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WRITTEN TESTIMONY
IN SUPPORT OF SENATE BILL 778

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

Before the Senate Finance Committee

Maryland General Assembly

INTRODUCTION

My name is Alan Freeman and I am the Chief Strategy Officer and General Counsel for a boutique rare disease clinical trial company that is revolutionizing the way clinical trials for rare diseases are conducted. I am pleased to submit this testimony in support of Senate Bill 778, 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. This legislation 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. The legislation also would clarify that clinical trial sites need not be owned by physicians, providing much needed clarity. It has the endorsement of the Maryland Chamber of Commerce and the Maryland Tech Council.

I. CURRENT RESTRICTIONS ON PHARMACY OWNERSHIP PRESENT UNIQUE CHALLENGES FOR CLINICAL RESEARCH

A. Maryland's Existing Pharmacy Ownership Laws

Under current law, physicians face significant restrictions on holding substantial ownership interests in pharmacies. These restrictions 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 where, as further discussed below, fraud and abuse concerns related to potential inappropriate profiting are lessened and the role of physician-owners is more meaningful.

B. The Critical Role of On-Site Pharmacy Capabilities in Clinical Trials

Modern clinical trial sites require sophisticated on-site pharmacy capabilities. On-site research pharmacists manage investigational drugs, ensure compliance with FDA-registered and Institutional Review Board (IRB)-approved protocols, and maintain strict adherence to Good Clinical Practice standards. They must handle complex tasks, including:

- (1) compounding, dispensing and distributing investigational drugs exclusively according to IRB-approved protocols;
- (2) maintaining chain of custody;

- (3) ensuring storage and security in accordance with United States Pharmacopeia standards;
- (4) collaborating with principal investigators, research nurses and study coordinators; and
- (5) documenting all activities for regulatory compliance.

C. Physician Expertise is Essential for Successful Clinical Trial Sites

Within this dynamic and at-times challenging environment, physicians who specialize in treating complicated diseases and biological disorders 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. Their specialized medical knowledge is particularly critical for:

- (1) identifying appropriate candidates for specific trials;
- (2) understanding complex inclusion and exclusion criteria;
- (3) monitoring participant safety throughout the trial process;
- (4) interpreting adverse events and efficacy signals; and
- (5) ensuring that trial protocols align with real-world clinical practice.

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.

II. THE RATIONALE FOR RETAIL PHARMACY OWNERSHIP RESTRICTIONS DOES NOT APPLY TO CLINICAL RESEARCH PHARMACIES

A. The Anti-Kickback Purpose of Retail Pharmacy Ownership Restrictions

Maryland's restrictions on physician ownership of pharmacies serve 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 robust 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.

B. Clinical Research Pharmacies Operate Under Fundamentally Different Constraints

The concerns that justify retail pharmacy ownership restrictions do not exist in the clinical research pharmacy context. Senate Bill 778 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 conducted under IRB-approved protocols that meet FDA guidelines (§ 12-401.1(C)(1));
- (2) dispense pharmaceuticals solely incident to the research being conducted and consistent with related protocols (§ 12-401.1(C)(2));
- (3) are not open to the general public for retail pharmaceutical services and are strictly limited to dispensing to clinical trial participants (§ 12-401.1(C)(3)); and
- (4) comply with security and storage protocols established by USP and the State Board of Pharmacy (§ 12-401.1(C)(4)).

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

- (1) could not write prescriptions for personal profit, because the pharmacy could only dispense according to IRB-approved protocols;
- (2) could not steer patients toward expensive medications, because drug selection would be dictated by the IRB-approved protocol, not physician discretion;
- (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.

Senate Bill 778 includes additional safeguards that prohibit physician-owners from directing patients to a single pharmacist or pharmacy in accordance with existing law, and that prohibit remuneration for referring patients to a pharmacist or pharmacy.¹ The bill also 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.²

¹ See SB 778, § 12-102(c)(2)(VII)(3)(A)-(B).

² See SB 778, § 12-102(c)(2)(VII)(2).

III. ROBUST FEDERAL AND STATE OVERSIGHT MECHANISMS ADEQUATELY ADDRESS POTENTIAL CONFLICTS OF INTEREST

I have heard concern that physician ownership of clinical research pharmacies could create conflicts of interest, specifically, that financial incentives tied to study drug dispensing might influence enrollment decisions, continuation determinations, adverse event assessment and reporting or otherwise compromise pharmacist independence.

