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January 5, 2022

The Honorable Delores G. Kelley
Senate Finance Committee
3 East Miller Senate Bldg.
11 Bladen Street
Annapolis, MD 21401-1991

The Honorable Shane Pendergrass,
House Health and Government Operations Committee
241 House Office Bldg.
6 Bladen Street
Annapolis, MD 21401-1991

Re: Report of the Maryland Insurance Administration on *Rutledge v. Pharmaceutical Care Management Association* and its impact on Title 15, Subtitle 16 of the Maryland Insurance Article.

Dear Chair Kelley and Chair Pendergrass:

On behalf of the Maryland Insurance Administration (MIA), I am pleased to submit this report as required by House Bill 601, Chapter 358, 2021 Laws of Maryland. This report fulfills the requirement of the MIA to report on *Rutledge v. Pharmaceutical Care Management Association* and its impact on Title 15, Subtitle 16 of the Maryland Insurance Article.

Five printed copies of this report have been mailed to the DLS Library for their records. Should you have any questions regarding this report, please do not hesitate to contact us.

Sincerely,

Kathleen A. Birrane
Commissioner
Maryland Insurance Administration

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

Maryland

INSURANCE ADMINISTRATION

Report of the Maryland Insurance Administration on *Rutledge v. Pharmaceutical Care Management Association* and its impact on Title 15, Subtitle 16 of the Maryland Insurance Article.

Kathleen A. Birrane
Commissioner
January 5, 2022

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This document is available in alternative format upon request from a qualified individual with a disability.

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

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Introduction

As discussed in further detail below, pharmacy benefit manager ("PBM") contracts and services are regulated under Title 15, Subtitle 16 of the Insurance Article. Prior to the 2021 legislative session, those laws did not apply when the purchaser of the PBM services was a self-insured health and welfare benefit plan exempt from state regulation under the preemption provisions of the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 *et seq*. (referred to hereinafter as an "ERISA plan"). That legislative carve-out reflected a concern that the application of state laws to PBMs when providing services to ERISA plans would be preempted by ERISA.

In 2020, the Supreme Court of the United States held that an Arkansas law that requires PBMs to reimburse pharmacies for at least the actual cost of purchased drugs was not preempted by ERISA, even when applied to a contract between the PBM and an ERISA plan. *Rutledge v. Pharmaceutical Care Management Assoc*, 141 S. Ct. 474, 479 (2020) (upholding state law requiring PBMs to update maximum allowable cost ("MAC") lists and allowing pharmacies to appeal MAC reimbursements). In response, legislation was introduced in the 2021 legislative session to eliminate the carve-out for ERISA plans from Maryland PBM laws and to apply PBM regulation to PBMs when providing services to ERISA plans. During hearings on proposed legislation, there was rigorous debate and disagreement on the intended scope of *Rutledge* and the extent to which PBM regulation beyond the specific MAC provisions addressed in that case could be applied to a PBM acting for an ERISA plan without triggering ERISA preemption.

The final legislation, enacted as Chapter 358, Acts of 2021 (HB 601), expanded provisions of Maryland's PBM regulation requirements to PBMs when acting on behalf of ERISA plans with respect to activities expressly addressed in *Rutledge*. The law also required the Maryland Insurance Administration ("MIA") to report to the Senate Finance Committee and the House Health and Government Operations Committee, in accordance with § 2–1257 of the State Government Article, on the scope of the U.S. Supreme Court opinion in *Rutledge* and how to apply that decision to other provisions of Title 15, Subtitle 16 of the Insurance Article on or before December 31, 2021.

This report is provided in response to that directive.

Summary Conclusion

Rutledge recognizes that PBMs are not health benefit plans as defined under ERISA and, thus, that the regulation of PBMs is not preempted by ERISA. *Rutledge* confirmed that this is so, even when the purchaser of PBM services is an ERISA plan, as long as the state's regulation of the PBM does not effectively regulate the ERISA plan itself. While that line has been the subject of much litigation, as a general rule this means that state laws that direct the decisions of the ERISA plan itself, such as requiring certain benefits, benefit structures, or benefit determinations, are preempted; while state laws regulating PBMs that may also impact ERISA plan costs and design structures or that might result in some lack of uniformity in plan design are not preempted.

Applying that standard to Maryland law, it is the view of the MIA that should the legislature determine to apply additional provisions of Title 15, Subtitle 16 to PMBs when providing services to an ERISA plan, ERISA would not preempt the MIA's enforcement of those laws in that context. This view is informed in part by the recent opinion of the U.S. Court of Appeals for the Eighth Circuit in *Pharmaceutical Care Management Assoc. v. Wehbi,* No. 18-2926 (8th Cir. Nov. 17, 2021) ("*Wehbi*"), the first case applying the *Rutledge* decision. On remand from the U.S. Supreme Court following *Rutledge*, the Eighth Circuit in *Wehbi* found that North Dakota laws broadly regulating PBMs were not preempted by ERISA.[1] While not binding on Maryland (which is in the Fourth Circuit), the reasoning of the Eighth Circuit is persuasive and presents a logical application of *Rutledge* and prior Supreme Court jurisprudence relating to ERISA preemption to legislative provisions similar to those in force in Maryland respecting PBMs.

Regulations of PBMs in Maryland

PBMs function as intermediaries between health plans[2] and pharmaceutical providers. While they play no role in the physical distribution of prescription drugs, by handling negotiations and payments within the supply chain, PBMs have a significant impact on the total drug cost for payors, patient access to medications, and determining how much pharmacies are paid. PBM activities typically include the creation of formularies, the negotiation of drug discounts, the creation of pharmacy networks, the processing of claims, and the review of drug utilization. In addition to cost management and drug price negotiations, PBMs may offer a variety of administrative services to a health plan, all related to prescription drug benefits.

Status of PBM Legislation and Regulation in Maryland

State regulation of PBMs in Maryland began in 2008. Five different bills related to PBMs passed unanimously in both chambers of the Maryland General Assembly and were signed into law. Chapters 202, 204, 206, 262, and 279, Acts of 2008 became effective on October 1, 2008, and together, these laws established a comprehensive regulatory framework for PBMs under Title 15, Subtitle 16 of the Insurance Article. In summary,

- Chapter 202 required PBMs to register with the MIA Commissioner, and granted the Commissioner general enforcement authority to suspend, deny, and revoke a registration, conduct financial exams of PBMs, and impose civil penalties for violations of the PBM Subtitle.

[1] The *Wehbi* Court did, however, conclude that certain of North Dakota's PBM laws were preempted by Medicare Part D. The MIA is currently reviewing that conclusion with respect to Maryland PBM laws, but that analysis is outside of the scope of this report.

[2] Health plans include plans offered by insurance companies, health maintenance organizations, nonprofit health service plans, and ERISA plans (typically employee benefit plans that are self-funded by employers).

- Chapter 204 established limitations on therapeutic interchanges (i.e., when a PBM requests a prescriber to change from one prescription drug to another for the purposes of drug coverage under a health plan).
- Chapter 206 established requirements for PBMs to disclose to a purchaser specified information about manufacturer payments and the sharing and selling of drug utilization information, and also provide the purchaser with a report of certain revenue and payment information.
- Chapter 262 required a PBM to disclose certain information to a pharmacy at the time of entering a contract and at least 30 days prior to a contract change related to reimbursement, verifying beneficiary eligibility and formulary requirements, and explaining the dispute resolution process. The law also established specific terms and limitations for how and when a PBM may audit a pharmacy.
- Chapter 279 outlined requirements for pharmacy and therapeutics committees established by PBMs, relating to the composition of the committees, disclosures, required policies and procedures, and accreditation.

Importantly, all of the laws enacted in 2008 were limited in applicability to activities a PBM performed on behalf of a "purchaser." A "purchaser" was defined to include the State Employee and Retiree Health and Welfare Benefits Program, an insurer, a nonprofit health service plan, or a health maintenance organization ("HMO"). The definition expressly excluded a person that provides prescription drug coverage or benefits through plans subject to ERISA and does not provide prescription drug coverage or benefits through insurance, unless the person is a multiple employer welfare arrangement.

The legislature enacted additional PBM laws and revised existing laws between 2011 and 2020. Specifically,

- Additional pharmacy protections were established with respect to PBM audits in 2011 (Chapter 569).
- Certain retroactive denials and modifications of reimbursement by PBMs for approved pharmacy claims were prohibited in 2012 (Chapter 319).
- In 2014, Chapter 363 established the first iteration of Maryland's MAC pricing law, which included protections for independent pharmacies and required greater transparency from PBMs in their MAC pricing policies for generic drugs.
- Maryland's MAC pricing law was further strengthened in 2018 (Chapter 451), and 2019 (Chapter 400). Chapter 451 in 2018 also prohibited a PBM, with few exceptions, from reimbursing a pharmacy less for pharmacy products or services than it would an affiliate of the PBM.
- A separate law enacted in 2018 (Chapter 218) prohibited PBMs from imposing gag clauses prohibiting discussions between pharmacists and beneficiaries about the retail costs and cost-sharing for drug alternatives.
- In addition to strengthening the MAC pricing law, Chapter 400, Acts of 2019, also established several additional obligations for PBMs, including a requirement to include an appeals process for non-MAC pricing disputes in all contracts with a pharmacy, a

requirement to provide certain advance disclosures of fees and potential recoupments under performance-based reimbursement arrangements, and a requirement that PBMs must file their participating pharmacy contracts with the MIA for review before a contract may become effective.

- Another piece of legislation from 2019, Chapter 550, prohibited a PBM from requiring a beneficiary of a purchaser to use a specific pharmacy to fill a prescription if there is a common corporate affiliation or ownership between the PBM and pharmacy, except for specialty drugs.

In response to the 2019 legislation, the MIA promulgated regulations at COMAR 31.10.46, .47. and .48 to implement the statutory provisions related to the contract filing requirement, and the appeals and complaint process for MAC pricing disputes and disputes about cost pricing and reimbursement other than MAC. As a result of the significantly increased oversight responsibilities for PBMs, the MIA issued Bulletin 19-15 on September 12, 2019, which advised PBMs that the initial and renewal registration fees for PBMs would be increasing from $250 and $150, respectively, to $5,000 on September 1, 2020.

In 2020, the General Assembly enacted additional changes to the PBM laws under Chapters 452 and 455. Chapter 452 established certain new time requirements related to disputed pharmacy claims subject to an audit or an internal appeal request. Chapter 455 prohibited a PBM, with a limited exception for specialty pharmacies, from requiring a pharmacy to renew credentialing more frequently than once every 3 years or from charging a pharmacy a credentialing fee. Chapter 455 also enacted an outright prohibition on the fee or performance-based reimbursement recoupments for which Chapter 400, Acts of 2019 had only required a PBM to provide advance notice to the pharmacy. Up through the 2020 legislative session, all of Maryland's PBM laws continued to be limited in applicability to activities a PBM performed on behalf of a "purchaser," excluding ERISA self-funded plans.

Chapter 358, Acts of 2021 will become effective on January 1, 2022. Once this law goes into effect, the state of regulation of PBMs in Maryland will change significantly. Traditionally, PBM laws (and enforcement of those laws) have applied to the activities a PBM performs on behalf of the State Employee and Retiree Health and Welfare Benefits Program, an insurer, a nonprofit health service plan, or a HMO. Beginning on January 1, 2022, PBM laws (and the MIA's enforcement of those laws) will expand to certain regulated activities when a PBM is performing them on behalf of an ERISA plan. Specifically, the expanded authority under Chapter 358 will apply to the laws in Title 15, Subtitle 16 related to PBM registration, financial and market conduct exams, contracts between pharmacies and PBMs, required disclosures by PBMs to pharmacies, and requirements for MAC pricing and other reimbursement practices. PBM laws related to gag clauses, the prohibition on a PBM reimbursing a pharmacy less than it would an affiliate, choice of pharmacy, financial disclosures between PBMs and purchasers, therapeutic interchanges, pharmacy and therapeutics committees, and PBM audits of pharmacies only apply to PBMs acting on behalf of the State Employee and Retiree Health and Welfare Benefits Program, an insurer, a nonprofit health service plan, or a HMO.

MIA Enforcement of PBM Legislation and Regulation

As the PBM laws in Maryland changed over the years, the MIA's enforcement activities with respect to these entities has likewise changed. As previously mentioned, the MIA began registering PBMs in 2008. Registrations must be renewed every 2 years, and currently, there are approximately 50 PBMs registered in Maryland. In 2011, the MIA completed targeted market conduct exams on several PBMs, focusing on contract requirements, accreditations, pharmacy and therapeutic committees, audits, and appeal processes in Maryland. Apart from the PBM Subtitle (Title 15, Subtitle 16 of the Insurance Article), § 15-10B-20 of the Insurance Article requires the MIA to conduct an exam every 3 years of any PBM registered as a private review agent to determine whether the PBM is acting in compliance with Maryland's private review agent laws under Title 15, Subtitle 10B of the Insurance Article. Recent PBM market conduct activities by the MIA include a market conduct survey in 2019 regarding audit processes to investigate PBM compliance with § 15-1629 of the Insurance Article, and a market conduct survey in 2020 regarding compliance with § 15-1628(b) of the Insurance Article to ensure each PBM had filed their contracts and amendments to contracts at least 30 days before the contract or amendment became effective.

The MIA also investigates individual complaints against PBMs filed by consumers and health care providers, including pharmacists and pharmacies. There are two main categories of complaints. Consumers and their treating health care providers are most likely to file complaints regarding authorization requirements and denials based on whether the prescription drug is medically necessary, efficient, or appropriate. Pharmacists are most likely to file complaints regarding pricing, or adjustments to pricing, of prescription drugs by PBMs.

Medical necessity determinations related to prescription drugs that are made by PBMs on behalf of health plans are subject to the MIA's complaint process for adverse decisions and grievances under Title 15, Subtitle 10A of the Insurance Article. Even before the PBM registration requirement became effective in 2008, the MIA was investigating and resolving many of these complaints each year, and that trend continues today.

For PBM complaints not related to medical necessity determinations, the MIA received very few formal complaints before Chapter 451, Acts of 2018 revised the MAC pricing law to give the Commissioner more specific authority to investigate MAC complaints. Following the MIA's adoption of regulations establishing a specific complaint process for PBM-pharmacy disputes under COMAR 31.10.46 and .47, the MIA has started receiving more complaints against PBMs from pharmacies. However, the volume of these complaints has remained much lower than anticipated.

Beginning in 2019, the MIA also started reviewing PBM participating pharmacy contracts for compliance with Maryland law, as required by Chapter 400, Acts of 2019. Although PBM participating pharmacy contracts are not formally approved by the MIA, the MIA does have the authority to disapprove any contract that violates one of the PBM laws under Title 15, Subtitle 16 of the Insurance Article, or any other applicable Maryland law or regulation.

As noted above, Chapter 358 expanded PBM regulation related to PBM registration, financial and market conduct exams, contracts between pharmacies and PBMs, required disclosures by PBMs to pharmacies, and requirements for MAC pricing and other reimbursement practices to ERISA plans. At this time, it is unclear whether the expansion of these particular PBM laws to the self-funded market under Chapter 358 will require significant additional MIA resources to assure adequate enforcement.

ERISA Preemption Issues for PBM Regulation

On December 10, 2020, the U.S. Supreme Court issued its opinion in *Rutledge v. Pharmaceutical Care Management Assoc*, holding that an Arkansas law that requires PBMs to reimburse pharmacies for at least the actual cost of their purchased drugs was not preempted by ERISA. 141 S. Ct. 474, 479 (2020). *Rutledge* addressed legislation passed in Arkansas in 2015 (Act 900) amending the state's existing law on maximum allowable cost lists.[3] The Supreme Court noted that

> [t]he amount a PBM "reimburses" a pharmacy for a drug is not necessarily tied to how much the pharmacy paid to purchase that drug from a wholesaler. Instead, PBMs' contracts with pharmacies typically set reimbursement rates according to a list specifying the maximum allowable cost (MAC) for each drug. PBMs normally develop and administer their own unique MAC lists. Likewise, the amount that prescription-drug plans reimburse PBMs is a matter of contract between a given plan and a PBM. A PBM's reimbursement from a plan often differs from and exceeds a PBM's reimbursement to a pharmacy. That difference generates a profit for PBMs.

