



State of Wisconsin
2021 - 2022 LEGISLATURE

LRB-5283/1
JPC:cjs

2021 ASSEMBLY BILL 979

February 15, 2022 - Introduced by Representatives RAMTHUN and WICHGERS,
cosponsored by Senator JACQUE. Referred to Committee on Health.

AUTHORS SUBJECT TO CHANGE

1 **AN ACT to amend** 450.137 (title), 450.137 (2) (b), 450.137 (2) (c), 450.137 (2) (d),
2 450.137 (2) (e), 450.137 (2) (f), 450.137 (3), 450.137 (4) (a), 450.137 (4) (b),
3 450.137 (5) and 450.137 (6); and **to create** 450.137 (1) (d) of the statutes;
4 **relating to:** right to try off-label therapies.

Analysis by the Legislative Reference Bureau

Under current law, a manufacturer of an investigational drug, device, or biological product may make the investigational drug, device, or biological product available to an eligible patient. “Investigational drug, device, or biological product” is defined to mean a drug, device, or biological product that has not been approved or licensed for use by the federal Food and Drug Administration and that meets certain conditions relating to its status in clinical trials approved by the FDA. A patient is eligible to receive an investigational drug, device, or biological product if the patient meets several conditions, including that he or she has been diagnosed with a life-threatening disease or condition, he or she has exhausted approved treatment options and is unable to participate in a clinical trial involving the investigational drug, device, or biological product, and he or she has received a recommendation or prescription order from his or her treating physician for the investigational drug, device, or biological product. If a manufacturer decides to make an investigational drug, device, or biological product available to an eligible patient, the manufacturer may charge an amount for the investigational drug, device, or biological product that is not more than the cost to manufacture the investigational drug, device, or biological product provided to the eligible patient. Current law also

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protects certain individuals and entities from liability resulting from the design, development, clinical testing, investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administration, or use of the investigational drug, device, or biological product in certain circumstances.

This bill adds off-label therapies to those drugs, devices, or biological products that an eligible patient may receive. Under the bill, “off-label therapy” is defined to mean a use of a drug, device, or biological product approved by the FDA other than a use approved by the FDA. The same requirements and protections that exist under current law for investigational drugs, devices, and biological products also apply to off-label therapies.

For further information see the state fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

1 **SECTION 1.** 450.137 (title) of the statutes is amended to read:

2 **450.137** (title) **Access to off-label therapies, investigational drugs,**
3 **devices, and biological products for terminally ill patients.**

4 **SECTION 2.** 450.137 (1) (d) of the statutes is created to read:

5 **450.137 (1)** (d) “Off-label therapy” means a use of a drug, device, or biological
6 product approved by the federal food and drug administration other than a use
7 approved by the federal food and drug administration.

8 **SECTION 3.** 450.137 (2) (b) of the statutes is amended to read:

9 **450.137 (2)** (b) Has exhausted approved treatment options and is unable to
10 participate in a clinical trial involving the off-label therapy or the investigational
11 drug, device, or biological product.

12 **SECTION 4.** 450.137 (2) (c) of the statutes is amended to read:

13 **450.137 (2)** (c) Has received a recommendation or prescription order from the
14 individual’s treating physician for an off-label therapy or an investigational drug,
15 device, or biological product.

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1 **SECTION 5.** 450.137 (2) (d) of the statutes is amended to read:

2 450.137 (2) (d) Has given written informed consent to use the off-label therapy
3 or the investigational drug, device, or biological product. The content of the written
4 informed consent provided by the patient shall be consistent with and at least as
5 comprehensive as the consent used in clinical trials for the off-label therapy or the
6 investigational drug, device, or biological product.

7 **SECTION 6.** 450.137 (2) (e) of the statutes is amended to read:

8 450.137 (2) (e) Is aware of the potential costs that may be associated with or
9 otherwise result from the use of the off-label therapy or the investigational drug,
10 device, or biological product under this section.

11 **SECTION 7.** 450.137 (2) (f) of the statutes is amended to read:

12 450.137 (2) (f) Possesses a written verification executed by the individual's
13 treating physician attesting that the individual meets the conditions under pars. (a)
14 to (e), and that the physician is not compensated directly by the manufacturer of the
15 off-label therapy or the investigational drug, device, or biological product for making
16 that attestation.

17 **SECTION 8.** 450.137 (3) of the statutes is amended to read:

18 450.137 (3) MANUFACTURERS. A manufacturer of an off-label therapy or an
19 investigational drug, device, or biological product may, but is not required to, make
20 that off-label therapy or that investigational drug, device, or biological product
21 available to an eligible patient. If the manufacturer charges an eligible patient for
22 an off-label therapy or an investigational drug, device, or biological product, the
23 manufacturer may not charge more than an amount that is equal to the
24 manufacturer's actual cost to manufacture the off-label therapy or the
25 investigational drug, device, or biological product provided to the eligible patient.

ASSEMBLY BILL 979**SECTION 9**

1 **SECTION 9.** 450.137 (4) (a) of the statutes is amended to read:

2 450.137 (4) (a) A physician is immune from civil or criminal liability or from
3 professional discipline under s. 448.02 based solely on the physician's
4 recommendation to an eligible patient for the use of an off-label therapy or an
5 investigational drug, device, or biological product to treat the patient's
6 life-threatening disease or condition if the eligible patient gives written informed
7 consent that satisfies sub. (2) (d) and s. 448.30.

8 **SECTION 10.** 450.137 (4) (b) of the statutes is amended to read:

9 450.137 (4) (b) Any manufacturer, distributor, pharmacist, practitioner, health
10 care facility, or other person who lawfully makes available, delivers, distributes,
11 prescribes, dispenses, or administers an off-label therapy or an investigational drug,
12 device, or biological product to an eligible patient consistent with this section, and
13 who in doing so exercises reasonable care, may not be held liable in any action under
14 state law for any loss, damage, or injury arising out of, relating to, or resulting from
15 any of the following:

16 1. The design, development, clinical testing, investigation, manufacture,
17 labeling, distribution, sale, purchase, donation, dispensing, prescribing,
18 administration, or use of the off-label therapy or the investigational drug, device, or
19 biological product.

20 2. The lack of safety or effectiveness of the off-label therapy or the
21 investigational drug, device, or biological product.

22 **SECTION 11.** 450.137 (5) of the statutes is amended to read:

23 450.137 (5) **REPORTING.** The manufacturer or sponsor of an off-label therapy
24 or an investigational drug, device, or biological product that makes the off-label
25 therapy or the investigational drug, device, or biological product available to a

ASSEMBLY BILL 979**SECTION 11**

1 patient in this state shall submit to the federal food and drug administration an
2 annual summary of the use of the off-label therapy or the investigational drug,
3 device, or biological product. The summary shall include the number of doses
4 supplied, the number of patients treated, the uses for which it was made available,
5 and any known serious adverse events.

6 **SECTION 12.** 450.137 (6) of the statutes is amended to read:

7 450.137 (6) STATE OFFICIALS. No official, employee, or agent of this state may
8 block or attempt to block an eligible patient's access to an off-label therapy or an
9 investigational drug, device, or biological product. Any counseling, advice, or
10 recommendation of a practitioner that is consistent with the applicable standard of
11 care for the practitioner is not a violation of this subsection.

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(END)