


**I MINA'TRENTAI SINGKO NA LIHESLATURAN GUÅHAN**  
**2020 (SECOND) Regular Session**  
**LEGISLATIVE SESSION VOTING RECORD**

Bill No. 304-35 (COR)	Speaker Antonio R. Unpingco Legislative Session Hall Guam Congress Building December 17, 2020					
NAME	Aye	Nay	Not Voting/ Abstained	Out During Roll Call	Absent	Excused
Senator William M. CASTRO	✓					
Senator Régine Biscoe LEE	✓					
Senator Kelly G. MARSH (TAITANO), PhD	✓					
Senator James C. MOYLAN						✓
Senator Louise B. MUÑA	✓					
Speaker Tina Rose MUÑA BARNES	✓					
Vice Speaker Telena Cruz NELSON						✓
Senator Sabina Flores PEREZ	✓					
Senator Clynton E. RIDGELL	✓					
Senator Joe S. SAN AGUSTIN	✓					
Senator Amanda L. SHELTON	✓					
Senator Telo T. TAITAGUE	✓					
Senator Jose "Pedo" TERLAJE	✓					
Senator Therese M. TERLAJE	✓					
Senator Mary Camacho TORRES	✓					

<b>TOTAL:</b>	<b>13</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>
	Aye	Nay	Not Voting/ Abstained	Out During Roll Call	Absent	Excused

CERTIFIED TRUE AND CORRECT:

  
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 RENNAE V. C. MENO  
 Clerk of the Legislature

I = Pass

***I MINA'TRENTAI SINGKO NA LIHESLATURAN GUÅHAN***  
**2020 (SECOND) Regular Session**

**Bill No. 304-35 (COR)**

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Introduced by:

Louise B. Muña

**AN ACT TO *ADD* A NEW ARTICLE 26 TO PART 2 OF CHAPTER 12, TITLE 10, GUAM CODE ANNOTATED, 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; TO RESTRICT CERTAIN CAUSES OF ACTION ARISING FROM EXPERIMENTAL TREATMENT; AND TO BE KNOWN AS THE “RIGHT TO TRY ACT.”**

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

2           **Section 1. Legislative Findings and Intent.** *I Liheslaturan Guåhan* finds  
3 that forty-one (41) states and the U.S. Congress have enacted “Right to Try”  
4 legislation that is intended to provide additional treatment options to terminally ill  
5 persons.

6           *I Liheslatura* further finds that the best information available on “Right To  
7 Try” legislation is contained in the FAQ section of the website: “righttotry.org/rtt-

1 faq” on the federal law passed by the U.S. Congress and signed into law by President  
2 Trump in May of 2018 as follows:

3 “On May 30, 2018, President Donald Trump signed S.204, the  
4 Trickett Wendler, Frank Mongiello, Jordan McLinn and Matthew  
5 Bellina Right to Try Act. Right to Try opens a new pathway for  
6 terminally ill patients who have exhausted their government-approved  
7 options and can’t get into a clinical trial to access treatments. Although  
8 41 states have passed Right to Try laws, the signing of S.204 makes  
9 Right to Try the law of the land, creating a uniform system for terminal  
10 patients seeking access to investigational treatments.

### 11 **Who qualifies for Right to Try?**

12 To be eligible for Right to Try, a patient must meet the following  
13 conditions:

- 14 • Be diagnosed with a life-threatening disease or condition;
- 15 • Have exhausted approved treatment options;
- 16 • Be unable to participate in a clinical trial involving the eligible  
17 investigational drug, as certified by a doctor, who is in good  
18 standing with her licensing organization and will not be  
19 compensated directly by the manufacturer for so certifying; and
- 20 • Give written informed consent regarding the risks associated  
21 with taking the investigational treatment.

### 22 **What is a life-threatening disease or condition?**

23 Federal law defines a life-threatening disease or condition as: “Diseases  
24 or conditions where the likelihood of death is high unless the course of the  
25 disease is interrupted”. 21 C.F.R. § 312.81.

### 26 **What drugs or treatments qualify for Right to Try?**

1           The treatments available under the law must meet the following  
2 conditions:

- 3           • Have completed an FDA-approved Phase 1 clinical trial;
- 4           • Be in an active clinical trial intended to form the basis of an  
5 application for approval or be the subject of an application for  
6 approval that has been filed with the FDA; and
- 7           • Be in ongoing active development or production and not  
8 discontinued by the manufacturer or placed on clinical hold.

