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PHARMACY PRACTICE AMENDMENTS

2022 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Evan J. Vickers

House Sponsor: _____

LONG TITLE

General Description:

This bill amends the Pharmacy Practice Act and the Insurance Code.

Highlighted Provisions:

This bill:

- prohibits an insurer or pharmacy benefit manager from asking a pharmacy or insured to disclose how a drug was paid for except to ensure compliance with state or federal law;
- amends provisions related to the accepting back and redistributing of an unused drug;
- amends the definition of "interchangeable biological drug product";
- requires the Division of Occupational and Professional Licensing to designate by rule therapeutically appropriate substitutes for insulin;
- amends refill provisions for insulin;
- amends provisions related to the dispensing of diabetes supplies;
- amends provisions related to the dispensing of prescription drugs by a hospital pharmacy;
- authorizes the dispensing of a drug to treat a sexually transmitted disease by a physician treating a patient at a state or local health department clinic; and
- makes technical changes.

Money Appropriated in this Bill:

S.B. 236

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-502, as last amended by Laws of Utah 2020, Chapter 25

58-17b-503, as last amended by Laws of Utah 2016, Chapter 405

58-17b-605.5, as last amended by Laws of Utah 2015, Chapter 266

58-17b-608.2, as enacted by Laws of Utah 2020, Chapter 310

58-17b-610.6, as enacted by Laws of Utah 2017, Chapter 44

58-17b-610.8, as enacted by Laws of Utah 2020, Chapter 372

58-17b-803, as last amended by Laws of Utah 2015, Chapter 206

ENACTS:

31A-22-657, Utah Code Annotated 1953

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

Section 1. Section **31A-22-657** is enacted to read:

31A-22-657. Method of payment for drugs may not be requested.

Except to ensure compliance with state or federal law, neither an insurer nor a pharmacy benefit manager as defined in Section 31A-46-102 may ask a pharmacy or an enrollee of the insurer to disclose how a drug purchased from the pharmacy by the enrollee was paid for, including whether payment was received from one or more persons other than the enrollee.

Section 2. Section **58-17b-502** is amended to read:

58-17b-502. Unprofessional conduct.

(1) "Unprofessional conduct" includes:

(a) willfully deceiving or attempting to deceive the division, the board, or their agents as to any relevant matter regarding compliance under this chapter;

(b) except as provided in Subsection (2):

(i) paying or offering rebates to practitioners or any other health care providers, or receiving or soliciting rebates from practitioners or any other health care provider; or

(ii) paying, offering, receiving, or soliciting compensation in the form of a commission, bonus, rebate, kickback, or split fee arrangement with practitioners or any other health care provider, for the purpose of obtaining referrals;

(c) misbranding or adulteration of any drug or device or the sale, distribution, or dispensing of any outdated, misbranded, or adulterated drug or device;

(d) engaging in the sale or purchase of drugs or devices that are samples or packages bearing the inscription "sample" or "not for resale" or similar words or phrases;

(e) except as provided in Section 58-17b-503 or Part 9, Charitable Prescription Drug Recycling Act, accepting back and redistributing any unused drug, or a part of it, after it has left the premises of [~~any~~] a pharmacy, unless the drug is in a unit pack, as defined in Section 58-17b-503, or the manufacturer's sealed container, as defined in rule;

(f) an act in violation of this chapter committed by a person for any form of compensation if the act is incidental to the person's professional activities, including the activities of a pharmacist, pharmacy intern, or pharmacy technician;

(g) violating:

(i) the federal Controlled Substances Act, Title II, P.L. 91-513;

(ii) Title 58, Chapter 37, Utah Controlled Substances Act; or

(iii) rules or regulations adopted under either act;

(h) requiring or permitting pharmacy interns or technicians to engage in activities outside the scope of practice for their respective license classifications, as defined in this chapter and division rules made in collaboration with the board, or beyond their scope of training and ability;

(i) administering:

(i) without appropriate training, as defined by rule;

(ii) without a physician's order, when one is required by law; and

(iii) in conflict with a practitioner's written guidelines or written protocol for administering;

(j) disclosing confidential patient information in violation of the provisions of the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936, as amended, or other applicable law;

(k) engaging in the practice of pharmacy without a licensed pharmacist designated as

the pharmacist-in-charge;

(l) failing to report to the division any adverse action taken by another licensing jurisdiction, government agency, law enforcement agency, or court for conduct that in substance would be considered unprofessional conduct under this section;

(m) as a pharmacist or pharmacy intern, compounding a prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner;

(n) failing to act in accordance with Title 26, Chapter 64, Family Planning Access Act, when dispensing a self-administered hormonal contraceptive under a standing order;

(o) violating the requirements of Title 26, Chapter 61a, Utah Medical Cannabis Act; or

(p) falsely making an entry in, or altering, a medical record with the intent to conceal:

(i) a wrongful or negligent act or omission of an individual licensed under this chapter or an individual under the direction or control of an individual licensed under this chapter; or

(ii) conduct described in Subsections (1)(a) through (o) or Subsection 58-1-501(1).