While these concerns merit careful consideration, they are fully resolved by the comprehensive regulatory framework that *already governs all clinical trials in the United States*. Clinical research operates under multiple layers of independent oversight specifically designed to prevent and detect potential bias, *regardless of ownership structure*. And, it merits emphasis that Senate Bill 778 would preserve, not eliminate, the State Board of Pharmacy's oversight function.

A. Institutional Review Boards Provide Independent Ethical Oversight³

Every clinical trial in the United States must receive approval from an Institutional Review Board (IRB) before enrolling a single participant. IRBs are independent committees charged with protecting the rights and welfare of human research participants through rigorous advance and periodic review of research protocols.

IRB Independence and Composition: Federal regulations mandate specific structural protections to ensure IRB independence. IRBs must include at least five members with varying backgrounds, including at least one member whose primary concerns are scientific, another whose primary concerns are non-scientific, and at least one who is not affiliated with the institution. Members with conflicts of interest are prohibited from voting on or participating in the review of any research in which they have a conflicting interest.⁴

Comprehensive Protocol Review: Before any trial begins, the IRB conducts a thorough evaluation of the study protocol, informed consent documents, investigator qualifications, facilities and potential risks to participants.⁵ The protocol would contain essential information about investigational product handling and administration – *i.e.*, the pharmacy function. The IRB specifically assesses whether:

- (1) risks to subjects are minimized and reasonable in relation to anticipated benefits;
- (2) selection of subjects is equitable;

³ See generally 21 CFR Part 56 (establishing standards for IRBs to ensure the protection of human subjects in FDA-regulated clinical trials) & 45 CFR Part 46 (outlining regulations for the protection of human subjects in research); see also U.S. Food and Drug Administration, *Institutional Review Boards: Frequently Asked Questions* (guidance document, Food and Drug Administration), last updated February 2025), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-boards-frequently-asked-questions>; Christine Grady, *Institutional Review Boards: Purpose and Challenges*, *Chest* 148, no. 5 (Nov. 2015): 1148-1155, <https://doi.org/10.1378/chest.15-0706> (PMCID: PMC4631034).

⁴ See 21 CFR § 56.107.

⁵ See 21 CFR §§ 56-108 – 56-111.

- (3) informed consent is adequate and appropriately documented;
- (4) data monitoring is sufficient to ensure participant safety; and
- (5) participant privacy and confidentiality are protected.

Critically, Federal regulations require that the IRB be “able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, *and standards of professional conduct and practice*.”⁶ These requirements necessarily dictate that the IRB review whether the research protocol and site employ procedural guidelines and guardrails to protect against any potential conflicts of interest – whether arising with the investigator, the pharmacy or the owner/operator of the clinical site.

Ongoing Oversight: IRB oversight does not end with initial approval. Federal regulations require continuing review at least annually for the duration of the study.⁷ IRBs review protocol amendments, safety reports and adverse events throughout the trial. If safety concerns arise or participant welfare is compromised, IRBs have the authority to suspend or terminate research approval immediately.⁸

Pharmacy Manual Oversight: Beyond the protocol that describes the scientific design, objectives, methodology, statistical considerations and the organization of a clinical trial, the pharmacy manual is a separate document that provides specific instructions for handling, preparing, storing, dispensing and accounting for investigational products. Clinical trials involving investigational products fall under *FDA oversight* and must (i) comply with Good Clinical Practice (GCP) guidelines; (ii) be reviewed and approved by the sponsor; (iii) be subject to FDA inspection during site audits; (iv) remain part of the Trial Master File and Investigator Site File; and (v) be updated as needed without triggering protocol amendments. These guardrails are operational tools that support execution of the approved protocol and constrain investigator and pharmacist discretion under FDA oversight.

B. Data and Safety Monitoring Boards Independently Monitor Trial Safety⁹

For trials involving significant risks, multiple sites, or mortality/major morbidity endpoints, Federal guidance recommends the creation of an independent Data and Safety Monitoring Board (DSMB), also known as a Data Monitoring Committee. DSMBs provide an additional layer of independent oversight specifically focused on participant safety.

Independence from Investigators and Sponsors: DSMBs consist of independent experts who have no conflicts of interest with the study, sponsor or investigators. Members typically

⁶ See 21 CFR § 56-107(a) (emphasis added).

