WES MOORE
Governor

ARUNA MILLER
Lt. Governor

MARIE GRANT
Commissioner

JOY Y. HATCHETTE
Deputy Commissioner

MARY M. KWEI
Associate Commissioner
Market Regulation & Producer Licensing

Maryland
INSURANCE ADMINISTRATION

200 St. Paul Place, Suite 2700, Baltimore, Maryland 21202
Direct Dial: 410-468-2471 Fax: 410-468-2020
1-800-492-6116 TTY: 1-800-735-2258
insurance.maryland.gov

December 29, 2025

The Honorable Pamela Beidle
Chair, Senate Finance Committee
3 East Miller Senate Building
11 Bladen Street
Annapolis, MD 21401

The Honorable Bonnie Cullison
Vice Chair, House Health and Government Operations Committee
241 House Office Building
6 Bladen Street
Annapolis, MD 214011

Re: Interim Report required by HB 813/Ch. 730, 2025 (MSAR # 16614) – Workgroup to Study Pharmacy Benefits Managers

Dear Chair Beidle and Vice Chair Cullison:

Pursuant to HB 813/Ch. 730, 2025 (MSAR # 16614) and in accordance with § 2–1257 of the State Government Article of the Annotated Code of Maryland, the Maryland Insurance Administration and the Maryland Department of Health, in consultation with the Prescription Drug Affordability Board, is pleased to submit the enclosed interim report on the Workgroup to study Pharmacy Benefits Managers (PBMs).

Five printed copies of this report have been mailed to the DLS library for its records.

Should you have any questions regarding this report, please do not hesitate to contact us.

Respectfully yours,

Marie Grant
Insurance Commissioner

Meena Seshamani, MD
Secretary of Health

cc: Sarah T. Albert, Department of Legislative Services (5 copies)

Workgroup to Study Pharmacy Benefits Managers

Interim Report

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

December 29, 2025

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. The extension of regulation of pharmacy benefit managers ("PBMs") that perform services on behalf of self-funded plans was a topic of concern for many stakeholders. During the public meeting, some workgroup attendees argued that changes to the current model of benefit delivery for self-funded 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. Other workgroup members expressed concern that failure to extend Maryland Law to ERISA plans would allow PBMs to manipulate these plans to their financial advantage and harm non-PBM owned pharmacies. Written comments submitted following the meeting provided PBM financial data in support of increased regulation on ERISA plans while others echoed the concerns of attendees who opposed changes to exemptions for PBMs working on behalf of self-funded plans. Particularly, as the regulation of PBMs that perform services on behalf of self-funded plans remains unsettled in courts across the country as they consider whether such regulation is preempted by ERISA, 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.

[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.

Legislation passed in 2020 (HB652/SB931)[4] excluded prescription drugs prescribed to treat diabetes, HIV, or AIDS from the definition of "specialty drug."

Similarly, COMAR 10.67.06.04[5] 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:
    - 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."[6] 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.

[4] For a more complete record of past Maryland legislative activity regarding PBMs, ERISA, and Specialty Drugs, see Appendix C.
[5] https://www.law.cornell.edu/regulations/maryland/COMAR-10-67-06-04.
[6] https://www.congress.gov/crs-product/R48470.

ERISA Preemption[7]

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."[8] A law "relates to" an employee benefit plan when "it has a connection with or reference to such a plan." The "connection with" inquiry centers on state laws that dictate the fundamental architecture of employee benefit plans. A preempted regulation under this test characteristically mandates that providers "structure benefit plans in a particular way, such as by requiring payment of specific benefits or by binding plan administrators to specific rules for determining beneficiary status. *Rutledge v. Pharmaceutical Care Management Ass'n*, 593 U.S. 80, 87 (2020). Further, a state law has a "connection with" an ERISA plan if it "governs…a central matter of plan administration," but the mere fact that a state law "affects an ERISA plan or causes some disuniformity in plan administration" does not entail that the law meets this standard, "especially… if the law merely affects costs." *Id*. at 87. 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.

Additionally, 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:

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.[9]

---

[7] MIA (2025), Slide 7: https://insurance.maryland.gov/Consumer/Documents/agencyhearings/PBM-Workgroup-Meeting-2.pdf.
[8] 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.
[9] *Kentucky Ass'n of Health Plans, Inc. v. Miller,* 538 U.S. 329, 342 (2003).

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[10]

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. The Court in *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[11]

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.

[10] 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.
[11] 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[12]

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.

[12] 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[13]

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, and 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. Twenty distinct provisions were challenged and seven were found to be preempted by ERISA:

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

[13] 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.

Other provisions such as the limitation on guidance to preferred pharmacies, the dispensing fee provision, and various reporting and transparency provisions were found not to be preempted by ERISA. The July 21, 2025, order has been appealed to the circuit court. Currently, there is no ongoing ERISA preemption litigation relating to the regulations of PBMs in the Fourth Circuit, of which Maryland is a part..[14]

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.

[14] For a more complete record of past Maryland legislative activity regarding PBMs, ERISA, and Specialty Drugs, see Appendix C.

§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.[15]

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.

[15] *See* Appendix A.

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.[16]

1. August 27, 2025 Workgroup Meeting

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.[17] An overview of the workgroup's agenda for 2025 and expectations for 2026 was provided.[18] 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.

---

[16] https://insurance.maryland.gov/Consumer/Pages/Pharmacy-Benefits-Workgroup-Meeting-Dates.aspx.
[17] *See* Appendix A.
[18] MIA (2025) Slides 9-17: https://insurance.maryland.gov/Consumer/Documents/agencyhearings/PBM-Workgroup-Meeting-1.pdf.

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.

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[19] 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

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.

[19] *See* Appendix B.

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.

To Be Continued from 2025

- 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.

