


I MINA' TRENTAI TRES NA LIHESLATURAN GUÁHAN
2016 (SECOND) Regular Session

Bill No. 316-33 (COR)

Introduced by:

V. Anthony Ada 

AN ACT TO ADD A NEW ARTICLE 24 TO PART 2 OF CHAPTER 12, 10 GCA RELATIVE TO AUTHORIZING ACCESS TO AND USE OF EXPERIMENTAL TREATMENTS FOR PATIENTS WITH AN ADVANCED ILLNESS; TO ESTABLISH CONDITIONS FOR USE OF EXPERIMENTAL TREATMENT; TO PROHIBIT SANCTIONS OF HEALTH CARE PROVIDERS SOLELY FOR RECOMMENDING OR PROVIDING EXPERIMENTAL TREATMENT; TO CLARIFY DUTIES OF A HEALTH INSURER WITH REGARD TO EXPERIMENTAL TREATMENT AUTHORIZED UNDER THIS ACT; TO PROHIBIT CERTAIN ACTIONS BY PUBLIC OFFICIALS, EMPLOYEES, AND AGENTS; AND TO RESTRICT CERTAIN CAUSES OF ACTION ARISING FROM EXPERIMENTAL TREATMENT.

2016 MAY 12 PM 4:14 AD

1 **BE IT ENACTED BY THE PEOPLE OF GUAM:**

2 **Section 1.** A new Article 24 is added to Chapter 12 of 10GCA to read as follows:

3

4 **"Article 24**

5 **Right to Try Act**

6

7 **§122401. As Used in this Article.**

8 (1) This act shall be known and may be cited as the "right to try act".

9 (2) As used in this act, and unless the context otherwise requires:

10 (a) "Advanced illness", for purposes of this section only, means a

1 progressive disease or medical or surgical condition that entails
2 significant functional impairment, that is not considered by a treating
3 physician to be reversible even with administration of current federal
4 drug administration approved and available treatments, and that, without
5 life-sustaining procedures, will soon result in death.

6 (b) "Eligible patient" means an individual who meets all of the
7 following conditions:

8 (i) Has an advanced illness, attested to by the patient's treating
9 physician.

10 (ii) Has considered all other treatment options currently
11 approved by the United States food and drug administration.

12 (iii) Has received a recommendation from his or her
13 physician for an investigational drug, biological product,
14 or device.

15 (iv) Has given written, informed consent for the use of the
16 investigational drug, biological product, or device.

17 (v) Has documentation from his or her physician that he or
18 she meets the requirements of this subdivision.

19 (c) "Investigational drug, biological product, or device" means a drug,
20 biological product, or device that has successfully completed phase I of a
21 clinical trial but has not yet been approved for general use by the United
22 States food and drug administration and remains under investigation in a
23 United States food and drug administration-approved clinical trial.

24 (d) "Written, informed consent" means a written document that is
25 signed by the patient; parent, if the patient is a minor; legal guardian; or
26 patient advocate designated by the patient under 19 GCA, and attested to
27 by the patient's physician and a witness and that, at a minimum, includes
28 all of the following:

1 (i) An explanation of the currently approved products and
2 treatments for the disease or condition from which the patient
3 suffers.

4 (ii) An attestation that the patient concurs with his or her
5 Physician in believing that all currently approved and
6 conventionally recognized treatments are unlikely to prolong the
7 patient's life.

8 (iii) Clear identification of the specific proposed investigational
9 drug, biological product, or device that the patient is seeking to
10 use.

11 (iv) A description of the potentially best and worst outcomes of
12 using the investigational drug, biological product, or device and a
13 realistic description of the most likely outcome. The description
14 shall include the possibility that new, unanticipated, different, or
15 worse symptoms might result and that death could be hastened by
16 the proposed treatment. The description shall be based on the
17 physician's knowledge of the proposed treatment in conjunction
18 with an awareness of the patient's condition.

19 (v) A statement that the patient's health plan or third party
20 administrator and provider are not obligated to pay for any care or
21 treatments consequent to the use of the investigational drug,
22 biological product, or device, unless they are specifically required
23 to do so by law or contract.

24 (vi) A statement that the patient's eligibility for hospice care may
25 be withdrawn if the patient begins curative treatment with the
26 investigational drug, biological product, or device and that care
27 may be reinstated if this treatment ends and the patient meets
28 hospice eligibility requirements.

1 (vii) A statement that the patient understands that he or she is
2 liable for all expenses consequent to the use of the investigational
3 drug, biological product, or device and that this liability extends to
4 the patient's estate, unless a contract between the patient and the
5 manufacturer of the drug, biological product, or device states
6 otherwise.

7
8 **§122402. Conditional Authorization to Use Investigational Drugs.**

9 (1) A manufacturer of an investigational drug, biological product, or device
10 may make available and an eligible patient may request the manufacturer's
11 investigational drug, biological product, or device under this act. This act does
12 not require that a manufacturer make available an investigational drug,
13 biological product, or device to an eligible patient.

14 A manufacturer may do all of the following:

- 15 (a) Provide an investigational drug, biological product, or device to
16 an eligible patient without receiving compensation.
- 17 (b) Require an eligible patient to pay the costs of, or the costs
18 associated with, the manufacture of the investigational drug,
19 biological product, or device.

20
21 **§122403. No Requirement to Provide Services.**

- 22 (1) This act does not expand the coverage required of an insurer under
23 Division 2 of 22GCA
- 24 (2) A health plan, third party administrator, or governmental agency may, but
25 is not required to, provide coverage for the cost of an investigational drug,
26 biological product, or device, or the cost of services related to the use of an
27 investigational drug, biological product, or device under this act.
- 28 (3) This act does not require any governmental agency to pay costs

1 associated with the use, care, or treatment of a patient with an
2 investigational drug, biological product, or device.

3 (4) This act does not require a hospital or facility licensed 10GCA to
4 provide new or additional services, unless approved by the hospital or facility.
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6 **§122404. Death of a Patient.**

7 If a patient dies while being treated by an investigational drug, biological product, or
8 device, the patient's heirs are not liable for any outstanding debt related to the
9 treatment or lack of insurance due to the treatment.
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11 **§122405. No Disciplinary Action under Certain Conditions.**

12 A licensing board or disciplinary subcommittee shall not revoke, fail to renew,
13 suspend, or take any action against a health care provider's license issued under
14 Chapter 12 of 10GCA, based solely on the health care provider's recommendations to
15 an eligible patient regarding access to or treatment with an investigational drug,
16 biological product, or device. An entity responsible for Medicare certification shall not
17 take action against a health care provider's Medicare certification based solely on the
18 health care provider's recommendation that a patient have access to an investigational
19 drug, biological product, or device.
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21 **§122406. Public Officials.**

22 An official, employee, or agent of the Government of Guam shall not block or attempt
23 to block an eligible patient's access to an investigational drug, biological product, or
24 device. Counseling, advice, or a recommendation consistent with medical standards of
25 care from a licensed health care provider is not a violation of this section.
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27 **§122407. No Cause of Action**

28 (1) This act does not create a private cause of action against a manufacturer

1 of an investigational drug, biological product, or device or against any other
2 person or entity involved in the care of an eligible patient using the
3 investigational drug, biological product, or device for any harm done to the
4 eligible patient resulting from the investigational drug, biological product, or
5 device, if the manufacturer or other person or entity is complying in good faith
6 with the terms of this act and has exercised reasonable care.

7 (2) This act does not affect any mandatory health care coverage for
8 participation in clinical trials under Public Law or Federal Law. "