⁷ See 21 CFR § 56.109(f).

⁸ See 21 CFR § 56.109(a).

⁹ See generally Scott R. Evans, *Independent Oversight of Clinical Trials through Data and Safety Monitoring Boards*, *NEJM Evidence* 1, no. 1 (Jan. 2022): EVIDctw2100005, <https://doi.org/10.1056/EVIDctw2100005>; U.S. Department of Health and Human Services, Food and Drug Administration, *Use of Data Monitoring Committees in Clinical Trials* (Draft Guidance for Industry, Feb. 2024), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-data-monitoring-committees-clinical-trials> (intended to supersede March 2006 guidance, and reflective of FDA’s current thinking and recommendations, but not yet finalized and not binding).

include biostatisticians and clinicians expert in the disease under study, and they may include ethicists or patient advocates. DSMB members are the only individuals who have access to unblinded data comparing treatment arms during the trial.

Safety Monitoring Authority: DSMBs have the power to recommend continuation, modification or termination of trials based on their independent assessment of accumulating safety and efficacy data. If adverse events are more common in the experimental arm, if early efficacy is definitively established or if the trial appears futile, the DSMB can halt the study in order to protect participants from unnecessary risk and ensure ethical conduct.

Frequency and Scope: DSMBs meet at predetermined intervals throughout the trial to review cumulative safety data, enrollment progress and data quality. They assess whether new safety signals have emerged, they evaluate the balance of risks and benefits and they consider whether external developments (such as newly published research) affect the ethics of continuing the trial. NIH policy requires DSMBs for all Phase III clinical trials and most Phase II multicenter randomized trials.

C. Protocol-Dictated Dispensing Eliminates Prescriber Discretion

Unlike retail pharmacy practice, where physicians exercise judgment about what to prescribe and in what quantities, clinical research pharmacies operate under strict IRB-approved protocols and pharmacy manuals that limit investigator discretion over dispensing decisions:

- (1) Enrollment decisions are constrained by detailed inclusion and exclusion criteria that are reviewed and approved by the IRB. Investigators cannot enroll participants who fail to meet protocol criteria simply to increase pharmacy revenue.
 - (2) Drug selection and dosing are determined by the study protocol – not the investigator, and they are monitored by the DSMB. Investigators have no discretion to change medications or doses for financial gain. Any change in the medication or dose would undermine the validity of the research findings sought by the study sponsor.
 - (3) Adverse event reporting is subject to Federal regulations that require investigators to immediately report serious and unexpected adverse events to the sponsor, the IRB and the FDA.¹⁰ Failure to report is a serious violation that can result in disqualification of the investigator and rejection of study data.
 - (4) Participant discontinuation is governed by protocol-specified criteria and participant safety considerations. DSMBs monitor discontinuation rates and patterns as potential safety signals.
- and
- (5) Study duration is predetermined by the protocol. Investigators cannot extend trials for financial benefit without IRB and sponsor approval.

¹⁰ See 21 CFR § 312.32 (IND safety reporting).

The rigid structure of clinical trial protocols, coupled with IRB and DSMB oversight, creates a system where a physician's financial interest in a research pharmacy could not meaningfully influence study conduct or participant safety. To the contrary, a physician owner's financial incentive would be to ensure strict and unwavering compliance with protocols in all respects. Any deviation from protocol requirements could result in disqualification of the investigator, rejection of study data, loss of the pharmacy permit and significant personal liability-consequences that far outweigh any hypothetical short-term financial benefit from non-compliance.

D. Senate Bill 778 Includes Additional Specific Safeguards

Beyond the comprehensive Federal oversight framework, Senate Bill 778 incorporates specific protections tailored to clinical research pharmacies:

- (1) **Licensed pharmacist oversight:** Section 12-102(c)(2)(VII)(2) requires that a licensed pharmacist be present on-site during all hours of operation and be responsible for all compounding, dispensing and oversight of pharmacy services. This ensures professional pharmaceutical judgment independent of physician-owner financial interests.
- (2) **Prohibition on patient steering:** Section 12-102(c)(2)(VII)(3)(A) prohibits physician-owners from directing patients to a single pharmacist or pharmacy, preventing inappropriate referral patterns.
- (3) **Ban on referral remuneration:** Section 12-102(c)(2)(VII)(3)(B) prohibits physician-owners from receiving remuneration for referring patients to a pharmacist or pharmacy.
- (4) **Strict limitation to IRB-approved protocols:** Section 12-401.1(C)(1) limits clinical research pharmacies to compounding, dispensing or distributing drugs exclusively as part of scientific research conducted under IRB-approved protocols meeting FDA guidelines.
- (5) **Prohibition on retail services:** Section 12-401.1(C)(3) prohibits clinical research pharmacies from being open to the general public, and it restricts dispensing strictly to clinical trial participants.
- (6) **State Board oversight:** Section 12-401.1(D) requires the State Board of Pharmacy to adopt regulations establishing required operational standards, suspension and revocation standards, and inspection requirements.