To Be Considered in 2026

- Review reimbursement for pharmacists, including:
  - (i) existing Maryland Medical Assistance Program requirements for pharmacy benefits managers and managed care organizations related to dispensing fee reimbursement, pharmacy benefits managers fees charged to pharmacies and the Maryland Medical Assistance Program, transparency in pricing and reimbursement data, specialty drug designations, and appeals processes;
  - (ii) how other states' pharmacy benefits services operate in Medicaid, including in Ohio, Kentucky, New York, California, and West Virginia;

    - (iii) measures that offset the Department's costs to fund the Medicaid Managed Care Program and adopt NADAC plus the Fee–for–Service Professional Dispensing, including:
        - 1. savings associated with NADAC ingredient cost pricing and managed care organizations; and
        - 2. pharmacy benefits managers administrative fee consolidation and rebate allocations; and
    - (iv) 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.

As requested by Delegate Cullison, information to aid in discussions of Maryland's definition of "specialty drug" have been provided in Appendices D and E. The Workgroup came to no formal recommendation in regards to charge 3, but does not oppose the issue being addressed during the 2026 legislative session. However, a full analysis of drug formularies across carriers and their commonalities as requested in charge 3 cannot be provided by the MIA at this time.

Following the 2026 legislative session, workgroup meetings will resume and discussions regarding the charges set forth will continue or be initiated. 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.

APPENDICES

APPENDIX A

601 Pennsylvania Avenue, NW
South Building, Suite 500
Washington, D.C. 20004

T 202.778.3200
F 202.331.7487
ahip.org

September 18, 2025

Mary Kwei
Co-Chair, Pharmacy Benefits Managers Workgroup
Maryland Insurance Administration

Athos Alexandrou
Co-Chair, Pharmacy Benefits Managers Workgroup
Maryland Department of Health

Re: Workgroup meeting #2: ERISA exemptions for PBM regulation

Dear Co-Chairs Kwei and Alexandrou:

As the Pharmacy Benefits Managers Workgroup considers its charge to review ERISA exemptions for pharmacy benefits management regulation, AHIP thought it might be helpful to provide the Workgroup with the accompanying legal analysis for informational purposes.

AHIP previously provided this same legal analysis to the chairs of the Senate Finance Committee and House Health and Government Operations Committee as their committees considered Senate Bill 303 and cross-filed House Bill 321 earlier this year. We believe the analysis is also pertinent to the Workgroup discussion, particularly as it relates to the scope of *Rutledge v. Pharmaceutical Care Management Association* and subsequent case law and federal guidance.

This analysis, conducted by ERISA experts at The Groom Law Group, is intended to provide a brief overview of the current federal preemption law and jurisprudence under both ERISA and the Medicare Part D statute. It also identifies the specific statutory provisions of House Bill 321 preempted by ERISA and the basis for the federal preemption.

In addition, we believe it is both important and relevant to note two significant developments that have taken place since the attached analysis was drafted:

1. On June 30, 2025, the U.S. Supreme Court declined to review a 2023 ruling by the U.S. Court of Appeals for the Tenth Circuit in *PCMA v. Mulready*.[1] By declining to review this ruling, the Court let stand the Tenth Circuit's holding that, when a state's law restricts the ability of an ERISA-covered plan to utilize benefit designs that encourage participant utilization of certain providers, that law is preempted under ERISA. The decision also addresses the appropriate scope of *Rutledge* and how it aligns with longstanding ERISA jurisprudence.

2. On March 31, 2025, the U.S. District Court for the Eastern District of Tennessee found that ERISA preempts the "any willing provider" provisions of Tennessee's pharmacy benefit manager (PBM) law.[2] The decision relies on established Sixth Circuit precedent finding that, when a state's law has

[1] *Pharmaceutical Care Mgmt. Ass'n v. Mulready*, 78 F.4th 1183 (10th Cir. 2023), cert. denied, 2025 WL 1787716 (2025).

[2] *McKee Foods Corp. v. BFP Inc. d/b/a Thrifty Med Plus Pharmacy*, No. 1:21-cv-279, 2025 WL 968404 (E.D. Tenn. Mar. 31, 2025), on appeal, No. 25-5416 (6th Cir.).

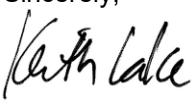
> the effect of dictating the design or provision of substantive benefits of an ERISA-covered plan, it implicates a central matter of plan administration and is preempted by ERISA.[3]

Today, more than half of Americans receive their health insurance through employer-sponsored coverage that is governed by ERISA, which affords employers consistency and uniformity of health plan administration. This encourages health care coverage that improves the health and financial stability of employees and their families. In Maryland, more than 3.2 million residents (54% of the state's covered population) are covered by employer-sponsored insurance. Of those Maryland employers that provide coverage to their employees, 48% of those employers offer self-insured ERISA plans.[4]

This single, cost-saving national standard of regulation for employer-provided health care coverage gives employers the option to assume financial risk and allows employers to choose specifically tailored and uniform benefits for their employees regardless of where they live. This ensures more affordable coverage that is easier to administer and understand.

We appreciate your consideration of our analysis and are happy to provide any additional information or analysis as the Workgroup conducts its review.

Sincerely,



Keith Lake
Regional Director, State Affairs
klake@ahip.org / 220-212-8008

AHIP is the national association whose members provide insurance coverage for health care and related services. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities, and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers.

[3] *Kentucky Ass'n of Health Plans, Inc. v. Nichols*, 227 F.3d 352, 363 (6th Cir. 2000), aff'd sub nom. *Kentucky Ass'n of Health Plans, Inc. v. Miller*, 538 U.S. 329, 123 S. Ct. 1471, 155 L. Ed. 2d 468 (2003

[4] AHIP's Health Coverage: State-to-State 2023. 202407-EPC_StateData-Maryland.pdf

GROOM LAW GROUP

March 21, 2025

ERISA Preemption of Maryland House Bill 321

ERISA preempts any state law that "relates to" an ERISA-covered employee benefit plan. ERISA § 514(a). As recognized by the Supreme Court of the United States, a central purpose of ERISA's broad preemption provision is to allow for the uniform administration of ERISA plans. *See, e.g., Egelhoff v. Egelhoff*, 432 U.S. 141, 148 (2001) (holding that ERISA preempted a state statute governing beneficiaries under an ERISA plan). A state law "relates to" a plan, and implicates preemption, when it has a "connection with or reference to" an ERISA plan. *Id*. at 147. The Supreme Court has made clear that a central purpose of ERISA's broad preemption provision is to allow for the uniform administration of ERISA plans. *See, e.g., Egelhoff v. Egelhoff*, 432 U.S. 141, 148 (2001) (holding that ERISA preempted a state statute governing beneficiaries under an ERISA plan).