9           **I do not live in a state with a Right to Try law. Can I still use Right  
10 to Try?**

11           Yes. S.204 makes Right to Try the law of the land. So long as a patient  
12 and treatment meet the qualifications of the federal law, Right to Try applies,  
13 regardless of whether the patient’s state adopted Right to Try.

14           **Does medical cannabis qualify?**

15           Right to Try only applies to treatments that have completed an FDA-  
16 approved Phase 1 clinical trial and remain under study in an active clinical  
17 trial. If there is a Phase 2 or 3 clinical trial for medical cannabis as a treatment  
18 of an underlying terminal condition, it may qualify.

19           **Does a treatment that is already FDA-approved for something else  
20 qualify for Right to Try?**

21           Doctors may already prescribe treatments ‘off-label.’ Off-label means  
22 prescribing an FDA approved treatment for a condition, dose, or population  
23 other than what the FDA approved. Therefore, no special permission is needed  
24 for a physician to prescribe treatments that are approved for other conditions.  
25 Right to Try applies to treatments that are being given to patients in clinical  
26 trials but are not already FDA approved.

27           **What can companies charge for treatments?**

1 Federal law bans companies from making a profit on any drug or  
2 treatment that has not been approved by the FDA, but the law does allow  
3 companies to recover the costs that are directly related to providing an  
4 individual treatment. Existing regulations govern what can and cannot be  
5 included in the calculation for determining the direct costs that can be charged.

6 This means that a patient could be charged for the direct costs of  
7 providing their individual treatment, but the company cannot make a profit.

### 8 **How will payment work?**

9 Just like with the FDA's existing Expanded Access program, insurance  
10 companies and taxpayer-funded healthcare programs like Medicaid or  
11 Medicare are not required to cover the cost of investigational treatments, but  
12 they may choose to do so. Some insurance companies have covered the costs  
13 of investigational treatments used by patients under state Right to Try laws,  
14 but others have not. Each patient's cost situation will be different and  
15 determined by their individual insurance company or program and their own  
16 financial resources.

### 17 **How do I initiate a request?**

18 The patient, the patient's representative, or physician should send a  
19 letter to the drug manufacturer's director of compassionate use or other  
20 designated representative to discuss options for access.

### 21 **Where can I find a list of potential treatments?**

22 If your physician is not yet aware of investigational treatments, there  
23 are several websites that can assist in locating potential treatments:

24 [https://clinicaltrials.gov/https://platform.emergingmed.com/find-clinical-  
26 trials/cri#partnerhome](https://clinicaltrials.gov/https://platform.emergingmed.com/find-clinical-<br/>25 trials/cri#partnerhome)

27 <https://www.cancer.gov/about-cancer/treatment/clinical-trials/search>

### **Is a drug company required to make a treatment available?**



1 **RIGHT TO TRY ACT**

2 **§ 122601. Short Title; Definitions.**

3 (a) This Article shall be known and may be cited as the “Right to Try Act.”

4 (b) As used in this Article, and unless the context otherwise requires:

5 (1) *Advanced illness*, for purposes of this Article only, means a  
6 progressive disease or medical or surgical condition that entails significant  
7 functional impairment, that is not considered by a treating physician to be  
8 reversible even with administration of current federal drug administration  
9 approved and available treatments, and that, without life-sustaining  
10 procedures, will soon result in death.

11 (2) *Eligible patient* means an individual who meets all of the  
12 following conditions:

13 (A) has an advanced illness, attested to by the patient's treating  
14 physician;

15 (B) has considered all other treatment options currently  
16 approved by the United States Food and Drug Administration;

17 (C) has received a recommendation from his or her physician  
18 for an investigational drug, biological product, or device;

19 (D) has given written, informed consent for the use of the  
20 investigational drug, biological product, or device; and

21 (E) has documentation from his or her physician that he or she  
22 meets the requirements of this Subsection.

23 (3) *Investigational drug, biological product, or device* means a drug,  
24 biological product, or device that has successfully completed Phase 1 of a  
25 clinical trial but has not yet been approved for general use by the United States  
26 Food and Drug Administration and remains under investigation in a United  
27 States Food and Drug Administration-approved clinical trial.

