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H.B. 94
5th Sub. (Salmon)

Senator Evan J. Vickers proposes the following substitute bill:

INVESTIGATIONAL DRUG AND DEVICE ACCESS FOR TERMINALLY ILL PATIENTS

2015 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Gage Froerer

Senate Sponsor: Evan J. Vickers

LONG TITLE

General Description:

This bill amends provisions related to investigational drugs and devices.

Highlighted Provisions:

This bill:

- provides that a terminally ill patient may obtain an investigational drug or device from the drug's or device's manufacturer under certain circumstances;
- exempts certain conduct from the definition of unlawful and unprofessional conduct for a physician who administers an investigational drug or uses an investigational device to treat a terminally ill patient;
- allows an insurance company to deny, under certain circumstances, coverage to an individual who is treated with an investigational drug or device; and
- provides that certain health care providers are not subject to civil or criminal liability or licensure sanctions for treating a patient with an investigational drug or device.

Money Appropriated in this Bill:

None

Other Special Clauses:

5th Sub. H.B. 94

None

Utah Code Sections Affected:

AMENDS:

58-67-501, as last amended by Laws of Utah 2001, Chapter 116

58-67-502, as last amended by Laws of Utah 2014, Chapter 72

58-68-501, as last amended by Laws of Utah 2001, Chapter 116

58-68-502, as last amended by Laws of Utah 2014, Chapter 72

ENACTS:

58-85-101, Utah Code Annotated 1953

58-85-102, Utah Code Annotated 1953

58-85-103, Utah Code Annotated 1953

58-85-104, Utah Code Annotated 1953

58-85-105, Utah Code Annotated 1953

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

Section 1. Section **58-67-501** is amended to read:

58-67-501. Unlawful conduct.

(1) "Unlawful conduct" includes, in addition to the definition in Section 58-1-501:

(a) buying, selling, or fraudulently obtaining, any medical diploma, license, certificate, or registration;

(b) aiding or abetting the buying, selling, or fraudulently obtaining of any medical diploma, license, certificate, or registration;

(c) substantially interfering with a licensee's lawful and competent practice of medicine in accordance with this chapter by:

(i) any person or entity that manages, owns, operates, or conducts a business having a direct or indirect financial interest in the licensee's professional practice; or

(ii) anyone other than another physician licensed under this title, who is engaged in direct clinical care or consultation with the licensee in accordance with the standards and ethics of the profession of medicine; or

(d) entering into a contract that limits a licensee's ability to advise the licensee's patients fully about treatment options or other issues that affect the health care of the licensee's

patients.

(2) "Unlawful conduct" does not include:

(a) establishing, administering, or enforcing the provisions of a policy of accident and health insurance by an insurer doing business in this state in accordance with Title 31A, Insurance Code;

(b) adopting, implementing, or enforcing utilization management standards related to payment for a licensee's services, provided that:

(i) utilization management standards adopted, implemented, and enforced by the payer have been approved by a physician or by a committee that contains one or more physicians; and

(ii) the utilization management standards does not preclude a licensee from exercising independent professional judgment on behalf of the licensee's patients in a manner that is independent of payment considerations;

(c) developing and implementing clinical practice standards that are intended to reduce morbidity and mortality or developing and implementing other medical or surgical practice standards related to the standardization of effective health care practices, provided that:

(i) the practice standards and recommendations have been approved by a physician or by a committee that contains one or more physicians; and

(ii) the practice standards do not preclude a licensee from exercising independent professional judgment on behalf of the licensee's patients in a manner that is independent of payment considerations;

(d) requesting or recommending that a patient obtain a second opinion from a licensee;

(e) conducting peer review, quality evaluation, quality improvement, risk management, or similar activities designed to identify and address practice deficiencies with health care providers, health care facilities, or the delivery of health care;

(f) providing employment supervision or adopting employment requirements that do not interfere with the licensee's ability to exercise independent professional judgment on behalf of the licensee's patients, provided that employment requirements that may not be considered to interfere with an employed licensee's exercise of independent professional judgment include:

