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:	**Health Committee**
POSITION:	**Letter of Support As Amended**

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") writes in strong support of Senate Bill 778, as amended, which would establish a clinical research pharmacy permit under the Maryland Pharmacy Act. The Board thanks the sponsors and the General Assembly for their continued engagement with the Board on this important regulatory matter.

Maryland's existing pharmacy licensure framework does not currently provide a dedicated permit category for pharmacy operations conducted exclusively in support of FDA-regulated clinical research. As a result, institutions conducting legitimate clinical trials faced regulatory ambiguity regarding the handling, compounding, and dispensing of investigational drug products within their research programs.

The Board supports SB 778 as amended for the following reasons:

1. Patient Safety: The bill establishes clear standards for the procurement, storage, preparation, and dispensing of investigation drugs within a regulated framework overseen

by the Board. This protects research participants who may be among Maryland's most vulnerable patients.

2. Regulatory Clarity: A dedicated clinical research pharmacy permit eliminates the current uncertainty faced by academic medical centers, hospital systems, and independent research facilities operating in Maryland. Clear rules benefit both permittees and the Board's compliance and enforcement functions.
3. Alignment with National Standards: The permit structure is consistent with approaches taken by peer state pharmacy boards and reflects guidance from the National Association of Boards of Pharmacy (NABP) on the regulation of investigational drug services.
4. Operational Feasibility: The amendments address the Board's earlier concerns and allows the Board to implement effective regulatory guidelines.

The Board respectfully urges the General Assembly to pass SB 778 as amended. The Board stands ready to promulgate regulations, develop permit applications, and work collaboratively with stakeholders to implement this legislation in a manner that advances patient safety, supports Maryland's research enterprise, and upholds the integrity of the pharmacy profession.

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.