1                   (4) *Written, informed consent* means a written document that  
2 is signed by the patient; a parent, if the patient is a minor; a legal  
3 guardian; or a patient advocate designated by the patient under Title 19,  
4 Guam Code Annotated, and attested to by the patient's physician and a  
5 witness; and that, at a minimum, includes all of the following:

6                   (A) an explanation of the currently approved products  
7 and treatments for the disease or condition from which the patient  
8 suffers;

9                   (B) an attestation that the patient concurs with his or her  
10 physician in believing that all currently approved and  
11 conventionally recognized treatments are unlikely to prolong the  
12 patient's life;

13                   (C) clear identification of the specific proposed  
14 investigational drug, biological product, or device that the patient  
15 is seeking to use;

16                   (D) a description of the potentially best and worst  
17 outcomes of using the investigational drug, biological product,  
18 or device, and a realistic description of the most likely outcome.  
19 The description shall include the possibility that new,  
20 unanticipated, different, or worse symptoms might result, and  
21 that death could be hastened by the proposed treatment. The  
22 description shall be based on the physician's knowledge of the  
23 proposed treatment in conjunction with an awareness of the  
24 patient's condition;

25                   (E) a statement that the patient's health plan or third  
26 party administrator and provider are not obligated to pay for any  
27 care or treatments consequent to the use of the investigational

1 drug, biological product, or device, unless they are specifically  
2 required to do so by law or contract;

3 (F) a statement that the patient's eligibility for hospice  
4 care may be withdrawn if the patient begins curative treatment  
5 with the investigational drug, biological product, or device and  
6 that care may be reinstated if this treatment ends and the patient  
7 meets hospice eligibility requirements; and

8 (G) a statement that the patient understands that he or  
9 she is responsible for all expenses resulting from the use of the  
10 investigational drug, biological product, or device.

11 **§ 122602. Conditional Authorization to Use Investigational Drugs.**

12 (a) A manufacturer of an investigational drug, biological product, or device  
13 may make available, and an eligible patient may request the manufacturer's  
14 investigational drug, biological product, or device under this Article. This Article  
15 does not require that a manufacturer make available an investigational drug,  
16 biological product, or device to an eligible patient.

17 (b) A manufacturer may do all of the following:

18 (1) provide an investigational drug, biological product, or device to  
19 an eligible patient without receiving compensation; and

20 (2) require an eligible patient to pay the costs of, or the costs  
21 associated with, the manufacture of the investigational drug, biological  
22 product, or device.

23 **§ 122603. No Requirement to Provide Services.**

24 (a) This Article does not expand the coverage required of an insurer under  
25 Division 2 of Title 22, Guam Code Annotated.

26 (b) A health plan, third party administrator, or governmental agency may,  
27 but is not required to, provide coverage for the cost of an investigational drug,

1 biological product, or device, or the cost of services related to the use of an  
2 investigational drug, biological product, or device under this Article.

3 (c) This Article does not require any governmental agency to pay costs  
4 associated with the use, care, or treatment of a patient with an investigational drug,  
5 biological product, or device.

6 (d) This Article does not require a hospital or facility licensed under Title  
7 10, Guam Code Annotated to provide new or additional services, unless approved  
8 by the hospital or facility.

9 **§ 122604. Death of a Patient.**

10 If a patient dies while being treated by an investigational drug, biological  
11 product, or device, the patient's heirs are not liable for any outstanding debt related  
12 to the treatment or lack of insurance due to the treatment.

13 **§ 122605. No Disciplinary Action under Certain Conditions.**

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

22 **§ 122606. Public Officials.**

23 (a) An official, employee, or agent of the government of Guam shall not  
24 block or attempt to block an eligible patient's access to an investigational drug,  
25 biological product, or device. Counseling, advice, or a recommendation consistent  
26 with medical standards of care from a licensed health care provider is not a violation  
27 of this Section.

1 (b) The Director of Public Health and Social Services may ban the use of  
2 investigational drugs if it is determined that such drugs are determined by the U.S.  
3 Food and Drug Administration to be harmful or possibly harmful to humans. The  
4 Director of Public Health and Social Services and the Department of Public Health  
5 and Social Services are not liable for any form of damages associated with the use  
6 of drugs authorized by this Article.

7 **§ 122607. No Cause of Action.**

8 (a) This Article does not create a private cause of action against a  
9 manufacturer of an investigational drug, biological product, or device, or against any  
10 other person or entity involved in the care of an eligible patient using the  
11 investigational drug, biological product, or device for any harm done to the eligible  
12 patient resulting from the investigational drug, biological product, or device, if the  
13 manufacturer or other person or entity is complying in good faith with the terms of  
14 this Article and has exercised reasonable care.

15 (b) This Article does not affect any mandatory health care coverage for  
16 participation in clinical trials under public law or federal law.

17 **§ 122608. Conflicts with Federal Law.**

18 If any of the provisions of this Article diminish any rights, protections,  
19 privileges or benefits available to patients, caregivers, clinics, hospitals, physicians,  
20 health care providers, pharmacies, pharmaceutical companies or other party under  
21 federal law, the provisions of federal law shall apply.”