These provisions complement Federal oversight and they reaffirm the Board of Pharmacy's oversight function, which creates multiple redundant protections against conflicts of interest.

E. The Comprehensive Regulatory Framework Works¹¹

The United States clinical trials system, which is built on IRB review, DSMB oversight, FDA financial disclosure requirements, Good Clinical Practice standards and rigorous protocol adherence, represents decades of refinement following historical research abuses. This system successfully protects hundreds of thousands of participants annually in trials conducted across diverse ownership structures, including:

- (1) academic medical centers where physician-investigators may benefit indirectly from grant funding and publications;
- (2) private research sites where physicians derive substantial income from clinical trial participation;
- (3) hospital-based trials where institutions have financial interests in positive outcomes; and
- (4) contract research organizations that profit from efficient trial completion.

In 2023 alone, over 906,000 participants enrolled in nearly 5,300 industry-sponsored clinical trials across the United States under this oversight framework. The system's effectiveness is demonstrated by the fact that these trials generate high-quality data acceptable to FDA for regulatory decision-making, while maintaining strong participant safety records. It is the global gold standard for a reason and places clinical research pharmacies in a uniquely protected position.

The concern that physician ownership of clinical research pharmacies requires different treatment than existing clinical trial environments ignores both the comprehensive oversight already in place, and the fundamental structural differences between clinical research and retail pharmacies. The variety of forms of independent review, which include IRB approval, DSMB monitoring, FDA oversight, protocol constraints and professional pharmacist supervision, adequately address potential conflicts of interest, regardless of ownership structure.

Maryland does not need an additional layer of regulatory restriction that does not provide additional protections for trial participants and instead puts Maryland at a competitive disadvantage in opening new clinical trial sites and supporting important clinical research for the betterment of Maryland residents.

¹¹ See TEconomy Partners, LLC, *Biopharmaceutical Industry-Sponsored Clinical Trials: Impacting State Economies* (March 2025), prepared for PhRMA (Pharmaceutical Research and Manufacturers of America), https://cdn.aglty.io/phrma/fact-sheets/clinical-trials/TEconomy_PhRMA-_Biopharma-Industry-Sponsored-Clinical-Trials.2025-Report.Final_.pdf.

IV. SENATE BILL 778 WOULD EXPAND CLINICAL TRIAL ACCESS, CREATE JOBS AND STRENGTHEN MARYLAND'S ECONOMY WITHOUT COMPROMISING PATIENT SAFETY

A. The Substantial Economic Impact of Clinical Trials¹²

Clinical trials represent a significant economic driver for states that are able to successfully attract them. According to a comprehensive 2025 study by TEconomy Partners, which was prepared for the Pharmaceutical Research and Manufacturers of America (PhRMA), biopharmaceutical industry-sponsored clinical trials generated substantial economic activity nationwide in 2023:

- (1) Nearly 5,300 industry-sponsored clinical trials were active across the United States, involving more than 906,000 participants.¹³
 - (2) The biopharmaceutical industry invested more than \$30 billion in direct site-based clinical trial research expenditures.¹⁴
- and
- (3) Including economic ripple effects through vendors, contractors, and employee spending, these investments generated more than \$62 billion in total economic impact across communities nationwide.¹⁵

These figures represent only site-based activities, so they do not capture the full economic contribution of clinical trials, which also includes trial design, coordination, data analysis, hotel stays and related activities.

