I Mina'trentai Singko Na Liheslaturan Guåhan
BILL STATUS

BILL NO.	SPONSOR	TITLE	DATE INTRODUCED	DATE REFERRED	CMTE REFERRED	PUBLIC HEARING DATE	DATE COMMITTEE REPORT FILED	FISCAL NOTES	NOTES
304-35 (COR)	Louise B. Muña	AN ACT TO *ADD* A NEW ARTICLE 26 TO PART 2, 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; AND TO RESTRICT CERTAIN CAUSES OF ACTION ARISING FROM EXPERIMENTAL TREATMENT. THIS ACT IS KNOWN AS THE "RIGHT TO TRY ACT."	2/24/20 9:30 a.m.						

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

Bill No. 304-35(COR)

Introduced by: Louise B. Muña LBM

AN ACT TO *ADD* A NEW ARTICLE 26 TO PART 2, 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; AND TO RESTRICT CERTAIN CAUSES OF ACTION ARISING FROM EXPERIMENTAL TREATMENT. THIS ACT IS KNOWN AS THE "RIGHT TO TRY ACT."

2020 FEB 24 AM 9:30

BE IT ENACTED BY THE PEOPLE OF GUAM:

Section 1. Legislative Findings and Intent. *I Liheslaturan Guåhan* finds that 41 states and the United States Congress have enacted "Right to Try" legislation that is intended to provide additional treatment options to terminally ill persons.

I Liheslatura further finds that the best information available on "Right To Try" legislation is contained in the FAQ section of website *"righttotry.org/rtt-faq"* on the federal law passed by Congress and Signed into law by President Trump in May of 2018 as follows:

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

Who qualifies for Right to Try?

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

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

What is a life-threatening disease or condition?

Federal law defines a life-threatening disease or condition as: "Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted" (21 CFR 312.81).

What drugs or treatments qualify for Right to Try?

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

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

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

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

Does medical cannabis qualify?

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

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

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

What can companies charge for treatments?

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

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

How will payment work?

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

How do I initiate a request?

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

Where can I find a list of potential treatments?

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

https://clinicaltrials.gov/

https://platform.emergingmed.com/find-clinical-trials/cri#partnerhome

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

Is a drug company required to make a treatment available?

No. Drug companies are not required to provide treatments to patients under Right to Try laws. It would not be appropriate to force companies to provide treatments that they do not think are the right fit for a patient or if they do not have enough supply to provide the treatment outside of its clinical trial.

Can I make my doctor submit a request for a treatment I want to try?

No. Doctors have a responsibility to ensure that patients are given treatments that they believe, in their professional opinion, could help them. A doctor who does not think a treatment will help is not obligated to make a request for the treatment. In addition, doctors who pursue treatments under Right to Try must be in good standing with their state licensing or certifying board, and they cannot be compensated for certifying that patients qualify for Right to Try.

How will a company decide if they will give me the treatment?

Each company will develop its own process and procedures for approving Right to Try requests."

I Liheslatura further finds that although the "Right to Try" is now federal law and thus "the law of the land", it is prudent for states and territories to enact their versions of the law to protect caregivers, clinics, health care professionals and physicians from liability associated the use of experimental drugs and procedures.

It is the intent of *I Liheslatura* to enact the "Right to Try Act" on Guam so that terminally ill patients may opt to for such treatments to extend their lives and improve their health.

Section 2. A new Article 26 is *added* to Chapter 12 of Title 10, Guam Code Annotated to read as follows:

"Article 26

Right to Try Act

§ 122601. As Used in this Article.

(1) This Act shall be known and may be cited as the "Right to Try Act".

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

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

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

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

(ii) Has considered all other treatment options currently approved by the United States Food and Drug Administration.

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

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

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

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

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

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

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

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

(iv) A description of the potentially best and worst outcomes of using the investigational drug, biological product, or device and a realistic description of the most likely outcome. The description

shall include the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment. The description shall be based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition.

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

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

(vii) A statement that the patient understands that he or she is responsible for all expenses resulting from the use of the investigational drug, biological product, or device.

§ 122602. Conditional Authorization to Use Investigational Drugs.

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

(2) A manufacturer may do all of the following:

(a) Provide an investigational drug, biological product, or device to an eligible patient without receiving compensation.

(b) Require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device.

§ 122603. No Requirement to Provide Services.

(1) This Act does not expand the coverage required of an insurer under Division 2 of Title 22, Guam Code Annotated.

(2) A health plan, third party administrator, or governmental agency may, but is not required to, provide coverage for the cost of an investigational drug, biological product, or device, or the cost of services related to the use of an investigational drug, biological product, or device under this Act.

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

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

§ 122604. Death of a Patient.

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

§ 122605. No Disciplinary Action under Certain Conditions.

A licensing board or disciplinary subcommittee shall not revoke, fail to renew, suspend, or take any action against a health care provider's license issued under Chapter 12 of Title 10, Guam Code Annotated, based solely on the health care provider's recommendations to an eligible patient regarding access to or treatment with

an investigational drug, biological product, or device. An entity responsible for Medicare certification shall not take action against a health care provider's Medicare certification based solely on the health care provider's recommendation that a patient have access to an investigational drug, biological product, or device.

§ 122606. Public Officials.

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

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

§ 122607. No Cause of Action

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

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

§ 122608. Conflicts with Federal Law.

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