

# HOUSE BILL 1426

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CF SB 778

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By: **Delegate Solomon**

Introduced and read first time: February 13, 2026

Assigned to: Health

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## A BILL ENTITLED

1 AN ACT concerning

2 **Clinical Research Pharmacies and Clinical Trials – Permits, Ownership, and**  
3 **Definition of Practice of Medicine**

4 FOR the purpose of establishing a clinical research pharmacy permit; authorizing the State  
5 Board of Pharmacy to issue a clinical research pharmacy permit; authorizing a  
6 health care provider to hold an ownership interest in a clinical research pharmacy  
7 under certain circumstances; exempting the conduct of an investigational or  
8 experimental treatment or clinical trial by a corporation or other legal entity from  
9 the definition of “practice medicine” for purposes of certain provisions of law  
10 requiring that an individual be licensed in the State to practice medicine; and  
11 generally relating to clinical research pharmacies and clinical trials.

12 BY repealing and reenacting, without amendments,  
13 Article – Health Occupations  
14 Section 12–101(a), (d), (f), (j), (k), (l), (p), and (t) and 14–101(a)  
15 Annotated Code of Maryland  
16 (2021 Replacement Volume and 2025 Supplement)

17 BY adding to  
18 Article – Health Occupations  
19 Section 12–101(d–1) and (d–2), 12–102(c)(2)(vii), and 12–401.1  
20 Annotated Code of Maryland  
21 (2021 Replacement Volume and 2025 Supplement)

22 BY repealing and reenacting, with amendments,  
23 Article – Health Occupations  
24 Section 12–101(d–1), 12–102(c)(2)(v) and (vi), and 14–101(o)  
25 Annotated Code of Maryland  
26 (2021 Replacement Volume and 2025 Supplement)

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



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

3 **Article – Health Occupations**

4 12–101.

5 (a) In this title the following words have the meanings indicated.

6 (d) “Board” means the State Board of Pharmacy.

7 **(D–1) “CLINICAL RESEARCH PHARMACY” MEANS A PHARMACY THAT MEETS**  
8 **THE REQUIREMENTS FOR A CLINICAL RESEARCH PHARMACY PERMIT UNDER §**  
9 **12–401.1(C) OF THIS TITLE.**

10 **(D–2) “CLINICAL RESEARCH PHARMACY PERMIT” MEANS A PERMIT ISSUED BY**  
11 **THE BOARD TO ESTABLISH AND OPERATE A CLINICAL RESEARCH PHARMACY.**

12 ~~[(d–1)]~~ **(D–3)** “Compounded nonsterile preparations” means products  
13 compounded in accordance with USP 795.

14 (f) (1) “Compounding” means the preparation, mixing, assembling, packaging,  
15 or labeling of a drug or device:

16 (i) As the result of a practitioner’s prescription drug order or  
17 initiative based on the practitioner/patient/pharmacist relationship in the course of  
18 professional practice; or

19 (ii) For the purpose of, or incident to, research, teaching, or chemical  
20 analysis and not for the sale or dispensing of the drug or device.

21 (2) “Compounding” includes the preparation of drugs or devices in  
22 anticipation of a prescription drug order based on routine, regularly observed prescribing  
23 patterns.

24 (j) “Dispense” or “dispensing” means the procedure which results in the receipt  
25 of a prescription or nonprescription drug or device by a patient or the patient’s agent and  
26 which entails the:

27 (1) Interpretation of an authorized prescriber’s prescription for a drug or  
28 device;

29 (2) Selection and labeling of the drug or device prescribed pursuant to that  
30 prescription; and

1 (3) Measuring and packaging of the prescribed drug or device in accordance  
2 with State and federal laws.

3 (k) (1) “Distribute” means the process resulting in the provision of a  
4 prescription or nonprescription drug or device to a separate, intervening individual,  
5 licensed and practicing under this article, prior to administration of the provided drug or  
6 device to the patient pursuant to a prescription issued by an authorized prescriber.

7 (2) “Distribute” does not include the operations of a person who holds a  
8 permit issued under § 12–6C–03 of this title.

9 (l) “Drug” has the meaning stated in § 21–101 of the Health – General Article.