(2) Subsection (1)(b) does not apply to:

(a) giving or receiving a price discount based on purchase volume;

(b) passing along a pharmaceutical manufacturer's rebate; or

(c) providing compensation for services to a veterinarian.

(3) "Unprofessional conduct" does not include, in accordance with Title 26, Chapter 61a, Utah Medical Cannabis Act:

(a) when registered as a pharmacy medical provider, as that term is defined in Section 26-61a-102, providing pharmacy medical provider services in a medical cannabis pharmacy; or

(b) when acting as a state central patient portal medical provider, as that term is defined in Section 26-61a-102, providing state central patient portal medical provider services.

(4) Notwithstanding Subsection (3), the division, in consultation with the board and in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, shall define unprofessional conduct for a pharmacist described in Subsections (3)(a) and (b).

Section 3. Section **58-17b-503** is amended to read:

58-17b-503. Exception to unprofessional conduct.

(1) For purposes of this section:

(a) "Licensed intermediate care facility for people with an intellectual disability" means

an intermediate care facility for people with an intellectual disability that is licensed as a nursing care facility or a small health care facility under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.

(b) "Nursing care facility" means the same as that term is defined in Section 26-21-2.

(c) "Unit pack" means a tamper-resistant nonreusable single-dose single-drug package with identification that indicates the lot number and expiration date for the drug.

(2) A pharmacist may:

(a) accept and redistribute an unused drug under Part 9, Charitable Prescription Drug Recycling Act; or

(b) accept back and redistribute any unused drug, or a part of it, after it has left the premises of the pharmacy if:

(i) the drug was prescribed to a patient in a nursing care facility, licensed intermediate care facility for people with an intellectual disability, or state prison facility, county jail, or state hospital;

(ii) the drug was stored under the supervision of a licensed health care provider according to manufacturer recommendations;

(iii) the drug is in a unit pack or in the manufacturer's sealed container;

(iv) the drug was returned to the original dispensing pharmacy;

(v) the drug was initially dispensed by a licensed pharmacist or licensed pharmacy intern; and

(vi) accepting back and redistributing of the drug complies with federal Food and Drug Administration and Drug Enforcement Administration regulations.

(3) A pharmacist may accept back and redistribute any unused drug, or a part of it, after it has left the premises of the pharmacy if:

(a) the pharmacy has attempted to deliver the drug to a patient or a patient's agent via the United States Postal Service, a licensed common carrier, or supportive personnel;

(b) the drug is returned to the pharmacy by the same person or carrier that attempted to deliver the drug; and

(c) in accordance with United States Food and Drug Administration regulations and rules established by the division, a pharmacist at the pharmacy determines that the drug has not been adversely affected by the drug's attempted delivery and return.

Section 4. Section **58-17b-605.5** is amended to read:

58-17b-605.5. Interchangeable biological products.

(1) For the purposes of this section:

(a) "Biological product" means the same as that term is defined in 42 U.S.C. Sec. 262.

(b) "Interchangeable biological product" means:

(i) a biological product that the [~~federal~~] United States Food and Drug Administration:

[~~(i) has:~~]

[~~(A) licensed; and~~]

[~~(B)~~] (A) has licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. Sec. 262(k)(4); or

[~~(ii)~~] (B) has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the [~~federal~~] United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations[~~.~~]; and

(ii) notwithstanding Subsection (1)(b)(i), a therapeutically appropriate substitute for insulin designated by division rule made under Subsection (9).

(2) A pharmacist or pharmacy intern dispensing a prescription order for a specific biological product by brand or proprietary name may substitute an interchangeable biological product for the prescribed biological product only if:

(a) the purchaser specifically requests or consents to the substitute of an interchangeable biological product;

(b) the interchangeable biological product is permitted to move in interstate commerce;

(c) the pharmacist or pharmacy intern counsels the patient on the use and the expected response to the prescribed biological product, whether a substitute or not, and the substitution is not otherwise prohibited by this chapter;

(d) the prescribing practitioner has not prohibited the substitution of an interchangeable biological product for the prescribed biological product, as provided in Subsection (6); and

(e) the substitution is not otherwise prohibited by law.

