

Department of Legislative Services
 Maryland General Assembly
 2026 Session

FISCAL AND POLICY NOTE
 Third Reader - Revised

House Bill 1426
 Health

(Delegate Solomon, *et al.*)

Rules

Clinical Research Pharmacies and Clinical Trials - Permits and Ownership

This bill authorizes the Maryland Board of Pharmacy (MBOP) to issue a clinical research pharmacy permit. A permit may be issued to a pharmacy that (1) exclusively compounds, dispenses, or distributes drugs as part of scientific research conducted under specified protocols; (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 specified security and storage protocols; and (5) satisfies any other board requirements. MBOP must adopt specified regulations for clinical research pharmacies. The bill also authorizes certain health care providers to have ownership interests in a clinical research pharmacy and authorizes a health occupations board to investigate certain allegations related to clinical research pharmacies.

Fiscal Summary

State Effect: MBOP special fund expenditures increase by at least \$85,600 in FY 2027 for staff, as discussed below. MBOP special fund revenues increase by an indeterminate but likely minimal amount as early as FY 2027 to the extent the board implements an application or permit fee and issues permits.

(in dollars)	FY 2027	FY 2028	FY 2029	FY 2030	FY 2031
SF Revenue	-	-	-	-	-
SF Expenditure	\$85,600	\$100,500	\$105,200	\$110,000	\$114,800
Net Effect	(\$85,600)	(\$100,500)	(\$105,200)	(\$110,000)	(\$114,800)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate increase; (-) = indeterminate decrease

Local Effect: None.

Small Business Effect: None.

Analysis

Bill Summary: A person must hold a clinical research pharmacy permit before establishing or operating a clinical research pharmacy in the State. A separate permit is required for each clinical research pharmacy that a person establishes or operates.

A health care provider licensed under MBOP may have ownership interest in a clinical research pharmacy if (1) the operations of the pharmacy are limited to the requirements for a clinical research pharmacy permit; (2) a licensed pharmacist is present on-site during all hours of operation and is responsible for all compounding, dispensing, and oversight of pharmacy services; and (3) any health care provider with a substantial ownership interest does not direct patients to a single pharmacist or pharmacy, nor do they receive remuneration for referring patients to a pharmacist or pharmacy.

Except as provided in the Title 12 of the Health Occupations Article, an individual may not be required to obtain a license, certification, or other authorization to practice under the Health Occupations Article to own or have ownership interest in a clinical research pharmacy.

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 the Health Occupations Article may not be the sole basis for MBOP to initiate disciplinary action against the individual.

The applicable health occupations board may investigate an allegation that an individual employed by a clinical research pharmacy (1) is practicing a profession regulated by the board without a license, certificate, or other authorization or with an unauthorized person or (2) has violated a provision of the Health Occupations Article under the jurisdiction of the appropriate board.

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 pharmacy or (2) impede or impair a pharmacist's ability to fully exercise professional judgment.

The board must adopt regulations that include (1) required standards for operation of a clinical research pharmacy; (2) application procedures; (3) standards for the suspension and revocation of a clinical research pharmacy permit; and (4) requirements related to the entry and inspection of clinical research pharmacies.

The bill does not limit an individual's right to practice under a health occupation that the individual is authorized to practice, nor does it limit the right of a person to establish or operate a pharmacy under other provisions of Title 14 of the Health Occupations Article.

Current Law: Generally, a physician with a dispensing permit may not hold substantial financial interest in a pharmacy.

Clinical Trials

Chapter 771 of 2017 (the Right to Try Act) permits a manufacturer of an “investigational drug, biological product, or device” to provide the investigational drug, biological product, or device to an “eligible patient.”

An “investigational drug, biological product, or device” has successfully completed Phase I of a clinical trial but has not yet been approved for general use by the U.S. Food and Drug Administration (FDA) and remains under investigation in an FDA-approved clinical trial. An “eligible patient” means an individual who has (1) a terminal illness; (2) considered all other treatment options currently approved by the FDA; (3) received a recommendation by the treating physician for the use of an investigational drug, biological product, or device; (4) given informed consent or, if the individual is a minor or lacks the mental capacity to provide informed consent, the parent or legal guardian has given informed consent; (5) been found ineligible for or unable to participate in a clinical trial; and (6) documentation from the individual's treating physician that the individual meets the other eligibility requirements.

Section 505 of the federal Food, Drug, and Cosmetic Act prohibits the sale or distribution of a drug into interstate commerce until the drug is proven safe and effective. Under FDA's Expanded Access Program, also referred to as “compassionate use,” an investigational medical product (one that has not received FDA approval) may be used outside of a clinical trial.

State Revenues: MBOP special fund revenues may increase minimally to the extent that the board requires an application or permit fee, and applicants for a clinical research pharmacy pay the fee.

State Expenditures: MBOP advises that it would require significant updates to its licensing system for the new permit. This would likely require a large information technology (IT) contract in fiscal 2027, though an exact cost cannot be estimated at this time.

Additionally, the board requires staff to manage the new permit type. The board advises it needs two part-time (75%) staff – one licensing specialist to process applications and renewals and provide customer services, and one investigator to handle compliance, complaint, and disciplinary issues. Under these circumstances, the Maryland Department

of Health special fund expenditures would increase by *at least* \$120,233 beginning in fiscal 2027. This estimate includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses. This would not include the indeterminate contractual cost mentioned above.

However, the Department of Legislative Services disagrees. Given the standards to operate as a clinical research pharmacy, it seems unlikely that enough pharmacies would apply for the permit to require two additional staff. Thus, MBOP special fund expenditures increase by *at least* \$85,616 in fiscal 2027, which accounts for the bill's October 1, 2026 effective date. This estimate reflects the cost of hiring one full-time licensing specialist to process applications, provide customer service, and handle any compliance issues under the clinical research pharmacy program. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses. It does not include any indeterminate IT contract costs.

Position	1.0
Salary and Fringe Benefits	\$76,475
Operating Expenses	<u>9,141</u>
Total FY 2027 State Expenditures	\$85,616

Future year expenditures reflect a full salary with annual increases and employee turnover as well as annual increases in ongoing operating expenses.

To the extent that the clinical research pharmacy permit program grows, the board may require additional staff in the future.

Additional Information

Recent Prior Introductions: Similar legislation has not been introduced within the last three years.

Designated Cross File: SB 778 (Senator Feldman) - Finance.

Information Source(s): Maryland Department of Health; Department of Legislative Services

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