Workgroup to Study Pharmacy Benefits Managers

Interim Report

PUBLIC EXPOSURE DRAFT

HB 813/Ch. 730, 2025

Maryland Insurance Administration

Marie Grant

Commissioner

Maryland Department of Health

Meena Seshamani, MD

Secretary of Health

In consultation with the

Prescription Drug Affordability Board

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For further information concerning this document, contact:

Mary Kwei, Associate Commissioner, Market Regulation and Producer Licensing
Maryland Insurance Administration
200 St. Paul Place, Suite 2700
Baltimore, MD 21202
TTY 1-800-735-2258

The Administration's website address:
insurance.maryland.gov

Athos Alexandrou, Director, Office of Pharmacy Services
Maryland Department of Health
201 W. Preston Street
Baltimore, MD 21201
1-877-463-3464

The Department's website address:
health.maryland.gov

Table of Contents

I. EXECUTIVE SUMMARY

For the reasons discussed in detail below, the Report concludes:

1. Discussions involving the coverage and network limitation requirements for specialty drugs, including revisions of the definition for "specialty drug," will continue and conclude during workgroup meetings in 2026. Workgroup attendees expressed a range of opinions regarding the sufficiency of the current definition and how to best use it to protect consumers.
2. ERISA preemption of pharmacy benefits management ("PBM") regulation was a topic of concern for many stakeholders. During the public meeting, some workgroup attendees felt that changes to the current model of benefit delivery for ERISA plans through PBMs would bring overall net harm to employers, beneficiaries, and their families, while other stakeholders were concerned about how the lack of State regulatory protections would result in disruptions to care. Written comments submitted following the meeting echoed the concerns of attendees who opposed changes to exemptions for PBMs working on behalf of ERISA plans. Particularly, as PBM regulation under ERISA preemption is still unsettled in courts across the country, some interested parties believe that it is premature to take legislative action in this area.
3. Discussions involving State law regarding PBMs, including anti-steering laws, will continue and conclude during workgroup meetings in 2026.

II. INTRODUCTION

House Bill 813/Senate Bill 438, enacted in the 2025 Legislative Session of the Maryland General Assembly, directs the Maryland Insurance Administration ("MIA") and the Maryland Department of Health ("MDH"), in consultation with the Prescription Drug Affordability Board, to convene a workgroup to study Pharmacy Benefits Managers ("PBMs") and review reimbursement for pharmacists. The workgroup is required to submit an interim report by December 31, 2025, and a final report with their findings and recommendations to the Senate Finance Committee and the House Health and Government Operations Committee of the General Assembly by December 31, 2026. In developing this interim report, the workgroup reviewed, in part:

- Coverage requirements for specialty drugs, including:
    - Which drugs are considered specialty for purposes of formularies across carriers and PBMs; and
    - What these drugs have in common for purposes of developing a new definition for "specialty drug."
- ERISA preemption, which potentially limits PBM regulation, including:
    - The scope of *Rutledge v. Pharmaceutical Care Management Association* and subsequent case law and federal guidance;
    - How other states have responded to the *Rutledge* decision; and
    - What, if any, other State laws should be amended.
- Provisions of State law regarding pharmacy benefit managers, specialty pharmacies, and anti-steering, including:
    - § 15–1611.1 of the Insurance Article related to the use of specific pharmacies or entities and the effect the section has on pharmacy costs in the fully insured market; and
    - § 15–1612 of the Insurance Article related to reimbursement and the effect the section has on pharmacy costs in the fully insured market.

III. BACKGROUND

A multi-stakeholder workgroup chaired by representatives from the MIA and MDH was established by legislation enacted by the Maryland General Assembly during the 2025 Legislative Session in order to review and collect feedback on State law concerning PBMs. The workgroup first convened in August of 2025 and, over the course of four meetings, discussions for three of the six charges identified by the General Assembly were initiated, with the rest to be addressed in 2026. Contextual information for topics discussed by the workgroup in 2025 is provided below.

Definitions and Coverage Requirements for Specialty Drugs

The Maryland General Assembly charged the workgroup with the task of reviewing the current definition of a specialty drug for the purposes of formularies across carriers and PBMs, as well as what commonalities across drugs can be identified for the purpose of developing a new definition of "specialty drug."