(3) Each out-of-state mail service pharmacy dispensing an interchangeable biological product as a substitute for another biological product into this state shall:

(a) notify the patient of the substitution either by telephone or in writing; and

(b) comply with the requirements of this chapter with respect to an interchangeable

biological product substituted for another biological product, including labeling and record keeping.

(4) Pharmacists or pharmacy interns may not substitute without the prescriber's authorization biological product prescriptions unless the product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product.

(5) A pharmacist or pharmacy intern who dispenses a prescription with an interchangeable biological product under this section assumes no greater liability than would be incurred had the pharmacist or pharmacy intern dispensed the prescription with the biological product prescribed.

(6) (a) If, in the opinion of the prescribing practitioner, it is in the best interest of the patient that an interchangeable biological product not be substituted for a prescribed biological product, the practitioner may prohibit a substitution either by writing "dispense as written" or by signing in the appropriate space where two lines have been preprinted on a prescription order and captioned "dispense as written" or "substitution permitted."

(b) (i) If the prescription is communicated orally by the prescribing practitioner to the pharmacist or pharmacy intern, the practitioner shall direct the prohibition or substitution.

(ii) The pharmacist or pharmacy intern shall make a written note of the practioner's direction by writing the name of the practitioner and the words "orally by" and the initials of the pharmacist or pharmacy intern written after it.

(7) A pharmacist or pharmacy intern who substitutes an interchangeable biological product for a prescribed biological product shall communicate the substitution to the purchaser. The interchangeable biological product container shall be labeled with the name of the interchangeable biological product dispensed, and the pharmacist, pharmacy intern, or pharmacy technician shall indicate on the file copy of the prescription both the name of the prescribed biological product and the name of the interchangeable biological product dispensed in its place.

(8) Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry into an interoperable electronic medical

records system, through an electronic prescribing technology, a pharmacy benefit management system, or a pharmacy record that is electronically accessible by the prescriber. Entry into an electronic records system as described in this Subsection (8) is presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where:

(a) there is no FDA-approved interchangeable biological product for the product prescribed;

(b) a refill prescription is not changed from the product dispensed on the prior filling of the prescription; or

(c) the product is paid for using cash or cash equivalent.

(9) (a) The division shall by rule made in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, and in consultation with the board, the Physicians Licensing Board, created in Section 58-67-201, and the Osteopathic Physician and Surgeon's Licensing Board, created in Section 58-68-201, designate therapeutically appropriate substitutes for insulin:

(i) by insulin type; and

(ii) with restrictions according to patient characteristics.

(b) Subsections (4) and (8)(a) do not apply to the substitution of an interchangeable biological product for insulin.

Section 5. Section **58-17b-608.2** is amended to read:

58-17b-608.2. Insulin prescriptions and diabetes supplies.

(1) As used in this section, "exhausted prescription" means a prescription for an insulin that the patient is currently using that:

(a) expired no earlier than six months before the patient requests the pharmacist for a refill; or

(b) is not expired and has no refills remaining.

(2) If a valid prescription for insulin includes an authorization for one or more refills, a pharmacist may combine refills to dispense a supply for [~~90~~] 100 days but may not exceed the total supply authorized by the refills.

(3) Notwithstanding Section 58-17b-608 and Subsection (2), a pharmacist may, on an

emergency basis, dispense a refill for an exhausted prescription based on the prescribing practitioner's instructions for the exhausted prescription in an amount up to a supply for 60 days.

(4) A pharmacist may dispense insulin for an exhausted prescription described in Subsection (3) no more than one time per exhausted prescription.

(5) Before a pharmacist may dispense insulin under Subsection (3), the pharmacist shall:

(a) attempt to contact the prescribing practitioner to inform the prescribing practitioner that the patient's prescription has expired; and

(b) notify the patient of the outcome of the attempt described in Subsection (5)(a).

(6) Within 30 days after the day on which a pharmacist dispenses insulin under Subsection (3), the pharmacist shall inform the prescribing practitioner of:

(a) the amount of insulin dispensed; and

(b) the type of insulin dispensed.