Id. at 478. Arkansas was concerned that PBM reimbursement rates "were often too low to cover pharmacies' costs, and that many pharmacies, particularly rural and independent ones, were at risk of losing money and closing." *Id.* Act 900 was designed to prevent this by setting a floor for drug reimbursement costs. Act 900 also required PBMs to timely update their MAC lists when drug wholesale prices increase, Ark. Code Ann. §17–92–507(c)(2), and to provide pharmacies an administrative appeal procedure to challenge MAC reimbursement rates, §17–92–507(c)(4)(A)(i)(b). Act 900 also permits Arkansas pharmacies to refuse to sell a drug if the reimbursement rate is lower than its acquisition cost. §17–92–507(e).

The Pharmaceutical Care Management Association ("PCMA") challenged Act 900 in the U.S. District Court for the Eastern District of Arkansas, arguing that Act 900 was unconstitutional and was preempted by ERISA and Medicare Part D. The district court ruled that Act 900 was neither unconstitutional nor preempted by Medicare Part D. However, following precedent from the Eighth Circuit in a case involving a similar Iowa statute, the district court held that Act 900 was preempted by ERISA. The decision was appealed to the Eighth Circuit, which affirmed the district court's ruling on ERISA preemption and reversed the district court's ruling on Medicare

[3] Ark. Code Ann. §17–92–507(c)(2).

Part D preemption. The U.S. Supreme Court agreed to hear the case solely with respect to the issue of ERISA preemption.

In reversing the Eighth Circuit and finding against ERISA preemption, the Supreme Court applied classic ERISA preemption analysis, concluding that Act 900 was not preempted as a law that "relates" to an ERISA plan because it had no impermissible connection with or reference to such plans. 141 S. Ct. at 483. ERISA preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C. § 1144(a) (2018). A state law relates to an ERISA plan if it has an impermissible "connection with" or a "reference to" a plan. *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co.*, 514 U.S. 645, 656 (1995).

With respect to the "impermissible connection" prong, *Rutledge* noted that in applying this standard, the Court focuses on ERISA's objectives, explaining that ERISA is

> primarily concerned with preempting laws that require providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits, *Shaw v. Delta Air Lines, Inc*., 463 U. S. 85 (1983), or by binding plan administrators to specific rules or determining beneficiary status, *Egelhoff [v. Egelhoff*], 532 U. S. 141. A state law may also be subject to pre-emption if "acute, albeit indirect, economic effects of the state law force an ERISA plan to adopt a certain scheme of substantive coverage." *Gobeille [v. Liberty Mut. Ins. Co.]*, 577 U. S. [312], at 320 (internal quotation marks omitted).

141 S. Ct. at 480.

Rutledge affirmed that a state law does not meet this standard if it merely "affects an ERISA plan or causes some disuniformity in plan administration." *Id.* at 480. This is true "especially… if a law merely affects costs." *Id.* Rather the "impermissible connection" standard is "primarily concerned with preempting laws that require providers to 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." *Id.*

> ERISA does not pre-empt state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage. . . . The logic of *Travelers* decides this case. Like the New York surcharge law in *Travelers*, Act 900 is merely a form of cost regulation. It requires PBMs to reimburse pharmacies for prescription drugs at a rate equal to or higher than the pharmacy's acquisition cost. PBMs may well pass those increased costs on to plans, meaning that ERISA plans may pay more for prescription-drug benefits in Arkansas than in, say, Arizona. But "cost uniformity was almost certainly not an object of pre-emption." *Travelers*, 514 U. S., at 662. Nor is the effect of Act 900 so acute that it will effectively dictate plan choices. *See id*., at 668. Indeed, Act 900 is less intrusive than the law at issue in *Travelers*, which created a compelling incentive for plans to buy insurance from the Blues instead of other insurers. Act 900, by contrast, applies equally to all PBMs and pharmacies in

> Arkansas. As a result, Act 900 does not have an impermissible connection with an ERISA plan.

141 S. Ct. at 481.

Moving to the second prong, the U.S. Supreme Court stated that a state law has an impermissible "reference to" an ERISA plan if it "acts immediately and exclusively upon ERISA plans" or the existence of ERISA plans is essential to the law's operation. *Id.* at 479, 481. The *Rutledge* Court clarified that "the existence of ERISA plans is essential to a law's operation only if the law cannot apply to a non ERISA plan." *Pharmaceutical Care Management Association v. Wehbi*, No. 15-2926 at 11 (8th Cir, Nov. 17, 2021) citing *Rutledge*, 141 S. Ct at 481. As *Rutledge* concluded, "Act 900 does not act immediately and exclusively upon ERISA plans because it applies to PBMs whether or not they manage an ERISA plan." 141 S. Ct. at 481.

Stakeholder Response to the *Rutledge* Decision

The scope and effect of the *Rutledge* decision was very much at issue during the 2021 legislative session in discussing HB 601. In light of differing views on the scope of the opinion, the subcommittee considered the crafted amendments to the original version of HB 601 to expand the application of Title 15, Subtitle 16 to PBMs contracted to ERISA plans in some instances, but not others. HB 601 was also amended to direct the MIA to produce this report.

In response to that directive, the MIA issued Bulletin 21-18 in June 2021 to solicit written comments from stakeholders about the potential impact of *Rutledge* on PBM regulation in the state. Stakeholders were given until September 10, 2021 to provide written comments.

The MIA received comments from the League of Life & Health Insurers of Maryland ("League"), America's Health Insurance Plans ("AHIP"), Pharmaceutical Care Management Association ("PCMA"), EPIC Pharmacy Network, Inc. ("EPIC"), The Independent Pharmacies of Maryland ("IPMD"), and the National Association of Chain Drug Stores ("NACDS") jointly with the Maryland Association of Chain Drug Stores ("MACDS"). As was the case before the subcommittee, stakeholders generally took one of two positions: (i) that *Rutledge* should be construed narrowly and limited to the provisions of Maryland law that, like Arkansas Act 900, address reimbursement costs or (ii) that *Rutledge* affirms ERISA preemption standards that extend more broadly to all of the provisions of Title 15, Subtitle 16 of the Insurance Article and justify the elimination of any exemption from state law for PBMs when contracted to ERISA plans.

The positions taken by each commenter are summarized below. The full text of all comments received by the MIA is included in the Appendix to this report. The MIA considered all stakeholder input and analysis in reaching the conclusions set forth in this report.

League of Life & Health Insurers of Maryland

The League of Life & Health Insurers of Maryland argued that *Rutledge* only limits ERISA preemption of PBM laws that can be considered rate regulation similar to those in Act 900. The League also noted that any Maryland-specific changes would only serve to complicate the

administration of health care policies for large employers with employees in multiple states. Therefore, the League urged that the scope of ERISA preemption not be narrowed and that the recommendation in the report to the General Assembly should not authorize extensions of Title 15, Subtitle 16 to ERISA plans.

Pharmaceutical Care Management Association

PCMA argued that numerous provisions of HB 601 would either dictate plan benefit design, regulate the same subject matter as ERISA itself or interfere with central matters of plan administration. In its view, HB 601 has a "connection with" plan design and therefore should be considered preempted under ERISA. Similar to the League, it argued that *Rutledge* was based "merely" on a rate regulation and that the opinion leaves open the possibility some indirect economic influence could dictate plan choice, leading to preemption.

America's Health Insurance Plans

AHIP similarly argued that *Rutledge* was narrow and specific and that the decision did not alter or create new categories of permissible state regulation. AHIP suggested that the MIA speak with employer groups as extending Subtitle 16 to self-funded policies may result in a financial impact to employees.

Independent Pharmacies of Maryland

IPMD argued that *Rutledge* should be applied to all provisions of Subtitle 16. In support of this argument, IPMD acknowledged that *Rutledge* concerned "in part, a cost regulation, [but] its language clearly does not limit the holding to cost regulations." IPMD at 5. Rather, it argued that as long as the statute does not require payment of specific benefits, or enact specific rules for determining eligibility status, there is no ERISA preemption. In further support of its argument, IPMD also cited the advisory letter provided by Counsel to the General Assembly on HB 601, that stated that the holding in *Rutledge* was not limited to issues relating to reimbursement. Similarly, the letter cited the amicus brief submitted by 16 states, including Maryland, in *Wehbi*. The brief argued that ERISA does not preempt state laws unless they affect the who or what of benefits. The brief challenged the attempt by the Plaintiff in *Wehbi* to limit *Rutledge's* holding to cost regulations, noting that *Rutledge* reaffirmed that regulations that do not "force plans to adopt a particular scheme of substantive coverage" are not preempted. Amicus at 19. The letter goes on to list those provisions of Subtitle 16 that still exempt PBMs acting for ERISA plans, and argues that these exemptions should be removed.

EPIC Pharmacy Network, Inc.

EPIC in its letter incorporates the comments of IPMD and gives examples of what it terms the "absurd" nature of the PBMs' arguments regarding the narrow scope of *Rutledge*, including the insistence of their advocate during past legislative sessions to exclude PBMs acting on behalf of ERISA plans from having to comply with § 15-1611.1 (PBM may not require a beneficiary to use a specific pharmacy to fill prescriptions where there is a common affiliation or ownership between the PBM and the pharmacy, except for specialty drugs) and § 15-1612 (Generally prohibits a PBM from reimbursing a pharmacy less than the amount it reimburses itself or an

affiliate for the same drug or service). In EPIC's view, these two provisions are critical to maintaining the vitality of independent pharmacies and these provisions do not implicate who is a permitted beneficiary of a large group plan, or what such a plan covers.

National Association of Chain Drug Stores jointly with the Maryland Association of Chain Drug Stores

Finally, the NACDS letter makes many of the same arguments as EPIC and IPMD, but also cited recently passed legislation in other states that: 1) regulate fair pharmacy reimbursement; 2) reform retroactive adjustments to pharmacies; 3) provide an avenue for pharmacists to serve patients; and 4) advocate for the enforcement of "pro-pharmacy" laws. Interestingly, with regard to HB 601, NACDS states that "[i]mportantly, these laws already encapsulate much of what NACDS has identified as laws that will pass or strengthen to align with the *Rutledge* decision."

Post-*Rutledge* Developments

On November 17, 2021, the Eighth Circuit issued its opinion in *Wehbi,* finding that PBM laws enacted in North Dakota in 2017 were not preempted by ERISA. *Wehbi* is the first opinion applying *Rutledge* to be issued by a federal appellate court and is particularly significant because, following *Rutledge,* the U.S. Supreme Court vacated an earlier judgment of the Eighth Circuit finding that the North Dakota law was preempted by ERISA and ordered the appellate court to reconsider its ruling in light of *Rutledge.*

The North Dakota PBM laws at issue in *Wehbi* are more comprehensive than the reimbursement laws at issue in *Rutledge.* In concluding that ERISA did not preempt laws such as anti-gag provisions, the Eighth Circuit rejected the argument that *Rutledge* is limited to reimbursement-related laws. Rather, *Wehbi* focused on the standards affirmed in *Rutledge* to assess the impact of each of the laws in question on the ERISA plan itself.

The 2017 North Dakota laws in question were codified at North Dakota Century Code sections 19-02.1-16.1 and -16.2. The relevant provisions in section 16.1 provide:

> 2. A pharmacy benefit manager or third-party payer may not directly or indirectly charge or hold a pharmacy responsible for a fee related to a claim:
>
> a. That is not apparent at the time of claim processing;
>
> b. That is not reported on the remittance advice of an adjudicated claim; or
>
> c. After the initial claim is adjudicated at the point of sale.
>
> 3. Pharmacy performance measures or pay for performance pharmacy networks shall utilize the electronic quality improvement platform for plans and pharmacies or other unbiased nationally recognized entity aiding in improving pharmacy performance measures.

a. A pharmacy benefits manager or third-party payer may not collect a fee from a pharmacy if the pharmacy's performance scores or metrics fall within the criteria identified by the electronic quality improvement platform for plans and pharmacies or other unbiased nationally recognized entity aiding in improving pharmacy performance measures.

b. If a pharmacy benefits manager or third-party payer imposes a fee upon the pharmacy for scores or metrics or both scores and metrics that do not meet those established by the electronic quality improvement platform for plans and pharmacies or other nationally recognized entity aiding in improving pharmacy performance measures, a pharmacy benefits manager or third-party payer is limited to applying the fee to the professional dispensing fee outlined in the pharmacy contract.

c. A pharmacy benefits manager or third-party payer may not impose a fee relating to performance metrics on the costs of goods sold by a pharmacy.

4 If a patient pays a copayment, the dispensing provider or pharmacy shall retain the adjudicated cost and the pharmacy benefits manager or third-party payer may not redact the adjudicated cost.

5. A pharmacy or pharmacist may disclose to the plan sponsor or to the patient information regarding the adjudicated reimbursement paid to the pharmacy which is compliant under the federal Health Insurance Portability and Accountability Act of 1996.

7. A pharmacy or pharmacist may provide relevant information to a patient if the patient is acquiring prescription drugs. This information may include the cost and clinical efficacy of a more affordable alternative drug if one is available. Gag orders of such a nature placed on a pharmacy or pharmacist are prohibited.

8. A pharmacy or pharmacist may mail or deliver drugs to a patient as an ancillary service of a pharmacy.

9. A pharmacy benefits manager or third-party payer may not prohibit a pharmacist or pharmacy from charging a shipping and handling fee to a patient requesting a prescription be mailed or delivered.

10. Upon request, a pharmacy benefits manager or third-party payer shall provide a pharmacy or pharmacist with the processor control number, bank identification number, and group number for each pharmacy network

established or administered by a pharmacy benefits manager to enable the pharmacy to make an informed contracting decision.

11. A pharmacy benefits manager or third-party payer may not require pharmacy accreditation standards or recertification requirements inconsistent with, or more stringent than, or in addition to federal and state requirements for licensure as a pharmacy in this state.

The relevant provisions in section 16.2 read as follows:

2. If requested by a plan sponsor contracted payer, a pharmacy benefits manager or third-party payer that has an ownership interest, either directly or through an affiliate or subsidiary, in a pharmacy shall disclose to the plan sponsor contracted payer any difference between the amount paid to a pharmacy and the amount charged to the plan sponsor contracted payer.

3. A pharmacy benefits manager or a pharmacy benefits manager's affiliates or subsidiaries may not own or have an ownership interest in a patient assistance program and a mail order specialty pharmacy, unless the pharmacy benefits manager, affiliate, or subsidiary agrees to not participate in a transaction that benefits the pharmacy benefits manager, affiliate, or subsidiary instead of another person owed a fiduciary duty.

4. A pharmacy benefits manager or third-party payer may not require pharmacy accreditation standards or recertification requirements to participate in a network which are inconsistent with, more stringent than, or in addition to the federal and state requirements for licensure as a pharmacy in this state.

5. A licensed pharmacy or pharmacist may dispense any and all drugs allowed under that license.

The Eighth Circuit found that none of these provisions meets the "connection with" or "referenced to" standards necessary for ERISA preemption. The appellate court noted that several of the provisions merely authorize pharmacies to do certain things, such as disclosing certain information to a plan sponsor, § 16.1(5); providing relevant information to a patient, § 16.1(7); "mail or deliver drugs to patient as an ancillary service," § 16.1(8); and charging a shipping and handling fee to a patient requesting a prescription be mailed or delivered., § 16.1(9). *Wehbi* at 9. The appellate circuit found that these provisions affect PBMs only to the extent that they prevent PBMs from preventing pharmacies from engaging in these practice and that this constitutes "at most, a regulation of a noncentral 'matter of plan administration' with a *de minimis* economic effect and impact on the uniformity of plan administration across states." *Id.* at 9, citing *Gobeille*, 577 U.S. at 320 and *Rutledge*, 141 S. Ct. at 482.

