Councilmember Jack Evans

Councilmember Ywette M. Alexander

Councilmember Mary Cheh

Councilmember Charles Allen

A BILL

IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

To provide patients with an advanced illness access to investigational products that have not been approved by the Federal Food and Drug Administration that other patients have access to when they participate in clinical trials; to authorize provision of certain pharmaceutical and therapeutic products by manufacturers; to specify that gratuitous provision and insurance coverage of certain treatments are not required; and to prohibit actions against licenses of physicians in specific instances.

BE IT ENACTED BY THE COUNCIL BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, That this act may be cited as the "Clinical Right to Try Act of 2015."

Sec. 2. Definitions.

For the purposes of this act, the term:

(1) "Advanced illness" 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 with administration of current FDA approved and available treatments, and that, without life-sustaining procedures, will soon result in death.

(2) "Eligible patient" means a person who has:

(A) An advanced illness, as attested to by the patient's treating physician;

(B) Has, in consultation with a treating physician, considered all other treatment options currently approved by the FDA;

(C) Has been given a prescription or recommendation by the patient's treating physician for an investigational drug, biological product, or device; and

(D) Has given written informed consent for the use of the investigational drug, biological product, or device or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian has given written, informed consent on the patient's behalf.

(3) "FDA" means the United States Food and Drug Administration.

(4) "Health care facility" means any institution providing individual care or treatment of diseases or other medical, physiological, or psychological conditions, including, but not limited to, hospitals, clinics, laboratories, nursing homes, or homes for the aged or chronically ill.

(5) "Health care provider" means a physician, clinic, hospital, or neighborhood health center, licensed by the District of Columbia, to provide medical care.

(6) "Health insurance provider" means any person that provides one or more health benefit plans or insurance in the District of Columbia, including a group health plan, as defined in section 607(1) of the Employee Retirement Income Security Act of 1974, approved April 7, 1986 (100 Stat. 231; 29 U.S.C. § 1167(1)), a plan administrator as defined in section 3(16) of the Employee Retirement Income Security Act of 1974, approved September 2, 1974 (88 Stat. 835; 29 U.S.C.§ 1002(16)), an insurer, a hospital and medical service corporation, a health maintenance organization, a multiple employer welfare arrangement, or any other person

providing a plan of health insurance subject to the authority of the Commissioner of the Department of Insurance and Securities Regulation.

(7) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase one 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.

(8) "Written informed consent" means a written document signed by the patient and attested to by the patient's physician and a witness that, at a minimum, includes the following:

(A) A description of the currently approved products and treatments for the advanced illness from which the patient suffers;

(B) 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;

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

(D) A description of the potential best and worst outcomes of using the investigational drug, biological product, or device and a realistic description of the most likely outcome, including 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;

(E) A statement that the patient understands that his or her health benefit plan is

not obligated to pay for the investigational drug, biological product, or device or any care or treatment consequent to the use of such drug, product, or device, unless such health benefit plan is specifically required to do so by law or contract;

(F) A statement that the patient understands that his or her eligibility for hospice care may be withdrawn if the patient begins curative treatment with the investigational drug, biological product, or device and that hospice care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements;

(G) A statement that the patient understands that his or her in-home health care may be denied if treatment begins; and

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

Sec. 3. Availability of investigational drugs, biological products, or devices.

(a) A manufacturer may:

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

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

(b) Nothing in section shall be construed to require a manufacturer to make available an investigational drug, biological product or device to an eligible patient.

(c) A hospital licensed under the Health-Care and Community Residence Facility, Hospice and Home Care Licensure Act of 1983, effective February 24, 1984 (D.C. Law 5-48; D.C. Official Code § 44-501 *et seq.*) or health care facility, may make available

investigational drugs, biological products, or devices if the hospital or health care facility has a procedure for doing so in place, and this practice is approved and adopted by the hospital or health care facility.

Sec. 4. Health insurance coverage for investigational drugs, biological products, or devices.

(a) A health insurance provider or governmental agency may provide coverage for the cost of the investigational drug, biological product, or device to an eligible patient.

(b) Nothing in this section shall be construed to require a health insurance provider or governmental agency to provide coverage for the cost of any investigational drug, biological product, or device.

Sec. 5. Action against physician license prohibited.

(a) Notwithstanding any provision of law to the contrary, no state agency or regulatory board shall revoke, fail to renew, or take any action against a physician's license issued under the Health Occupations Revision Act of 1985, effective March 26, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1201.01 *et seq.*), based solely on a physician's recommendation to an eligible patient regarding prescription for, or treatment with, an investigational drug, biological product, or device so long as the recommendation is consistent with medical standards of care

Sec. 6. Liability.

(a) Except in cases of gross negligence or willful misconduct, any person or entity who manufactures, imports, distributes, prescribes, dispenses, or administers an investigational drug, biological product, or device to an eligible patient in accordance with this act shall not be liable for any loss, damage, or injury arising out of, relating to, or resulting from:

(1) The design, development, clinical testing and investigation, manufacturing, labeling, distribution, sale, purchase, donation, dispensing, prescription, administration, or use of the drug or device.

(2) The safety or effectiveness of the drug or device.

Sec. 7. Prevention of District interference.

(a) An official, employee, or agent of the District may not block or attempt to block an eligible patient's access to an investigational drug, biological product, or device.

(b) Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this section.

Sec. 8. Impact on existing laws

(a) This act shall not affect mandatory health coverage for participation in clinical trials as required by the Clinical Trials Insurance Coverage Act of 2008, effective June 5, 2008 (D.C. Law 17-166; D.C. Official Code § 31-2993.01 *et seq.*).

Sec. 9. Fiscal impact statement.

The Council adopts the fiscal impact statement in the committee report as the fiscal impact statement required by section 602(c)(3) of the District of Columbia Home Rule Act, approved December 24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(3)).

Sec. 10. Effective date.

This act shall take effect following approval by the Mayor (or in the event of veto by the Mayor, action by the Council to override the veto), a 30-day period of congressional review as provided in section 602(c)(1) of the District of Columbia Home Rule Act, approved December 24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(1)), and publication in the District of Columbia Register.