(i) an employment requirement that restricts the licensee's access to patients with whom the licensee's employer does not have a contractual relationship, either directly or through contracts with one or more third-party payers; or

(ii) providing compensation incentives that are not related to the treatment of any particular patient;

(g) providing benefit coverage information, giving advice, or expressing opinions to a patient or to a family member of a patient to assist the patient or family member in making a decision about health care that has been recommended by a licensee; [~~or~~]

(h) in compliance with Section 58-85-103:

(i) obtaining an investigational drug or investigational device;

(ii) administering the investigational drug to an eligible patient; or

(iii) treating an eligible patient with the investigational drug or investigational device; or

[~~(h)~~] (i) any otherwise lawful conduct that does not substantially interfere with the licensee's ability to exercise independent professional judgment on behalf of the licensee's patients and that does not constitute the practice of medicine as defined in this chapter.

Section 2. Section **58-67-502** is amended to read:

58-67-502. Unprofessional conduct.

(1) "Unprofessional conduct" includes, in addition to the definition in Section 58-1-501:

[~~(1)~~] (a) using or employing the services of any individual to assist a licensee in any manner not in accordance with the generally recognized practices, standards, or ethics of the profession, state law, or division rule;

[~~(2)~~] (b) making a material misrepresentation regarding the qualifications for licensure under Section 58-67-302.7; or

[~~(3)~~] (c) violating the dispensing requirements of Section 58-17b-309 or Chapter 17b, Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, if applicable.

(2) "Unprofessional conduct" does not include, in compliance with Section 58-85-103:

(a) obtaining an investigational drug or investigational device;

(b) administering the investigational drug to an eligible patient; or

(c) treating an eligible patient with the investigational drug or investigational device.

Section 3. Section **58-68-501** is amended to read:

58-68-501. Unlawful conduct.

(1) "Unlawful conduct" includes, in addition to the definition in Section 58-1-501:

(a) buying, selling, or fraudulently obtaining any osteopathic medical diploma, license, certificate, or registration; and

(b) aiding or abetting the buying, selling, or fraudulently obtaining of any osteopathic medical diploma, license, certificate, or registration;

(c) substantially interfering with a licensee's lawful and competent practice of medicine in accordance with this chapter by:

(i) any person or entity that manages, owns, operates, or conducts a business having a direct or indirect financial interest in the licensee's professional practice; or

(ii) anyone other than another physician licensed under this title, who is engaged in direct clinical care or consultation with the licensee in accordance with the standards and ethics of the profession of medicine; or

(d) entering into a contract that limits a licensee's ability to advise the licensee's patients fully about treatment options or other issues that affect the health care of the licensee's patients.

(2) "Unlawful conduct" does not include:

(a) establishing, administering, or enforcing the provisions of a policy of accident and health insurance by an insurer doing business in this state in accordance with Title 31A, Insurance Code;

(b) adopting, implementing, or enforcing utilization management standards related to payment for a licensee's services, provided that:

(i) utilization management standards adopted, implemented, and enforced by the payer have been approved by a physician or by a committee that contains one or more physicians; and

(ii) the utilization management standards does not preclude a licensee from exercising independent professional judgment on behalf of the licensee's patients in a manner that is independent of payment considerations;

(c) developing and implementing clinical practice standards that are intended to reduce morbidity and mortality or developing and implementing other medical or surgical practice standards related to the standardization of effective health care practices, provided that:

(i) the practice standards and recommendations have been approved by a physician or by a committee that contains one or more physicians; and

(ii) the practice standards do not preclude a licensee from exercising independent professional judgment on behalf of the licensee's patients in a manner that is independent of payment considerations;

(d) requesting or recommending that a patient obtain a second opinion from a licensee;

(e) conducting peer review, quality evaluation, quality improvement, risk management, or similar activities designed to identify and address practice deficiencies with health care providers, health care facilities, or the delivery of health care;