Wehbi also found that neither § 16.1(11) nor 16.2(4) met the connection with standard, as they merely limit the accreditation requirements that a PBM may impose on pharmacies as a condition for participation in its network. *Id.* at 9. Similarly, § 16.1(1) and 16.2(2), which require

PBMs to disclose basic information to pharmacies and plan sponsors, were found not to meet the connection with standard. *Id.* at 10.

Finally, the last provision that PCMA claimed was preempted by ERISA, § 16.2(3), prohibits a PBM from having "an ownership interest in a patient assistance program and a mail order specialty pharmacy, unless the [PBM] agrees not to participate in a transaction that benefits the [PBM] instead of another person owed a fiduciary duty." Citing *Rutledge*, the appellate court found that "'[t]o the extent this provision causes a drug to be unavailable to ERISA plans' North Dakota beneficiaries, 'the responsibility lies first with the PBM' for refusing to satisfy the condition that would permit the drug to be available." *Id*. at 11, quoting *Rutledge*, 141 S. Ct. at 482. In sum, none of the challenged provisions were found to have an impermissible connection with ERISA plans.

Wehbi also held that none of the challenged provisions of the North Dakota PBM law has an impermissible reference to ERISA plans. Echoing *Rutledge*, the opinion emphasized that the challenged provisions apply to PBMs both when they administer ERISA plans and when they administer non-ERISA plans. Thus, "they do not 'act[]… exclusively upon ERISA plans." And ERISA plans are not 'essential to [their] operation.'" *Id*. at 12 quoting *Rutledge*, 141 S. Ct. at 481.[4]

Stakeholder Response to the Eighth Circuit Decision in *PCMA v. Wehbi*

In response to the *Wehbi* decision, the MIA issued Bulletin 21-28 in November 2021 to solicit written comments from stakeholders about the potential impact of *Wehbi* on the industry. The MIA received comments from PCMA, IPMD, NACDS jointly with MACDS, and Navitus Health Solutions ("Navitus"). The positions taken by each commenter are summarized below. The full text of all comments received by the MIA are included in the Appendix to this report. The MIA considered all stakeholder input and analysis in reaching the conclusions set forth in this report.

[4] It is important to note that the Eighth Circuit also addressed and found that some provisions of the North Dakota PBM statutes were preempted by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Part D") with respect to Medicare Part D plans, and that other provisions were not. *Id.* at 23. This conclusion is consistent with the Eighth Circuit's vacated opinion in *Rutledge*, which also found Medicare Part D preemption. The Supreme Court did not review the Eighth Circuit's Medicare Part D preemption analysis in *Rutledge* and the *Wehbi* Medicare Part D analysis relies, in part, on federal legislation enacted in 2018 that North Dakota concedes as preemptive of two provisions of its PBM laws. An analysis of whether any provisions of Title 15, Subtitle 16 could be deemed to be preempted as to Medicare Part D plans is beyond the scope of this Report. The MIA is currently analyzing this issue.

Pharmaceutical Care Management Association

PCMA argued that numerous provisions of HB 601 would either dictate plan benefit design, regulate the same subject matter as ERISA itself or interfere with central matters of plan administration even with the *Webhi* decision. PCMA noted that the Eighth Circuit's decision did not substantially change the underlying ERISA preemption standard, but instead, confirmed that ERISA preemption applies to laws that regulate PBMs even if they do not regulate ERISA plans directly and that there is no presumption against ERISA preemption. PCMA also highlighted that *Webhi* is a narrow decision, limited to the North Dakota statutory provisions at issue.

Independent Pharmacies of Maryland

IPMD filed supplemental comments and, as set out in its original comments, reiterated that there would be no ERISA preemption with respect to the various provisions regulating PBMs under Title 15, Subtitle 16, of the Insurance Article. Therefore, all of those provisions should be made applicable to ERISA PBMs.

National Association of Chain Drug Stores jointly with the Maryland Association of Chain Drug Stores

NACDS made many of the same arguments as IPMD, but also cited recently passed legislation in other states that: 1) regulates fair pharmacy reimbursement; 2) reform retroactive adjustments to pharmacies; 3) provide an avenue for pharmacists to serve patients; and 4) advocate for the enforcement of "pro-pharmacy" laws.

Navitus Health Solutions

Navitus argued that ERISA is the controlling federal law, and therefore preempts state law, HB 601. Any application of HB 601 to PBMs would increase the burden to manage and enforce pharmacy benefits and increase the cost to patients.

Impact of *Rutledge* and *Wehbi* on Maryland PBM Regulation.

It is the view of the MIA that, should the legislature elect to make all of the current provisions of Title 15, Subtitle 16 applicable to PBMs when contracted with an ERISA plan, the enforcement of those laws by the MIA would not be preempted by ERISA. Relying on *Rutledge*, we conclude that none of the Maryland PBM laws if applied to a PBM contracted to an ERISA plan would have an impermissible connection with or an impermissible reference to ERISA plans. The laws in question are concerned primarily with PBM-pharmacy relationships. They do not require an ERISA plan to pay specific benefits or bind plan administrators to specific rules for determining beneficiary status, adopt particular benefits, force ERISA plans to report detailed information, or otherwise control the benefit design and administration of an ERISA plan. And, they apply whether the PBM is contracted to an ERISA plan or a non-ERISA plan.

Our view is informed by *Wehbi*. The Eighth Circuit opinion in *Wehbi* is not binding precedent in Maryland, which is in the Fourth Circuit. Nevertheless, we believe that it is helpful

guidance as to how courts will interpret and apply *Rutledge* in general, as well as how they are likely to interpret an expansion of the provisions of Maryland PBM statutes specifically.

Currently, §§ 15-1611, 15-1611.1, 15-1612, 15-1622, 15-1623, 15-1624, 15-1629, 15-1630 and 15-1633 only apply to PBMs that are acting on behalf of the State Employee and Retiree Health and Welfare Benefits Program, an insurer, a nonprofit health services plan or a HMO. *See e.g.* IN § 15-1601(o) (definition of "purchaser"). However, these provisions, like the North Dakota statutes at issue in *Wehbi*, legislate in the categories of (1) reimbursements; (2) transparency; and (3) contract terms. They do not affect the "who" and "what" of benefits. *Rutledge*, 141 S. Ct at 480 (recognizing ERISA's primary concern of preempting laws that "determin[e] beneficiary status" or require "special benefits").

Our view is also guided by the advice letter provided by the Office of the Attorney General on HB 601, which stated the author's view "that the current provisions of Title 15, Subtitle 16 that House Bill 601 [as originally introduced] would make applicable to PBMs would not be preempted." We are likewise mindful of the position taken by the Maryland Attorney General, who participated in the *Wehbi* litigation as amicus along with several other states and supported the view that so long as the regulation of PBMs does not require special benefits or determine beneficiary status, the Maryland statutes would not be preempted by ERISA. As none of the Maryland statutes referenced above fall into that category, we believe that any litigation raising ERISA preemption would not be successful.

While we have considered positions taken by those stakeholders that argue a narrower reading of *Rutledge* and *Wehbi*, we are not persuaded that the federal courts would accept their reasoning. There can be no good faith argument that any of the Maryland PBM laws impermissibly reference ERISA plans. And any argument that has been made as to the impact that such laws could have on an ERISA plan does not rise to the level of the "impermissible connection" standard, because none of the Maryland laws dictate benefits or determine beneficiary status.

We do note that Part VI of Subtitle 16 of Title 15 addresses therapeutic interchanges and regulates when a PBM can require such interchanges. While, on balance, the MIA believes that the application of these constraints on a PBM would not be preempted by ERISA when applied to a PBM contracted to an ERISA plan, we would anticipate the argument by PBMs that limiting therapeutic interchanges could impact benefit design. In that regard, the MIA is prepared to work with stakeholders to provide technical analysis with respect to specific provisions of Part VI of Subtitle 16 of Title 15 as they may relate to ERISA preemption challenges.

APPENDIX

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September 10, 2021

The Honorable Kathleen Birrane
Commissioner, Maryland Insurance Administration
200 St. Paul Place, Suite 2700
Baltimore, MD 21202
Submitted to: michael.paddy@maryland.gov

RE: Response to Bulletin 21-18

Dear Commissioner Birrane,

AHIP is providing comments in response to MIA Bulletin 21-18 requesting feedback on HB 601 / Chapter 358, passed in 2021. The law, Section 2 under 15-1663.1, requires:

> That, on or before December 31, 2021, the Maryland Insurance Administration shall report to the Senate Finance Committee and the House Health and Government Operations Committee, in accordance with § 2–1257 of the State Government Article, on the scope of the U.S. Supreme Court opinion in Rutledge v. Pharmaceutical Care Management Association and how to apply the decision to Title 15, Subtitle 16 of the Insurance Article.

To determine what insurance requirements should be applied to ERISA policies is critically important to review carefully. As of 2020, 67% of covered workers are in a plan that is self-funded nationwide, with 53% in Maryland (see attached AHIP State Data Book). Self-funding is common among larger firms because it can spread the risk of costly claims over a large number of workers and dependents.[1] To avoid potential litigation, Maryland should follow the narrow Rutledge decision precisely so as not to have confusion on applicability.

Rutledge Background: On December 10, in an opinion authored by Justice Sotomayor, the U.S. Supreme Court found that an Arkansas state law regulating PBMs' reimbursement of pharmacies for generic prescription drugs (Act 900) was not pre-empted by ERISA because it was a form of cost regulation. The underlying lawsuit, ***Rutledge v. PCMA***, was brought by the Pharmaceutical Care Management Association (PCMA), who argued that Act 900 was preempted by ERISA. Arkansas Attorney General Rutledge brought the appeal to the Supreme Court, asking them to overrule an earlier Eighth Circuit decision that found Act 900 was preempted by ERISA. AHIP submitted an amicus brief emphasizing ERISA's vital role in employers' ability to design and administer their own health plans and employ third-party administrators to assist in such functions.

The Rutledge Decision was Narrow and Fact Specific: Arkansas Act 900 contains provisions that require PBMs to:

1. Reimburse pharmacies at a price equal to or higher than a pharmacy's acquisition cost;
2. Update maximum allowable cost (MAC) lists in a certain time frame and disclose these lists, and;
3. Provide reimbursement rate appeal procedures that pharmacies may use to dispute a payment rate.

[1] 2020 Employer Health Benefits Survey, KFF, October 8, 2020.[https://www.kff.org/report-section/ehbs-2020-section-10-plan-funding/] Accessed September 8, 2021.

4. The law also allows pharmacies to decline to dispense medication if payment would result in a reimbursement less than the pharmacy's acquisition cost.

The *Rutledge* decision upholds a type of "cost regulation." that was specific to the AR law (Act 900) at issue in the case. This decision does not create a new category of permissible state regulation and left the preemption principles of ERISA that prevent states from regulating plan design or central matters of plan administration intact. The Court differentiated Act 900 from state PBM laws that interfere with benefit design by stating that ERISA preemption is "primarily concerned with preempting laws that require providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits, or by binding plan administrators to specific rules for determining beneficiary status." [2] Applying other state laws to self-insured plans could open the state to potential litigation.

Cost & National Considerations: AHIP encourages the department to speak with employer groups, as extending subtitle 16 to self-funded policies may result in a financial impact to their employees, which was also noted in the Court's opinion. Maryland should also consider that ERISA was designed to simplify insurance oversight and promote the uniform administration of benefit offerings for large employers with employees located throughout multiple, or all states. Implementation of ERISA changes specific to Maryland requires large companies to make changes for just enrollees in one state, which would lead to a whole host of administrative complexities for both employers and their employees.

While this is a high-level review of *Rutledge*, we are happy to answer any comprehensive legal questions utilizing our subject matter experts and retained legal counsel. Thank you for the opportunity to provide insight on this issue. Please let me know if you have any questions or concerns related to our comments at khathaway@ahip.org or (202) 870-4468. Thank you for your time.

Sincerely,

Kris Hathaway

Kris Hathaway
Vice President, State Affairs
America's Health Insurance Plans

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.

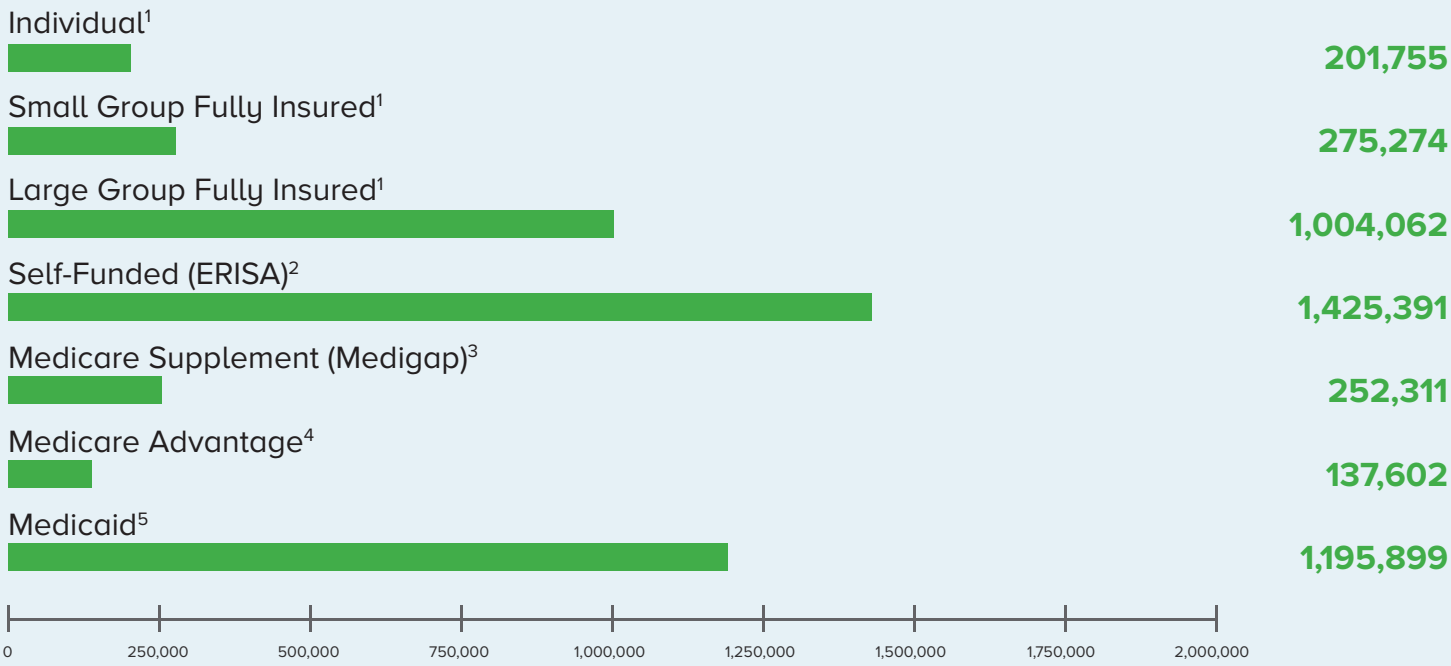
[2] *Rutledge v. Pharm. Care Mgmt.*, 141 S. Ct. 474, (2020)

Maryland

HEALTH INSURANCE BY THE NUMBERS

ACCESS TO INSURANCE

COVERED LIVES



Health Insurance Employment in Maryland

EMPLOYEES

Health Plan Employees[6]	11,726
Insurance-Related Employees[7]	18,103

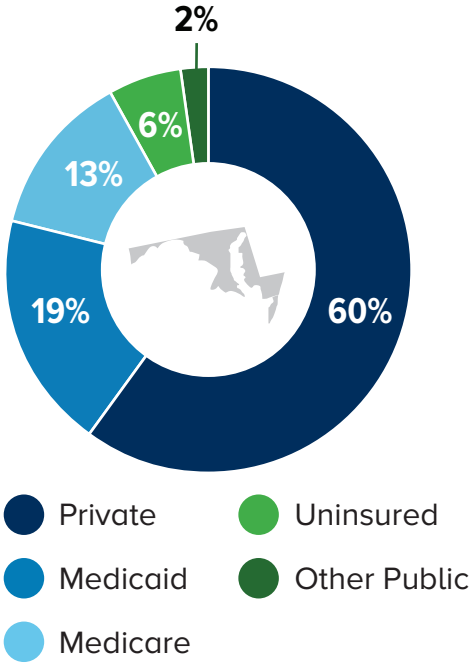
PAYROLL

Health Plan Employees[6]	$1,000,895,000
Insurance-Related Employees[7]	$1,338,849,000

AVERAGE WAGE

Health Plan Employees[6]	$85,357
Insurance-Related Employees[7]	$73,957

Health Insurance Coverage of Maryland Residents[8]



Data compiled by America's Health Insurance Plans (AHIP), Center for Policy and Research, March 2021.

