Chapter 206

(Senate Bill 778)

AN ACT concerning

Clinical Research Pharmacies and Clinical Trials – Permits~~,~~ and Ownership~~, and Definition of Practice of Medicine~~

FOR the purpose of establishing a clinical research pharmacy permit; authorizing the State Board of Pharmacy to issue a clinical research pharmacy permit; authorizing a health care provider to hold an ownership interest in a clinical research pharmacy under certain circumstances; ~~exempting the conduct of an investigational or experimental treatment or clinical trial by a corporation or other legal entity from the definition of "practice medicine" for purposes of certain provisions of law requiring that an individual be licensed in the State to practice medicine~~ prohibiting an individual from being required to obtain a license, certification, or authorization to practice under certain provisions of law to own or have an ownership interest in a clinical research pharmacy; authorizing certain health occupations boards to investigate certain allegations, under certain circumstances; and generally relating to clinical research pharmacies and clinical trials.

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

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

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

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

Article – Health Occupations

12–101.

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

(d) "Board" means the State Board of Pharmacy.

(D–1) "CLINICAL RESEARCH PHARMACY" MEANS A PHARMACY THAT MEETS THE REQUIREMENTS FOR A CLINICAL RESEARCH PHARMACY PERMIT UNDER § 12–401.1(C) OF THIS TITLE.

(D–2) "CLINICAL RESEARCH PHARMACY PERMIT" MEANS A PERMIT ISSUED BY THE BOARD TO ESTABLISH AND OPERATE A CLINICAL RESEARCH PHARMACY.

[(d–1)**] (D–3)** "Compounded nonsterile preparations" means products compounded in accordance with USP 795.

(f) (1) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

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

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

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

(j) "Dispense" or "dispensing" means the procedure which results in the receipt of a prescription or nonprescription drug or device by a patient or the patient's agent and which entails the:

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

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

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

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

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

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

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

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

12–102.

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

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

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

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

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

2. A PHARMACIST LICENSED UNDER THIS SUBTITLE:

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

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

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

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

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

12–401.1.

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

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

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

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

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

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

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

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

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

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

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

(II) APPLICATION PROCEDURES;

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

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

(E) EXCEPT AS OTHERWISE PROVIDED IN THIS TITLE, AN INDIVIDUAL MAY NOT BE REQUIRED TO OBTAIN A LICENSE, CERTIFICATION, OR OTHER AUTHORIZATION TO PRACTICE UNDER THIS ARTICLE TO OWN OR HAVE AN OWNERSHIP INTEREST IN A CLINICAL RESEARCH PHARMACY.

(F) (1) THE OWNERSHIP OR POSSESSION OF AN OWNERSHIP INTEREST IN A CLINICAL RESEARCH PHARMACY BY AN INDIVIDUAL WHO IS NOT LICENSED, CERTIFIED, OR OTHERWISE AUTHORIZED TO PRACTICE UNDER THIS ARTICLE MAY NOT BE THE SOLE BASIS FOR THE BOARD TO INITIATE A DISCIPLINARY ACTION AGAINST THE INDIVIDUAL.

(2) THE APPLICABLE HEALTH OCCUPATIONS BOARD MAY INVESTIGATE AN ALLEGATION THAT AN INDIVIDUAL EMPLOYED BY A CLINICAL RESEARCH PHARMACY:

(I) IS PRACTICING A PROFESSION REGULATED BY THE HEALTH OCCUPATIONS BOARD UNDER THIS ARTICLE WITHOUT A LICENSE, CERTIFICATE, OR OTHER AUTHORIZATION OR WITH AN UNAUTHORIZED PERSON; OR

(II) HAS VIOLATED A PROVISION OF THIS ARTICLE UNDER THE JURISDICTION OF THE HEALTH OCCUPATIONS BOARD.

(G) A HEALTH CARE PROVIDER WITH A SUBSTANTIAL OWNERSHIP INTEREST IN A CLINICAL RESEARCH PHARMACY MAY NOT:

(1) SERVE AS A CLINICAL INVESTIGATOR FOR A SCIENTIFIC RESEARCH PROTOCOL CONDUCTED BY THE CLINICAL RESEARCH PHARMACY; OR

(2) IMPEDE OR IMPAIR A PHARMACIST'S ABILITY TO FULLY EXERCISE THE PHARMACIST'S PROFESSIONAL JUDGMENT.

(H) THIS SECTION DOES NOT LIMIT:

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

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

~~14–101.~~

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

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

~~(i) Diagnosis;~~

~~(ii) Healing;~~

~~(iii) Treatment; or~~

~~(iv) Surgery.~~

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

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

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

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

~~(ii) Ending of a human pregnancy; and~~

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

~~(3) "Practice medicine" does not include:~~

~~(i) Selling any nonprescription drug or medicine;~~

~~(ii) Practicing as an optician; **[**or**]**~~

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

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

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

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

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

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

Approved by the Governor, April 28, 2026.