ ▶ repeals provisions of a pilot program; and
- ▶ makes technical corrections.

### Money Appropriated in this Bill:

This bill appropriates in fiscal year 2016:

- ▶ to the Department of Commerce - Division of Occupational and Professional Licensing - Controlled Substance Database, as an ongoing appropriation:
  - from the General Fund, \$46,000.

### Other Special Clauses:

This bill provides a special effective date.

### Utah Code Sections Affected:

AMENDS:

**58-37f-203**, as last amended by Laws of Utah 2014, Chapter 72

**58-37f-301**, as last amended by Laws of Utah 2014, Chapters 68 and 401

~~{ **58-37f-501**, as enacted by Laws of Utah 2010, Chapter 287 and last amended by Coordination Clause, Laws of Utah 2010, Chapter 287~~

‡REPEALS:

**58-37f-801**, as last amended by Laws of Utah 2013, Chapter 167

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*Be it enacted by the Legislature of the state of Utah:*

Section 1. Section **58-37f-203** is amended to read:

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

(1) (a) The division shall implement on a statewide basis, including non-resident pharmacies as defined in Section 58-17b-102, ~~the following two options for a program of~~ pharmacist to submit information:

(i) real-time submission of the information required to be submitted under this part to the controlled substance database; and

(ii) 24-hour daily ~~or next business day, whichever is later,~~ batch submission of the information required to be submitted under this part to the controlled substance database.

(b) (i) On and after January 1, 2016, a pharmacist shall comply with either:

(A) the submission time requirements established by the division under Subsection

## HB0395S01 compared with HB0395

(1)(a)(i); or

(B) the submission time requirements established by the division under Subsection

(1)(a)(ii).

(ii) Prior to January 1, 2016, a pharmacist may submit information using either option under this Subsection (1).

~~(b)(c)~~ The division shall comply with Title 63G, Chapter 6a, Utah Procurement Code.

~~(+)~~ (2) (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)~~ (3) The pharmacist described in Subsection ~~(+)~~ (2) 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;

## HB0395S01 compared with HB0395

- (l) the name of the pharmacist dispensing the controlled substance; and
- (m) other relevant information as required by division rule.

~~[(3)-(a)]~~ (4) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to establish submission requirements under this part, including the electronic format in which the information required under this section shall be submitted to the division.

~~[(b)]~~ (5) The division shall ensure that the database system records and maintains for reference:

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

~~[(ii)]~~ (b) the information provided to each individual; and

~~[(iii)]~~ (c) the date and time that the information is requested or provided.

Section 2. Section **58-37f-301** is amended to read:

### **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:

## HB0395S01 compared with HB0395

(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~~ one or more regional or national accrediting agencies recognized by the United States Department of Education;

(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:

## HB0395S01 compared with HB0395

(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

## HB0395S01 compared with HB0395

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)](5) 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

## HB0395S01 compared with HB0395

58-37f-203[(3)(b)](5) 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)(h)(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)](5) 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:

## HB0395S01 compared with HB0395

(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)(m)(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)(m)(i)(A); and

(iii) the licensed substance abuse treatment program described in Subsection (2)(m)(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)(m), 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:

## HB0395S01 compared with HB0395

(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)(g), (2)(h), 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)](5) with respect to the employee.

## HB0395S01 compared with HB0395

(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.

~~{~~ ~~Section 3. Section 58-37f-501 is amended to read:~~

~~58-37f-501. Costs of operating database and recording, submitting, and accessing information.~~

~~(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] information as required in this chapter shall be assumed by the submitting pharmacy.~~

~~(3) All costs associated with accessing the information contained in the controlled substance database shall be assumed by the accessing pharmacy, pharmaceutical facility, or prescribing practitioner.~~

~~†~~ Section ~~{4}~~3. **Repealer.**

This bill repeals:

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

Section ~~{5}~~4. **Appropriation.**

Under the terms and conditions of Title 63J, Chapter 1, Budgetary Procedures Act, for the fiscal year beginning July 1, 2015, and ending June 30, 2016, the following sums of money are appropriated from resources not otherwise appropriated, or reduced from amounts previously appropriated, out of the funds or accounts indicated. These sums of money are in

## HB0395S01 compared with HB0395

addition to any amounts previously appropriated for fiscal year 2016.

To Department of Commerce - Division of Occupational and Professional Licensing

From General Fund \$46,000

Schedule of Programs:

Controlled Substance Database \$46,000

Section ~~6~~5. **Effective date.**

This bill takes effect on July 1, 2015.

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**Legislative Review Note**

~~as of 2-23-15 4:33 PM~~

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~~Office of Legislative Research and General Counsel~~