The definition applicable to the commercial market[1] in Maryland in §15-847 of the Insurance Article[2] was developed in 2014 under House Bill 761. House Bill 761 authorized insurers to use specialty pharmacy networks to distribute specialty drugs, and prohibited insurers from imposing a copayment or coinsurance over $150 for a 30-day supply of a specialty drug.[3] A "specialty drug" was originally defined as a prescription drug that:

- is prescribed for an individual with a complex or chronic medical condition or a rare medical condition;
- costs $600 or more for up to a 30–day supply;
- is not typically stocked at retail pharmacies; and
- requires a difficult or unusual process of delivery to the patient in the preparation, handling, storage, inventory, or distribution of the drug; or requires enhanced patient education, management, or support, beyond those required for traditional dispensing, before or after administration of the drug.

Legislation passed in 2020 excluded prescription drugs prescribed to treat diabetes, HIV, or AIDS from the definition of "specialty drug."

Similarly, COMAR 10.67.06.04[4] outlines a definition applicable to Maryland Medicaid and Managed Care Organizations. It also includes the provision that:

> I. If an enrollee subsequently requests to use a retail pharmacy for specialty drugs the MCO may not limit the enrollee to the use of a mail order pharmacy.

On January 1, 2026, a law providing guidance on where Marylanders can obtain specialty drugs on the commercial market will take effect. Through this statute, insurers can require a specialty drug to be obtained through:

- A designated pharmacy or other source authorized under the Health Occupations Article to dispense or administer prescription drugs; or
- A pharmacy participating in the entity's provider network, if the entity determines that the pharmacy:

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[1] The use of "commercial market" refers to all health plans or insurance products regulated explicitly by the MIA. Plans that are purchased through Medicaid, Medicare and related Medicare products, self-funded, Tricare, and Veterans Affairs ("VA") benefits may not apply or have a different applicable definition.
[2] https://mgaleg.maryland.gov/mgawebsite/Laws/StatuteText?article=gin&section=15-847&enactments=false
[3] https://mgaleg.maryland.gov/2014RS/bills/hb/hb0761E.pdf
[4] https://www.law.cornell.edu/regulations/maryland/COMAR-10-67-06-04

- meets the entity's performance standards; and
- accepts the entity's network reimbursement rates.

ERISA - An Overview

The Employee Retirement Income Security Act of 1974 ("ERISA") was enacted by Congress to protect the interests of participants in employee benefit plans and their beneficiaries by establishing substantive regulatory requirements for such plans and ensuring "appropriate remedies, sanctions, and ready access to the Federal courts."[5] ERISA establishes uniform standards and requirements for employee benefit plans with the exception of those maintained by governmental entities and churches. The statute's requirements encompass both pension arrangements and employee welfare benefit plans, including prescription-drug coverage.

ERISA Preemption[6]

ERISA preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan" and "nothing in [ERISA] shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking or securities."[7] Fully insured health benefit plans may be subject to ERISA, but regulated by the states under insurance laws; self-funded employee health benefit plans subject to ERISA are generally exempt from state regulation. The line between permissible and impermissible state regulation of plans subject to ERISA has been the subject of litigation for decades. In recent years, states have expanded regulation of PBMs under insurance laws. Some states have applied their regulation of PBMs to all types of plans, including self-funded ERISA plans, and litigation over ERISA preemption has ensued.

Two clauses of the statute, the "Savings Clause" and "Deemer Clause" provide the framework for reviewing the issue of ERISA preemption.

Under the insurance regulation Savings Clause, states can regulate the terms and conditions of health insurance. The Supreme Court has clarified a two-part test for determining whether a state law regulates insurance and avoids ERISA preemption:

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[5] https://www.congress.gov/crs-product/R48470
[6] MIA (2025), Slide 7: https://insurance.maryland.gov/Consumer/Documents/agencyhearings/PBM-Workgroup-Meeting-2.pdf
[7] https://uscode.house.gov/view.xhtml?req=(title:29%20section:1144%20edition:prelim)%20OR%20(granuleid:USC-prelim-title29-section1144)&f=treesort&edition=prelim&num=0&jumpTo=true

1. The state law must be specifically directed towards entities engaged in insurance; and
2. The state law must substantially affect a risk pooling arrangement between the insurer and the insured.

By contrast, the Deemer Clause constrains the authority of the States by providing that no ERISA-covered plan "shall be deemed to be an insurance company" for the purposes of state regulation, thus preventing states from treating self-funded plans as insurance entities subject to state regulation.