Largest Health Plans by Number of Covered Lives

Commercial[9]	Aetna, a CVS Health Company	CareFirst	Cigna	Kaiser Permanente	UnitedHealthcare
Medigap[10]	Aetna, a CVS Health Company	CareFirst	Cigna	Mutual Of Omaha	UnitedHealthcare
Medicare Advantage[11]	Aetna, a CVS Health Company	Cigna	Johns Hopkins Healthcare	Kaiser Permanente	UnitedHealthcare
Medicaid[5]	Amerigroup Community Care (Anthem)	Maryland Physicians Care	MedStar Family Choice	Priority Partners	UnitedHealthcare

State Premium Tax Collected[12] **$556,409,000**

Individual Marketplace Coverage in Maryland

Marketplace Enrollees Receiving Premium Subsidies[13]

119,227 (81%)

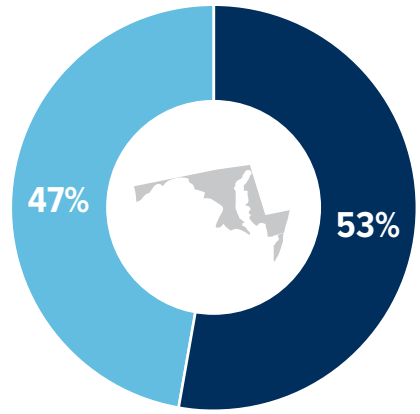
Average Monthly Premium Subsidy in Maryland[13]

$441

Percent of Subsidy-Eligible Population Enrolled in Marketplaces[14]

50%

Employer-Sponsored Insurance by Type[15]



Coverage by Employers in Maryland

Share of Workers in Companies Offering Insurance[16]

87%

Share of Workers in Companies Offering a Choice From Among Two or More Plans[17]

75%

Percent of Single Coverage Premiums Paid by Employers[18]

75%

Sources & Notes

All data sources and notes, labeled 1 - 18, are referenced in detail on the "Sources & Notes" page at the end of the full report, or at this link: http://www.ahip.org/2021-State-Data

Illustrations are for graphical representation only and may not be exact.

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MEMORANDUM

VIA EMAIL: michael.paddy@maryland.gov

TO: Michael Paddy, Director of Government Relations
Maryland Insurance Administration

FROM: James J. Doyle

RE: HB 601 (Chapter 358, Acts of 2021); Supplemental comments by the Independent Pharmacies of Maryland (IPMD)

DATE: November 19, 2021

In light of the recent decision by the U.S. Circuit Court of Appeals for the 8th Circuit on November 17, 2021, in the case of *Pharmaceutical Care Management Association v. Nizar Wehbi*, et al, No. 18-2926, IPMD files these supplemental comments to its original comments of September 1, 2021.

The 8th Circuit decision in *Wehbi* completely supports the position of IPMD in its memo to MIA on September 1. Our comments at that time pointed out that the State of Maryland had joined in an *amicus* brief in this case specifically rejecting the views of the PBMs that attempted to limit the scope of the *Rutledge* decision. Maryland took the position, as a matter of record, that state regulation of ERISA PBMs was permitted by *Rutledge*, as long as the statute or regulation did not force plans to adopt any particular scheme of substantive coverage. That is, as long as the state regulation did not require payment of specific benefits, or bind plan administrators to

specific rules for determining beneficiary status, state regulation was permissible under *Rutledge*.

The *Wehbi* decision fully agrees with the position of this State of Maryland, and IPMD. *Wehbi* concerned state laws that, among other provisions, prohibited a PBM from charging certain retroactive fees, allowed pharmacies to provide relevant information to patients, and placed limits on PBM ownership on mail order specialty pharmacies. PCMA, the lobbying arm of the PBMs, sued on the claim that various provisions were pre-empted by ERISA, and by Medicare Part D. The original 8th Circuit decision, finding ERISA pre-emption, was vacated by the U.S. Supreme Court, on the basis of the *Rutledge* decision, and remanded for further consideration in view of that decision.

On remand in *Wehbi*, the 8th Circuit rejected every pre-emption challenge under ERISA to the state law regulating PBMs. It repeatedly found that the state statute did not "require payment of specific benefits", and did not "bind plan administrators to specific rules for determining beneficiary status", or were, at most, regulation of a noncentral matter of plan administration. In addition, the Court found that each of the challenged provisions applied not only to ERISA PBMs, but also to non-ERISA plans. Thus, there was no ERISA pre-emption as to any of the provisions of the state law.

The Court also examined Medicare Part D pre-emption, but the question of Medicare preemption is not within the scope of HB 601 as enacted in Chapter 358, or the directive of the General Assembly to report on the scope of *Rutledge* to Title 15, Subtitle 16, of the Insurance Article.

In conclusion, it is clear from the recent decision of the 8th Circuit, that there would be no ERISA pre-emption with respect to the various provisions regulating PBMs in Title 15, Subtitle 16, of the Insurance Article. All of those provisions should be made applicable to ERISA PBMs, as set out in IPMD's original comments.

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Memorandum

VIA EMAIL to michael.paddy@maryland.gov

TO: Michael Paddy, Director of Government Relations
Maryland Insurance Administration

FROM: James J. Doyle, III

RE: HB 601 (Chapter 358, Acts of 2021) - Study of scope of Rutledge opinion by MIA-Comments by Independent Pharmacies of Maryland (IPMD)

DATE: September 1, 2021

The MD General Assembly, in HB 601 as enacted in 2021 in Chapter 358, has requested the MIA to study the scope of *Rutledge v. Pharmaceutical Care Management Association*, 592 U.S. __, 141 S. Ct. 474 (2020), and the application of that decision to Title 15, Subtitle 16 of the Insurance Article, and to report back to it. The Independent Pharmacies of Maryland (IPMD), a professional organization of independently owned and operated pharmacies throughout MD, submits these comments to MIA concerning that study.

For the reasons set out in these comments, IPMD believes that *Rutledge* allows for and should be applied fully to all provisions of Title 15, Subtitle 16; that ERISA PBMs should be fully regulated throughout Subtitle 16; and that HB 601 (as enacted in Chapter 358, Acts of 2021) should be amended to eliminate each of the exemptions to regulation that were given to ERISA plan PBMs in HB 601 as enacted. Those carve outs and exemptions given to ERISA plan PBM regulation are inconsistent with *Rutledge*, and certainly not required by the decision, and MIA

should report to the General Assembly that those carve outs and exemptions should be eliminated.

As more fully explained in these comments, IPMD's position is fully supported by (1) the clear holding expressed in the *Rutledge* decision, (2) the written advice given by legislative counsel, AAG Kathryn Rowe, on the scope of *Rutledge*, and (3) the official, record position of the State of Maryland taken in the United States Court of Appeals for the Eighth Circuit concerning the scope of *Rutledge*.

BACKGROUND OF HB 601

During the 2021 session of the MD General Assembly, a number of bills were introduced to help reign in various practices of Pharmacy Benefit Managers (PBMs) who function as middlemen between pharmacies, drug manufacturers, and insurers or prescription drug benefit plans. PBMs engage in very questionable practices that have enabled them to reap huge profits, to a large degree at the expense of local, community pharmacies, as well as consumers who pay higher prices as a result. This is not simply a MD problem; it is occurring throughout the United States, and individual states have attempted over the years to deal with some of the abusive practices of PBMs.

One large obstacle to meaningful reform has been the federal ERISA statute, which preempts certain actions by the states to regulate employer sponsored health and prescription drug plans. Many prescription plans are ERISA plans, and, therefore, the scope of ERISA preemption comes into play.

On December 10, 2020, the U.S. Supreme Court decided *Rutledge v. Pharmaceutical Care Management Association*, which concerned the scope of preemption for PBMs of ERISA plans. *Rutledge* held that an Arkansas law requiring PBMs to at least reimburse pharmacies for the cost of their drugs, was not preempted by ERISA. This decision opened the door wide to potential broad regulation of ERISA PBMs by individual states.

But *Rutledge* could not take effect in MD until statutory changes were made to MD law, specifically in the Insurance Code. That was due to the fact that the MD statute defined a PBM and the "purchaser" of PBM services, to specifically exclude PBMs under an ERISA plan. HB 601, as originally introduced by Delegate Kipke, simply, and correctly in accordance with the scope of *Rutledge*, completely removed the ERISA plan exemption from the MD statute.

During hearings and work sessions on HB 601, a clear difference of opinion emerged as to the scope of *Rutledge*. IPMD took the position that its scope was broad, allowing state regulation of ERISA PBMs as long as a state did not require a PBM to "structure benefit plans in particular ways, such as by requiring payment of specific benefits, … or by binding plan administrators to specific rules for determining beneficiary status." 141 S. Ct. at 480. The PBMs, on the other hand, sought to narrow the scope of *Rutledge* as much as possible, stating that it effectively did nothing new in terms of permissible PBM regulation. As something of an alternative, since this interpretation was completely at odds with the clear language of the opinion, but still desiring to limit *Rutledge* as much as possible, the PBMs took the position that *Rutledge* was simply limited to "cost regulation."

As a result of the different views on the scope of the opinion, the subcommittee crafted amendments to HB 601that eliminated the ERISA plan exemption from the scope of a "purchaser" of PBM services, but retained the ERISA exemption for certain provisions of the Insurance Code. **So, the bill as revised and enacted into law, eliminates the ERISA exemption for some provisions, but also retains that exemption for a number of others.**

In order to resolve these conflicting interpretations of the case, HB 601, as enacted, contains a study and reporting requirement to the General Assembly:

> AND BE IT FURTHER ENACTED, That, on or before December 31, 2021, the Maryland Insurance Administration shall report to the Senate Finance Committee and the House Health and Government Operations Committee, in accordance with S 2-1257 of the State Government Article, on the scope of the U.S. Supreme Court opinion in Rutledge v. Pharmaceutical Care Management Association and how to apply the decision to Title 15, Subtitle 16 of the Insurance Article.

THE HOLDING AND SCOPE OF *RUTLEDGE* GIVES BROAD AUTHORITY TO THE STATE TO REGULATE ERISA PLAN PBMs; IT IS NOT LIMITED, AS THE PBMs CONTEND, TO "COST REGULATION"

Rutledge upheld an Arkansas requiring PBMs to at least reimburse pharmacies for the actual cost of their purchased drugs. The PBM trade group, PCMA, had challenged the law as violating ERISA preemption. But the Supreme Court disagreed with the PBMs, finding no preemption and in its opinion, giving broad authority to the states to regulate ERISA plan PBMs. As the Court stated, "**ERISA is therefore primarily concerned with pre-empting laws that require providers to structure benefit plans in particular ways, such as requiring payment of specific benefits, …, or by binding plan administrators to specific rules for determining beneficiary status…**." 141 S. Ct. at 480 (emphasis added). "In short, ERISA does not pre-empt state rate regulations that merely increase costs or alter incentives for ERISA plans **without forcing plans to adopt any particular scheme of substantive coverage."** 141 S. Ct. at 480. (emphasis added)

Nor did the Arkansas law act immediately and exclusively upon ERISA plans so as to cause preemption. The state law "applies to PBMs whether or not they manage an ERISA plan." The act "regulates PBMs whether or not the plans they service fall within ERISA's coverage." 141 S. Ct. at 481.

Specifically, "[r]equiring PBMs to reimburse pharmacies at or above their acquisition costs does not require plans to provide any particular benefit to any particular beneficiary in any particular way." Further, the state law's "appeal procedure does not govern central matters of plan administration." 141 S. Ct. at 482. While the Court conceded that the state law may increase costs and "operational inefficiencies", "creating inefficiencies alone is not enough to trigger ERISA pre-emption." Quoting an earlier case, *De Buono*, 520 U.S. at 816, "Any state tax, or other law, that increases the cost of providing benefits to covered employees will have some effect on the administration of ERISA plans, but that simply cannot mean that every state law with such an effect is pre-empted by the federal statute." 141 S. Ct. at 483.

While *Rutledge* concerned, in part, a cost regulation, its language clearly does not limit the holding to cost regulations. As the decision holds, as long as a statute does not require payment of specific benefits, or enact specific rules for determining eligibility status, there is no ERISA preemption.

LEGISLATIVE COUNSEL TO THE GENERAL ASSEMBLY AGREES THAT *RUTLEDGE* IS NOT LIMITED TO "COST REGULATION."

In addition, the Attorney General's legislative counsel weighed in HB 601 and the scope of *Rutledge* during the 2021 session. Assistant Attorney General Kathryn Rowe essentially decided against the opinion of the PBMs, and in favor of the broad interpretation of the opinion by IPMD and others. In a letter of advice, Ms. Rowe stated, "**Specifically, you have asked whether the Rutledge ruling applies only to issues related to reimbursement. It is my view that the Rutledge holding is not so limited**, and that PBM laws may apply to ERISA plans so long as their application does not have the effect of dictating plan terms or effectively forcing certain options in plan structure." (emphasis added)

The letter continued,

> "Maryland laws regulate a number of aspects of the interactions between a PBM and a contracted pharmacy, but none address the structure of plans or place requirements or prohibitions on the structure of any plan. Nor does it appear that any of the provisions would have the effect of forcing a PBM to structure their plans in a particular way. In addition, like the Arkansas law, the provisions of the bill apply to PBMs whether or not they are ERISA plans and do not directly regulate health benefit plans**. For these reasons it is my view that the current provisions of Title 15, subtitle 16 that House Bill 601 [as originally introduced] would make applicable to PBMs would not be preempted." (emphasis added)**

The letter of advice by legislative counsel completely repudiates the contention of the PBMs and supports IPMD's view that ERISA plan PBMs may be fully regulated without the ERISA exemptions given by HB 601 as enacted.

THE STATE OF MARYLAND, AS A MATTER OF RECORD IN THE FEDERAL COURTS, SPECIFICALLY REJECTS THE VIEW OF THE PBMs THAT *RUTLEDGE* APPLIES ONLY TO COST REGULATION.

The State of Maryland has specifically rejected the argument of the PBMs that *Rutledge* is limited to cost regulation. Maryland has joined, as one of many state amici, in a pending case before the United States Court of Appeals for the Eighth Circuit, *Pharmaceutical Care Management Association v. Nizar Wehbi, et al*., no. 18-2926. That case was remanded by the U.S. Supreme Court to the Eighth Circuit for reconsideration in light of *the Rutledge* decision. **The amicus brief filed on behalf of Maryland and the other states, on July 2, 2021, specifically rejects the view that *Rutledge* is limited to cost regulations. See, amicus brief at pp 19-20 (available on the U.S. federal courts' PACER website).**

Maryland's amicus brief makes several points relevant to the issues here. **First, the brief notes that "State regulation [of PBMs] is necessary because PBMs harm Pharmacies, Consumers, and States."** PBMs "harm pharmacies by lowering reimbursement rates and favoring certain pharmacies." As the brief points out, PBMs use their "superior bargaining position to drive down reimbursements to pharmacies", and "by steering business-and offering preferable terms-to pharmacies affiliated with the PBM." "All but the largest retail pharmacies receive only 'take it or leave it' offers from PBMs." At the same time, PBMs "steer business away from independent pharmacies and toward PBM-owned or -affiliated pharmacies." In addition to harming independent pharmacies, the brief essentially indicts PBMs for harming consumers by driving up drug prices nationwide.