The Supreme Court clarified two main categories of state law that ERISA would preempt: (1) "where a state's law acts immediately and exclusively upon ERISA plans or where the existence of ERISA plans is essential to the law's operation" and (2) where there is "an impermissible connection with ERISA plans [which] govern a central matter of plan administration." *Gobeille v. Liberty Mut. Ins. Co*., 577 U.S. 312, 319-320 (2016) (internal quotations and citations omitted). Notably, the state law at issue in *Gobeille* applied to the third-party administrator ("TPA") acting on behalf of the ERISA-covered plan. In recognition of the statutory "deemer clause," which prevents states from "deeming" a self-insured, ERISA-covered plan to be an insurer for purposes of the insurance savings clause, the Court held that the Vermont law at issue was preempted, notwithstanding the fact that it applied to the insurer acting as a TPA for the plan. ERISA § 514(b)(2). A state law may also be preempted if its economic effects force an ERISA plan to adopt certain coverage or restrict its choice of insurers. *See id*. at 320.

In *Rutledge*, the most recent Supreme Court case analyzing ERISA preemption, the Court affirmed both *Egelhoff* and *Gobeille* when reviewing a state law that regulates the reimbursement amounts PBMs pay pharmacies for drugs covered by prescription drug plans. *Rutledge v. Pharm. Care Mgt. Assn.*, 592 U.S. 80, 86 (2020). In a narrowly tailored decision, the Court held that the state law was not preempted by ERISA because it merely regulated costs rather than dictate ERISA-plan choices. *See id.* at 81. Instead, the Court focused squarely on the facts of the Arkansas cost-regulation while applying earlier Court precedent addressing the extent to which state-level cost regulation is preempted. Importantly, the Court was clear that prior precedent outside the context of indirect cost regulation remained intact and found that the state law did not govern a "central matter of plan administration" by increasing costs for ERISA plans without forcing plans to adopt certain rules for coverage. *Id* at 80; *Gobeille* at 320. Moreover, the Court in *Rutledge* also reaffirmed the long-held view of the Court that a state law "which requires employers to pay employees specific benefits, clearly 'relate to' benefit plans," and are thus subject to preemption. *Shaw v. Delta Air Lines, Inc*., 463 U.S. 85, 97 (1983); *Rutledge*, 592 U.S. at 86-87.

More recently, the Tenth Circuit properly read *Rutledge* as being limited to indirect cost regulation. In *Mulready* the court examined an Oklahoma state law that imposed regulations on PBMs and pharmacy networks in an effort to establish minimum and uniform guidelines regarding a patient's right to choose a pharmacy provider. *PCMA. v. Mulready*, 78 F.4th 1183, 1190 (10th Cir. 2023). The state law included four key provisions that subjected PBMs to certain rules including pharmacy access network standards and restrictions on the incentives given to individuals who fill prescriptions at in-network pharmacies. *See id.* at 1190-1191. The court held that all four provisions were preempted by ERISA because they had an impermissible connection with ERISA plans by mandating certain benefit structures related to a key benefit design (*i.e.* the scope and differentiation of the plan's pharmacy network benefit). *Id.* at 1199-1200. The court found that the Oklahoma law was an attempt by the State to "govern[ ] a central matter of plan administration" and "interfere[ ] with nationally uniform plan administration." *Id.* at 1200.[1]

MD House Bill 321

Maryland House Bill 321 ("HB 321") seeks to impose certain of the state's insurance laws governing pharmacy benefit managers ("PBMs") on pharmacy benefit management services provided to ERISA-covered, self-insured group health plans. HB 321 accomplishes this by eliminating current law limitations on the applicability of state PBM requirements to "carriers". A number of these provisions should be preempted by ERISA based on existing Supreme Court jurisprudence, including *Rutledge*. In the following chart, we identify the specific legislative provision, provide a description of the provision, and include the basis for federal law preemption, assuming that the State seeks to impose these requirements with respect to self-insured, ERISA-covered plans.

Proposed Statutory Provision	***Description***	***Reason for ERISA Preemption***
Md. Code Ann., Ins. § 15-1611.1	Prohibits PBMs from requiring the use of pharmacies affiliated with the PBM.	This provision limits the ability of ERISA-covered plans to determine the scope of their pharmacy networks, which is inherent in the plan's benefit design. Thus, the provision should be preempted because it requires a specific benefit design choice by the plan sponsor consistent with the holding in *Mulready*.
Md. Code Ann., Ins. § 15-1612(b)	Prohibits a PBM from reimbursing a non-affiliated pharmacy less than the PBM reimburses affiliated pharmacies.	This provision limits the ability of ERISA-covered plans to contract for high-value pharmacy networks, which is inherent in the plan's

[1] Notably, the Tenth Circuit also squarely rejected the State's argument that the state law in question was not preempted by ERISA because the law regulates PBMs rather than the actual health plan. *Id*. at 1194. Many courts have recognized that state laws regulating PBMs function as the regulation of an ERISA plan because most plans cannot operate without a PBM. *Id*. at 1195

Proposed Statutory Provision	***Description***	***Reason for ERISA Preemption***
		benefit design. Thus, the provision should be preempted because it requires a specific benefit design choice by the plan sponsor consistent with the holding in *Mulready*.
Md. Code Ann., Ins. § 15-1629	Proscribes the manner in which PBMs may audit pharmacies and recover overpayments.	This provision could impose acute *and* direct economic burden on plans because it limits recovery of plan assets. Moreover, it could directly conflict with ERISA's fiduciary duty to act solely in the interest of the plan. As a result, the provision addresses a central matter of plan administration and fiduciary obligation, and should be preempted per *Gobeille*.

