



State of Wisconsin
2017 - 2018 LEGISLATURE

LRBs0014/1
MED:emw

**ASSEMBLY SUBSTITUTE AMENDMENT 1,
TO ASSEMBLY BILL 69**

February 28, 2017 - Offered by Representative SNYDER.

1 **AN ACT to create** 450.135 of the statutes; **relating to:** access to investigational
2 drugs, devices, and biological products and limitations on liability related to
3 their use.

Analysis by the Legislative Reference Bureau

This substitute amendment differs from 2017 Assembly Bill 69 in the following respects:

1. The substitute amendment adds two additional requirements that must be satisfied in order for an individual to be considered an eligible patient under the bill:

a. The individual must be ineligible for or otherwise unable to participate in a clinical trial for the investigational drug, device, or biological product within 100 miles of his or her home address, or have been determined by his or her treating physician to be unsuitable to participate in any clinical trial for the investigational drug, device, or biological product for which the individual may be eligible.

b. The individual must be aware of the potential costs that may be associated with or otherwise result from the use of the investigational drug, device, or biological product.

2. The substitute amendment adds a reference to health care facilities in the list of persons entitled to immunity under the bill.

For further information, see the analysis for the bill.

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

1 **SECTION 1.** 450.135 of the statutes is created to read:

2 **450.135 Access to investigational drugs, devices, and biological**
3 **products for terminally ill patients. (1) DEFINITIONS.** In this section:

4 (a) “Eligible patient” means a patient who is eligible under sub. (2).

5 (b) “Investigational drug, device, or biological product” means a drug, device,
6 or biological product that has not been approved for use by the federal food and drug
7 administration and meets all of the following conditions:

8 1. Has successfully completed a phase one clinical trial approved by the federal
9 food and drug administration.

10 2. Remains under investigation in a phase 2 or 3 clinical trial approved by the
11 federal food and drug administration or has completed a phase 3 clinical trial and
12 is pending approval by the federal food and drug administration.

13 3. Is not the subject of a clinical trial that was closed due to the toxicity or lack
14 of efficacy of the drug, device, or biological product.

15 (c) “Terminal illness” means a disease that, without life-sustaining procedures,
16 will soon result in death or a state of permanent unconsciousness from which
17 recovery is unlikely.

18 **(2) ELIGIBILITY.** An individual is an eligible patient for purposes of this section
19 if the individual meets all of the following conditions:

20 (a) Has a terminal illness.

21 (b) Has considered all other available treatment options.

1 (c) Has received a recommendation or prescription order from the individual's
2 treating physician for an investigational drug, device, or biological product.

3 (d) Is ineligible for or otherwise unable to participate in a clinical trial for the
4 investigational drug, device, or biological product within 100 miles of his or her home
5 address, or has been determined by the individual's treating physician to be
6 unsuitable to participate in any clinical trial for the investigational drug, device, or
7 biological product for which the individual may be eligible.

8 (e) Has given written informed consent to use the investigational drug, device,
9 or biological product. The content of the written informed consent provided by the
10 patient shall be consistent with and at least as comprehensive as the consent used
11 in clinical trials for the investigational drug, device, or biological product.

12 (f) Is aware of the potential costs that may be associated with or otherwise
13 result from the use of the investigational drug, device, or biological product under
14 this section.

15 (g) Possesses a written verification executed by the individual's treating
16 physician attesting that the individual meets the conditions under pars. (a) to (f).

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

24 **(4) LIMITATIONS OF LIABILITY.** (a) A physician is immune from civil or criminal
25 liability or from professional discipline under s. 448.02 based solely on the

1 physician's recommendation to an eligible patient for the use of an investigational
2 drug, device, or biological product to treat the patient's terminal illness if the eligible
3 patient gives written informed consent that satisfies sub. (2) (e) and s. 448.30.

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

11 1. The design, development, clinical testing, investigation, manufacture,
12 labeling, distribution, sale, purchase, donation, dispensing, prescribing,
13 administration, or use of the investigational drug, device, or biological product.

14 2. The lack of safety or effectiveness of the investigational drug, device, or
15 biological product.

16 **(5) STATE OFFICIALS.** No official, employee, or agent of this state may block or
17 attempt to block an eligible patient's access to an investigational drug, device, or
18 biological product. Any counseling, advice, or recommendation of a practitioner that
19 is consistent with the applicable standard of care for the practitioner is not a
20 violation of this subsection.

21 **(6) INSURANCE.** Nothing in this section alters the obligations of an eligible
22 patient's insurer under the contract of insurance and applicable law.

23 **(END)**