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H.B. 195
4th Sub. (Green)

Representative Edward H. Redd proposes the following substitute bill:

MEDICAL CANNABIS POLICY

2018 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Brad M. Daw

Senate Sponsor: Evan J. Vickers

LONG TITLE

General Description:

This bill creates a "right to try" cannabis-based treatment for qualified patients.

Highlighted Provisions:

This bill:

- defines terms;
- creates the Cannabis-Based Treatment Review Board within the Department of Health;
- provides that an individual who possesses or uses cannabis in a medicinal dosage form in compliance with Title 58, Chapter 85, Utah Right to Try Act, is not subject to the penalties described in Title 58, Chapter 37, Utah Controlled Substances Act; and
- describes the procedure for a qualified patient to receive a recommendation for a cannabis-based treatment from the qualified patient's physician.

Money Appropriated in this Bill:

None

Other Special Clauses:

This bill provides a coordination clause.

Utah Code Sections Affected:

AMENDS:

58-37-3.6, as enacted by Laws of Utah 2017, Chapter 398

58-85-102, as enacted by Laws of Utah 2015, Chapter 110

58-85-104, as last amended by Laws of Utah 2016, Chapter 348

58-85-105, as enacted by Laws of Utah 2015, Chapter 110

ENACTS:

26-1-41, Utah Code Annotated 1953

58-85-103.5, Utah Code Annotated 1953

Utah Code Sections Affected by Coordination Clause:

26-61-202, as enacted by Laws of Utah 2017, Chapter 398

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

Section 1. Section **26-1-41** is enacted to read:

26-1-41. Cannabis-Based Treatment Review Board.

(1) The department shall establish, in consultation with a professional association based in the state that represents physicians, a Cannabis-Based Treatment Review Board.

(2) The Cannabis-Based Treatment Review Board shall:

(a) use written summaries from the Cannabinoid Product Review Board regarding disease states, conditions, and symptoms that may respond favorably to cannabis-based medicines including cannabinoid products and expanded cannabinoid products as defined in Section 58-37-3.6;

(b) review medical records of a patient submitted by a physician pursuant to Title 58, Chapter 85, Utah Right to Try Act; and

(c) make a determination, based on Subsections (2)(a) and (2)(b), whether a patient qualifies for a cannabis-based treatment and relay that determination to the patient's physician.

(3) The department shall establish by rule, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, an appeals process for when the Cannabis-Based Treatment Review Board determines that a patient does not qualify for a cannabis-based treatment and the patient's physician disagrees with the determination.

Section 2. Section **58-37-3.6** is amended to read:

58-37-3.6. Exemption for possession or distribution of a cannabinoid product or

expanded cannabinoid product pursuant to an approved study.

(1) As used in this section:

(a) "Cannabinoid product" means a product intended for human ingestion that:

(i) contains an extract or concentrate that is obtained from cannabis;

(ii) is prepared in a medicinal dosage form; and

(iii) contains at least 10 units of cannabidiol for every one unit of tetrahydrocannabinol.

(b) "Cannabis" means any part of the plant cannabis sativa, whether growing or not.

(c) "Drug paraphernalia" means the same as that term is defined in Section 58-37a-3.

(d) "Expanded cannabinoid product" means a product intended for human ingestion that:

(i) contains an extract or concentrate that is obtained from cannabis;

(ii) is prepared in a medicinal dosage form; and

(iii) contains less than 10 units of cannabidiol for every one unit of tetrahydrocannabinol.

(e) "Medicinal dosage form" means:

(i) a tablet;

(ii) a capsule;

(iii) a concentrated oil;

(iv) a liquid suspension;

(v) a transdermal preparation; or

(vi) a sublingual preparation.

(f) "Tetrahydrocannabinol" means a substance derived from cannabis that meets the description in Subsection 58-37-4(2)(a)(iii)(AA).

(2) Notwithstanding any other provision of this chapter, an individual who possesses or distributes a cannabinoid product or an expanded cannabinoid product is not subject to the penalties described in this title for the possession or distribution of marijuana or tetrahydrocannabinol to the extent that the individual's possession or distribution of the cannabinoid product or expanded cannabinoid product complies with Title 26, Chapter 61, Cannabinoid Research Act.

(3) Notwithstanding any other provision of this chapter, an individual who possesses or uses cannabis in a medicinal dosage form is not subject to the penalties described in this title

for the possession or use of marijuana or tetrahydrocannabinol to the extent that the individual's possession or use of the cannabis complies with Chapter 85, Utah Right to Try Act.

Section 3. Section **58-85-102** is amended to read:

58-85-102. Definitions.

As used in this chapter:

(1) "Cannabis" means cannabis that has been grown by a state-approved grower and processed into a medicinal dosage form.

(2) "Cannabis-based treatment" means a course of treatment involving cannabis.