The League of Life and Health Insurers of Maryland

15 School Street, Suite 200
Annapolis, Maryland 21401
410-269-1554

September 17, 2025

Mary Kwei
Co-Chair, Pharmacy Benefits Managers Workgroup
Maryland Insurance Administration

Athos Alexandrou
Co-Chair, Pharmacy Benefits Managers Workgroup
Maryland Department of Health

Re: Workgroup meeting #2: ERISA exemptions for PBM regulation

Dear Co-Chairs Kwei and Alexandrou:

The League of Life and Health Insurers of Maryland, Inc. respectfully submitted similar comments on *House Bill 321* -- *Pharmacy Benefits Managers – Definition of Purchaser and Alteration of Application of Law* to the House Health & Government Operations as well as the Senate Finance Committees during the 2025 Maryland General Assembly Session. The comments are certainly appropriate for the continued conversation within the interim PBM workgroup on the topic.

Health insurance should be simple, effective, and affordable. Patients and employers should not have to navigate complex regulations to get the care they need at a cost they can afford. The League supports a single, cost-saving national standard of regulation for self-funded employer-provided coverage, ensuring more affordable coverage for all, that is easier to understand. A 50-state patchwork of complicated and inconsistent mandates for employer-provided coverage will cause more confusion and make coverage more expensive for Maryland's employers and employees.

For decades, state laws related to state health plans, including all prescription drug benefits, have only been applied to fully insured health plans subject to regulation by the Maryland Insurance Administration (MIA), and not plans exempted by the federal ERISA law.

We understand the Supreme Court Rutledge decision changed that landscape, but the subsequent *Mulready* challenge has swung the pendulum back towards status quo. It also doesn't change the fact that the proponents are trying to mandate changes to plan design, which carriers are fundamentally opposed to as it is not the carrier decision – the structure of the benefits are designed solely by the plan sponsor.

By extending the provisions of prior PBM law structure to self-insured plans these proposals would restrict the opportunity for health plans to reduce their prescription drug costs. This will also come as a surprise to a ton of these businesses as they will most likely have zero clue these discussions are taking place – they will see extreme sticker shock if this bill moves forward.

The League thinks that the intent of extending ERISA provisions misses where the financial burden ultimately lands, which is emplyers trying to provide coverage at affordable levels to their employees, who will ultimately bear the burden of this legislation. Contrary to what might have been shared with the workgroup, the introduced House Bill 321 from the 2025 Session does nothing to address the exploding price of prescription drugs and only adds costs to the health care system which will manifest itself in higher premiums for Marylanders.

The single, cost-saving national standard of regulation for ERISA coverage gives employers the option to assume financial risk and allows employers to choose specifically tailored and uniform benefits for their employees regardless of where they live. This ensures more affordable coverage that is easier to administer and understand. To circumvent this stability would be problematic and costly at best and we urge the workgroup to reject the premise

We appreciate your consideration of our comment and are always available to have continued conversation.

Very truly yours,

Matthew Celentano
Executive Director

FREDERICK COUNTY
CHAMBER OF COMMERCE

September 23, 2025

Maryland Insurance Administration
Pharmacy Benefit Managers Workgroup

Dear Pharmacy Benefits Managers Workgroup,

The Frederick County Chamber of Commerce Public Policy Committee, which represents 1,030 businesses and nonprofits, in Frederick County, thanks you for the chance to share our thoughts after the first meeting of Maryland's Pharmacy Benefits Manager (PBM) Workgroup.

As this process moves forward, we ask the Workgroup to keep in mind the needs of Maryland's employers, public institutions, and other plan sponsors, especially those that provide self-funded health plans for their employees and families.

Our members rely on these self-funded plans to make healthcare more affordable and accessible. These plans are based on a federal law called ERISA, which has guided employer-sponsored healthcare in Maryland and across the U.S. for more than 50 years.

We know the Workgroup has been asked to look at "ERISA exemptions for pharmacy benefits management regulation," as noted in HB813. When it comes to ERISA, it's important to remember that having one consistent federal standard helps employers keep benefits fair, manageable, and cost-effective across state lines. Maryland employers depend on this flexibility.

As the Workgroup reviews pharmacy benefit management, it's essential to include employer and plan sponsor voices. Employers are the ones actually operating these health plans, so their perspective needs to be part of the conversation.

It's also important to point out that ERISA preemption issues are still being debated in court. Because the law isn't settled yet, we believe it's too soon for this Workgroup to make big decisions on this matter.

We support a careful, data-driven approach that improves transparency, accountability, and competition. At the same time, reforms that take away tools like rebate negotiations or limit formulary management could backfire—making it harder for employers to keep coverage affordable in today's tough economic environment.

Thank you again for the chance to comment. We look forward to staying involved and contributing as the Workgroup works on its 2025 agenda and begins its interim report.

Respectfully,

Rick Weldon
President/CEO
Frederick County Chamber of Commerce

118 N. Market Street, Suite 100, Frederick, MD 21701
frederickchamber.org / 301.662.4164 /

the chamber
WASHINGTON COUNTY, MD

1 South Potomac St.
Hagerstown, MD 21740
301-739-2015
HAGERSTOWN.ORG

September 29, 2025

Written Testimony of the Washington County (MD) Chamber of Commerce
Prepared for the Pharmacy Benefits Managers Workgroup

Dear Pharmacy Benefits Managers Workgroup:

On behalf of the Washinton County (MD) Chamber of Commerce, which represents over 675 members organizations with over 40,000 employees, we appreciate the opportunity to submit written comments following the first meeting of Maryland's Pharmacy Benefits Manager (PBM) Workgroup.

As this process moves forward, we strongly urge the Workgroup to keep the needs of Maryland's employers, public institutions, and plan sponsors at the forefront, with a particular focus on those that offer self-funded health plans to their employees and beneficiaries.

Our members depend on self-funded plans to provide affordable and accessible healthcare. These plans are structured under the Employee Retirement Income Security Act of 1974 (ERISA), which has served as the foundation for employer-sponsored healthcare in Maryland and across the country for over five decades.

We are particularly attentive to the Workgroup's charge to "review ERISA exemptions for pharmacy benefits management regulation," as outlined in HB813. Any discussion of ERISA-related matters must account for the significant value that flexibility and uniformity bring to employer-sponsored plans. Maryland's diverse employers rely on consistent federal standards to manage benefits across jurisdictions and to design coverage that balances cost and care for their employees. Given the recent increase in health insurance premiums, this is especially not the time do anything.