10 (p) “Nonprescription drug” means a drug which may be sold without a  
11 prescription and which is labeled for use by the consumer in accordance with the  
12 requirements of the laws and regulations of this State and the federal government.

13 (t) “Pharmacy” means an establishment in which prescription or nonprescription  
14 drugs or devices are compounded, dispensed, or distributed.

15 12–102.

16 (c) (2) This title does not prohibit:

17 (v) A hospital–based clinic from dispensing prescriptions to its  
18 patients; [or]

19 (vi) An individual licensed or certified under Title 8 of this article  
20 from personally preparing and dispensing a drug or device as authorized under Title 8 of  
21 this article; OR

22 (VII) A HEALTH CARE PROVIDER LICENSED UNDER THIS ARTICLE  
23 FROM HAVING AN OWNERSHIP INTEREST IN A CLINICAL RESEARCH PHARMACY IF:

24 1. THE OPERATIONS OF THE CLINICAL RESEARCH  
25 PHARMACY ARE LIMITED TO THE REQUIREMENTS FOR A CLINICAL RESEARCH  
26 PHARMACY PERMIT IN § 12–101 OF THIS SUBTITLE;

27 2. A PHARMACIST LICENSED UNDER THIS SUBTITLE:

28 A. IS PRESENT ON–SITE DURING ALL HOURS OF  
29 OPERATION OF THE CLINICAL RESEARCH PHARMACY; AND

30 B. IS RESPONSIBLE FOR ALL COMPOUNDING,  
31 DISPENSING, AND OVERSIGHT OF PHARMACY SERVICES; AND

1                   **3. ANY HEALTH CARE PROVIDER WITH A SUBSTANTIAL**  
2 **OWNERSHIP INTEREST IN THE CLINICAL RESEARCH PHARMACY DOES NOT:**

3                   **A. DIRECT PATIENTS TO A SINGLE PHARMACIST OR**  
4 **PHARMACY IN ACCORDANCE WITH § 12-403(C)(8) OF THIS TITLE; OR**

5                   **B. RECEIVE REMUNERATION FOR REFERRING PATIENTS**  
6 **TO A PHARMACIST OR PHARMACY.**

7 **12-401.1.**

8                   **(A) A PERSON SHALL HOLD A CLINICAL RESEARCH PHARMACY PERMIT**  
9 **ISSUED BY THE BOARD BEFORE THE PERSON MAY ESTABLISH OR OPERATE A**  
10 **CLINICAL RESEARCH PHARMACY IN THE STATE.**

11                   **(B) A SEPARATE CLINICAL RESEARCH PHARMACY PERMIT IS REQUIRED**  
12 **FOR EACH CLINICAL RESEARCH PHARMACY THAT A PERSON ESTABLISHES OR**  
13 **OPERATES.**

14                   **(C) THE BOARD MAY ISSUE A CLINICAL RESEARCH PHARMACY PERMIT TO A**  
15 **PHARMACY THAT:**

16                   **(1) EXCLUSIVELY COMPOUNDS, DISPENSES, OR DISTRIBUTES**  
17 **PRESCRIPTION OR NONPRESCRIPTION DRUGS AS PART OF SCIENTIFIC RESEARCH**  
18 **CONDUCTED UNDER PROTOCOLS ESTABLISHED BY AN INSTITUTIONAL REVIEW**  
19 **BOARD THAT MEET U.S. FOOD AND DRUG ADMINISTRATION GUIDELINES;**

20                   **(2) COMPOUNDS, DISPENSES, OR DISTRIBUTES PHARMACEUTICALS**  
21 **SOLELY INCIDENT TO THE RESEARCH BEING CONDUCTED AND CONSISTENT WITH**  
22 **RELATED PROTOCOLS;**

23                   **(3) IS NOT OPEN TO THE GENERAL PUBLIC FOR RETAIL**  
24 **PHARMACEUTICAL SERVICES AND IS STRICTLY LIMITED TO DISPENSING TO**  
25 **PARTICIPANTS IN A CLINICAL TRIAL;**

26                   **(4) COMPLIES WITH SECURITY AND STORAGE PROTOCOLS**  
27 **ESTABLISHED BY UNITED STATES PHARMACOPEIA AND THE BOARD; AND**