B. Maryland's Current Share of Clinical Trial Activity

Maryland currently hosts a meaningful but relatively modest share of national clinical trial activity. According to the TEconomy study, in 2023:

- (1) Maryland had 936 active clinical trials involving an estimated 18,053 participants.¹⁶
- (2) The biopharmaceutical industry invested approximately \$658.3 million in direct site-based expenditures in Maryland.¹⁷

and

¹² See TEconomy Partners, LLC, *Biopharmaceutical Industry-Sponsored Clinical Trials: Impacting State Economies* (March 2025), prepared for PhRMA (Pharmaceutical Research and Manufacturers of America), https://cdn.aglty.io/phrma/fact-sheets/clinical-trials/TEconomy_PhRMA-_Biopharma-Industry-Sponsored-Clinical-Trials.2025-Report.Final_.pdf.

¹³ *Id.* at ii.

¹⁴ *Id.* at ii.

¹⁵ *Id.* at ii.

¹⁶ See *id.* at 10 (Table 4).

¹⁷ *Id.* at 10 (Table 4).

- (3) These investments generated a total economic impact of approximately \$1.24 billion for *Maryland's* economy.¹⁸

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.¹⁹ 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.

C. Removing Barriers to Clinical Trial Site Development

By allowing physician ownership of clinical research pharmacies under appropriate safeguards, Senate Bill 778 would remove a significant barrier to establishing new clinical trial sites in Maryland. The legislation would:

- (1) enable physician specialists to invest in and operate comprehensive clinical trial facilities that integrate medical expertise with essential pharmacy capabilities;
- (2) encourage physicians with expertise in complex diseases to establish specialized trial sites focused on their areas of clinical knowledge;
- (3) facilitate partnerships between medical professionals and research pharmacists, creating integrated teams optimized for conducting high-quality clinical research; and
- (4) attract additional clinical trial activity to Maryland by removing a structural disadvantage relative to states with more flexible regulatory frameworks.

By enacting a legislative clarification that Maryland joins with the mainstream of states in providing that the conduct of clinical research does not constitute the practice of medicine (because it does not involve diagnosis, treatment or prescriptions), Senate Bill 778 would provide the certainty companies seeking to do business in Maryland require. Importantly, the bill's exemption is carefully limited: it applies only to trials conducted in accordance with FDA-registered protocols and in compliance with all applicable ethical guidelines and Federal and State regulations; it requires that all medical decision-making within the clinical trial be carried out by individuals licensed to practice medicine in Maryland; and it prohibits the entity conducting the trial from engaging in the general practice of medicine or providing clinical patient care outside the scope of the registered trial. These conditions ensure that patient care remains under the supervision of licensed physicians while removing a legal ambiguity that currently deters clinical research companies from operating in Maryland.

These changes will position Maryland to compete more effectively for clinical trial site investments while maintaining robust patient protections through the bill's comprehensive safeguards. We believe the positive clinical and economic impact of this change for Maryland is

¹⁸ *Id.* at 11 (Table 5).

¹⁹ *Id.*

particularly important and timely at this time, when there continue to be reports of a national shortage in clinical trial sites.²⁰

D. Creating New Opportunities for Maryland Pharmacists

The expansion of clinical research pharmacy opportunities in Maryland would create valuable career paths for the state's pharmacists. Research pharmacy positions offer excellent compensation, professional development, job stability and meaningful work.²¹ By facilitating the establishment of more clinical research pharmacies in Maryland, Senate Bill 778 would create additional opportunities for Maryland's pharmacy graduates and professionals to pursue rewarding careers without leaving the state.

E. Improving Access to Clinical Trials for Maryland Residents

Perhaps most importantly, expanding clinical trial site capacity in Maryland would improve access to cutting-edge treatments for Maryland residents. This accomplishment would serve multiple positive policy objectives by:

- (1) increasing early access to innovative therapies;
- (2) reducing geographic barriers to trial participation; and
- (3) contributing to medical progress.

Geographic accessibility is particularly important for addressing health disparities. Research published in the American Society of Clinical Oncology Educational Book demonstrates that when access to clinical trials is uniform, differences in clinical outcomes between rural and urban patients dissipate.²² By facilitating additional trial sites, Senate Bill 778 would help ensure that more Maryland residents, regardless of where they live, can participate in potentially life-saving research.

²⁰ Bastek et.al, *Frontier Sites in Clinical Trials: Opportunities, Challenges, and Models*, Contemp. Clin. Trials Commun. (Nov. 25. 2025).

²¹ According to the U.S. Bureau of Labor Statistics, the median annual wage for pharmacists was \$137,480 in May 2024, with the highest 10 percent earning more than \$172,040. See Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook*, Pharmacists, at <https://www.bls.gov/ooh/healthcare/pharmacists.htm> (visited February 01, 2026).