Second, the Maryland amicus brief specifically rejects the view of the PBMs that Rutledge is limited to cost regulation. As the brief points out, Rutledge and ERISA preemption is only concerned "with the what and who of benefits". As the brief states, "Despite nearly forty years of

the Court holding that ERISA does not preempt state laws unless they affect the who or what of benefits, **PCMA [the lobbying arm of the PBMs] attempts to limit Rutledge's holding to cost regulations. PCMA is wrong**. **Rutledge reaffirmed that regulations that do not 'for[ce] plans to adopt any particular scheme of substantive coverage' are not preempted."** Amicus brief at p.19. (emphasis added)

Thus, not only is the position of the PBMs contrary to all the authority cited in our comments, the PBM position is contrary to the position taken by the State of Maryland as a matter of record before the federal appellate court in the Eighth Circuit. In light of the state's position of record, it would clearly be incongruous for MIA to adopt the contrary and unwarranted position of the PBMs restricting state regulation to cost regulations.

CHANGES MADE TO MD LAW BY HB 601

A "pharmacy benefit manager" is a person that provides pharmacy benefit management services. Ins Code, Sec 15-1601 (Q). PBM services require the administration or management of prescription drug coverage by a "purchaser" for beneficiaries. Sec. 15-1601 (P). Under the prior law, before passage of HB 601, a "purchaser" did not include a person providing benefits through an ERISA plan. Thus, ERISA plans were not covered by the PBM provisions of the Insurance Article because the definition of a "purchaser" excluded ERISA plans.

With the enactment of HB 601, the ERISA plan exemption was deleted from the definition of a "purchaser". As a result, a PBM under Subtitle 16 includes all PBMs that offer a pharmacy benefit plan or program in the state. Sec 15-1601 (S). And that includes PBMs in ERISA plans.

However, in an apparent effort to defer reaching a conclusion on the scope of *Rutledge*, HB 601 also added new language defining a "carrier." A "carrier" is the state employee and retiree plan, an insurer, a nonprofit health service plan, or an HMO that provides prescription drug benefits and enters into an agreement with a PBM to provide pharmacy benefit services. But, "carrier", under HB 601, does not include "a person that provides prescription drug coverage or benefits through plans subject to ERISA" and does not provide benefits through insurance. Sec 15-1601

(D). That new definition of a "carrier" was then used to preserve various exemptions for ERISA PBMs in sections 15-1611, 1611.1, 1612, 1613, 1622, 1629, 1630, and 1633 of HB 601.

So, ERISA plan PBMs are still exempt from the terms of each of these provisions under HB 601 as enacted.

HB 601, AS ENACTED, PRESERVED CERTAIN ERISA EXEMPTIONS TO STATE REGULATION THAT ARE INCONSISTENT WITH THE BROAD AUTHORITY GIVEN TO THE STATES BY *RUTLEDGE*

The enactment of HB 601 will apply, for the first time, many provisions of the Insurance Code to PBMs, including ERISA plan PBMs. So, for example, the provisions of 15-1604 through 1612, dealing with the registration and regulation of PBMs, will now apply to ERISA PBMs as well. Section 15-1628.3, prohibiting a host of fees by PBMs, including fees for adjudication of a claim, or an incentive program, or reductions under a reconciliation process to an effective rate of reimbursement, including generic effective rates, DIR fees, and other fees, may no longer directly or indirectly be charged by a PBM, including an ERISA PBM. Sections 1628.1 and .2 dealing with MAC appeals, will now also apply to ERISA PBMs. These are significant improvements to the state regulation of PBMs, but in other respects HB 601 fell far short of giving Maryland the full authority to regulate as permitted by *Rutledge*.

Specifically, Sections 15-1611, 1611.1, 1612, 1613, 1622, 1629, 1630 and 1633 of HB 601 will apply only to PBMs that are acting on behalf of a non-ERISA carrier; they will not apply to PBMs acting on behalf of an ERISA plan. **These sections will continue to exempt ERISA plans from state regulation under HB 601 as enacted, and thus fall far short of the regulatory authority given by *Rutledge* to the states.**

HB 601, AS ENACTED, SHOULD BE AMENDED TO ELIMINATE ALL LANGUAGE WHICH PRESERVES ANY ERISA PLAN PBM FROM MIA REGULATION

In its report to the General Assembly on the scope of *Rutledge*, MIA should take the position that the ERISA exemption should be repealed for each of the above cited sections. The broad scope of *Rutledge* should control, and each section of Title 15, Subtitle 16 should apply to all PBMs including ERISA plan PBMs.

Rutledge allows state regulation as long as an ERISA PBM is not required to "structure benefit plans in particular ways, such as by requiring payment of specific benefits… or by binding plan administrators to specific rules for determining beneficiary status." Each of the following sections of subtitle 16 does not require payment of specific benefits, or bind plans for determining beneficiary status:

Section 15-1611 provides that a PBM may not prohibit a pharmacy or pharmacist from providing price information or copay information to a beneficiary; discussing that information with the beneficiary, or making a more affordable drug available.

Section 15-1611.1 provides that a PBM may not require a beneficiary to use a specific pharmacy or entity to fill a prescription, where there is a common corporate affiliation or ownership between the PBM and pharmacy, except for specialty drugs.

Section 15-1612 prohibits, with certain exceptions, a PBM from reimbursing a pharmacy less than the amount it reimburses itself or an affiliate for the same drug or service.

Section 15-1613 makes therapeutics committees established by a PBM meet the various requirements of Part III of Subtitle 16. Those provisions deal with the composition of the committees, disclosures, required policies and procedures, and accreditation.

Section 15-1622 exempts sections 1623 and 1624 from ERISA PBMs for affiliated entities. Section 1623 requires a PBM to inform a purchaser, before entering into a contract with the purchaser, of various disclosures, and provide the purchaser certain revenue and payment information. Section 1624 requires certain fiscal reports to be provided to purchasers.

Section 1629 sets out in great detail the terms by which a PBM can conduct an audit of the pharmacy.

Section 15-1630 provides that a PBM shall establish an internal review process for failure to pay a contractual reimbursement of a submitted claim.

Finally, **section 15-1633** deals with therapeutic interchanges. It exempts sections 1633.1 through 1639 from applying to an ERISA PBM. Those sections relate to therapeutic interchanges, dealing with a change from one prescription drug to another. These provisions deal with authorization requirements, and disclosures to beneficiaries of such changes, among other provisions.

It is clear from a review of each of these provisions that **none of them require any ERISA plan to provide a specific benefit, nor do any of them deal with the determination of beneficiary status**. Thus, *Rutledge* permits each of those sections to be fully applicable to ERISA PBMs, and *Rutledge* provides no legal basis for the exemptions which have been preserved in these specific sections by HB 601 as enacted. Or, as the MD amicus brief in the Eighth Circuit states, ERISA preempts only laws affecting the "who" and "what" of benefits; these sections of subtitle 16 have nothing to do with the "who" or "what" of benefit plans. The definition of "carrier", and references to it in subtitle 16, should be eliminated.

Nor is there any policy reason that all of these provisions should not apply equally to ERISA PBMs, as well as other PBMs. Rather, good public policy would dictate that MD regulate ERISA PBMs to the full extent permitted by *Rutledge*. The abuses to independent pharmacies, to consumers, and to the price of prescription drugs is well documented in MD's Eighth Circuit amicus brief. MIA should recommend, and seek amendment to the law allowing for full MIA regulation of all ERISA plan PBMs.

Thank you for your consideration of these comments on behalf of IPMD.

December 3,2021

Submitted via email to michael.paddy@maryland.gov

Mr. Michael Paddy
Director of Government Relations
Maryland Insurance Administration
200 St. Paul Street #2700
Baltimore, MD 21202

Re: Scope of the U.S. Supreme Court opinion in *Rutledge v. Pharmaceutical Care Management Association* No. 18-540, slip on (Dec. 10, 2020); Application to Title 15, Subtitle 16 of the Insurance Article

Dear Mr. Paddy:

On behalf of our members operating in the state of Maryland, the National Association of Chain Drug Stores (NACDS) and the Maryland Association of Chain Drug Store (MACDS) jointly submit these updated comments on the scope of the U.S. Supreme Court opinion in *Rutledge v. Pharmaceutical Care Management Association* ("*Rutledge*") and its application to Maryland's insurance article regulating pharmacy benefit managers ("PBMs") in light of the recent federal court of appeals ruling applying *Rutledge*[1] and confirming the scope of *Rutledge's* application.

With the vast expansion of prescription drug coverage over the years, PBMs have become significant players in the U.S. health care market. Indeed, these entities touch a growing share of covered lives in the U.S. and are seemingly involved in most prescription drug transactions today. Given their impact, it is no surprise that states have been exploring ways to regulate PBMs to help ensure transparency, oversight, and efficiency of such entities operating in their respective states. As discussed below, the *Rutledge* decision, now reinforced by the *Wehbi* decision, helps states bolster that regulation.

I. Scope of *Rutledge Reinforced by Wehbi*

Rutledge upheld a 2015 Arkansas' state law that sought to regulate the relationship between PBMs and pharmacies. Specifically, the 2015 Arkansas law: (1) required PBMs to promptly update their Maximum Allowable Cost ("MAC") pricing lists when a drug's prevailing wholesale cost increases by 10% or more; (2) required PBMs to grant appeals and increase reimbursements if a pharmacy was reimbursed below its acquisition cost, and the pharmacy shows it could not have purchased the drug for less from its primary

[1] The ruling was issued by the United States Court of Appeals for the Eighth Circuit in *Pharmaceutical Care Management Association (PCMA) v. Wehbi* (*Wehbi*).

wholesaler; and (3) allowed pharmacies to decline to dispense a drug if a PBM's MAC is less than what the pharmacy paid to purchase it. The Court ruled that the Arkansas law was "merely a form of cost regulation" and as such, the law was not preempted by the federal Employee Retirement Income Security Act ("ERISA") law.

In the subsequent *Wehbi* decision, issued just last month, the Eighth Circuit, relying on *Rutledge*, upheld nearly all of the provisions of a North Dakota law regulating PBMs. Notably, overturning an earlier ruling by the same court finding all of the provisions of the North Dakota law to be preempted by ERISA and Medicare Part D law, the Eighth Circuit outright rejected the PBMs' argument that they could not be regulated in the federal or state arenas. Looking to *Rutledge*, the court stated that all provisions of the North Dakota law, which regulated the PBM/pharmacy relationship, including those related to patient co-payments; pharmacy mail service and related fees; network participation; pharmacy accreditation standards; PBM/pharmacy common ownership; the freedom of the pharmacy to dispense any drugs permitted by law; and restricting post-adjudication or claw-back fees were not preempted by ERISA. Further, most of these provisions were not otherwise preempted by federal law under Medicare Part D.[2]

Yet, the combined scope of the *Rutledge* and *Wehbi* decisions more clearly provide states with the ability to pass and/or enforce more comprehensive legislation that regulates the relationship between the PBM and pharmacy, ***including those serving ERISA plans.***Indeed, just this year NACDS identified the passage of roughly nine state laws that seek to regulate the PBM/pharmacy relationship and broadly fall under the purview of the *Rutledge* decision.[3]

For example, in West Virginia recently passed HB 2263, which requires PBMs operating in the commercial market to reimburse a pharmacy for a drug in an amount that is not less than the drug's National Average Drug Acquisition Cost (NADAC) plus a professional dispensing fee of $10.49. The law also prohibits PBMs from charging a pharmacy a retroactive fee and removes a provision exempting PBMs serving ERISA plans from existing regulations. We expect to see more states pass or strengthen similar laws already on the books in alignment with the *Rutledge* and *Wehbi* decisions, which generally fall into the following categories:

A. Laws that promote fair pharmacy reimbursement, including:

Provisions that establish a rate floor in Medicaid managed care or the commercial market – Some states have established a rate floor for Medicaid managed care plans that are set

[2] The specific provisions of the North Dakota law which were not upheld as applied to Medicare Part D plans due to Medicare Part D preemption were limited to restrictions on post-adjudication or anti-clawback fees; pharmacy performance measures; and requirements to share price spread.

[3] Arizona (SB 1356), Arkansas (HB 1804); Maryland (HB 601); New Mexico (SB 124); North Dakota (HB 1492); Oklahoma (HB 2677); Tennessee (HB 1398); Texas (HB 1763); West Virginia (HB 2263).

at the amount paid under the state's Medicaid fee-for-service program. We support these provisions because oftentimes the Medicaid fee-for-service rate is based on NADAC, which oftentimes covers a pharmacy's cost.

Provisions that place parameters around maximum allowable cost (MAC) lists – These provisions often regulate the time with which MAC lists must be updated and provide an appeal process for pharmacies to challenge a payment based on MAC.

Provisions that require fair audits of pharmacies – These provisions put parameters around how plans and/or PBMs can conduct audits of pharmacies and recoup money from a pharmacy. For example, some audits can be based on fraud, waste, and abuse violations, but not on a typographical or administrative error.

B. Laws that reform retroactive adjustments to pharmacies:

Provisions that prohibit retroactive payment adjustments – These provisions prohibit plans and/or PBMs from taking back monies from a pharmacy on a claim that has already been paid to the pharmacy.[4]

C. Laws that provide for an avenue for pharmacies to serve patients, including:

Provisions that permit any willing pharmacy to include in a plan and/or PBMs network – These provisions permit any pharmacy that is willing to accept the terms and conditions of a pharmacy network to be included in such network. These provisions combat plan and/or PBM practices that exclude pharmacies from a preferred network.

Provisions that prohibit mandatory mail-order programs – These provisions prohibit plans and/or PBMs from mandating that patients must receive their prescription from a mail-order pharmacy under certain circumstances (e.g., 90-day fill).

Provisions that prohibit steering a patient away from the pharmacy of their choice – Similar to the above, these provisions would prohibit plans and/or PBMs from mandating that a patient must receive their prescription drugs from one particular pharmacy over another, which could result in reduced quality of care, unnecessary and confusing access barriers, and delay to medications.

D. Laws that advocate for the enforcement of pro-pharmacy laws:

*Provisions regarding PBM licensure/registratio*n – These provisions require PBMs to be licensed by or register with a state regulatory body (state department of insurance or board of pharmacy) to help ensure the state has oversight authority over PBMs

[4] While the Eighth Circuit in *Wehbi* determined such provisions are preempted as applied to Part D plans due to Medicare Part D preemption, that question remains open in the Fifth Circuit Court of Appeals in which Maryland sits. Further, such federal preemption would not apply to PBM pharmacy contracts for plans outside of Medicare Part D.

II. Application of *Rutledge* to Maryland's Subtitle 16 of the Insurance Article

Maryland's recently passed HB 601, which removes provisions of law that exempt PBMs serving ERISA plans from regulation under the state's instance article, is the state's first step in passing or enforcing more comprehensive legislation in alignment with the *Rutledge* decision. This removal means that the following laws on Maryland's books clearly apply to PBM/pharmacy relationships, including but not limited to those occurring under ERISA plans:

- *Provisions that place parameters around maximum allowable cost (MAC) lists* (Md. Code, Ins. 15-1628.1),
- *Provisions that require fair audits of pharmacies* Fair Audit (Md. Code, Ins. 15-1629)
- *Provisions that prohibit mandatory mail-order programs* (Md. Code, Ins. 15-1611.1),
- *Provisions that prohibit retroactive payment adjustments* (Md. Code, Ins. 15-1631; Md. Code, Ins. 15-1628.3), [5]
- *Provisions regarding PBM licensure/registratio*n (Md. Code, Ins. 15-1604); *see also provisions that provide for the state to enforce such laws on PBMs operating in the state* (Md. Code, Ins. 15-1632)

Importantly, these laws already encapsulate much of what NACDS has identified as laws that states will pass or strengthen to align with the *Rutledge* decision.

