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THE MARYLAND HOUSE OF DELEGATES
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House Bill 1426 - Clinical Research Pharmacies and Clinical Trials
Health Committee
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Chair Bagnall, Vice Chair Cullison, and colleagues,

Thank you for your consideration of House Bill 1426 which would establish a new licensure category for clinical research pharmacies and allow authorized prescribers to hold ownership interests in clinical research pharmacies under appropriate safeguards.

What Does House Bill 1426 Do?

- Authorizes the State Board of Pharmacy to establish and issue a new clinical research pharmacy permit.
- Allows a health care provider to own an interest in a clinical research pharmacy with appropriate safeguards, including prohibiting physician-owners from directing patients to a single pharmacist or pharmacy in accordance with existing law, and prohibiting remuneration for referring patients to a pharmacist or pharmacy.
- Requires that a licensed pharmacist be present on-site during all hours of operation and remain responsible for all compounding, dispensing, and oversight of pharmacy services.

Medical clinical trials represent a significant economic driver for states that can successfully attract them.

Maryland currently hosts a meaningful but relatively modest share of national clinical trial activity. According to a 2023 study prepared for the Pharmaceutical Research and Manufacturers of America (PhRMA):

- (1) Maryland had 936 active clinical trials involving an estimated 18,053 participants.
- (2) The biopharmaceutical industry invested approximately \$658.3 million in direct site-based expenditures in Maryland.
- (3) These investments generated a total economic impact of approximately \$1.24 billion for *Maryland's* economy.

While Maryland benefits from the presence of world-class institutions such as the NIH Clinical Center, Johns Hopkins Hospital and the University of Maryland Medical Center, the state's industry-sponsored clinical trial activity represents only about 2.0% of national trial participants and 2.1% of direct site-based investments. Maryland ranked 14th in total economic impact, even though the BioHealth Capital Region is the third largest biohub in the country. In short, Maryland is leaving money on the table in this sector and the regulatory framework currently in place is one of the causes.

So, how can we remove barriers to clinical trial site development?

One option is before you in the form of House Bill 1426.

This bill establishes a new licensure category for clinical research pharmacies and represents a measured, evidence-based approach to removing unnecessary and burdensome barriers to clinical trial site development in Maryland, spurring economic activity in a high-impact industry sector while maintaining robust patient regulatory protections and safeguards against fraud and abuse.

Under current law, physicians are restricted from holding substantial ownership interests in pharmacies. These restrictions were set up to serve an important function in the **retail pharmacy** context, because they prevent physicians from profiting inappropriately from their prescribing practices; but those same restrictions create unintended and unnecessary obstacles for clinical research site development. By precluding physicians from holding substantial ownership interests in clinical research pharmacies, which are essential components of modern clinical trial sites, current Maryland law discourages those who are best positioned to advance medical research from establishing and engaging as owners of clinical trial facilities in the state.

To maintain and augment robust clinical trial activity in Maryland, we must incentivize both physicians and pharmacists. We need physicians who specialize in treating complicated diseases and biological disorders as they provide important input and possess unique insights into patient populations, disease progression and therapeutic needs that are essential to designing and operating successful clinical trial sites. Additionally, on-site research pharmacies are required as the pharmacists manage investigational drugs, ensure compliance with FDA-registered and Institutional Review Board-approved protocols, and maintain strict adherence to Good Clinical Practice standards.

Maryland's restrictions on physician ownership of pharmacies serve as a vital public health purpose in the retail pharmacy context. When physicians have financial interests in retail pharmacies, they may face perverse incentives to prescribe medications unnecessarily or in excessive quantities; favor more expensive branded drugs over generic alternatives; direct patients to their affiliated pharmacy rather than allowing patient choice; or otherwise allow profit motives to influence clinical judgment.

These concerns are well-founded and justify continuing to maintain strict restrictions on physician ownership of retail pharmacies. However, these same concerns are not present in the limited scope and context of clinical trials, which are governed by other strict regulatory oversight designed to protect patients and prevent abusive clinician behaviors.

The concerns that justify retail pharmacy ownership restrictions do not exist in the clinical research pharmacy context. HB 1426 recognizes this critical distinction by specifically identifying and limiting clinical research pharmacy permits to facilities that:

- (1) exclusively compound, dispense or distribute prescription drugs as part of scientific research.
- (2) dispense pharmaceuticals solely associated to the research being conducted and consistent with related protocols.
- (3) are **not** open to the general public for retail pharmaceutical services and are strictly **limited to dispensing to clinical trial participants**.
- (4) comply with security and storage protocols.

These restrictions identify a **unique type of pharmacy** and *eliminate* the anti-kickback concerns that justify retail pharmacy ownership limits. A physician with an ownership interest in a clinical research pharmacy:

- (1) could not write prescriptions for personal profit.
- (2) could not steer patients toward expensive medications.
- (3) could not operate a retail business, because the pharmacy would be prohibited from serving the general public; and
- (4) could not generate revenue from ordinary prescribing practices, because the facility would be limited strictly to clinical trial activities.

Additionally, the expansion of clinical research pharmacies would **create new career pathways for pharmacists in Maryland** as these positions offer excellent compensation and enhanced professional development. Finally, the State Board of Pharmacy will adopt regulations establishing required operational standards, suspension and revocation standards, and inspection requirements.

HB 1426 would strengthen Maryland's clinical research infrastructure, create high-quality employment opportunities for pharmacists, improve access to cutting-edge treatments for Maryland residents, and generate significant economic benefits for the state; without compromising the important patient protections that Maryland's pharmacy ownership laws are designed to safeguard. By precluding physicians from holding substantial ownership interests in clinical research pharmacies in Maryland, it discourages those who are best positioned to advance medical research from establishing and engaging as owners of clinical trial facilities in the state.

Thank you for your consideration and I urge a favorable report for HB 1426.