²² See *American Society of Clinical Oncology Educational Book*, "Equitable Access to Clinical Trials: How Do We Achieve It?"

CONCLUSION

Senate Bill 778 represents thoughtful, evidence-based legislation that addresses a specific barrier to clinical trial site development in Maryland while maintaining appropriate patient safeguards. The bill:

- (1) recognizes that clinical research pharmacies operate under fundamentally different constraints than retail pharmacies, eliminating the anti-kickback concerns that justify physician ownership restrictions in the retail context;
- (2) enables physicians with specialized expertise in complex diseases to establish comprehensive clinical trial facilities that integrate medical knowledge with essential pharmacy capabilities;
- (3) includes robust safeguards requiring licensed pharmacist oversight, prohibiting improper patient referrals, and limiting activities strictly to IRB-approved clinical research; and
- (4) positions Maryland to capture a larger share of the substantial economic activity generated by clinical trials nationwide.

By removing an unnecessary regulatory barrier, Senate Bill 778 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. At a time when the nation faces a growing shortage of clinical trial sites, Maryland has an opportunity to position itself as a leader in attracting this vital economic and medical activity that create high paying jobs in Maryland.

For these reasons, I respectfully urge the Committee to give Senate Bill 778 a favorable report.

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Position: FAV



MARYLAND TECH COUNCIL

ADVANCING LIFE SCIENCES AND TECHNOLOGY

Senate Finance Committee

March 3, 2026

Senate Bill 778 – *Clinical Research Pharmacies and Clinical Trials – Permits, Ownership, and Definition of Practice of Medicine*

POSITION: SUPPORT

The Maryland Tech Council (MTC), with over 800 members, is the State's largest association of technology companies. Our vision is to propel Maryland to be the country's number one innovation economy for life sciences and technology. MTC brings the State's life sciences and technology communities into a single, united organization that empowers members to achieve their goals through advocacy, networking, and education. On behalf of MTC, we submit this letter of **support** for Senate Bill 778.

Senate Bill 778 authorizes the Maryland Board of Pharmacy to issue a "clinical research pharmacy" permit when a pharmacy exclusively dispenses or distributes drugs as part of a scientific research clinical trial. The MTC supports this bill because it has the potential to further enhance Maryland's already-strong life sciences and research and development industries.

Clinical research facilities are key components of the life sciences ecosystem. Member companies in the life sciences sector are already conducting ground-breaking research and studies on new drugs and treatments. This bill establishes a streamlined pathway for additional clinical research conducted by the private sector, which we believe will increase the volume of industry-led clinical trials. Supporting this industry has the potential to generate an enormous economic impact in Maryland. Additionally, clinical research pharmacies support additional high-level job opportunities. Conducting clinical research trials requires licensed pharmacists, research coordinators, technicians, and regulatory compliance personnel. These are high-skill, high-wage jobs that benefit Maryland's workforce and support the state's growth in life sciences employment.

Consistent with our mission statement, MTC's vision is to be the country's top innovation economy for life science and tech. Easier establishment, and operation of research pharmacies and trials make Maryland a more attractive place for companies to conduct research. As clinical trials are a key step in developing new therapies, success can lead to follow-on investment, new start-ups, spinouts, and licensing deals. Each of these outcomes strengthens our life sciences industry and the state's long-term economic growth. The MTC also consistently urges policymakers to support policies to make Maryland more competitive in our region and across the Country. We are aware of several other states that do not bar clinical research pharmacies of the type contemplated by the bill, putting Maryland at a competitive disadvantage. Rather than ceding clinical research activity to our competitors, we must level the playing field and pave the way to ensure that this important research and its related economic impact occur in Maryland.

For these reasons, we urge a favorable report on Senate Bill 778.

For more information call:

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Position: FAV



Senate Bill 778

Position: Favorable
Committee: Finance
Date: March 3, 2026

Founded in 1968, the Maryland Chamber of Commerce (the Chamber) is the leading voice for business in Maryland. We are a statewide coalition of more than 7,000 members and federated partners, and we work to develop and promote strong public policy that ensures sustained economic growth for Maryland businesses, employees, and families.