III. Conclusion

We thank you for considering our perspectives on the scope of application of the *Rutledge* decision in Maryland. For any further discussion on this matter, please contact NACDS' Jill McCormack at 717-592-8977 or MACDS' Cailey Locklair at (410) 269-1440.

Sincerely,

Steven C. Anderson, FASAE, IOM, CAE
President and Chief Executive Officer

[5] *See* footnote 4, *above*.

Cailey E. Locklair
President
Maryland Association of Chain Drug Stores

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

MARYLAND ASSOCIATION OF CHAIN DRUG STORES

September 10, 2021

Submitted via email to michael.paddy@maryland.gov

Mr. Michael Paddy
Director of Government Relations
Maryland Insurance Administration
200 St. Paul Street #2700
Baltimore, MD 21202

Re: Scope of the U.S. Supreme Court opinion in *Rutledge v. Pharmaceutical Care Management Association* No. 18-540, slip on (Dec. 10, 2020); Application to Title 15, Subtitle 16 of the Insurance Article

Dear Mr. Paddy:

On behalf of our members operating in the state of Maryland, the National Association of Chain Drug Stores (NACDS) and the Maryland Association of Chain Drug Store (MACDS) jointly submit these comments on the scope of the U.S. Supreme Court opinion in *Rutledge v. Pharmaceutical Care Management Association* ("*Rutledge*") and its application to Maryland's insurance article regulating pharmacy benefit managers ("PBMs").

With the vast expansion of prescription drug coverage over the years, PBMs have become significant players in the U.S. health care market. Indeed, these entities touch a growing share of covered lives in the U.S. and are seemingly involved in most prescription drug transactions today. Given their impact, it is no surprise that states have been exploring ways to regulate PBMs to help ensure transparency, oversight, and efficiency of such entities operating in their respective states. As discussed below, the *Rutledge* decision has been an important state tool to help bolster that regulation.

I. Scope of *Rutledge*

Rutledge upheld a 2015 Arkansas' state law that sought to regulate the relationship between PBMs and pharmacies. Specifically, the 2015 Arkansas law: (1) required PBMs to promptly update their Maximum Allowable Cost ("MAC") pricing lists when a drug's prevailing wholesale cost increases by 10% or more; (2) required PBMs to grant appeals and increase reimbursements if a pharmacy was reimbursed below its acquisition cost, and the pharmacy shows it could not have purchased the drug for less from its primary wholesaler; and (3) allowed pharmacies to decline to dispense a drug if a PBM's MAC is less than what the pharmacy paid to purchase it. The Court ruled that the Arkansas law

was "merely a form of cost regulation" and as such, the law was not preempted by the federal Employee Retirement Income Security Act ("ERISA") law.

Yet, the scope of the *Rutledge* decision reaches beyond the three Arkansas provisions at the center of the *Rutledge* decision. The decision more clearly provides states with the ability to pass and/or enforce more comprehensive legislation that regulates the relationship between the PBM and pharmacy, ***including those serving ERISA plans***, such as regulations that amount to "cost regulation." Indeed, just this year NACDS identified the passage of roughly nine state laws that seek to regulate the PBM/pharmacy relationship and broadly fall under the purview of the *Rutledge* decision.[1]

For example, in West Virginia recently passed HB 2263, which requires PBMs operating in the commercial market to reimburse a pharmacy for a drug in an amount that is not less than the drug's National Average Drug Acquisition Cost (NADAC) plus a professional dispensing fee of $10.49. The law also prohibits PBMs from charging a pharmacy a retroactive fee and removes a provision exempting PBMs serving ERISA plans from existing regulations. We expect to see more states pass or strengthen similar laws already on the books in alignment with the *Rutledge* decision, which generally fall into the following categories:

A. Laws that promote fair pharmacy reimbursement, including:

Provisions that establish a rate floor in Medicaid managed care or the commercial market – Some states have established a rate floor for Medicaid managed care plans that are set at the amount paid under the state's Medicaid fee-for-service program. We support these provisions because oftentimes the Medicaid fee-for-service rate is based on NADAC, which oftentimes covers a pharmacy's cost.

Provisions that place parameters around maximum allowable cost (MAC) lists – These provisions often regulate the time with which MAC lists must be updated and provide an appeal process for pharmacies to challenge a payment based on MAC.

Provisions that require fair audits of pharmacies – These provisions put parameters around how plans and/or PBMs can conduct audits of pharmacies and recoup money from a pharmacy. For example, some audits can be based on fraud, waste, and abuse violations, but not on a typographical or administrative error.

[1] Arizona (SB 1356), Arkansas (HB 1804); Maryland (HB 601); New Mexico (SB 124); North Dakota (HB 1492); Oklahoma (HB 2677); Tennessee (HB 1398); Texas (HB 1763); West Virginia (HB 2263).

B. Laws that reform retroactive adjustments to pharmacies:

Provisions that prohibit retroactive payment adjustments – These provisions prohibit plans and/or PBMs from taking back monies from a pharmacy on a claim that has already been paid to the pharmacy.

C. Laws that provide for an avenue for pharmacies to serve patients, including:

Provisions that permit any willing pharmacy to include in a plan and/or PBMs network – These provisions permit any pharmacy that is willing to accept the terms and conditions of a pharmacy network to be included in such network. These provisions combat plan and/or PBM practices that exclude pharmacies from a preferred network.

Provisions that prohibit mandatory mail-order programs – These provisions prohibit plans and/or PBMs from mandating that patients must receive their prescription from a mail-order pharmacy under certain circumstances (e.g., 90-day fill).

Provisions that prohibit steering a patient away from the pharmacy of their choice – Similar to the above, these provisions would prohibit plans and/or PBMs from mandating that a patient must receive their prescription drugs from one particular pharmacy over another, which could result in reduced quality of care, unnecessary and confusing access barriers, and delay to medications.

D. Laws that advocate for the enforcement of pro-pharmacy laws:

*Provisions regarding PBM licensure/registratio*n – These provisions require PBMs to be licensed by or register with a state regulatory body (state department of insurance or board of pharmacy) to help ensure the state has oversight authority over PBMs

II. Application of *Rutledge* to Maryland's Subtitle 16 of the Insurance Article

Maryland's recently passed HB 601, which removes provisions of law that exempt PBMs serving ERISA plans from regulation under the state's instance article, is the state's first step in passing or enforcing more comprehensive legislation in alignment with the *Rutledge* decision. This removal means that the following laws on Maryland's books clearly apply to PBM/pharmacy relationships, including but not limited to those occurring under ERISA plans:

- *Provisions that place parameters around maximum allowable cost (MAC) lists* (Md. Code, Ins. 15-1628.1),
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- *Provisions that prohibit retroactive payment adjustments* (Md. Code, Ins. 15-1631; Md. Code, Ins. 15-1628.3),
- *Provisions regarding PBM licensure/registratio*n (Md. Code, Ins. 15-1604); *see also provisions that provide for the state to enforce such laws on PBMs operating in the state* (Md. Code, Ins. 15-1632)

Importantly, these laws already encapsulate much of what NACDS has identified as laws that states will pass or strengthen to align with the *Rutledge* decision.

III. Conclusion

We thank you for considering our perspectives on the scope of application of the *Rutledge* decision in Maryland. For any further discussion on this matter, please contact NACDS' Jill McCormack at 717-592-8977 or MACDS' Cailey Locklair at (410) 269-1440.

Sincerely,

Steven C. Anderson, FASAE, IOM, CAE
President and Chief Executive Officer

Cailey E. Locklair
President
Maryland Association of Chain Drug Stores

December 3, 2021

Sent via email to Michael Paddy at Michael.paddy@maryland.gov

Mr. Michael Paddy
Director of Government Relations
Maryland Insurance Administration
200 St. Paul Place, Suite 2700
Baltimore, MD 21202

Re: House Bill 601, Chapter 358, Acts of 2021 – Pharmacy Benefits Managers – Revisions Report – Stakeholder Comments

Dear Mr. Paddy:

I write on behalf of Pharmaceutical Care Management Association ("PCMA") in response to Bulletin 21-28, issued November 22, 2021, which seeks stakeholder input and analysis regarding the recent 8th Circuit decision, *Pharmaceutical Care Management Association v. Wehbi*, No. 18-2926 (8th Cir. 2021) ("*Wehbi*"). Bulletin 21-28 follows on the earlier Bulletin 21-18's request for input regarding the Supreme Court's decision in *Rutledge v Pharmaceutical Care Management Association*, 141 S. Ct. 474 (2020) ("*Rutledge*") so that the Maryland Insurance Administration may report on how to apply that decision to Title 15, Subtitle 16 of the Insurance Article of the Maryland Code, as codified in §§ 15-1601 – 15-1633.1, Maryland Code Ann. (hereinafter "the Act"). The Act regulates numerous significant PBM functions, including pharmacy networking, disclosures, drug selection, and drug pricing. It also requires PBMs to register with the Commissioner of Insurance.

PCMA is the national trade association representing pharmacy benefit managers ("PBMs"). PCMA's PBM member companies administer drug benefits for more than 266 million Americans who have health insurance through employer-sponsored health plans, commercial health plans, union plans, Medicare Part D plans, managed Medicaid plans and others. The ERISA benefit plans with which PCMA's members contract include both insured and self-funded benefit plans sponsored by employers and labor unions. PBMs use a variety of benefit management tools to help these plans provide high quality, cost-effective prescription drug coverage to plan beneficiaries (employees and their families).

This letter supplements my September 10, 2021 letter regarding Bulletin 21-18, which provided background on ERISA preemption and the *Rutledge* decision, and demonstrated that *Rutledge* does not permit Maryland to impose the Act's provisions on ERISA plans. This conclusion was

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based on the analysis that numerous of the Act's provisions would either dictate plan benefit design, regulate the same subject matter as ERISA itself, or interfere with central matters of plan administration—meaning that they would be subject to preemption under the "connection with" doctrine that remains unaffected by *Rutledge*'s holding.

I. ***Wehbi* Analysis**

The *Wehbi* decision does not change PCMA's conclusions or recommendations for several reasons. ***First***, the 8th Circuit's decision did not substantially change the underlying ERISA preemption standard. Instead, it confirmed that ERISA preemption applies to laws that regulate PBMs even if they do not regulate ERISA plans directly and that there is no presumption against ERISA preemption. It further confirmed that state laws that "require providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits or by binding plan administrators to specific rules for determining beneficiary status," are preempted. *Id.* at 9 (quoting *Rutledge*, 141 S. Ct. at 480). ***Second***, *Wehbi* is a narrow decision, limited to the North Dakota statutory provisions at issue, which differ in many respects from the provisions in the Act. ***Third***, the 8th Circuit's decision on remand is not binding on Maryland, and because it focused on relatively obscure provisions and employed cursory reasoning, the case should have limited persuasive impact on other federal courts.

Wehbi does not change fundamental ERISA preemption standards developed over decades of ERISA preemption litigation and recently reaffirmed by *Rutledge.* Accordingly, *Wehbi* relies on *Rutledge* and *Gobeille v. Liberty Mutual Ins.*, 577 U.S. 312, 320 (2016) to note that state laws that "govern . . . a central matter of plan administration;" are preempted, as well as those that "interfere with nationally uniform plan administration"; or impose "acute, albeit indirect, economic effects" that "force an ERISA plan to adopt a certain scheme of substantive coverage or effectively restrict its choice of insurers." *Wehbi* at 8-9.

Wehbi also rejects two of the state's arguments that could have weakened ERISA preemption, thereby reaffirming ERISA preemption's comprehensive nature. First, the state argued that ERISA preemption does not apply to state laws that directly regulate PBMs rather than ERISA plans. The court agreed with PCMA that challenged state laws do not escape preemption on the basis that they regulate PBMs rather than plans. Consistent with the D.C. Circuit's decision in *PCMA v. District of Columbia*, 613 F.3d 179, 188 (D.C. Cir. 2010), the court held that, "because PBMs manage benefits on behalf of plans, a regulation of PBMs functions as a regulation of an ERISA plan itself." *Wehbi* at 6-7. Second, the court declined the state's invitation to invoke a presumption against preemption when applying ERISA's express preemption provision. *Wehbi* at 7-8.

Wehbi's ERISA "connection with" analysis concerns two unique North Dakota statutes, and should not be read as a referendum on PBM laws in general. Specifically, *Wehbi* holds that eight provisions of North Dakota law were not preempted by ERISA because those specific provisions did not satisfy the ERISA preemption standards. Although the *Wehbi* court grouped the North Dakota provisions roughly into four groups (pharmacy conduct, pharmacy accreditation, disclosures to pharmacies and plans, and requirements for PBM pharmacy owners) to assess them, it did not go so far as to suggest that other provisions falling into the same categories would also survive preemption. To the contrary, the ERISA preemption analysis is fact-specific. Therefore, the *Wehbi* decision is only informative to the extent a court seeks to apply it to identical or near-identical PBM laws. Indeed, many of the North Dakota provisions at issue in *Webhi* were directed at pharmacies with only indirect impacts to PBMs and plans. By contrast, the Act's provisions manifestly seek to regulate PBMs and plans more directly and intrusively and with substantial economic effect.

Moreover, even if the Act included identical or near-identical provisions to those at issue in *Wehbi*, the *Wehbi* decision is not binding on the federal courts (either the United States District Court for the District of Maryland or the United States Court of Appeals for the Fourth Circuit), which would likely be tasked with considering whether the Act is preempted if it was designed to apply to ERISA plans. Moreover, the *Wehbi* opinion frequently relied on cursory reasoning that overlooked several aspects of PCMA's arguments. For instance, the *Wehbi* court failed to recognize that state laws implicating self-insured ERISA plan provider networks strike at the heart of plan benefit design and are subject to preemption. *See Kentucky Association of Health Plans v. Miller*, 538 U.S. 329 (2003) (recognizing that state any-willing-provider law that restricts network design has a "connection with" ERISA plans). Consequently, *Wehbi* may have limited persuasive impact (as well as no controlling impact) on federal courts in other jurisdictions. Therefore, the Insurance Administration should afford *Wehbi* little weight when preparing its report and recommendation to the Senate Finance Committee and the House Health and Government Operations Committee.

II. The Impact of *Wehbi*

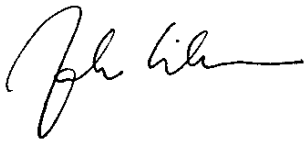
Like *Rutledge*, *Wehbi* merely reaffirmed existing precedent on state laws that involve cost regulation or have only incidental impacts to plan benefits, while retaining ERISA preemption principles that forbid states from regulating plan design or central matters of plan administration. No aspect of *Wehbi* permits Maryland to impose the varied provisions of the Act on ERISA plans. Numerous of the Act's provisions would either dictate plan benefit design, regulate the same subject matter as ERISA itself, or interfere with central matters of plan administration and would still therefore be subject to preemption.

Therefore, PCMA respectfully requests that the report from the Maryland Insurance Administration to the Senate Finance Committee and the House Health and Government Operations Committee incorporate the above analysis, including the critical points that the

scope of ERISA preemption ***was not narrowed by either Rutledge or Wehbi***, that ERISA preemption continues to apply to laws directed at PBMs, and that the 8th Circuit rejected any presumption against preemption. Accordingly, we recommend that the General Assembly refrain from authorizing the extension of Title 15, Subtitle 16 of the Insurance Article to ERISA plans, and thereby create an error that could only then be corrected through litigation. Such an act would do violence to Congress's underlying purposes in ensuring robust ERISA preemption, which are to preserve plan discretion to determine substantive benefit design and protect plans from undue administrative burdens imposed by a patchwork of non-uniform state laws. The resultant hinderances to drug benefits administered by ERISA self-insured employers and labor unions is likely to lead to higher premiums for hard-working employees and increase the costs of doing business for major employer sponsors in the State of Maryland. Extension of the Act's application to ERISA plans would likewise commandeer the Maryland Insurance Administration to enforce a law that is manifestly unfavorable to the interests of the employer and union plans it oversees and the insurance industry it aims to cultivate in the state.