ERISA - Rutledge v. Pharmaceutical Care Management Association[8]

At issue in the Supreme Court case *Rutledge v. Pharmaceutical Care Management Association* ("*Rutledge*") was an Arkansas law that required PBMs to reimburse pharmacies at a price no lower than what a pharmaceutical wholesaler would charge. It also authorized pharmacies to decline to dispense a drug if PBM reimbursements were less than the pharmacy's acquisition cost. The Pharmaceutical Care Management Association ("PCMA") argued that the statute interfered with "central matters of plan administration" and was therefore in violation of ERISA law. The supreme court unanimously disagreed, arguing that when a pharmacy declines to dispense a prescription, the responsibility lies first with the PBM for offering the pharmacy a below-acquisition reimbursement. *Rutledge* recognized that PBMs are not health benefit plans as defined under ERISA and that the regulation of PBMs are not preempted by ERISA, as long as the state's regulation of the PBM does not effectively regulate the ERISA plan itself.

PCMA v. Wehbi[9]

At issue in the case *PCMA v. Wehbi*, 18 F.4th 956 (8th Cir. 2021) was a 2017 North Dakota law that regulated PBMs in part by prohibiting PBMs from conditioning a pharmacy's participation in their network through satisfaction of accreditation standards more stringent than or in addition to state licensure requirements.

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[8] https://insurance.maryland.gov/Consumer/Appeals%20and%20Grievances%20Reports/Report-of-the-MIA-on-Rutledge-vs-Pharmaceutical-Care-Mgt-Assn-and-its-impact-on-Title-15-MSAR-13329.pdf

[9] MIA (2025) Slide 10: https://insurance.maryland.gov/Consumer/Documents/agencyhearings/PBM-Workgroup-Meeting-2.pdf

The 8th Circuit said these laws "constitute, at most, regulation of a noncentral 'matter of plan administration' with de minimis economic effects." While the laws may cause "disuniformity," the Court held that they do not require payment of specific benefits or bind plan administrators to specific rules. Other provisions that authorize pharmacies to do certain things –disclose certain information to patients; mail or deliver drugs to a patient as an ancillary service; charge shipping and handling fees when a prescription is mailed or delivered—were all also upheld.

The Court also considered Medicare Part D preemption and found that some provisions were not preempted by Medicare while others were. Those that were preempted required PBMs to utilize an electronic quality improvement platform for plans and pharmacies and limits performance based fees that PBMs can charge pharmacies, and a prohibition on retroactive fees (which are contemplated by federal regulations).

PCMA v. Mulready[10]

At issue in the case *PCMA v. Mulready*, 78 F.4th 1183 (10th Cir. 2023) was Oklahoma's Patient's Right to Pharmacy Choice Act. The Act included provisions that were "network restrictions" that:

- prohibited PBMs from cutting off rural patient's access to in-network pharmacies
- forbade PBMs from steering patients to favored pharmacies by offering discounts at those pharmacies (and not others); and
- an "any willing provider provision" that required PBMs to accept into their network all pharmacies willing to accept the network terms and conditions.

Additionally, a fourth provision prohibited PBMs from terminating a contract with a pharmacy based on a pharmacist's active probation status.

The 10th Circuit ruled that all three network restrictions" were all impermissibly connected with ERISA plans because they operate to winnow the PBM-network-design options available to benefit plans. Similarly, the Court found the probation prohibition implicated a central matter of plan administration and was therefore preempted.

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[10] MIA (2025) Slides 11-12:
https://insurance.maryland.gov/Consumer/Documents/agencyhearings/PBM-Workgroup-Meeting-2.pdf

The 10th Circuit expressly disagreed with the 8th Circuit when it noted that the North Dakota laws resembled the Oklahoma Probation Prohibition, but found that the law dictated which pharmacies must be included in the plan's PBM network. The 10th Circuit also found that Medicare Part D preempted the "any willing provider" provision as applied to Part D plans.

A petition for writ of certiorari to the Supreme Court was denied.