As the Workgroup reviews the structure of pharmacy benefit management, we encourage continued inclusion of employer and plan sponsor voices. Given the central role employers play in administering coverage, this perspective must be actively considered throughout the Workgroup's work.

Additionally, as was made clear during the ERISA meeting on September 17th, issues surrounding the ERISA preemption are unsettled law and will take some time to be resolved as the litigation proceeds through the court. Therefore, now is not the time for this workgroup to make decisions while this issue is ongoing.

We support data-driven review and welcome appropriate guardrails to ensure transparency, accountability, and fair competition. But reforms that restrict formulary management, weaken rebate negotiation authority, or duplicate existing ERISA protections risk doing more harm than good, particularly for employers trying to provide coverage in a challenging economic environment.

Thank you again for the opportunity to comment. We look forward to continued participation and thoughtful dialogue as the Workgroup completes its 2025 agenda and begins drafting its interim report.

Sincerely,

Paul Frey

Paul Frey, President and CEO

MARYLAND Association of COUNTIES

Written Testimony of the Maryland Association of Counties
Prepared for the Pharmacy Benefits Managers Workgroup

Dear Pharmacy Benefits Managers Workgroup,

On behalf of the Maryland Association of Counties (MACo), which represents Maryland's 23 county governments and Baltimore City, we appreciate the opportunity to submit written comments following the first meeting of the Pharmacy Benefits Manager (PBM) Workgroup.

As this process moves forward, we respectfully urge the Workgroup to keep the concerns of Maryland's counties, and the employees and residents they serve, at the forefront, particularly those counties that self-insure their employee health plans. Self-funded plans remain a critical tool for counties to provide affordable, flexible, and accessible healthcare. These plans operate under the Employee Retirement Income Security Act of 1974 (ERISA), which has provided uniform federal standards for employer-sponsored health coverage for more than five decades.

We note the Workgroup's charge under HB 813 to "review ERISA exemptions for pharmacy benefits management regulation." Any discussion regarding ERISA must recognize the value of consistent federal standards, which allow counties to manage benefits efficiently, maintain fiscal responsibility, and balance costs and care for employees.

Given the ongoing legal uncertainties surrounding ERISA preemption, as highlighted during the September 17 ERISA-focused meeting, now is not the time for the Workgroup to make policy decisions that could disrupt county health plan administration. We strongly support a data-driven approach that promotes transparency, accountability, and fair competition in PBM practices, but caution against reforms that would restrict formulary management, weaken rebate negotiation authority, or duplicate existing ERISA protections. Such changes risk harming counties and their ability to provide cost-effective healthcare to employees.

Thank you for the opportunity to provide input. MACo looks forward to continued engagement and constructive dialogue as the Workgroup advances its 2025 agenda and prepares its interim report.

MARYLAND
Chamber of Commerce

Via Electronic Mail

October 1, 2025

Co-Chair Mary M. Kwei
Maryland Insurance Administration
Market Regulation and Professional Licensing
200 St. Paul Place, Suite 2700
Baltimore, MD 21202

Co-Chair Athos P. Alexandrou
Maryland Department of Health
Office of Pharmacy Services
201 West Preston Street
Baltimore, MD 21201

Re: Comments from the Maryland Chamber of Commerce

Dear Pharmacy Benefits Managers Workgroup:

On behalf of The Maryland Chamber of Commerce, which represents more than 7,000 Maryland employers, we appreciate the opportunity to submit written comments following the first meeting of Maryland's Pharmacy Benefits Manager (PBM) Workgroup.

As this process moves forward, we strongly urge the Workgroup to keep the needs of Maryland's employers, public institutions, and plan sponsors at the forefront, with a particular focus on those that offer self-funded health plans to their employees and beneficiaries.

Our members depend on self-funded plans to provide affordable and accessible healthcare. These plans are structured under the Employee Retirement Income Security Act of 1974 (ERISA), which has served as the foundation for employer-sponsored healthcare in Maryland and across the country for more than five decades.

We are particularly attentive to the Workgroup's charge to "review ERISA exemptions for pharmacy benefits management regulation," as outlined in House Bill 813 of 2025. Any discussion of ERISA-related matters must account for the significant value that flexibility and uniformity bring to employer-sponsored plans. Maryland's diverse employers rely on consistent federal standards to manage benefits across jurisdictions and to design coverage that balances cost and care for their employees.

As the Workgroup reviews the structure of pharmacy benefit management, we encourage continued inclusion of employer and plan sponsor voices. Given the central role employers play in administering coverage, this perspective must be actively considered throughout the Workgroup's work.

Additionally, as was made clear during Workgroup meeting on September 17, 2025, issues surrounding the ERISA preemption are unsettled law and will take time to resolve as litigation proceeds through the courts. Therefore, it stands to reason that now is *not* the time to make decisions impacting ERISA exemptions.

We support a data-driven policy review that ensures transparency, accountability, and fair competition, but reforms that restrict formulary management, weaken an employer's rebate negotiation authority, or duplicate existing ERISA protections risk doing more harm than good, particularly on employers providing coverage in a challenging and uncertain economic environment.

Thank you again for the opportunity to comment. We look forward to continued participation and thoughtful dialogue as the Workgroup completes its 2025 agenda and begins drafting its interim report.

Sincerely,

Mary Kane
CEO & President
Maryland Chamber of Commerce

INTERNATIONAL BROTHERHOOD OF ELECTRICAL WORKERS - LOCAL UNION No. 24

AFFILIATED WITH:
Baltimore-D.C. Metro Building Trades Council - AFL-CIO
Baltimore Port Council
Baltimore Metro Council - AFL-CIO
Central MD Labor Council - AFL-CIO
Del-Mar-Va Labor Council - AFL-CIO
Maryland State - D.C. - AFL-CIO
National Safety Council

AFL-CI0-CLC

BALTIMORE, MARYLAND 21230

JON McLAUGHLIN, President
CARMEN F. VOSO., Recording Secretary
JEROME T. MILLER, Financial Secretary
MICHAEL J. MCHALE, Business Manager

OFFICE:
2701 W. PATAPSCO AVENUE
SUITE 200

Phone: 410-247-5511
FAX: 410-536-4338

To Whom It May Concern:

My name is Rico Albacarys and I am writing on behalf of the International Brotherhood of Electrical Workers Local 24, in Baltimore. IBEW 24 represents more than 2,800 working men and women in Maryland, with offices and training locations in Frederick, Baltimore, and Salisbury. We want to share our perspective as the PBM Workgroup begins reviewing pharmacy benefit manager practices, ERISA protections, and pharmacy reimbursement policies.

