

SENATE BILL 572

J1, J2, C3

7lr1349
CF HB 584

By: ~~Senator Simonaire~~ Senators Simonaire, Middleton, Astle, Benson, Feldman,
Hershey, Jennings, Klausmeier, Mathias, Oaks, Reilly, and Rosapepe

Introduced and read first time: February 2, 2017

Assigned to: Finance

Committee Report: Favorable with amendments

Senate action: Adopted with floor amendments

Read second time: March 24, 2017

CHAPTER _____

1 AN ACT concerning

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

3 FOR the purpose of authorizing a manufacturer of an investigational drug, biological
4 product, or device to provide the investigational drug, biological product, or device to
5 certain patients; specifying the manner in which an investigational drug, biological
6 product, or device may be provided to certain patients; authorizing a manufacturer
7 of an investigational drug, biological product, or device to require an eligible patient
8 to pay certain costs, subject to certain limitations; ~~establishing that the heirs of~~
9 ~~certain patients are not liable for certain debts~~ requiring a manufacturer of an
10 investigational drug, biological product, or device to notify a certain patient and a
11 certain health care provider of certain side effects or risks; requiring the Office of the
12 Attorney General to develop an informed consent form that meets certain
13 requirements; providing for the construction of certain provisions of this Act;
14 ~~establishing that a certain manufacturer may enforce a certain claim against the~~
15 ~~estate of a certain patient, but not the patient's heirs or legatees, except under~~
16 ~~certain circumstances;~~ prohibiting a health occupations board, under certain
17 circumstances, from revoking, failing to renew, suspending, or taking certain action
18 against a health care provider's license based solely on a certain recommendation of
19 the health care provider; prohibiting the Department of Health and Mental Hygiene
20 from taking action against a health care provider's Medicare certification based
21 solely on a certain recommendation of the health care provider or certain treatment
22 provided by a health care provider; prohibiting an official, employee, or agent of the
23 State from blocking or attempting to block a certain patient's access to an
24 investigational drug, biological product, or device; establishing that this Act does not

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.



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.

~~(D)~~ (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

1 DEVICE WITH A REALISTIC DESCRIPTION OF THE MOST LIKELY OUTCOME,
2 INCLUDING THE POSSIBILITY THAT NEW, UNANTICIPATED, DIFFERENT, OR WORSE
3 SYMPTOMS MIGHT RESULT AND THAT DEATH COULD BE HASTENED BY THE
4 PROPOSED TREATMENT, BASED ON THE TREATING PHYSICIAN'S KNOWLEDGE OF
5 THE PROPOSED TREATMENT IN CONJUNCTION WITH AN AWARENESS OF THE
6 PATIENT'S CONDITION;

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

13 ~~(VI)~~ (VII) MAKES CLEAR THAT THE PATIENT'S ELIGIBILITY FOR
14 HOSPICE CARE MAY BE WITHDRAWN IF THE PATIENT BEGINS CURATIVE TREATMENT
15 WITH THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE AND THAT
16 HOSPICE CARE MAY BE REINSTATED IF THIS TREATMENT ENDS AND THE PATIENT
17 MEETS HOSPICE ELIGIBILITY REQUIREMENTS; AND

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

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

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

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

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

(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 THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE AND DURING THE TIME THE ELIGIBLE PATIENT IS TAKING 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 U. S. 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.

1 ~~21-2B-06.~~ 21-2B-05.

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

10 ~~21-2B-07.~~ 21-2B-06.

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

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

Approved:

Governor.

President of the Senate.

Speaker of the House of Delegates.