28                   **(5) SATISFIES ANY OTHER REQUIREMENT ESTABLISHED BY THE**  
29 **BOARD IN REGULATION.**

1           **(D) (1) THE BOARD SHALL ADOPT REGULATIONS TO CARRY OUT THIS**  
2 **SECTION.**

3           **(2) THE REGULATIONS ADOPTED BY THE BOARD SHALL INCLUDE:**

4                   **(I) REQUIRED STANDARDS FOR THE OPERATION OF A**  
5 **CLINICAL RESEARCH PHARMACY;**

6                   **(II) APPLICATION PROCEDURES;**

7                   **(III) STANDARDS FOR THE SUSPENSION AND REVOCATION OF A**  
8 **CLINICAL RESEARCH PHARMACY PERMIT; AND**

9                   **(IV) REQUIREMENTS RELATED TO THE ENTRY AND INSPECTION**  
10 **OF CLINICAL RESEARCH PHARMACIES.**

11           **(E) THIS SECTION DOES NOT LIMIT:**

12                   **(1) THE RIGHT OF AN INDIVIDUAL TO PRACTICE A HEALTH**  
13 **OCCUPATION THAT THE INDIVIDUAL IS AUTHORIZED TO PRACTICE UNDER THIS**  
14 **ARTICLE; OR**

15                   **(2) THE RIGHT OF A PERSON TO ESTABLISH OR OPERATE A**  
16 **PHARMACY UNDER OTHER PROVISIONS OF THIS TITLE.**

17 14-101.

18           (a) In this title the following words have the meanings indicated.

19           (o) (1) "Practice medicine" means to engage, with or without compensation, in  
20 medical:

21                   (i) Diagnosis;

22                   (ii) Healing;

23                   (iii) Treatment; or

24                   (iv) Surgery.

25           (2) "Practice medicine" includes doing, undertaking, professing to do, and  
26 attempting any of the following:

27                   (i) Diagnosing, healing, treating, preventing, prescribing for, or  
28 removing any physical, mental, or emotional ailment or supposed ailment of an individual:

1                           1.     By physical, mental, emotional, or other process that is  
2 exercised or invoked by the practitioner, the patient, or both; or

3                           2.     By appliance, test, drug, operation, or treatment;

4                           (ii)   Ending of a human pregnancy; and

5                           (iii)   Performing acupuncture as provided under § 14–504 of this title.

6                   (3)   “Practice medicine” does not include:

7                           (i)     Selling any nonprescription drug or medicine;

8                           (ii)    Practicing as an optician; [or]

9                           (iii)   Performing a massage or other manipulation by hand, but by no  
10 other means; **OR**

11                   **(IV)   CONDUCTING AN INVESTIGATIONAL OR EXPERIMENTAL**  
12 **TREATMENT OR CLINICAL TRIAL BY A CORPORATION OR OTHER LEGAL ENTITY THAT**  
13 **IS NOT AN INDIVIDUAL LICENSED UNDER THIS TITLE IF:**

14                           **1.     THE INVESTIGATIONAL OR EXPERIMENTAL**  
15 **TREATMENT OR CLINICAL TRIAL IS CONDUCTED IN ACCORDANCE WITH PROTOCOLS**  
16 **REGISTERED BY THE U.S. FOOD AND DRUG ADMINISTRATION, THE EUROPEAN**  
17 **MEDICINES AGENCY, OR ANOTHER OFFICIAL INTERNATIONAL BODY AND IN**  
18 **COMPLIANCE WITH ALL APPLICABLE ETHICAL GUIDELINES AND FEDERAL AND**  
19 **STATE REGULATIONS GOVERNING HUMAN SUBJECTS RESEARCH;**

20                           **2.     ALL MEDICAL DECISION MAKING WITHIN THE**  
21 **CLINICAL TRIAL IS CARRIED OUT BY INDIVIDUALS WHO ARE LICENSED UNDER THIS**  
22 **ARTICLE; AND**

23                           **3.     THE CORPORATION OR OTHER ENTITY CONDUCTING**  
24 **THE TRIAL DOES NOT ENGAGE IN THE GENERAL PRACTICE OF MEDICINE OR**  
25 **PROVIDE CLINICAL PATIENT CARE OUTSIDE THE SCOPE OF THE REGISTERED**  
26 **CLINICAL TRIAL.**

27                   SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect  
28 October 1, 2026.