Many of our members are covered by self-funded, ERISA-based health plans. These plans are what keep working families healthy and financially stable. Without ERISA's protections, many of the benefits our members rely on would be unaffordable or unavailable.

For decades, ERISA has created a consistent and affordable system for employers and workers alike. Changes that disrupt this structure, such as restrictions on plan design, drug formularies, or cost-sharing rules, would quickly drive up costs for families. When plans lose the ability to negotiate rebates or manage prescriptions effectively, the impact is felt in higher co-pays, fewer choices, and interruptions in care.

We encourage the PBM Workgroup to listen to organized labor and plan sponsors as this process plays out. Both have first-hand knowledge of what it takes to deliver strong health coverage. We also note that the legal questions surrounding ERISA preemption remain unsettled in the courts. Until those cases are resolved, we feel it is premature to take actions that could destabilize established benefit systems.

We urge you to protect the tools that have allowed unions and employers to provide affordable, dependable health care. Maryland's working families cannot afford policies that raise costs or weaken coverage, especially now.

Sincerely,

Rico Albacarys
Political Director
IBEW Local 24

MICUA
MARYLAND INDEPENDENT COLLEGE and UNIVERSITY ASSOCIATION
140 South Street, Annapolis, MD 21401
410-269-0306
www.micua.org

October 01, 2025

Mary Kwei
Maryland Insurance Administration
Associate Commissioner
Market Regulation and Professional Licensing
Co-Chair
St. Paul Plaza
200 St. Paul Place, Suite 2700
Baltimore, MD 21202 – 2272

Athos Alexandrou
Maryland Department of Health
Director
Office of Pharmacy Services
Co-Chair
Herbert R. O'Conor State Office Building
201 West Preston Street
Baltimore, MD 21201 – 2399

Re: ERISA Working Group

Dear Associate Commissioner Kwei and Director Alexandrou:

I am writing on behalf of the member institutions of the Maryland Independent College and University Association (MICUA) and the nearly 55,000 students we serve to share our concerns surrounding the exemptions for pharmacy benefits management under the Employee Retirement Income Security Act of 1974 (ERISA).

ERISA has governed the State since its passage and federal preemption has kept legislatures from overriding the laws that govern self-funded plans. Several MICUA institutions offer self-funded plans, and this change in practice would impact their operations and capability to offer reasonably priced employee benefits packages.

Changes to Maryland's self-funded plans which have existed in the State for over 50 years would come at a time when MICUA schools are experiencing overburdened budgets while working to offer affordable plans to their employees. Institutions of higher education aim to attract highly qualified individuals to their campuses to educate students who will enter the workforce. Employee benefits are used as a recruiting tool to attract skilled academic and administrative personnel, and this legislation could interfere with these efforts.

Thank you for the opportunity to provide this information on behalf of our member institutions. If you have any questions or would like additional information contact Irnande Altema, Vice President for Government and Business Affairs, ialtema@micua.org.

Sincerely,

Matt Power
President

November 14, 2025

Mary Kwei
Co-Chair, Workgroup to Study Pharmacy Benefits Managers
Maryland Insurance Administration

Athos Alexandrou
Co-Chair, Workgroup to Study Pharmacy Benefits Managers
Maryland Department of Health

Re: Workgroup to Study Pharmacy Benefit Managers – Interim Report Comments

The Independent Pharmacies of Maryland (IPMD) respectfully submit the following comments in response to the interim report for the Workgroup to Study Pharmacy Benefits Managers. Independent pharmacies serve as an integral part of the community by providing essential health services that go beyond merely dispensing medications, while also focusing on personalized patient care, health consultations, and fostering long-term relationships with patients to improve their well-being.

Executive Summary Comments

We believe the Executive Summary, as drafted, is narrow and one sided. Specifically point 2. Currently the draft only highlights those workgroup members and their overall concern about extending certain PBM regulations to ERISA plans, the sentence in parts states "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," and "while other stakeholders were concerned about how the lack of State regulatory protections would result in disruptions to care." We believe additional language should be added to point 2 that states there were workgroup members supportive of extending these PBM regulations to ERISA plans, and rebutted that other stakeholders would be harmed.

Background Comments

As drafted, the report accurately reflects when the current law was passed and mentions how Insurance Article §15-847 has been amended over the years. However, we believe this section should, at a minimum, reference the nearly 26 other bills that have been

introduced before the General Assembly since 2015, that while not having passed, continue to highlight how the current law has been flawed from the perspective of a number of stakeholders.

In the same section, with the paragraph starting with "On January 1, 2026, a law providing guidance on where Maryland can obtain specialty drugs on the commercial market will take effect," it is unclear which law is being referred to and which statute has been amended. We believe a footnote citation would be helpful.

Additional language should be included in the ERISA background section that highlights the number of bills that have been introduced before the General Assembly as well.

2026 Workgroup Charges Comments

As drafted, we believe that the "To Be Considered in 2026" charges could more closely mirror what was passed in House Bill 813. As we review the bullet points, some statutory language is included while other parts are either glossed over or completely omitted. We recommend amending the first two bullet points and instead insert language that specifies this workgroup must:

> (2) review reimbursement for pharmacists, including:
>
> (i) existing Maryland Medical Assistance Program requirements for pharmacy benefits managers and managed care organizations related to dispensing fee reimbursement, pharmacy benefits managers fees charged to pharmacies and the Maryland Medical Assistance Program, transparency in pricing and reimbursement data, specialty drug designations, and appeals processes;
>
> (ii) how other states' pharmacy benefits services operate in Medicaid, including in Ohio, Kentucky, New York, California, and West Virginia;
>
> (iii) measures that offset the Department's costs to fund the Medicaid Managed Care Program and adopt NADAC plus the Fee–for–Service Professional Dispensing, including:
>
> 1. savings associated with NADAC ingredient cost pricing and managed care organizations; and
>
> 2. pharmacy benefits managers administrative fee consolidation and rebate allocations; and
>
> (iv) strategies for adopting pharmacy reimbursement parity and drug pricing transparency;

Currently the bullet points gloss over the fact that the workgroup has been charged to specifically look at other states and how those states handle PBMs in the Medicaid space and reimbursement. The General Assembly made the decision that the workgroup should focus its

research on certain states and we believe by failing to include those states in this section, it undermines the intent of the General Assembly.