Please feel free to contact me or Heather Cascone, PCMA's Assistant Vice President of State Affairs, at hcascone@pcmanet.org or 202-744-8416 with any questions or for further discussion.

Sincerely,



John S. Linehan
General Counsel

September 10, 2021

Michael Paddy
Director of Government Relations
Maryland Insurance Administration
200 St. Paul Place, Suite 2700
Baltimore, MD 21202
Michael.paddy@maryland.gov

Re: House Bill 601, Chapter 358, Acts of 2021 – Pharmacy Benefits Managers – Revisions Report – Stakeholder Comments

Dear Director Paddy,

I write on behalf of Pharmaceutical Care Management Association ("PCMA") in response to Bulletin 21-18, issued July 1, 2021, which seeks comments from stakeholders regarding the scope of the United States Supreme Court's opinion in *Rutledge v. Pharmaceutical Care Management Association*, 141 S. Ct. 474 (2020) ("*Rutledge*"). Specifically, the Bulletin requests input on how the *Rutledge* decision may apply to Title 15, Subtitle 16 of the Insurance Article of the Maryland Code, as codified in §§ 15-1601 – 15-1633.1, Maryland Code Ann. (hereinafter "the Act"). The Act regulates numerous significant PBM functions, including pharmacy networking, disclosures, drug selection, and drug pricing. It also requires PBMs to register with the Commissioner of Insurance.

PCMA is the national trade association representing pharmacy benefit managers ("PBMs"). PCMA's PBM member companies administer drug benefits for more than 266 million Americans who have health insurance through employer-sponsored health plans, commercial health plans, union plans, Medicare Part D. plans, managed Medicaid plans and others. The ERISA benefit plans with which PCMA's members contract include both insured and self-funded benefit plans sponsored by employers and labor unions. PBMs use a variety of benefit management tools to help these plans provide high quality, cost-effective prescription drug coverage to plan beneficiaries (employees and their families).

I. ERISA Preemption Background

In order to understand the scope and significance of *Rutledge*, it is important first to understand the context, purpose, and background of ERISA preemption. Congress enacted ERISA to provide a "uniform regulatory regime over employee benefit plans." 29 U.S.C. §1001, *et. seq.*; *Aetna Health Inc. v. Davila*, 542 U.S. 200, 248 (2004). ERISA does not mandate "any given set of minimum benefits, but instead controls the administration of benefit plans" and leaves selection and design of plan benefits to plan administrators. *New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 651 (1995) ("*Travelers*"). "[B]y mandating certain oversight systems and other standard procedures" pursuant to uniform federal rules, ERISA "make[s] the benefits promised by an employer more secure" for employees while at the

same time reducing the administrative burdens for multi-state employers. *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943 (2016).

In order to achieve this objective, Congress included an express preemption clause in ERISA, which preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plans." 29 U.S.C. §1144(a). ERISA's preemption clause is "comprehensive." *Gobeille*, 136 S. Ct. at 943. Congress "intended to preempt the field for Federal regulations, thus eliminating the threat of conflicting or inconsistent State and local regulation of employee benefit plans." *Shaw v. Delta Air Lines*, 463 U.S. 85, 99 (1983) (quoting 120 Cong. Rec. 29933 (Aug. 22, 1974)). *See also Davila*, 542 U.S. at 208 (Congress sought to ensure that "employee benefit plan regulation would be 'exclusively a federal concern.") (internal quotations omitted). As a corollary, "[s]tates are precluded from regulating in a field that Congress, acting within its proper authority has determined must be regulated by its exclusive governance." *Arizona v. United States*, 567 U.S. 387, 399 (2012). By protecting plans from competing state laws, ERISA's preemption clause "minimiz[es] the administrative and financial burdens on plan administrators – burdens ultimately borne by the beneficiaries." *Egelhoff v. Egelhoff*, 532 U.S. 141, 149-50 (2001) (internal quotation omitted).

Consistent with this Congressional intent, the Supreme Court has construed the operative words "relate to" in ERISA's express preemption provision to mean state laws that have either a "connection with" or a "reference to" ERISA plans. *Gobeille*, 136 S. Ct. at 943. It is PCMA's position that the Act implicates the former, "connection with," basis for ERISA preemption.[1] According to existing precedent on this doctrine, state laws may be deemed to have an impermissible "connection with" ERISA plans in any one of the following circumstances.

First, a state law has an impermissible "connection with" ERISA plans if it "bind[s] plan administrators to [a] particular choice" concerning the substance of plan benefits. *Rutledge*, 141 S. Ct. at 480. Accordingly, state regulations that "prohibit[] employers from structuring their employee benefit plans in a [particular] manner" are preempted. *Shaw v. Delta Air Lines*, 463 U.S. 85, 97 (1983). Such provisions stand in contrast to mere "rate regulation[s]," which have "an indirect economic effect on choices made by … ERISA plans" but do not "bind plan administrators to any particular choice" concerning plan design. *Travelers*, 514 U.S. at 659, 667.

Second, "state laws dealing with the subject matters covered by ERISA" also have a "connection with" ERISA plans and are preempted. *Shaw*, 463 U.S. at 98; *Rutledge*, 141 S. Ct. at 482 n.2 (distinguishing laws that "overlap with fundamental components of ERISA regulation") (internal quotes omitted). In *Gobeille*, for example, the Court explained that "ERISA's reporting, disclosure, and recordkeeping requirements for welfare benefit plans are extensive." 136 S. Ct. at 944. The Court thus concluded that a state law that "compels [the disclosure of] detailed information" by third-party administrators to state authorities was preempted. *Id.* at 945. Congress's intent to provide ERISA plan administrators a uniform set of rules makes it clear Congress carved out these decisions as the exclusive domain of federal authorities, and not for the states. *Id.*

[1] To the extent that the Act were to act "immediately and exclusively on ERISA plans," or operate in a manner that ERISA plans were "essential to [the Act's] operation," it would also be preempted under the "reference to" analysis. *Rutledge*, 141 S. Ct. at 481.

Third, state laws that "'govern[] a central matter of plan administration" have a connection with ERISA plans and are preempted. *Gobeille*, 136 S. Ct. at 943 (internal quotes omitted). "Plan administration includes determining the eligibility of claimants, calculating benefit levels, making disbursements, monitoring the availability of funds for benefit payments, and keeping appropriate records in order to comply with applicable reporting requirements." *PCMA v. District of Columbia*, 613 F.3d 179, 185 (D.C. Cir. 2010) (internal quotes omitted).

II. The Supreme Court's Decision in *Rutledge*

Rutledge did not change the framework set forth above for determining whether a law bears an impermissible "connection with" ERISA plans. Rather, it applied that framework to the targeted law in that case, Arkansas's Act 900 ("Act 900"), which regulates maximum allowable cost ("MAC") lists for generic drug reimbursements. Act 900 is a drug pricing law: its provisions operate together to set a price floor for generic prescription drugs, in the form of the "pharmacy acquisition cost," which was defined as "the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy's billing invoice."[2] Ark. Code Ann. § 17-92-507(a)(6). Act 900 sets the price floor using several mechanisms aimed at the same goal; namely, requiring PBMs to update and disclose MAC lists periodically, mandating that PBMs provide reasonable appeal procedures for pharmacies to challenge MAC, and by permitting a pharmacy to decline to dispense a prescription to a patient where the reimbursement would be less than the pharmacy's invoice price. Ark. Code Ann. §§ 17-92-507(c); 17-92-507(e).

The Supreme Court held that ERISA did not preempt Act 900. The Court's reasoning in *Rutledge* rested on its long-standing precedent in *Travelers*, where the Court held that a New York law requiring hospitals to add a surcharge to the bill for patients covered by commercial insurers, but not patients covered by Blue Cross and Blue Shield insurers was a "basic rate regulation" not preempted under ERISA. *Id.* at 667, n.6, 668. Although the New York law in *Travelers* made Blue Cross "more attractive" and "thus ha[d] an indirect economic effect on choices made by insurance buyers, including ERISA plans," those indirect economic effects did not trigger ERISA preemption because differential charges merely affected "a plan's shopping decisions." *Id*. at 659-60. The state law did not "bind plan administrators to any particular choice" and thus did not "function as a regulation of an ERISA plan itself." *Id.*

On this basis, the Court in *Rutledge* deemed Act 900 "merely a form of cost regulation" that "requires PBMs to reimburse pharmacies for prescription drugs at rates equal to or higher than the pharmacy's acquisition cost," and was therefore not preempted. 141 S. Ct at 481. Recognizing that an indirect economic influence does not dictate preemption, the Court found that the effect of Act 900 is not "so acute that it will effectively dictate plan choices," therefore leaving open the possibility that some indirect economic influence could dictate plan choice, leading to preemption. *Id*. Further, the Court compared those provisions of Act 900 that required PBMs to recalculate and reprocess pharmacy claims to other state-laws mechanisms for enforcing judgements for

[2] This price does not accurately reflect a pharmacy's cost for generic drugs, which is frequently reduced by post-invoice discounts such as prompt pay discounts and rebates.

breach of contract, which the Court has previously held as permissible under ERISA. *Id.* (citing *Mackey v. Lanier Collection Agency & Service, Inc.*, 486 U.S. 825, 831-32 (1988)). In this way, *Rutledge* did not change existing law regarding the scope of ERISA preemption; instead, it applied long-standing precedent regarding cost regulations to a state law regulating the use of MAC pricing.

III. The Scope and Impact of *Rutledge*

While *Rutledge* reaffirmed existing precedent on state laws that involve cost regulation, ERISA preemption principles that forbid states from regulating plan design or central matters of plan administration remain intact. Because *Rutledge* was narrowly tailored to the Arkansas law at issue in the case, it only limits ERISA preemption of PBM laws that are rate regulations similar to Act 900.[3]

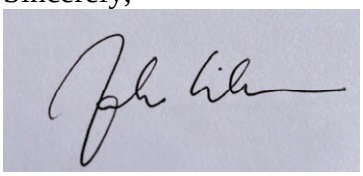
Notably, the Supreme Court specifically distinguished the Arkansas MAC law at issue in *Rutledge* from those state PBM laws that interfere with benefit design. *Rutledge*, 141 S. Ct. at 480 (stating that ERISA preemption is "primarily concerned with preempting laws that require providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits, or by binding plan administrators to specific rules for determining beneficiary status"). Further, *Rutledge* reinforced the principle that laws directed at third parties rather than plans themselves may be preempted by rejecting without discussion the argument that only plans may invoke ERISA preemption. *See Gobeille*, 136 S. Ct. at 947 (holding Vermont law regulating ERISA third-party plan administrator was preempted by ERISA). In so doing, the Court left open the possibility that a panoply of potential state PBM laws, such as those that regulate plan design, benefit selection, and other central matters of plan administration, may still be preempted.

Rutledge does not permit Maryland to impose the provisions of the Act on ERISA plans. Numerous of the Act's provisions would either dictate plan benefit design, regulate the same subject matter as ERISA itself, or interfere with central matters of plan administration—meaning that they would be subject to preemption under the "connection with" doctrine that remains unaffected by *Rutledge*'s holding. Therefore, PCMA respectfully requests that the report from the Maryland Insurance Administration to the Senate Finance Committee and the House Health and Government Operations Committee incorporate the above analysis, including the critical points that the scope of ERISA preemption ***was not narrowed*** by *Rutledge*, and that ERISA preemption remains "comprehensive." *Gobeille*, 136 S. Ct. at 943. Accordingly, we recommend that the General Assembly refrain from authorizing the extension of Title 15, Subtitle 16 of the Insurance Article to ERISA plans. Such an act would do violence to Congress's underlying purposes in ensuring robust ERISA preemption, which are to preserve plan discretion to determine substantive benefit design and protect plans from undue administrative burdens imposed by a patchwork of non-uniform state laws.

Please feel free to contact me or Heather Cascone, PCMA's Assistant Vice President of State Affairs, at hcascone@pcmanet.org or 202-744-8416 with any questions or for further discussion.

[3] Notably, however, the Supreme Court did not take a policy position on Act 900, and offered no opinion regarding whether Act 900 was prudent law. The Court also acknowledged that Act 900 could increase prescription drug costs, but found that this was not enough for preemption. *Rutledge*, 141 S. Ct. at 483.

Sincerely,



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Maryland

Michael Paddy -MDInsurance- <michael.paddy@maryland.gov>

Comments from Navitus Health Solutions on MIA Bulletin 21-28

Collan B. Rosier <Collan.Rosier@navitus.com> Fri, Dec 3, 2021 at 3:07 PM
To: "Mike Paddy (michael.paddy@maryland.gov)" <michael.paddy@maryland.gov>

Good afternoon, Michael!

I hope you're well. Long time no see. On behalf of Navitus Health Solutions, I wanted to provide some thoughts below in response to the Maryland Insurance Administration's (MIA's) Bulletin 21-28 related to House Bill 601 and the scope of the Supreme Court's *Rutledge v. PCMA* opinion and the 8th Circuit's recent *PCMA v. Wehbi* decision with regard to Title 1, Subtitle 16 of the Insurance Article.

In response to the ongoing discussions around state and federal regulation of pharmacy benefit managers (PBMs) following the *Rutledge and Wehbi* decisions, the team at Navitus believes that ERISA generally should control rather than state law. ERISA provides uniform federal standards for self-funded health plans and can help avoid a patchwork of inconsistent, conflicting, and confusing state laws. ERISA also can ensure equitable and affordable benefits for patients. The result of states enacting widely varying regulation of PBMs would be increased costs for patients, employers, benefit plans, insurers, pharmacies, and PBMs. A patchwork of state PBM laws, with widely varying requirements from state to state, would create increased burden for all parties to manage and enforce. This is not in the best interest of anyone as it will result in increased costs to provide pharmacy benefits and increased costs for patients.

As background, Navitus is a 100% pass-through, fully transparent PBM. Since the founding of our company in 2003, Navitus has relentlessly worked to reduce the overall drug costs paid by our clients, while improving member health, providing superior customer service, and ensuring regulatory compliance. Navitus administers pharmacy benefits for more than seven million members across our commercial, ACA/Exchange, Medicaid, Medicare Part D, and discount card lines of business. Navitus also has a wholly-owned subsidiary, Lumicera Health Services, which is an ACHC and URAC accredited specialty pharmacy offering innovative solutions, an integrated care model, clinical expertise, and which dispenses medications to help patients manage complex conditions throughout the country. In Maryland, we have a growing footprint, including earlier this year when our specialty pharmacy, Lumicera, acquired a specialty pharmacy in Gaithersburg (CareMetx) to better serve our clients in the eastern United States and expand our members' access to care.

Please let me know if we can provide any additional information or materials to assist MIA in its decision-making process. In the meantime, I hope we cross paths again soon in Annapolis or Baltimore.

Best wishes,

Collan

Collan B. Rosier

Director of Government Relations

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September 10, 2021

By email to michael.paddy@maryland.gov

Mr. Michael Paddy
Director of Government Relations
Maryland Insurance Administration
200 St. Paul Place, Suite 2700
Baltimore, MD 21202

Re: HB 601 -- Study by MIA of scope of Rutledge opinion -- comments from EPIC Pharmacy Network, Inc.

Dear Mr. Paddy,

EPIC Pharmacy Network, Inc. ("EPIC"), a pharmacy services administrative organization indirectly owned by over 1,000 independent pharmacies throughout the United States, including Maryland, submits these comments regarding the scope of *Rutledge v. Pharmaceutical Care Management Association*, 592 U.S. __, 141 S. Ct. 474 (2020), and its application to Title 15, Subtitle 16 of the Maryland Insurance Code. EPIC's Board of Directors includes the owners of several Maryland independent pharmacies, and EPIC has a long history of service on behalf of Maryland pharmacies.