Iowa Association of Business and Industry v. Ommen[11]

In the recent case *Iowa Ass'n of Business and Industry v. Ommen*, Case No. 4:25-cv-00211 (S.D. Iowa), which is ongoing, a coalition of Iowa employers and employee benefit plans who filed suit against the Iowa Insurance Commissioner, with regard to Iowa Senate File 383 ("SF 383"), which went into effect on June 11, 2025. Among other things, the bill prohibits discrimination against pharmacies by PBMs, health carriers, health benefit plans and third-party payors, requires identical treatment regarding "participation, referral reimbursement of covered service or indemnification. This essentially is an "any willing provider" standard. The Iowa bill also establishes mandatory reimbursement standards (PBMs must reimburse at no less than the published National Average Drug Acquisition Cost ("NADAC") and must pay a minimum dispensing fee of $10.68 per prescription), as well as what the court described as extensive transparency and contractual requirements. Finally, the bill restricts communications between plans and participants, prohibits PBMs from promotion of one participating pharmacy over another, and bars disclosures comparing the reimbursement rates between pharmacies and mail-order options that might affect a person's choice of pharmacy provider.

On July 21, 2025, The Southern District of Iowa issued an 87 page order granting a preliminary injunction as to several provisions of the bill, echoing the Plaintiffs claim that cost regulations under Rutledge are permissible but those provisions that dictate the structure and administration of employee benefit plans are not. 20 distinct provisions were challenged and seven were found to be preempted by ERISA:

- The anti-discrimination requirements;
- The any-willing provider standards;

[11] MIA (2025) Slides 13-14: https://insurance.maryland.gov/Consumer/Documents/agencyhearings/PBM-Workgroup-Meeting-2.pdf

- Open access standard for specialty drugs;
- Mail order pharmacy and cost-sharing provisions;
- Deductible credit requirements;
- Mandatory contract terms and supersession provisions; and
- The general enforcement provision.

The July 21, 2025, order has been appealed to the circuit court.

Provisions of State Law Regarding PBMs, Specialty Pharmacies, and Anti-Steering

This charge refers to current state laws concerning PBMs, specialty pharmacies, and anti-steering and their impact on pharmacy costs in the fully insured market. The two statutes under review in this charge are listed below. Both go into effect on January 1, 2026.

§15–1611.1 of the Insurance Article states:

- (a) This section applies only to a pharmacy benefits manager that provides pharmacy benefits management services on behalf of a carrier.
- (b) Except as provided in subsection (c) of this section, a pharmacy benefits manager may not require that a beneficiary use a specific pharmacy or entity to fill a prescription if:
    - (1) the pharmacy benefits manager or a corporate affiliate of the pharmacy benefits manager has an ownership interest in the pharmacy or entity; or
    - (2) the pharmacy or entity has an ownership interest in the pharmacy benefits manager or a corporate affiliate of the pharmacy benefits manager.
- (c) Except as provided in § 15–847.2 of this title, a pharmacy benefits manager may require a beneficiary to use a specific pharmacy or entity for a specialty drug as defined in § 15–847 of this title.

§15–1612 of the Insurance Article states:

- (a) This section applies only to a pharmacy benefits manager that provides pharmacy benefits management services on behalf of a carrier.
- (b) This section does not apply to reimbursement:
    - (1) except as provided in § 15–847.2 of this title, for specialty drugs;

    - (2) for mail order drugs; or
    - (3) to a chain pharmacy with more than 15 stores or a pharmacist who is an employee of the chain pharmacy.
- (c) A pharmacy benefits manager may not reimburse a pharmacy or pharmacist for a pharmaceutical product or pharmacist service in an amount less than the amount that the pharmacy benefits manager reimburses itself or an affiliate for providing the same product or service.

IV. MULTI-STAKEHOLDER WORKGROUP: 2025 CHARGES

The aforementioned multi-stakeholder workgroup, chaired by representatives from the MIA and MDH, in consultation with the Prescription Drug Affordability Board, was convened in 2025 to lead discussion on the charges set by the Maryland General Assembly. As mandated by legislation, the workgroup consists of interested stakeholders, including community pharmacies from both chain and independent settings, pharmacy services administrative organizations, health insurance carriers, plan sponsor representatives, drug wholesalers and distributors, non–pharmacy benefit manager–owned mail order pharmacies, brand name and generic drug manufacturers, pharmacists, PBMs, and managed care organizations, and third–party experts in the field of drug pricing in Medicaid.[12]

Members of the workgroup met regularly to review research gathered by the Co-chairs of the workgroup, the MIA and MDH, and to discuss potential implications of legislative and regulatory changes on PBMs.