Senate Bill 778 (SB 778) clarifies the legal and regulatory framework governing clinical research pharmacies in Maryland by establishing a specific permit category for these entities and aligning statutory language with the operational realities of modern clinical trials. The bill recognizes the unique structure and purpose of clinical research pharmacies while preserving appropriate oversight and compliance standards.

Maryland is home to a nationally recognized life sciences ecosystem, including leading academic medical centers, biotechnology companies, and research institutions. As clinical trials become increasingly complex and specialized, the infrastructure that supports them, including the safe handling, preparation, and dispensing of investigational products, must be clearly defined in statute. SB 778 provides that clarity.

By authorizing the Maryland Board of Pharmacy to issue permits tailored to clinical research pharmacies, the bill ensures that these entities operate under appropriate regulatory supervision while acknowledging that their functions differ from traditional retail or hospital pharmacies. Clinical research pharmacies are designed to support investigational studies conducted in accordance with federal law, Institutional Review Board approval, and Good Clinical Practice standards. Clarifying their role in Maryland law removes ambiguity without diminishing professional accountability or patient protections.

Importantly, SB 778 does not weaken medical oversight or alter the standards governing the practice of medicine. Rather, it recognizes that clinical research activities, when conducted pursuant to approved protocols, require a regulatory structure that reflects their distinct purpose. Providing this clarity will reduce unnecessary administrative barriers, encourage investment in Maryland-based trials, and make it easier for sponsors and research institutions to conduct studies in the State.

Strengthening Maryland's clinical trial infrastructure has meaningful economic and public health benefits. Clinical research supports high-skilled jobs, attracts private investment, and gives Maryland patients earlier access to innovative therapies. In a competitive national environment for research dollars and trial placement, a clear and modern statutory framework signals that Maryland is committed to being a leader in medical innovation.

For these reasons, the Maryland Chamber of Commerce respectfully requests a **favorable report on SB 778**.

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Position: UNF



DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Meena Seshamani, M.D., Ph.D., Secretary

2026 SESSION MARYLAND BOARD OF PHARMACY POSITION PAPER

BILL NO: SB 778 – Clinical Research Pharmacies and Clinical Trials – Permits, Ownership, and Definition of Practice of Medicine
COMMITTEE: Finance Committee
POSITION: Letter of Opposition

TITLE: SB 778 – 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 submits this letter opposition to express significant concerns regarding Senate Bill 778, specifically the provisions under §12-102(c)(2)(vii) which permit a health care provider to hold an ownership interest in a clinical research pharmacy.

When physicians who serve as investigators also seek ownership in a pharmacy dispensing investigational drugs, the inherent conflict of interest is amplified. Financial incentives tied to study drug dispensing may influence enrollment, continuation, adverse-event assessment, and reporting, thereby compromising participant safety, informed consent, and the independence of pharmacy oversight. Given the heightened vulnerability of research participants and the experimental nature of investigational therapies, strict separation between investigators and dispensing entities is essential to protect human subjects and maintain research integrity and ensure solid checks and balances.

Furthermore, a pharmacist is licensed as an independent practitioner who has a separate and distinct role in ensuring that drugs dispensed are clinically appropriate. However, a pharmacist's

clinical independence would be significantly impaired if the prescriber of the drugs to be dispensed is also the pharmacist's employer. It is equally important to note that current law already permits a physician to own up to 10% of a pharmacy, thereby making this bill unnecessary

The Board is committed to finding ways to best support clinical innovation without compromising the integrity of Maryland's healthcare system.

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.

SB 778_HB 1426_ Clinical Research Pharmacies and

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Position: UNF

SB 778/HB 1426: Clinical Research Pharmacies and Clinical Trials - Permits, Ownership, and Definition of Practice of Medicine: Please vote to **OPPOSE** this bill.

Dear Finance Committee and Health Committee:

I am writing to strongly urge you to **OPPOSE SB 778/HB 1426** during committee consideration or floor votes.

While supporting clinical research and innovation in Maryland is important, this legislation represents an unnecessary and risky expansion of pharmacy scope that could undermine physician-led patient care. The practice of medicine—including decisions about investigational treatments in clinical trials—should remain under the direct supervision of qualified physicians who can fully assess patient risks, eligibility, informed consent, and overall health needs. Allowing permitted research pharmacies (and potentially non-physician-owned entities) to handle dispensing and oversight without clear physician involvement risks fragmenting care, reducing accountability, and compromising patient safety in high-stakes experimental contexts.