[~~(1)~~] (3) "Eligible patient" means an individual who has been diagnosed with a terminal illness by a physician.

(4) "Health care facility" means the same as that term is defined in Section 26-55-102.

[~~(2)~~] (5) "Insurer" means the same as that term is defined in Section 31A-1-301.

[~~(3)~~] (6) "Investigational device" means a device that:

(a) meets the definition of "investigational device" in 21 C.F.R. Sec. 812.3; and

(b) has successfully completed the United States Food and Drug Administration Phase 1 testing for an investigational device described in 21 C.F.R. Part 812.

[~~(4)~~] (7) "Investigational drug" means a drug that:

(a) meets the definition of "investigational new drug" in 21 C.F.R. Sec. 312.3; and

(b) has successfully completed the United States Food and Drug Administration Phase 1 testing for an investigational new drug described in 21 C.F.R. Part 312.

(8) "Medicinal dosage form" means the same as that term is defined in Section 58-37-3.6.

[~~(5)~~] (9) "Physician" means an individual who is licensed under:

(a) Title 58, Chapter 67, Utah Medical Practice Act; or

(b) Title 58, Chapter 68, Utah Osteopathic Medical Practice Act.

(10) "Qualified patient" means a person:

(a) who has an incurable and irreversible disease that has been medically confirmed and that will, within reasonable medical judgment, produce death in six months; or

(b) (i) whose documented medical records confirm that FDA-approved treatments, which are readily accepted as effective treatment for the person's condition by medical literature, have failed to adequately manage the person's symptoms, control the person's disease

state, or have caused the person side-effects that are dangerous or intolerable;

(ii) for whom it is indicated in written summaries by the Cannabinoid Product Board based on by published peer-review medical literature that cannabis-based treatment may be effective in managing the person's symptoms, disease states, or side-effects from treatments for other disease states;

(iii) whose physician submits the person's medical records documenting the treatment failures, as described in Subsection (10)(b)(i), to the Cannabis-Based Treatment Review Board created in Section 26-1-41 for review; and

(iv) whose physician:

(A) receives a determination from the Cannabis-Based Treatment Review Board that the patient qualifies for a cannabis-based treatment; or

(B) has been notified by the Cannabis-Based Treatment Review Board that the patient did not qualify for cannabis-based treatment, and the physician has submitted a second request for consideration through the appeals process described in Subsection 26-1-41(3), and the physician has received from the department a determination that the patient does qualify for a cannabis-based treatment.

(11) "State-approved grower and processor" means a person who grows cannabis pursuant to state law and processes the cannabis into a medicinal dosage form.

[~~(6)~~] (12) "Terminal illness" means a condition of a patient that:

(a) as determined by a physician:

(i) is likely to pose a greater risk to the patient than the risk posed to the patient by treatment with an investigational drug or investigational device; and

(ii) will inevitably lead to the patient's death; and

(b) presents the patient, after the patient has explored conventional therapy options, with no treatment option that is satisfactory or comparable to treatment with an investigational drug or device.

Section 4. Section **58-85-103.5** is enacted to read:

58-85-103.5. Right to request a recommendation for a cannabis-based treatment.

(1) A qualified patient's physician may give the qualified patient a recommendation to try a cannabis-based treatment if:

(a) the physician believes, in the physician's professional judgment, that the

cannabis-based treatment may provide some benefit to the qualified patient; and

(b) the physician recommends a cannabis-based treatment to no more than 40 new qualified patients a year and no more than 100 qualified patients at any given time.

(2) (a) A recommendation may be for up to a one-month supply of cannabis.

(b) Once a qualified patient has exhausted a one-month supply of cannabis, the qualified patient's physician may renew the original recommendation for an additional one-month supply of cannabis, so long as:

(i) the qualified patient's physician continues to believe, in the physician's professional judgment, that the cannabis-based treatment may provide some benefit to the qualified patient; and

(ii) the physician documents in the medical record at a minimum of every 6 months, the apparent clinical outcomes from the recommended cannabis-based medicine treatment.

(3) A qualified patient may possess and use cannabis if the qualified patient:

(a) has a recommendation from the qualified patient's physician as described in this section; and

(b) procures cannabis from a state-approved source.

(4) The physician shall provide a qualified patient with a recommendation to use a cannabis-based treatment with an informed consent document that, based on the physician's knowledge of the cannabis-based treatment:

(a) describes the possible positive and negative outcomes the qualified patient could experience;

(b) states that an insurer is not required to cover the cost of providing cannabis to the qualified patient; and

(c) states that, subject to Section 58-85-105, an insurer may deny coverage for the qualified patient.

Section 5. Section **58-85-104** is amended to read:

58-85-104. Standard of care -- Medical practitioners not liable -- No private right of action.

(1) (a) It is not a breach of the applicable standard of care for a physician, other licensed health care provider, or hospital to treat an eligible patient with an investigational drug or investigational device under this chapter.