Summary of Public Workgroup Meetings

The workgroup invited input and comments from public stakeholders during and following each workgroup meeting. The workgroup had four public meetings between August and October of 2025. A brief description of each meeting is provided below. More detailed information, including the full agendas, presentation slides and materials, meeting recordings, and written public comments, may be accessed on the MIA website.[13]

1. August 27, 2025 Workgroup Meeting

[12] Placeholder: See Appendix A
[13] https://insurance.maryland.gov/Consumer/Pages/Pharmacy-Benefits-Workgroup-Meeting-Dates.aspx

The first public workgroup meeting was held on Wednesday, August 27, 2025. During the first meeting, Co-chairs Mary Kwei, representing the MIA, Athos Alexandrou, representing the MDH, and other members of the workgroup were introduced.[14] An overview of the workgroup's agenda for 2025 and expectations for 2026 was provided.[15] Comments made by workgroup members and public stakeholders during the meeting included concerns around the order in which Bill charges were being addressed and a request for a representative from the Maryland Office of the Attorney General to be present during the next meeting.

The comment period for items discussed during this meeting remained open until Wednesday, September 10, 2025. No additional written comments were submitted.

2. September 17, 2025 Workgroup Meeting

The second public workgroup meeting was held on Wednesday, September 17, 2025. This meeting focused on ERISA preemption and its impact on the regulations of PBMs. Van Dorsey ("Mr. Dorsey"), the MIA's Principal Counsel, provided contextual information regarding the topic and led the discussion among attendees. Comments made by workgroup members and public stakeholders began with concern surrounding the inclusion references to ERISA in laws not specifically pertaining to ERISA-related products. Mr. Dorsey responded to that comment stating that the reference to ERISA in Maryland statute is permissible. Stakeholders went on to state a need to review Maryland law based on current ERISA case law or to reconvene on the issue following the settlement of litigation in other parts of the country.

Some stakeholders expressed fears that if PBM regulation is extended to cover self-funded plans, employers would lose exemption from the statutory requirements applicable to PBMs in Maryland, that organizations would lose the ability to retain employees by offering satisfactory benefits packages, and that increased PBM regulation would place an increased burden on self-insured employers and their employees. Another stakeholder commented that these changes in legislation would negatively impact the uniformity provided by ERISA that employers benefit from.

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[14] Placeholder: See Appendix A
[15] MIA (2025) Slides 9-17: https://insurance.maryland.gov/Consumer/Documents/agencyhearings/PBM-Workgroup-Meeting-1.pdf

Other stakeholders commented on the use of transparency provisions in Maryland law and how they could be beneficial to policyholders. They also stated that a lack of regulation over PBMs could negatively impact providers which in turn would also negatively impact policyholders. The idea that increased PBM regulation would increase costs is an oversimplification of the issue. They pointed out that the ability to offer benefits is moot if the patient cannot access those benefits. As neighborhood pharmacies close due to a lack of PBM regulation, some services and medications will be more difficult for patients to access. Final stakeholder suggestions included further investigation on why regulations requiring fair payments to pharmacies by PBMs would result in increases in premiums, ways to ensure access to comprehensive services while respecting ERISA regulations, and methods of cooperation between employer groups and pharmacy groups.

The comment period for items discussed during this meeting remained open until Wednesday, October 1, 2025. In that time, the MIA received eight additional comment letters[16] on this issue. Interested parties who submitted public written comments included the Frederick County (MD) Chamber of Commerce Public Policy Committee, the Association of Health Insurance Plans ("AHIP"), The League of Life and Health Insurers of Maryland, the International Brotherhood of Electrical Workers, the Maryland Chamber of Commerce, the Maryland Independent College and University Association, the Maryland Association of Counties, and the Washington County (MD) Chamber of Commerce. All listed organizations opposed changes to regulations that impact self-funded plans at this time, citing concerns relating to the affordability of coverage for employees, the benefit of uniformity provided by federal ERISA guidelines, the difficulty in navigating complicated regulations, the ability to use employee benefits as recruiting tools for highly skilled employees, and the ongoing legal uncertainty surrounding ERISA preemption.