[~~(7) The division, in consultation with the Board of Pharmacy and the Physicians Licensing Board, shall make rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to ensure the safe dispensing of insulin under Subsection (3).~~]

[~~(8) Notwithstanding Section 58-17b-605.5, a pharmacist, when filling a prescription for insulin, may dispense an interchangeable biological product, as defined in Subsection 58-17b-605.5(1), except that the pharmacist may not dispense an interchangeable biological product if a prescribing practitioner prohibits the substitution through a method described in Subsection 58-17b-605.5(6).~~]

[~~(9)~~] (7) A pharmacist may dispense [~~the~~]:

(a) a therapeutic equivalent when filling a prescription for:

[~~(a)~~] (i) a glucometer;

[~~(b)~~] (ii) diabetes test strips;

[~~(c)~~] (iii) lancets; [~~or~~]

[~~(d)~~] (iv) syringes[~~.~~];

(v) needles; or

(vi) other supplies for treating diabetes designated by rule made by the division in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act; and

(b) a therapeutically appropriate substitute for insulin in accordance with Section 58-17b-605.5.

(8) The division, in consultation with the Board of Pharmacy and the Physicians Licensing Board, shall make rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to:

(a) ensure the safe dispensing of insulin under Subsection (3); and

(b) designate other supplies for which a therapeutic equivalent may be dispensed under Subsection (7)(a)(vi).

Section 6. Section **58-17b-610.6** is amended to read:

58-17b-610.6. Hospital pharmacy dispensing prescription drugs.

(1) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, in consultation with hospital pharmacies, to establish guidelines under which a hospital pharmacy may dispense a limited supply of a prescription drug to an individual who is no longer a patient in the hospital setting if:

(a) the individual is discharged from the hospital on the same day that the hospital pharmacy dispenses the prescription drug to the individual;

[~~(b) the prescription drug relates to the reason for which the individual was a patient at the hospital before being discharged;~~]

[~~(c)~~] (b) the class A pharmacy with which the patient has an established pharmacy-patient relationship:

(i) is not open at the time of the patient's discharge; or

(ii) unable to dispense the medication for any reason;

[~~(d)~~] (c) the hospital pharmacy dispenses a quantity of the prescription drug that is [~~the lesser of:(i)~~] not more than a 72-hour supply; [~~or~~] and

[~~(ii) an adequate amount to treat the discharged patient through the first day on which the pharmacy described in Subsection (1)(c) is open after the patient's discharge from the hospital; and~~]

[~~(e)~~] (d) dispensing the prescription drug complies with protocols established by the hospital pharmacy.

(2) A hospital pharmacy may dispense a prescription drug in accordance with rules made under Subsection (1).

Section 7. Section **58-17b-610.8** is amended to read:

58-17b-610.8. Prescription devices.

(1) The following documents from a prescribing practitioner shall be considered a prescription for purposes of dispensing of and payment for a device described in Subsection (3), if the device is prescribed or indicated by the document and the document is on file with a pharmacy:

(a) a written prescription; or

(b) a written record of a patient's:

(i) current diagnosis; or

(ii) treatment protocol.

(2) A pharmacist or pharmacy intern at a pharmacy at which a document that is considered a prescription under Subsection (1) is on file may dispense [~~a~~] under prescription a device described in Subsection (3) to the patient in accordance with:

(a) the document that is considered a prescription under Subsection (1); and

(b) rules made by the division under Subsection (4).

(3) This section applies to:

(a) nebulizers;

(b) spacers for use with nebulizers or inhalers; and

(c) diabetic [~~testing~~] supplies.

(4) The division shall make rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, and in consultation with the board, the Physicians Licensing Board created in Section 58-67-201, and the Osteopathic Physician and Surgeon's Licensing Board created in Section 58-68-201, to implement this section.

Section 8. Section **58-17b-803** is amended to read:

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 Section 58-17b-802;

(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[~~.~~]; and

(d) a drug to treat a sexually transmitted disease if:

(i) the dispensing medical practitioner is currently licensed as:

(A) a physician and surgeon under Chapter 67, Utah Medical Practice Act;

(B) an osteopathic physician and surgeon under Chapter 68, Utah Osteopathic Medical Practice Act;

(C) a physician assistant under Chapter 70a, Utah Physician Assistant Act; or

(D) a nurse practitioner under Chapter 31b, Nurse Practice Act;

(ii) the drug is a prepackaged drug as defined in Section 58-17b-802; and

(iii) the dispensing medical practitioner treats and dispenses the drug to a patient at a clinic operated by the Department of Health or a local health department as defined in Section 26A-1-102.

(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 68, Utah Osteopathic Medical Practice Act.