(b) It is not a breach of the applicable standard of care for a physician to recommend a cannabis-based treatment to a qualified patient under this chapter, or a health care facility to aid or assist in any way a qualified patient's use of cannabis.

(2) A physician, other licensed health care provider, or hospital that treats an eligible patient with an investigational drug or investigational device under this chapter, or a physician who recommends a cannabis-based treatment to a qualified patient or a health care facility that facilitates a qualified patient's recommended use of a cannabis-based treatment under this chapter, may not, for any harm done to the eligible patient by the investigational drug or device, or for any harm done to the qualified patient by the cannabis-based treatment, be subject to:

(a) civil liability;

(b) criminal liability; or

(c) licensure sanctions under:

(i) for a physician:

(A) Title 58, Chapter 67, Utah Medical Practice Act; or

(B) Title 58, Chapter 68, Utah Osteopathic Medical Practice Act;

(ii) for the other licensed health care provider, the act governing the other licensed health care provider's license; or

(iii) for the hospital or health care facility, Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.

(3) A member of the Cannabis-Based Treatment Review Board, Cannabinoid Product Review Board, or employee of the Department of Health may not, for any harm done to a qualified patient by a cannabis-based treatment or any harm incurred by a patient who is denied a cannabis-based treatment, be subject to:

(a) civil liability;

(b) criminal liability; or

(c) licensure sanctions under:

(i) for a physician, Title 58, Chapter 67, Utah Medical Practice Act or Title 58, Chapter 68, Utah Osteopathic Medical Practice Act; or

(ii) for a licensed health care provider who is not a physician, the act governing the licensed health care provider's license.

[~~(3)~~] (4) This chapter does not:

(a) require a manufacturer of an investigational drug or investigational device to agree to make an investigational drug or investigational device available to an eligible patient or an eligible patient's physician;

(b) require a physician to agree to:

(i) administer an investigational drug to an eligible patient under this chapter; [~~or~~]

(ii) treat an eligible patient with an investigational device under this chapter; or

(iii) recommend a cannabis-based treatment to a qualified patient; or

(c) create a private right of action for an eligible patient:

(i) against a physician or hospital, for the physician's or hospital's refusal to:

(A) administer an investigational drug to an eligible patient under this chapter; [~~or~~]

(B) treat an eligible patient with an investigational device under this chapter; or

(C) recommend a cannabis-based treatment to the qualified patient; or

(ii) against a manufacturer, for the manufacturer's refusal to provide an eligible patient with an investigational drug or an investigational device under this chapter.

Section 6. Section **58-85-105** is amended to read:

58-85-105. Insurance coverage.

(1) This chapter does not:

(a) require an insurer to cover the cost of:

(i) administering an investigational drug under this chapter; [~~or~~]

(ii) treating a patient with an investigational device under this chapter; or

(iii) a cannabis-based treatment; or

(b) prohibit an insurer from covering the cost of:

(i) administering an investigational drug under this chapter; [~~or~~]

(ii) treating a patient with an investigational device under this chapter[~~.~~]; or

(iii) a cannabis-based treatment.

(2) Except as described in Subsection (3), an insurer may deny coverage to an eligible patient who is treated with an investigational drug or investigational device, for harm to the eligible patient caused by the investigational drug or investigational device.

(3) An insurer may not deny coverage to an eligible patient under Subsection (2) for:

(a) the eligible patient's preexisting condition;

(b) benefits that commenced before the day on which the eligible patient is treated with the investigational drug or investigational device; or

(c) palliative or hospice care for an eligible patient that has been treated with an investigational drug or device, but is no longer receiving curative treatment with the investigational drug or device.

Section 7. **Coordinating H.B. 195 with H.B. 25 -- Technical amendments.**

If this H.B. 195 and H.B. 25, Cannabinoid Product Board Membership Amendments, both pass and become law, it is the intent of the Legislature that the Office of Legislative Research and General Counsel shall prepare the Utah Code database for publication by modifying Subsections 26-61-202(3) and (4) to read:

"(3) Based on the board's evaluation under Subsection (2), the board shall:

(a) develop guidelines for a physician recommending treatment with a cannabinoid product or an expanded cannabinoid product that includes a list of medical conditions, if any, that the board determines are appropriate for primary treatment with a cannabinoid product or an expanded cannabinoid product; and

(b) maintain an Internet accessible list of medical conditions, symptoms, and disease states where, based on results of reviewed medical research described in Subsections (1) and (2), cannabis-based treatment may be considered for a qualified patient as described in Title 58, Chapter 85, Utah Right to Try Act.

(4) The board shall submit treatment guidelines and updates described in Subsection (3) to:

(a) the director of the Division of Occupational and Professional Licensing;

(b) the Cannabis-Based Treatment Review Board as defined in Section 26-1-41; and

(c) the Health and Human Services Interim Committee."