3. October 8, 2025 Workgroup Meeting

[16] Placeholder: See Appendix B

The third public workgroup meeting was held on Wednesday, October 8, 2025. The meeting began with a presentation from Co-chairs Mary Kwei ("Ms. Kwei") and Athos Alexandrou, who discussed topics related to specialty drugs and anti-steering laws. Some stakeholders expressed interest in the interim report resulting from the workgroup, which Ms. Kwei also addressed. One stakeholder commented that the workgroup meetings so far did not provide sufficient opportunity for discussion and debate on the presented topics. Ms. Kwei explained that there were certain limitations on the workgroup discussions due to the virtual setting.

In regard to the presentation on the definition of "specialty drug," one stakeholder began the discussion by referring to the way PBMs utilize the definition of "specialty drug" to dispense them through affiliate or specialty pharmacies, therefore removing them from retail pharmacies. A new definition should be able to distinguish between non-specialty drugs and drugs that are categorized as specialty in order to increase profits for PBMs, which in turn is a cost-driver in commercial and Medicaid markets. Some stakeholders indicated that the current definition is too broad and outdated when considering inflation and modern prescription drug prices.

Other stakeholders believed the current definition and the flexibility provided to PBMs to be beneficial in terms of affordability, safety, and patient compliance. As a trade-off to the limits on co-pays required by the law, PBMs and insurers play a larger role in controlling distribution. It is not about advantages for insurers or pharmacies, but ensuring that patients have access to affordable coverage and prescriptions. By narrowing the definition, the number of patients who are protected by cost-sharing limits will also decrease.

In response, some participants pointed to the fact that, aside from these protections, out-of-pocket costs for Marylanders have still increased dramatically since the definition first went into effect. They noted large mark-ups in prescription costs for PBM-affiliated mail-order pharmacies and indicated a need for more price transparency in this regard.

Finally, Delegate Bonnie Cullison indicated that, based on the presentation and feedback from stakeholders, the Workgroup should prioritize improving the definition of "specialty drug" to remove discretion, identifying appropriate methods of dispensing these drugs, and protecting consumers from cost.

In regard to the presentation on anti-steering laws, some participants believed it best not to spend much discussion time on this charge, due to its exemption of ERISA plans and specialty drugs. Another stakeholder recommended the inclusion of third-party experts to more effectively present evidence for each charge.

The comment period for items discussed during this meeting remained open until Wednesday, October 22, 2025. No additional written comments were submitted.

4. October 31, 2025 Workgroup Meeting

The fourth and final workgroup meeting for 2025 was held on Friday, October 31, 2025. Here, the workgroup discussed the draft of the interim report, which was released for public review and comment on this date. During the meeting, the workgroup was provided with a short summary of the contents of this report and accepted verbal feedback on the draft.

The comment period for items discussed during this meeting remained open until Friday, November 14, 2025.

V. 2026 WORKGROUP CHARGES

In 2026, the workgroup will continue unfinished discussions from the 2025 meetings as well as address the remaining charges from House Bill 813. Also, as required by legislation, the final report will be developed before December 31, 2026, and will include recommendations on all listed charges included in the bill.

<u>To Be Continued from 2025</u>

- Review coverage requirements for specialty drugs, including:
    - Which drugs are considered specialty for purposes of formularies across carriers and PBMs; and
    - What these drugs have in common for purposes of developing a new definition for "specialty drug."
- Review provisions of State law regarding pharmacy benefit managers, specialty pharmacies, and anti-steering, including:
    - § 15–1611.1 of the Insurance Article related to the use of specific pharmacies or entities and the effect the section has on pharmacy costs in the fully insured market; and

- § 15–1612 of the Insurance Article related to reimbursement and the effect the section has on pharmacy costs in the fully insured market.

<u>To Be Considered in 2026</u>

- Review the savings associated with NADAC ingredient cost pricing and managed care organizations
- Review the pharmacy benefits managers administrative fee consolidation and rebate allocations:
  - Strategies for adopting pharmacy reimbursement parity and drug pricing transparency
- Review the costs associated with pharmacies contracting with commercial plans versus pharmacies contracting with the Maryland Medical Assistance Program

VI. CONCLUSION

As required by House Bill 813, this is an interim report describing the progress made by the statutorily mandated workgroup. At this time, no recommendations or conclusions have been made on the charges set forth by House Bill 813 and Senate Bill 438. By December 31, 2026, the MIA, in collaboration with the MDH and in consultation with the Prescription Drug Affordability Board, will release a final report containing a final analysis and recommendations as required by the Maryland General Assembly.

VII. APPENDICES

Appendix A: Membership List

Appendix B: Public Comment Letters