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H.B. 195
2nd Sub. (Gray)

Representative Brad M. Daw 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 terminally ill patients.

Highlighted Provisions:

This bill:

- defines terms;
- 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 an eligible patient to receive a recommendation for a cannabis-based treatment from the eligible patient's physician or the eligible patient's advanced practice registered nurse.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

2nd Sub. H.B. 195

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:
58-85-103.5, Utah Code Annotated 1953

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

Section 1. 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 Title 58, Chapter 85, Utah Right to Try Act.

Section 2. Section **58-85-102** is amended to read:

58-85-102. Definitions.

As used in this chapter:

(1) "Advanced practice registered nurse" or "APRN" means a person who is licensed as an advanced practice registered nurse under Section 58-31b-301.

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

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

[~~(1)~~] (4) "Eligible patient" means an individual who has been diagnosed with a terminal illness by a physician.

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

[~~(2)~~] (6) "Insurer" means the same as that term is defined in Section 31A-1-301.

[~~(3)~~] (7) "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)~~] (8) "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.

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

[~~(5)~~] (10) "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.

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

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

(1) An eligible patient's physician or APRN may give the eligible patient a recommendation to try a cannabis-based treatment if:

(a) the physician or APRN believes, in the physician's or APRN's professional judgment, that the cannabis-based treatment may provide some benefit to the eligible patient; and

(b) the physician or APRN recommends a cannabis-based treatment to no more than 15 eligible patients at any given time.

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

(b) Once an eligible patient has exhausted a one-month supply of cannabis, the eligible patient's physician or APRN may renew the original recommendation for an additional one-month supply of cannabis, so long as the eligible patient's physician or APRN continues to believe, in the physician's or APRN's professional judgment, that the cannabis-based treatment may provide some benefit to the eligible patient.

(3) An eligible patient may possess and use cannabis if the eligible patient:

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

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

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

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

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

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

Section 4. 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 or advanced practice registered nurse to recommend a cannabis-based treatment to an eligible patient under this chapter, or a health care facility to aid or assist in any way an eligible 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 or advanced practice registered nurse who recommends a cannabis-based treatment to an eligible patient or a health care facility that facilitates an eligible 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 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) 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 or advanced practice registered nurse 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 an eligible patient; or

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

(i) against a physician, advanced practice registered nurse, 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 eligible 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 5. 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.