HOUSE BILL 584

J1, J2, C3 (7lr1545)

ENROLLED BILL

— Health and Government Operations/Finance —

Introduced by **Delegates K. Young, Pena–Melnyk, Anderton, Frush, Grammer, Gutierrez, Hixson, Jalisi, Kaiser, Krebs, Lierman, Lisanti, McComas, McCray, McMillan, Metzgar, Rose, Turner, ~~and Vogt~~ Vogt, Angel, Barron, Bromwell, Cullison, Hayes, Hill, Kelly, Kipke, Miele, Morales, Morgan, Pendergrass, Platt, Rosenberg, Saab, Sample–Hughes, Szeliga, and West**

Read and Examined by Proofreaders:

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Proofreader.

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Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this _____ day of _____ at _____ o'clock, _____M.

_____

Speaker.

CHAPTER _____

AN ACT concerning

Investigational Drugs, Biological Products, and Devices – Right to Try Act

FOR the purpose of authorizing a manufacturer of an investigational drug, biological product, or device to provide the investigational drug, biological product, or device to certain patients; specifying the manner in which an investigational drug, biological product, or device may be provided to certain patients; authorizing a manufacturer of an investigational drug, biological product, or device to require an eligible patient to pay certain costs, subject to certain limitations; ~~establishing that the heirs of certain patients are not liable for certain debts~~ requiring a manufacturer of an investigational drug, biological product, or device to notify a certain patient and a certain health care provider of certain side effects or risks; requiring the Office of the

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.
Underlining indicates amendments to bill.
~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.
Italics indicate opposite chamber/conference committee amendments.

Attorney General to develop an informed consent form that meets certain requirements; providing for the construction of certain provisions of this Act; ~~establishing that a certain manufacturer may enforce a certain claim against the estate of a certain patient, but not the patient's heirs or legatees, except under certain circumstances;~~ prohibiting a health occupations board, under certain circumstances, from revoking, failing to renew, suspending, or taking certain action against a health care provider's license based solely on a certain recommendation of the health care provider; prohibiting the Department of Health and Mental Hygiene from taking action against a health care provider's Medicare certification based solely on a certain recommendation of the health care provider or certain treatment provided by a health care provider; prohibiting an official, employee, or agent of the State from blocking or attempting to block a certain patient's access to an investigational drug, biological product, or device; establishing that this Act does not create a certain cause of action; providing for the effect of certain provisions of this Act; defining certain terms; and generally relating to the provision of investigational drugs, biological products, and devices in the State.

BY adding to
Article – Health – General
Section 21–2B–01 through ~~21–2B–07~~ *21–2B–06* to be under the new subtitle "Subtitle 2B. Right to Try Act"
Annotated Code of Maryland
(2015 Replacement Volume and 2016 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health – General

SUBTITLE 2B. RIGHT TO TRY ACT.

21–2B–01.

(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(B) "CARRIER" HAS THE MEANING STATED IN § 15–10A–01(C) OF THE INSURANCE ARTICLE.

~~(B)~~ (C) "ELIGIBLE PATIENT" MEANS AN INDIVIDUAL WHO:

(1) HAS A TERMINAL ILLNESS, ATTESTED TO BY THE INDIVIDUAL'S TREATING PHYSICIAN;

(2) HAS CONSIDERED ALL OTHER TREATMENT OPTIONS CURRENTLY APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION;

(3) HAS RECEIVED A RECOMMENDATION FROM THE INDIVIDUAL'S TREATING PHYSICIAN FOR THE USE OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE;

(4) (I) HAS GIVEN INFORMED CONSENT FOR THE USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE; OR

(II) IF THE INDIVIDUAL IS A MINOR OR LACKS THE MENTAL CAPACITY TO PROVIDE INFORMED CONSENT, HAS A PARENT OR LEGAL GUARDIAN WHO HAS GIVEN INFORMED CONSENT ON THE INDIVIDUAL'S BEHALF FOR THE USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE;

(5) IS INELIGIBLE FOR OR UNABLE TO PARTICIPATE IN A CLINICAL TRIAL; AND

(6) HAS DOCUMENTATION FROM THE INDIVIDUAL'S TREATING PHYSICIAN THAT THE INDIVIDUAL MEETS THE REQUIREMENTS OF ITEMS (1) THROUGH (5) OF THIS SUBSECTION.

~~(C)~~ (D) "HEALTH OCCUPATIONS BOARD" MEANS A BOARD ESTABLISHED UNDER THE HEALTH OCCUPATIONS ARTICLE THAT ISSUES LICENSES TO PRACTICE A HEALTH OCCUPATION IN THE STATE.