Additional Comments

We recognize that there were a number of hurdles after the conclusion of the 2025 legislative session which delayed the start of the workgroup until August. We believe this report should include, at a minimum, a schedule of 2026 meetings with expected topics to be covered. We are concerned that with the upcoming 2026 legislative session this planning work will not only be delayed by session but then there will be an additional delay in the workgroup resuming its work upon the conclusion of the session.

As previously mentioned, House Bill 813 also requires this workgroup to "review reimbursement for pharmacists, including how other states' pharmacy benefits services operate in Medicaid, including in Ohio, Kentucky, New York, California, and West Virginia" this report does not outline with any specifics when these state reviews will be conducted or if they are currently being conducted. We were disappointed to learn at the first meeting that the MDH specifics of the workgroup would be delayed until 2026, however we are unclear if this background work is currently being conducted or will completely be delayed until 2026 or upon the conclusion of the 2026 legislative session. We belie including additional language will assist stakeholders in planning for 2026 meetings.

Conclusion

The Independent Pharmacies of Maryland appreciate the opportunity to provide comments on the interim report of the Workgroup to Study Pharmacy Benefit Managers. We strongly urge the Workgroup to ensure that the interim report reflects the full range of stakeholder perspectives, particularly those of independent pharmacies that play a vital role in patient access and community care. We look forward to continued engagement in this process and to working collaboratively with the workgroup to promote a fair, transparent, and sustainable pharmacy benefit system that best serves patients, providers, and the broader healthcare community.

Appendix B

Pharmacy Benefits Managers Workgroup Members

Entity Required to be Represented	Representative Name	Representative's Organization
community pharmacies - chain setting	Jill McCormack	National Association of Chain Drug Stores
community pharmacies - independent setting	Steve Wienner	Mt. Vernon Pharmacy
pharmacy services administrative organizations	Brian Hose	EPIC Pharmacy Network
health insurance carriers	Kim Robinson	CareFirst
plan sponsor representatives	VACANT	
drug wholesalers and distributors	Leah Lindahl	Healthcare Distribution Alliance
non–pharmacy benefit manager–owned mail order pharmacies	Scott Glasscock	Walmart
brand name drug manufacturers	Deron Johnson	Amgen
generic drug manufacturers	VACANT	
pharmacists	Aliyah Horton	Maryland Pharmacists Association
pharmacy benefit managers	Heather Cascone	Pharmaceutical Care Management Association
third party experts in the field of drug pricing in Medicaid	Allan Hansen	Myers and Stauffer
managed care organizations	Meredith Fleming	WellPoint
Maryland Board of Pharmacy (*not a required entity)	Deena Speights-Napata	Maryland Board of Pharmacy

Appendix C

History of PBM, ERISA, or Specialty Drug Legislation in Maryland

Year	Bill Name	Outcome
2025	HB0813/SB0438 Maryland Insurance Administration and Maryland Department of Health - Workgroup to Study Pharmacy Benefits Managers	Approved by the Governor
2025	HB1243/SB0975 Health Insurance - Coverage for Specialty Drugs	Approved by the Governor
2024	HB1270/SB1019 Health Benefit Plans - Prescription Drugs - Rebates and Calculation of Cost Sharing Requirements	Withdrawn by Sponsor
2023	HB0374/SB0565 Health Insurance – Pharmacy Benefits Managers – Audits of Pharmacies and Pharmacists	Approved by the Governor
2022	HB0973/SB0823 Pharmacy Services Administrative Organizations and Pharmacy Benefits Managers - Contracts	Approved by the Governor
2022	HB1006 Pharmacy Benefits Managers – Network Adequacy, Credentialing, and Reimbursement	Withdrawn by Sponsor
2022	HB1008 Pharmacy Benefits Managers and Purchasers - Beneficiary Choice of Pharmacy	Withdrawn by Sponsor
2022	HB1219 Pharmacists - Status as Health Care Providers and Study on Reimbursement	Approved by the Governor
2022	HB1274 Prescription Drugs - Pharmacy Benefits Managers - Federal 340B Program	Approved by the Governor
2022	SB1004 Health Insurance - Pharmacy Benefits Managers - Reimbursement Amounts	Failed
2021	HB0601 Pharmacy Benefits Managers - Revisions	Approved by the Governor
2021	SB0964 Pharmacy Benefits Managers - Definition of Purchaser and ERISA	Failed
2021	HB0603 Health Insurance - Pharmacy Benefits Managers - Explanation of Benefits Statements	Withdrawn by Sponsor
2021	HB0709/SB0614 Pharmacy Benefits Managers - Drug Reimbursement - Reporting Requirements	Failed
2020	HB0978/SB0915 Maryland Insurance Administration - Pharmacy Services Administrative Organizations - Regulation	Enacted

2020	HB1307 Pharmacy Benefits Managers – Credentialing and Reimbursement	Enacted
2020	SB1017 Pharmacy Benefits Managers - Network Adequacy and Reimbursement	Failed
2020	HB0652/SB0931 Maryland Medical Assistance Program and Health Insurance - Specialty Drugs - Definition	Approved by the Governor

