2026 SESSION
MARYLAND BOARD OF PHARMACY
POSITION PAPER

BILL NO:	**SB 778/HB 1426 – Clinical Research Pharmacies and Clinical Trials – Permits, Ownership, and Definition of Practice of Medicine**
COMMITTEE:	**Finance Committee**
POSITION:	**Letter of Support with Amendments**

TITLE: HB 1426 – Clinical Research Pharmacies and Clinical Trials – Permits, Ownership, and Definition of Practice of Medicine

BILL ANALYSIS : The primary purpose of the bill is to facilitate clinical research by establishing new regulatory frameworks for specialized pharmacies and medical practice definitions. The bill establishes a "clinical research pharmacy permit" issued by the State Board of Pharmacy and these pharmacies are defined as establishments that exclusively compound, dispense, or distribute drugs as part of scientific research conducted under Institutional Review Board protocols. The bill also allows a licensed healthcare provider to hold an ownership interest in a clinical research pharmacy.

POSITION AND RATIONALE:

The Maryland Board of Pharmacy (the "Board") respectfully submits this testimony in support of Senate Bill 778, which would establish a clinical research pharmacy permit, authorize certain health care providers to hold an ownership interest in a clinical research pharmacy, and exempt the conduct of investigational or experimental treatment or clinical trial by a corporation or other legal entity from the definition of the "practice of medicine."

The Board recognizes the sponsors measures to modernize Maryland's regulatory framework to support the growth of clinical research in the State. Creating a dedicated permit category for clinical research pharmacies will bring important clarity to a currently unaddressed area of pharmaceutical practice and provides the Board with the regulatory authority necessary to oversee these facilities in a manner consistent with public health and safety.

The Board supports this legislation and encourages its passage. At the same time, the Board respectfully requests that the Committee adopt one targeted amendment to address a conflict-of-interest gap that, if left unresolved, would undermine the very patient safety protections this permit

framework is designed to advance. The proposed amendment would prohibit a health care provider who holds a substantial ownership interest in a clinical research pharmacy from simultaneously serving as a clinical investigator for any research protocol in which that pharmacy is participating. This addition would strengthen the bill without altering its core purpose.

As currently drafted, the bill does not address the conflict of interest that arises when a health care provider holds a substantial ownership interest in a clinical research pharmacy while serving as the clinical investigator directing a research protocol dispensed by that same pharmacy. This dual role – owner and investigator – creates a direct financial conflict of interest that places the health care provider's personal economic interests in tension with the patient's safety and welfare. A clinical investigator who owns a stake in the participating pharmacy has a financial incentive to maximize dispensing volume, expedite enrollment, and minimize safety-related interruptions to the protocol, all of which increase the pharmacy's revenue. Federal regulations under 21 CFR Part 54 already impose financial disclosure requirements on clinical investigators precisely because ownership interests have been shown to distort clinical judgment. Maryland's new clinical research pharmacy framework should not be silent where federal law has already spoken.

Most critically, this gap implicates the pharmacist's independent professional judgment, Under Maryland Health Occupations Article § 12-601, a pharmacist's paramount duty is to the patient. The independent professional judgment of the pharmacist – including the authority to evaluate, question, and when necessary decline to dispense an investigational drug order - is a patient safety requirement codified in Maryland law and enforced by this Board. A pharmacist employed in a research pharmacy owned by the clinical investigator directing the research protocol faces institutional pressures, explicit or implicit, that compromise this independence. The Board does not impute bad intent to any individual; the concern is structural. Conflicts of interest distort institutional decision-making regardless of individual good faith.

The proposed amendment addresses this concern narrowly and proportionately. It does not prohibit health care providers from holding ownership interests in clinical research pharmacies. It does not prohibit health care providers from serving as clinical investigators. It prohibits only the combination of both roles with respect to the same pharmacy and same research protocol – the precise combination that creates the structural conflict that endangers patients and impedes pharmacist independence.

The Board respectfully requests the following amendment:

A new subsection:

CONFLICT-OF-INTEREST PROHIBITION FOR CLINICAL RESEARCH

A HEALTH CARE PROVIDER THAT HAS SUBSTANTIAL OWNERSHIP IN A CLINICAL RESEARCH PHARMACY CANNOT, "SERVE AS A CLINICAL INVESTIGATOR FOR ANY RESEARCH PROTOCOL IN WHICH THE PHARMACY IS PARTICIPATING."

"A HEALTH CARE PROVIDER THAT HAS SUBSTANTIAL OWNERSHIP IN A CLINICAL RESEARCH PHARMACY MAY NOT IMPEDE OR IMPAIR A PHARMACIST'S ABILITY TO FULLY EXERCISE THAT PHARMACIST'S PROFESSIONAL JUDGMENT."

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For more information, please contact Julie Gaskins, Legislative Liaison, Maryland Board of Pharmacy (410) 764-4709.

The opinion of the Board expressed in this document does not necessarily reflect that of the Department of Health or the Administration.

Respectfully submitted,

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