



LAWS OF ALASKA

2018

Source
CSHB 43(JUD)

Chapter No.

AN ACT

Relating to prescribing, dispensing, and administering an investigational drug, biological product, or device by physicians for patients who are terminally ill for the purpose of sustaining the patient's life; providing immunity related to manufacturing, distributing, or providing investigational drugs, biological products, or devices; and relating to licensed health care facility requirements.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

THE ACT FOLLOWS ON PAGE 1

AN ACT

1 Relating to prescribing, dispensing, and administering an investigational drug, biological
2 product, or device by physicians for patients who are terminally ill for the purpose of
3 sustaining the patient's life; providing immunity related to manufacturing, distributing, or
4 providing investigational drugs, biological products, or devices; and relating to licensed health
5 care facility requirements.

6

7 * **Section 1.** AS 08.64.367 is amended by adding new subsections to read:

8 (c) A physician may not be subject to disciplinary action by the board for
9 prescribing, dispensing, or administering an investigational drug, biological product,
10 or device, or providing related treatment, to a patient for the purpose of sustaining the
11 patient's life if the patient

12 (1) has a terminal illness;

13 (2) is ineligible or unable to participate in a current clinical trial for the

1 investigational drug, biological product, or device;

2 (3) has considered, after consultation with the physician, all other
3 treatment options currently approved by the United States Food and Drug
4 Administration; and

5 (4) has given informed consent in writing for the use of the
6 investigational drug, biological product, or device.

7 (d) In this section,

8 (1) "investigational drug, biological product, or device" means a drug,
9 biological product, or device that has successfully completed Phase 1 studies of
10 clinical trials for investigation and remains in ongoing clinical trials under Phase 2 or
11 Phase 3 or is in the new drug application process following Phase 3 of clinical trials,
12 but has not been approved for general use by the United States Food and Drug
13 Administration;

14 (2) "terminal illness" means a disease that, without life-sustaining
15 procedures, will result in death in the near future or a state of permanent
16 unconsciousness from which recovery is unlikely.

17 * **Sec. 2.** AS 09.65 is amended by adding a new section to read:

18 **Sec. 09.65.325. Immunity relating to use or nonuse of investigational**
19 **drugs, biological products, and devices.** (a) A person is not liable in an action for
20 damages for the injury or death of a patient with a terminal illness resulting from the
21 patient's use of an investigational drug, biological product, or device for the purpose of
22 sustaining the patient's life if the person, acting in good faith and with reasonable care,
23 is a

24 (1) physician or member of the medical team who prescribed,
25 dispensed, or administered the investigational drug, biological product, or device, or
26 provided related treatment, to the patient and, before prescribing, dispensing, or
27 administering the drug, product, or device, or providing related treatment, the
28 physician or member of the medical team

29 (A) obtained the informed consent of the patient in writing after
30 presenting to the patient all treatment options currently approved by the United
31 States Food and Drug Administration for treatment of the patient's terminal

1 illness; and

2 (B) provided to the patient written notice of the immunity
3 provided under this section; or

4 (2) manufacturer, importer, or distributor of the investigational drug,
5 biological product, or device and, before providing the drug, product, or device to the
6 patient's physician, presented to the physician all treatment options currently approved
7 by the United States Food and Drug Administration for treatment of the patient's
8 terminal illness and provided to the patient written notice of the immunity provided
9 under this section.

10 (b) A person, acting in good faith and with reasonable care, is not liable in an
11 action for damages solely for declining to

12 (1) prescribe, dispense, or administer an investigational drug,
13 biological product, or device to a patient; or

14 (2) provide an investigational drug, biological product, or device to a
15 patient's physician.

16 (c) In this section, "investigational drug, biological product, or device" and
17 "terminal illness" have the meanings given in AS 08.64.367.

18 * **Sec. 3.** AS 17.20.110 is amended by adding a new subsection to read:

19 (b) This section does not apply to a physician who prescribes or administers a
20 new drug in accordance with the conditions set out in AS 08.64.367(c).

21 * **Sec. 4.** AS 47.32.030 is amended by adding a new subsection to read:

22 (d) The department may not require a licensed entity to increase services for
23 the sole purpose of accommodating a physician's practice of prescribing, dispensing,
24 or administering an investigational drug, biological product, or device, or providing
25 related treatment, to a patient. In this subsection, "investigational drug, biological
26 product, or device" has the meaning given in AS 08.64.367.