~~(D)~~ (E) "INFORMED CONSENT" MEANS A WRITTEN DOCUMENT *PREPARED USING THE INFORMED CONSENT FORM DEVELOPED BY THE OFFICE OF THE ATTORNEY GENERAL IN ACCORDANCE WITH § 21–2B–02(D)(1) OF THIS SUBTITLE* THAT:

(1) IS SIGNED BY THE PATIENT OR A PARENT OR LEGAL GUARDIAN OF THE PATIENT;

(2) IS ATTESTED TO BY THE PATIENT'S TREATING PHYSICIAN AND A WITNESS; AND

(3) AT A MINIMUM:

(I) EXPLAINS THE CURRENTLY APPROVED PRODUCTS AND TREATMENTS FOR THE DISEASE OR CONDITION FROM WHICH THE PATIENT SUFFERS;

(II) ATTESTS TO THE FACT THAT THE PATIENT CONCURS WITH THE PATIENT'S TREATING PHYSICIAN IN BELIEVING THAT ALL CURRENTLY

APPROVED AND CONVENTIONALLY RECOGNIZED TREATMENTS ARE UNLIKELY TO PROLONG THE PATIENT'S LIFE;

(III) IDENTIFIES CLEARLY THE SPECIFIC PROPOSED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE THAT THE PATIENT IS SEEKING TO USE;

(IV) INFORMS THE PROVIDER AND ELIGIBLE PATIENT OF ANY KNOWN OR ANTICIPATED SIDE EFFECTS, RISKS, OR REPORTED PATIENT DISCOMFORT THAT IS LIKELY RELATED TO THE TREATMENT;

~~(IV)~~ (V) DESCRIBES THE BEST AND WORST POTENTIAL OUTCOMES OF USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE WITH 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, BASED ON THE TREATING PHYSICIAN'S KNOWLEDGE OF THE PROPOSED TREATMENT IN CONJUNCTION WITH AN AWARENESS OF THE PATIENT'S CONDITION;

~~(V)~~ (VI) MAKES CLEAR THAT THE PATIENT'S ~~HEALTH INSURANCE~~ CARRIER AND HEALTH CARE PROVIDER ARE NOT OBLIGATED TO PAY FOR ANY CARE OR TREATMENTS THAT ~~MAY BE~~ ARE NECESSARY AS A RESULT OF THE USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE ~~UNLESS THEY ARE SPECIFICALLY REQUIRED TO DO SO BY~~ EXCEPT AS REQUIRED BY FEDERAL OR STATE LAW OR CONTRACT;

~~(VI)~~ (VII) MAKES CLEAR 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 HOSPICE CARE MAY BE REINSTATED IF THIS TREATMENT ENDS AND THE PATIENT MEETS HOSPICE ELIGIBILITY REQUIREMENTS; AND

**~~(VII)~~ (VIII) STATES THAT THE PATIENT UNDERSTANDS THAT THE PATIENT ~~IS~~ MAY BE LIABLE FOR ALL EXPENSES RELATING TO THE USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE AND THAT THIS LIABILITY EXTENDS TO THE PATIENT'S ESTATE, BUT NOT THE HEIRS OR LEGATEES OF THE PATIENT~~, UNLESS A CONTRACT BETWEEN THE PATIENT AND THE MANUFACTURER OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE STATES OTHERWISE~~.~~

~~(E)~~ (F) "INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE" MEANS A DRUG, BIOLOGICAL PRODUCT, OR DEVICE THAT:

(1) HAS SUCCESSFULLY COMPLETED PHASE I OF A CLINICAL TRIAL BUT HAS NOT YET BEEN APPROVED FOR GENERAL USE BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION; AND

(2) REMAINS UNDER INVESTIGATION OR IN A CLINICAL TRIAL APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

~~(F)~~ (G) "TERMINAL ILLNESS" MEANS A DISEASE OR CONDITION THAT, WITHOUT LIFE–SUSTAINING PROCEDURES, WILL RESULT IN DEATH OR A STATE OF PERMANENT UNCONSCIOUSNESS FROM WHICH RECOVERY IS UNLIKELY WITHIN 12 MONTHS.

21–2B–02.

(A) A MANUFACTURER OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE MAY:

(1) PROVIDE THE MANUFACTURER'S INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE TO AN ELIGIBLE PATIENT WITHOUT COMPENSATION; OR

(2) SUBJECT TO SUBSECTION (B) OF THIS SECTION, REQUIRE AN ELIGIBLE PATIENT TO PAY THE COSTS OF OR ASSOCIATED WITH THE MANUFACTURE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE PROVIDED TO THE ELIGIBLE PATIENT.

(B) (1) ANY PAYMENT REQUIRED BY A MANUFACTURER UNDER SUBSECTION (A)(2) OF THIS SECTION SHALL BE LIMITED TO THE RECOVERY OF THE COSTS OF OR ASSOCIATED WITH THE MANUFACTURE OF THE SPECIFIC INVESTIGATIONAL DRUG OR BIOLOGICAL PRODUCT DOSAGES OR DEVICES PROVIDED TO THE ELIGIBLE PATIENT.

(2) A MANUFACTURER OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE MAY NOT PROFIT FROM PROVIDING AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE PROVIDED TO AN ELIGIBLE PATIENT.

