

HOUSE BILL 584

J1, J2, C3

(7lr1545)

ENROLLED BILL

— *Health and Government Operations/Finance* —

Introduced by **Delegates K. Young, Pena–Melnik, 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:

Proofreader.

Proofreader.

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

Speaker.

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

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.

~~(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

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

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

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

9 ~~(IV)~~ (V) DESCRIBES THE BEST AND WORST POTENTIAL
10 OUTCOMES OF USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR
11 DEVICE WITH A REALISTIC DESCRIPTION OF THE MOST LIKELY OUTCOME,
12 INCLUDING THE POSSIBILITY THAT NEW, UNANTICIPATED, DIFFERENT, OR WORSE
13 SYMPTOMS MIGHT RESULT AND THAT DEATH COULD BE HASTENED BY THE
14 PROPOSED TREATMENT, BASED ON THE TREATING PHYSICIAN'S KNOWLEDGE OF
15 THE PROPOSED TREATMENT IN CONJUNCTION WITH AN AWARENESS OF THE
16 PATIENT'S CONDITION;

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

23 ~~(VI)~~ (VII) MAKES CLEAR THAT THE PATIENT'S ELIGIBILITY FOR
24 HOSPICE CARE MAY BE WITHDRAWN IF THE PATIENT BEGINS CURATIVE TREATMENT
25 WITH THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE AND THAT
26 HOSPICE CARE MAY BE REINSTATED IF THIS TREATMENT ENDS AND THE PATIENT
27 MEETS HOSPICE ELIGIBILITY REQUIREMENTS; AND

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

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

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

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

6 ~~(F)~~ (G) “TERMINAL ILLNESS” MEANS A DISEASE OR CONDITION THAT,
7 WITHOUT LIFE-SUSTAINING PROCEDURES, WILL RESULT IN DEATH OR A STATE OF
8 PERMANENT UNCONSCIOUSNESS FROM WHICH RECOVERY IS UNLIKELY WITHIN 12
9 MONTHS.

10 21-2B-02.

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

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

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

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

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

28 (C) AFTER THE DATE THAT AN ELIGIBLE PATIENT BEGINS TAKING OR USING
29 THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE AND DURING THE
30 TIME THE ELIGIBLE PATIENT IS TAKING OR USING THE INVESTIGATIONAL DRUG,
31 BIOLOGICAL PRODUCT, OR DEVICE, THE MANUFACTURER SHALL NOTIFY THE
32 ELIGIBLE PATIENT AND THE ELIGIBLE PATIENT’S HEALTH CARE PROVIDER OF ANY
33 SIDE EFFECTS OR RISKS ASSOCIATED WITH THE INVESTIGATIONAL DRUG,
34 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

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

5 ~~21-2B-05.~~ 21-2B-04.

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

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

12 ~~21-2B-06.~~ 21-2B-05.

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

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

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

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