Current laws already enable clinical trials through established protocols involving physicians, institutional review boards, and licensed pharmacies. Creating a special permit category and narrowing the definition of medical practice could open doors to less regulated operations, potentially prioritizing research efficiency over rigorous medical standards.

Maryland should protect the integrity of medical practice by maintaining physician oversight in all aspects of patient treatment, including investigational drugs—rather than carving out exceptions that dilute professional responsibility.

For these reasons, I respectfully ask you to **vote against SB 778/HB 1426**.

Thank you for your time and thoughtful consideration of this critical health care and patient safety matter.

Sincerely,

Trudy Tibbals

SB 778 - FIN- BOP - LOI.docx.pdf

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Position: INFO



Board of Physicians

Wes Moore, Governor · Aruna Miller, Lt. Governor · Harbhajan Ajrawat, M.D., Chair

2026 SESSION POSITION PAPER

BILL NO.: Senate Bill 778 - Clinical Research Pharmacies and Clinical Trials - Permits, Ownership, and Definition of Practice of Medicine
COMMITTEE: Finance
POSITION: Letter of Information

The Maryland Board of Physicians (the Board) is respectfully submitting this Letter of Information for Senate Bill (SB) 778 - Clinical Research Pharmacies and Clinical Trials - Permits, Ownership, and Definition of the Practice of Medicine. SB 778 establishes a clinical research pharmacy permit issued by the Board of Pharmacy, authorizes a health care provider to hold ownership interest in a clinical research pharmacy under certain circumstances, and exempts the conduct of an investigational or experimental treatment or clinical trial by a corporation or other legal entity from the definition of “practice of medicine.”

The Board is concerned that the proposed alterations to the definition of “practice of medicine” are inappropriate and problematic. The proposed definition exempts certain actions conducted by a “corporation or other legal entity that is not an individual licensed under this title...” The Board regulates and disciplines only individual licensees and has no jurisdiction over facilities, corporations, or any other entities. A corporation should not be added to the definition because only individuals can practice medicine. Inserting this provision in the definition of the practice of medicine is confusing and unnecessary.

Furthermore, the definition states that the practice of medicine does not include conducting an investigation or experimental treatment by a corporation or other legal entity that is not an individual if: “all medical decision making within the clinical trial is carried out by individuals who are licensed under this article,” (*see* page 6, lines 11 through 22). All medical decision-making is the practice of medicine.

The Board licenses many other allied health professionals under the Health Occupations Article, including genetic counselors, polysomnographic technologists, athletic trainers, and others. In addition to all the allied health professions licensed by the Board, all other health occupations, including practitioners such as dentists, long-term care administrators, and music therapists, are licensed under this Article and would be authorized to make medical decisions and engage in the general practice of medicine.

The Board is unclear if it was the intent to include all health occupation practitioners and is concerned that exempting such a large group of practitioners from the definition could result in significant unintended consequences and improperly authorize anyone licensed to practice a health

occupation to make medical decisions.

The Board is also concerned that SB 778 allows corporations to determine what constitutes the practice of medicine. If the Board received a complaint from a Maryland citizen, it would not be able to investigate, even if the allegations were egregious or involved patient harm.

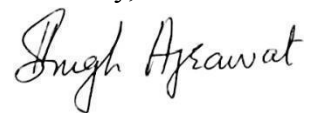
There are already statutory protections and exemptions for individual practitioners participating in investigational treatment and the “right to try”. Health General, [§ 21-2B-03](#), Annotated Code of Maryland, states, “A health occupations board may not revoke, fail to renew, suspend, or take any action against a health care provider’s license based solely on the health care provider’s recommendation to an eligible patient regarding access to or treatment with an individual investigational treatment.”

In addition, the Board seeks clarification on whether the clinical research pharmacy permit is issued to an individual or other entity, such as a corporation or facility.

In conclusion, the Board believes that an amendment to remove any proposed alteration to the definition of the practice of medicine is necessary. The Board requests to strike the proposed text on page 6, line 10 through 26.

Thank you for your consideration. For more information, please contact Madeline DelGreco, Manager of Policy and Legislation, at the Maryland Board of Physicians, at 410-764-5053.

Sincerely,

A handwritten signature in cursive script that reads "Harbhajan Ajrawat".

Harbhajan Ajrawat, M.D.
Chair, Maryland Board of Physicians

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