(C) AFTER THE DATE THAT AN ELIGIBLE PATIENT BEGINS TAKING OR USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE AND DURING THE TIME THE ELIGIBLE PATIENT IS TAKING OR USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, THE MANUFACTURER SHALL NOTIFY THE ELIGIBLE PATIENT AND THE ELIGIBLE PATIENT'S HEALTH CARE PROVIDER OF ANY SIDE EFFECTS OR RISKS ASSOCIATED WITH THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE THAT ARE REQUIRED TO BE DISCLOSED TO THE

UNITED STATES FOOD AND DRUG ADMINISTRATION DURING THE DRUG APPROVAL PROCESS.

(D) (1) THE OFFICE OF THE ATTORNEY GENERAL SHALL DEVELOP AN INFORMED CONSENT FORM THAT:

(I) COMPLIES WITH THE REQUIREMENTS OF ~~§ 21–2B–01(D)(3)~~ *§ 21–2B–01(E)(3)* OF THIS SUBTITLE;

(II) INCLUDES INSTRUCTIONS FOR THE PHYSICIAN OR PATIENT ON HOW TO COMPLETE THE FORM; AND

(III) PROVIDES SPACES FOR A PHYSICIAN TO INCLUDE THE INFORMATION RELATING TO A PARTICULAR PATIENT AND THE PHYSICIAN'S RECOMMENDATION FOR THE PATIENT.

(2) THIS SUBSECTION MAY NOT BE CONSTRUED TO PROHIBIT A TREATING PHYSICIAN OR A MANUFACTURER OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE FROM INCLUDING ADDITIONAL INFORMATION OR ADVISEMENTS WITH THE INFORMED CONSENT FORM DEVELOPED UNDER PARAGRAPH (1) OF THIS SUBSECTION.

21–2B–03.

~~IF AN ELIGIBLE PATIENT DIES WHILE BEING TREATED WITH AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, THE ELIGIBLE PATIENT'S HEIRS ARE NOT LIABLE~~ ~~MANUFACTURER OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE MAY ENFORCE A CLAIM AGAINST THE ESTATE OF THE ELIGIBLE PATIENT, BUT NOT THE ELIGIBLE PATIENT'S HEIRS OR LEGATEES, FOR ANY OUTSTANDING DEBT RELATED TO THE TREATMENT OR LACK OF INSURANCE COVERAGE FOR THE TREATMENT UNLESS A CONTRACT BETWEEN THE ELIGIBLE PATIENT AND THE MANUFACTURER STATES OTHERWISE.~~

~~**21–2B–04.**~~

(A) A HEALTH OCCUPATIONS BOARD MAY NOT REVOKE, FAIL TO RENEW, SUSPEND, OR TAKE ANY ACTION AGAINST A HEALTH CARE PROVIDER'S LICENSE BASED SOLELY ON THE HEALTH CARE PROVIDER'S RECOMMENDATION TO AN ELIGIBLE PATIENT REGARDING ACCESS TO OR TREATMENT WITH AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE~~~~, PROVIDED THE RECOMMENDATION IS CONSISTENT WITH MEDICAL STANDARDS OF CARE~~.**

(B) THE DEPARTMENT MAY NOT TAKE ACTION AGAINST A HEALTH CARE PROVIDER'S MEDICARE CERTIFICATION BASED SOLELY ON THE HEALTH CARE

PROVIDER'S RECOMMENDATION THAT AN ELIGIBLE PATIENT HAVE ACCESS TO AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE OR THE HEALTH CARE PROVIDER'S TREATMENT OF AN ELIGIBLE PATIENT WITH AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE.

~~**21–2B–05.**~~ ***21–2B–04.***

(A) AN OFFICIAL, EMPLOYEE, OR AGENT OF THE STATE MAY NOT BLOCK OR ATTEMPT TO BLOCK AN ELIGIBLE PATIENT'S ACCESS TO AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE.

(B) THIS SECTION DOES NOT PROHIBIT A LICENSED HEALTH CARE PROVIDER FROM PROVIDING COUNSEL, ADVICE, OR A RECOMMENDATION THAT IS CONSISTENT WITH MEDICAL STANDARDS OF CARE.

~~**21–2B–06.**~~ ***21–2B–05.***

THIS SUBTITLE DOES NOT CREATE A PRIVATE CAUSE OF ACTION AGAINST A MANUFACTURER OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE OR AGAINST ANOTHER PERSON INVOLVED IN THE CARE OF AN ELIGIBLE PATIENT USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE FOR ANY HARM TO THE ELIGIBLE PATIENT RESULTING FROM THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE IF THE MANUFACTURER OR OTHER PERSON IS COMPLYING IN GOOD FAITH WITH THIS SUBTITLE AND HAS EXERCISED REASONABLE CARE.

~~**21–2B–07.**~~ ***21–2B–06.***

THIS SUBTITLE DOES NOT AFFECT THE COVERAGE REQUIREMENTS UNDER TITLE 15, SUBTITLE 8 OF THE INSURANCE ARTICLE.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2017.