(f) providing employment supervision or adopting employment requirements that do not interfere with the licensee's ability to exercise independent professional judgment on behalf of the licensee's patients, provided that employment requirements that may not be considered to interfere with an employed licensee's exercise of independent professional judgment include:

(i) an employment requirement that restricts the licensee's access to patients with whom the licensee's employer does not have a contractual relationship, either directly or through contracts with one or more third-party payers; or

(ii) providing compensation incentives that are not related to the treatment of any particular patient;

(g) providing benefit coverage information, giving advice, or expressing opinions to a patient or to a family member of a patient to assist the patient or family member in making a decision about health care that has been recommended by a licensee; [~~or~~]

(h) in compliance with Section 58-85-103:

(i) obtaining an investigational drug or investigational device;

(ii) administering the investigational drug to an eligible patient; or

(iii) treating an eligible patient with the investigational drug or investigational device; or

[~~(h)~~] (i) any otherwise lawful conduct that does not substantially interfere with the licensee's ability to exercise independent professional judgment on behalf of the licensee's patients and that does not constitute the practice of medicine as defined in this chapter.

Section 4. Section **58-68-502** is amended to read:

58-68-502. Unprofessional conduct.

(1) "Unprofessional conduct" includes, in addition to the definition in Section 58-1-501:

[~~(1)~~] (a) using or employing the services of any individual to assist a licensee in any manner not in accordance with the generally recognized practices, standards, or ethics of the profession, state law, or division rule; or

[~~(2)~~] (b) violating the dispensing requirements of Section 58-17b-309 or Chapter 17b, Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, if applicable.

(2) "Unprofessional conduct" does not include, in compliance with Section 58-85-103:

(a) obtaining an investigational drug or investigational device;

(b) administering the investigational drug to an eligible patient; or

(c) treating an eligible patient with the investigational drug or investigational device.

Section 5. Section **58-85-101** is enacted to read:

CHAPTER 85. UTAH RIGHT TO TRY ACT

58-85-101. Title.

This chapter is known as the "Utah Right to Try Act."

Section 6. Section **58-85-102** is enacted to read:

58-85-102. Definitions.

As used in this chapter:

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

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

(3) "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) "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.

(5) "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.

(6) "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 7. Section **58-85-103** is enacted to read:

58-85-103. Right to request investigational drug or device.

(1) An eligible patient may obtain an investigational drug through an agreement with the investigational drug's manufacturer and the eligible patient's physician that provides:

(a) for the transfer of the investigational drug from the manufacturer to the physician; and

(b) that the physician will administer the investigational drug to the patient.

(2) An eligible patient may obtain an investigational device through an agreement with the investigational device's manufacturer and the eligible patient's physician that provides:

(a) for the transfer of the investigational device from the manufacturer to the physician; and

(b) that the physician will use the investigational device to treat the patient.

(3) An agreement described in Subsection (1) or (2), between an eligible patient, a physician, and a manufacturer, shall include an informed consent document that, based on the physician's knowledge of the relevant investigational drug or investigational device:

(a) describes the possible positive and negative outcomes the eligible patient could experience if the physician treats the eligible patient with the investigational drug or investigational device, including that the investigational drug or investigational device could increase the possibility of death;

(b) states that an insurer is not required to cover the cost of providing the investigational drug or investigational device to the patient;

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

(d) states that the patient may be liable for all expenses caused by the physician treating the patient with the investigational drug or investigational device, unless the agreement provides otherwise.

(4) A physician or an eligible patient shall notify the eligible patient's insurer of the day on which the physician treated an eligible patient with an investigational drug or investigational device, and the investigational drug or device used, under an agreement described in Subsection (1) or (2).

Section 8. Section **58-85-104** is enacted to read:

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

(1) 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.

(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 may not, for any harm done to the eligible patient by the investigational drug or device, be subject to:

(a) civil liability;

(b) criminal liability;

(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, 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 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

(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

(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 9. Section **58-85-105** is enacted to read:

58-85-105. Insurance coverage.

(1) This chapter does not require an insurer to:

(a) 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

(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.

(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.