Appendix D

Definitions of "Specialty Drug" in Other States

State	Text	Citation
Delaware	(7) "Specialty drug" means a prescription drug that: a. Is prescribed for a person with: 1. A complex or chronic medical condition, defined as a physical, behavioral, or developmental condition that may have no known cure and/or is progressive and/or can be debilitating or fatal if left untreated or under-treated, such as multiple sclerosis, hepatitis C, and rheumatoid arthritis; or 2. A rare medical condition, defined as any disease or condition that affects fewer than 200,000 persons in the United States, or about 1 in 1,500 people, such as cystic fibrosis, hemophilia, and multiple myeloma; and b. The total monthly cost of the prescription is $600 or more; and c. The drug is not stocked at a majority of retail pharmacies; and d. The drug has 1 or more of the following characteristics: 1. 1. It is an oral, injectible, or infusible drug product. 2. 3. 2. It has unique storage or shipment requirements, such as refrigeration. 4. 5. 3. Patients receiving the drug require education and support beyond traditional dispensing activities.	18 DE Code § 3364 (2024) https://law.justia.com/codes/delaware/title-18/chapter-33/subchapter-i/section-3364/
Iowa	21B. "Specialty Drug" means a drug used to treat chronic and complex, or rare medical conditions and that requires special handling or administration, provider care coordination, or patient education that cannot be provided by a nonspecialty pharmacy or pharmacist.	An Act Relating to Pharmacy Benefits Managers, Pharmacies, Prescription Drugs, and Pharmacy Services Administrative Organizations, and Including Applicability

		Provisions. Senate File 383. 91st General Assembly (2025). https://www.legis.iowa.gov/docs/publications/LGE/91/Attachments/SF383_GovLetter.pdf
Michigan	d. "Specialty drug" means a drug that provides treatment for serious, chronic, or life-threatening diseases that is covered under a patient's health plan or by a patient's carrier to which any of the following apply: (i) The cost of the drug exceeds the drug cost threshold established by the Centers for Medicare and Medicaid Services under the Medicare Part D program. (ii) The drug requires special administration, including, but not limited to, injection, infusion, or inhalation. (iii) The drug requires unique storage, handling, or distribution. (iv) The drug requires special oversight, intensive monitoring, complex education and support, or care coordination with a person licensed under article 15 of the public health code, 1978 PA 368, MCL 333.16101 to 333.18838.	MI Comp L § 550.819 (2024) https://law.justia.com/codes/michigan/chapter-550/statute-act-11-of-2022/section-550-819/
Washington D.C.	(10) "Specialty drug" means a prescription drug that: a. Is prescribed for a person with: (i) A physical, behavioral, or developmental condition that may have no known cure, is progressive, or can be debilitating or fatal if left untreated or undertreated, such as multiple sclerosis, hepatitis C, or rheumatoid arthritis; or (ii) A disease or condition that affects fewer than 200,000 persons in the United States or approximately one in 1,500 persons worldwide, such as cystic fibrosis, hemophilia, or multiple myeloma; b. Has a total monthly prescription cost of $600 or more; and	DC Code § 48–855.01 (2024) https://law.justia.com/codes/district-of-columbia/title-48/chapter-8h/section-48-855-01/

	c. Has one or more of the following characteristics: (i) Is an oral, injectible, or infusible drug product or a drug product that is delivered topically, through inhalation, implantation, or transmucosally; (ii) Requires unique storage or shipment, such as refrigeration; or (iii) Requires patient education and support beyond traditional dispensing activities.	

Appendix E

Suggested Revisions of §15–847 and §15–1612 as Proposed by Committee Members Brian Hose and Steve Wienner

§15–847

(a) (1) In this section the following words have the meanings indicated.

(1) (i) "Specialty drug" means a prescription drug that has a limited or exclusive distribution network as determined by the drug manufacturer.

(b) This section applies to:

(1) insurers and nonprofit health service plans that provide coverage for prescription drugs under individual, group, or blanket health insurance policies or contracts that are issued or delivered in the State; and

(2) health maintenance organizations that provide coverage for prescription drugs under individual or group contracts that are issued or delivered in the State.

(c) (1) Subject to paragraph (2) of this subsection, an entity subject to this section may not impose a copayment or coinsurance requirement on a covered specialty drug that exceeds $150 for up to a 30–day supply of the specialty drug.

(2) On July 1 of each year, the limit on the copayment or coinsurance requirement on a covered specialty drug shall increase by a percentage equal to the percentage change from the preceding year in the medical care component of the March Consumer Price Index for All Urban Consumers, Washington Metropolitan Area, from the U.S. Department of Labor, Bureau of Labor Statistics.

(d) Subject to § 15–805 of this subtitle and notwithstanding § 15–806 of this subtitle, nothing in this article or regulations adopted under this article precludes an entity subject to this section from requiring a covered specialty drug to be obtained through:

(1) a designated pharmacy or other source authorized under the Health Occupations Article to dispense or administer prescription drugs; or

(2) a pharmacy participating in the entity's provider network

(e) (1) A pharmacy registered under § 340B of the federal Public Health Services Act may apply to an entity subject to this section to be a designated pharmacy under subsection (d)(1) of

this section for the purpose of enabling the pharmacy's patients with hepatitis C to receive the copayment or coinsurance maximum provided for in subsection (c) of this section if:

(i) the pharmacy is owned by a federally qualified health center, as defined in 42 U.S.C. § 254B;

(ii) the federally qualified health center provides integrated and coordinated medical and pharmaceutical services to hepatitis C patients; and

(iii) the prescription drugs are covered specialty drugs for the treatment of hepatitis C.

(2) An entity subject to this section may not unreasonably withhold approval of a pharmacy's application under paragraph (1) of this subsection.

(f) An entity subject to this section may provide coverage for specialty drugs through a managed care system.

(g) (1) A determination by an entity subject to this section that a prescription drug is not a specialty drug is considered a coverage decision under § 15–10D–01 of this title.

(2) For complaints filed with the Commissioner under this subsection, if the entity made its determination that a prescription drug is not a specialty drug on the basis that the prescription drug did not meet the criteria listed in subsection (a)(5)(i) of this section:

(i) the Commissioner may seek advice from an independent review organization or medical expert on the list compiled under § 15–10A–05(b) of this title; and

(ii) the expenses for any advice provided by an independent review organization or medical expert shall be paid for as provided under § 15–10A–05(h) of this title.

§15–1612

(a) This section applies only to a pharmacy benefits manager that provides pharmacy benefits management services on behalf of a carrier.

(b) 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.