EPIC believes that *Rutledge* allows for and should be applied fully to all provisions of Title 15, Subtitle 16, that all pharmacy benefit managers (each a "PBM") should be fully regulated throughout Subtitle 16 when serving all payers, and that HB 601 (as enacted in Chapter 358, Acts of 2021) should be amended to eliminate each of the exemptions to regulation that were given to ERISA plan PBMs in HB 601 as enacted. Those carve outs and exemptions given to ERISA plan PBM regulation are inconsistent with *Rutledge*, and certainly not required by the decision, and MIA should report to the General Assembly that those carve outs and exemptions should be eliminated.

In presenting its argument, EPIC expresses its support for, and incorporates by reference, the comments on this topic submitted on behalf of the Independent Pharmacies of Maryland ("IPMD") by James J. Doyle, and also the amicus brief

submitted on July 2, 2021 by the State of Maryland (and 31 other states' attorneys general) to the United States Court of Appeals for the Eighth Circuit, *Pharmaceutical Care Management Association v. Nizar Wehbi*, et al., no. 18-2926. (The amicus brief also is attached to the electronic mail message by which I submit this letter.) The amicus brief eloquently expresses exactly why all aspects of state statutes regulating the relationship between each PBM and pharmacies, and those that protect payers in their relationship with a PBM, are not preempted by ERISA.

A notable example of the absurd nature of the PMBs arguments regarding the narrow scope of the *Rutledge* ruling was the insistence of their advocate, during the last legislative session, that ERISA prevents the following provisions to apply to its dealings with all pharmacies, regardless of the nature of the underlying payer:

Section 15-1611.1 provides that a PBM may not require a beneficiary to use a specific pharmacy or entity to fill a prescription, where there is a common corporate affiliation or ownership between the PBM and pharmacy, except for specialty drugs.

Section 15-1612 prohibits, with certain exceptions, a PBM from reimbursing a pharmacy less than the amount it reimburses itself or an affiliate for the same drug or service.

These two provisions are critical to maintaining the vitality of independent pharmacies, and indeed any pharmacies other than those owned by conglomerates such as CVS Health, Inc., and they are an important part of Maryland's efforts to limit monopolistic practices and preserve healthy competition. Indeed, such provisions are likely also necessary to preserve competition in the pharmacy benefit management services market, to prevent those conglomerates from destroying smaller PBM organizations through market power leveraging. Certainly, these provisions do not implicate who is a permitted beneficiary of a large group benefit plan, or what such a plan covers – but rather only what providers can serve such a plan's members, and how much those providers are paid.

Indeed, it is important to note that, for a large percentage of the contractual relationships between the large PBMs and self-insured groups, the drug cost reimbursement amount that the PBM pays to a pharmacy does not correlate with the amount that the benefit plan pays for that drug. Rather, the PBM typically promises to charge the plan a specified percentage of the average wholesale price that is substantially (and indeterminately) higher than what it pays to most pharmacies. The effect of PBM regulatory statutes is to inhibit the rent-seeking profitability of extremely large, powerful corporations, at the expense of consumers and small businesses, rather

than interfere unlawfully with the ability of self-insured groups to design and administer employee benefits.

Finally, once the PBM statute applies uniformly to all benefit plans, the rules governing the relationship between each PBM and each pharmacy will be clear and uniform for the vast bulk of consumers using insurance to pay for prescriptions. This will simplify pharmacy practice and relationships between pharmacies and PBMs, and thereby foster health care efficiency.

Thank you for your consideration submitted on behalf of EPIC Pharmacy Network, Inc. and its independent pharmacy members.

Sincerely,

/ David L. Cahn /

David L. Cahn

Cc: Mr. Dennis Rasmussen
Enclosure

11943470

No. 18-2926

IN THE
UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

Pharmaceutical Care Management Association,

Appellant,

vs.

Nizar Wehbi et al.,

Appellees.

ON APPEAL FROM UNITED STATES DISTRICT COURT
DISTRICT OF NORTH DAKOTA

BRIEF OF AMICI CURIAE STATES OF MINNESOTA, ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, GEORGIA, HAWAII, ILLINOIS, INDIANA, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MISSISSIPPI, NEBRASKA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, OREGON, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TEXAS, UTAH, VERMONT, VIRGINIA, AND WASHINGTON, AND THE DISTRICT OF COLUMBIA, IN SUPPORT OF APPELLEES AND AFFIRMANCE

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ATTORNEYS FOR AMICI CURIAE
STATES

STATEMENT UNDER FED. R. APP. P. 29(a)(4)(D)

The States of Minnesota, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Georgia, Hawaii, Illinois, Indiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Texas, Utah, Vermont, Virginia, and Washington, and the District of Columbia, submit this brief as amici curiae to support the appellees. The states have an interest in preserving states' authority to regulate companies doing business in their states and in protecting their residents' access to healthcare and shielding them from abusive business practices. To advance these interests, nearly all states regulate pharmacy benefit managers. The sweeping approach to ERISA and Medicare preemption that Appellant advocates would severely impede states' abilities to protect their residents and potentially upend licensing and regulatory structures in nearly every state.

The states file this brief under Fed. R. App. P. 29(a)(2), which permits a state to file an amicus brief without the parties' consent or leave of the Court.

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States have an inherent interest in ensuring their residents can afford their lives. Consumers across America struggle to afford healthcare. A principal cause for their plight is the increasing, unsustainable cost of prescription drugs. States have sought to address these concerns in myriad ways, more recently by regulating a source of these increasing costs: pharmacy benefit managers (PBMs) and their business practices. PBMs are not health plans. They are intermediaries in the prescription-drug insurance market, a segment of the healthcare industry that has grown exponentially, largely without regulation and largely to the detriment of consumers, who have lost access to affordable means of filling their prescriptions. States have enacted laws to curb some of the worst abuses in the PBM industry and to protect consumers, independent pharmacies, and states.

Because regulation cuts into their profits and provides accountability, PBMs naturally resist these laws. In an effort to perpetuate the industry's abuses, Appellant Pharmaceutical Care Management Association (PCMA), a national trade association, has filed multiple lawsuits claiming ERISA or Medicare preempts various states' regulations. PCMA advocates for nearly boundless ERISA and Medicare preemption. As the appellees argue, this position is meritless and the Court should reject it.

ARGUMENT

PCMA claims ERISA and Medicare broadly preempt state PBM regulations. As recently reaffirmed by the Supreme Court, ERISA preemption applies only to laws that require insurance providers to structure benefit plans in specific ways, such as by requiring specific benefits or rules to determine beneficiary status. *Rutledge v. Pharm. Care Mgmt. Ass'n*, 141 S. Ct. 474, 480 (2020). Medicare preempts state laws only if a Medicare "standard" particularly addresses the subject of state regulation. *Pharm. Care Mgmt. Ass'n v. Rutledge*, 891 F.3d 1109, 1113 (8th Cir. 2018), *rev'd on other grounds*, *Rutledge*, 141 S. Ct. 474. Because the challenged North Dakota laws do not dictate plan benefits or conflict with a Medicare standard, they are not preempted.

I. REGULATING PBMS PROTECTS CONSUMERS AND CURBS ABUSES BY A MULTI-BILLION-DOLLAR INDUSTRY.

Prescription drugs are an inescapable and increasingly prevalent facet of modern healthcare. In 2017, about 58% of adults aged 18-64, and 86% of adults over 65, were prescribed medication in the preceding year.[1] In 2019, annual prescription-drug spending in the United States grew 5.7% to $369.7 billion.[2]

[1] Ctrs. for Disease Control & Prevention, U.S. Dep't of Health & Hum. Servs., *QuickStats*, 68 Morbidity & Mortality Wkly Rep. 97 (2019), https://perma.cc/YAT6-B3SZ.

[2] Ctrs. for Medicare & Medicaid Servs., *National Health Expenditure Fact Sheet*, https://perma.cc/8YES-JUPJ.

Healthcare spending is projected to continue increasing and comprise more of the GDP.[3]

While early PBMs in the 1970s played a limited role in the healthcare system, their role steadily expanded over the past fifty years to control nearly every aspect of health plans' pharmacy benefits.[4] The way a medication gets to a consumer is relatively straightforward: manufacturer → distributor → pharmacy → consumer. How that medication is paid for is anything but simple, in large part due to PBMs. PBMs implement complicated processes and requirements that maximize PBM profits at the expense of pharmacies and patients.

PBMs' growing role in healthcare was largely overlooked for decades, cultivated by the lack of transparency PBMs designed into the system.[5] Within the healthcare industry, PBMs became an interwoven web, imposing self-serving protections that reduced reimbursement rates to pharmacies, maximized rebates to PBMs, and imposed various confidentiality requirements. For example, before states began regulating, basic information like the amount PBMs reimbursed pharmacies for dispensing medications was often confidential.[6] PBMs thrived in

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[3] *Id.*

[4] Oversight Hearing of the S. Comm. on Bus., Professions and Econ. Dev., *Pharmacy Benefit Managers 101* 2 (Cal. Mar. 20, 2017), https://perma.cc/D4SL-PBB6.

[5] Stephen Barlas, *Employers and Drugstores Press for PBM Transparency*, 40 Pharmacy & Therapeutics 206-08 (2015), https://perma.cc/G8RX-TP54.

[6] *Id.*

this opaque space in the healthcare industry so much that the PBM market is now estimated to be in the hundreds of billions of dollars annually. Coupled with many consumers' limited pharmacy choices, PBMs created a captive market that demanded regulation to safeguard the public's financial and physical health.

A. State Regulation Is Necessary Because PBMs Harm Pharmacies, Consumers, and States.

PBMs have exploited decades of lax or non-existent regulation to become a massive part of the prescription-medication industry. Because PBMs are essentially middlemen, their profits depend on reaping large fees and rebates while spending as little as possible to reimburse pharmacies for medications. This drives down reimbursement rates and increases drug prices, all while operating largely in the shadows. State regulation is necessary to curb PBM practices that harm pharmacies, consumers, and states.

1. PBMs harm pharmacies by lowering reimbursement rates and favoring certain pharmacies.

Local pharmacies are critical in providing healthcare to rural communities, and pharmacy closures have been particularly detrimental.[7] From 2003 to 2018, approximately 16% of independently owned rural pharmacies closed.[8] In major

[7] Abiodun Salako et al., RUPRI Ctr. for Rural Health Pol'y Analysis, *Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018* (2018), https://perma.cc/9XKN-7TU2.
[8] *Id.*

metropolitan areas between 2007 and 2015, pharmacies were less likely to open and more likely to close in neighborhoods with majority Black or Hispanic/Latinx residents.[9] This trend in closures spans the rural-urban divide and is traceable to PBMs. PBMs' historically unregulated business model harmed pharmacies in two principal ways: by using PBMs' superior bargaining position to drive down reimbursements to pharmacies and by steering business—and offering preferable terms—to pharmacies affiliated with the PBM.

First, PBMs' reimbursement rates and practices harm independent pharmacies. PBMs profit from the "spread" between the amount they charge health plans for a drug and the amount they reimburse pharmacies.[10] PBMs reimburse pharmacies for multi-source drugs based on PBM-created maximum allowable cost (MAC) schedules, which PBMs often keep confidential, even from health plans.[11] The less the PBM reimburses the pharmacy, the higher the "spread" and the higher the profit for the PBM.

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[9] Jenny S. Guadamuz et al., *Fewer Pharmacies in Black and Hispanic/Latino Neighborhoods Compared with White or Diverse Neighborhoods, 2007-15,* 40 Health Affairs 802, 805 (2021).

[10] Elizabeth Seeley & Aaron Kesselheim, Commonwealth Fund, *Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead* (2019), https://perma.cc/4Q36-B5YE.

[11] *Id.*

Independent pharmacies identify low reimbursements and outdated MAC lists as a major financial concern.[12] Minnesota has seen more pharmacies close in the last decade than any state.[13] Local pharmacies must work with PBMs but have relatively little bargaining power.[14] Of the fifteen largest U.S. companies, three own or operate PBMs.[15] Consolidation in the PBM industry is also a longstanding concern.[16] All major health insurers now operate PBMs.[17] And all but the largest retail pharmacies receive only "take it or leave it" offers from PBMs.[18] This bargaining disparity invariably results in independent pharmacies accepting financially detrimental terms.

Second, PBMs steer business away from independent pharmacies and toward PBM-owned or -affiliated pharmacies. In addition to limiting consumers' choice and creating potential conflicts of interest, this reduces non-affiliated pharmacies' business. Again, a lack of regulation perpetuates the problems. For example, when Ohio pharmacists reported conflicts of interests because PBMs were requiring

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[12] Abiodun Salako et al., *Financial Issues Challenging Sustainability of Rural Pharmacies*, 2 Am. J. Med. Research 147, 153 (2017).
[13] Sarah D. Kerr, *Pharmacist's View: Independent Pharmacies Threatened by Middlemen*, Duluth News Trib., Apr. 26, 2021, https://perma.cc/NN4C-2DSG.
[14] *Id.*
[15] *Fortune 500 – 2020*, Fortune Mag. (2020), https://perma.cc/2CKZ-VQ93.
[16] Allison Dabbs Garrett & Robert Garis, *Leveling the Playing Field in the Pharmacy Benefit Management Industry*, 42 Val. U. L. Rev. 33, 36 (2007).
[17] Bruce Japsen, *Express Scripts Boosts Cigna as Employers Stick with Larger Insurer*, Forbes Mag. (Aug. 1, 2019), https://perma.cc/C2W3-7JC2.
[18] Garrett & Garis, *supra* note 16, at 46.

customers to obtain prescriptions from PBM-owned pharmacies, the state auditor could not fully investigate because data needed from PBMs were inaccessible.[19] PBMs also divert prescriptions to their own pharmacies by "prescription trolling:" after local pharmacists work with patients, their insurers, and their doctors to obtain prior authorization for expensive medications, PBMs can divert prescriptions to their own mail-order pharmacies.[20] Independent pharmacies are forced to accept terms that are likely to put them out of business, while the PBM prefers its affiliated pharmacies for expensive and mail-order medications. This is often done behind the veil of gag clauses that shield PBMs' business practices from sight. State regulation in this space is sorely needed because these pharmacy closures reduce access to medical care for state residents and impair public health.

2. PBMs' historically unregulated business practices harmed consumers by driving up drug costs.

PBMs contribute to the crisis of increasing medical costs nationwide. While medical spending has increased by approximately 17% since 2014, prescription-medication list prices have increased 33%.[21] One-third of consumers have skipped

[19] Ohio Auditor of State, *Ohio's Medicaid Managed Care Pharmacy Services* 1, 13 (Aug. 16, 2018), https://perma.cc/V29P-DRA3.
[20] Hearing on HF 728 Before the H. Commerce Comm., 2019 Leg., 91st Sess. at 1:52:25 (Minn. 2019) (statement of Randy Schindelar), http://ww2.house.leg.state.mn.us/audio/mp3ls91/com022719.mp3.
[21] Tori Marsh, Good RX, *Prices for Prescription Drugs Rise Faster Than Prices for Any Other Medical Good or Service* (Sept. 17, 2020), https://perma.cc/L2LR-C643.

filling a prescription and 10% have reported rationing their medications.[22] The rising cost of medications directly affects the most vulnerable Americans' ability to afford their lives and access medications prescribed to them.

One contributing factor to rising drug costs is the increasingly large rebates that PBMs demand from drug manufacturers. A recent study found that increases in rebates to PBMs correlated to a nearly equal increase in list prices.[23] Consolidation of the PBM market is leading manufacturers to offer increasingly attractive rebates: with three PBMs controlling an estimated 80-90% the market, if one PBM excludes a drug then the manufacturer loses access to a relatively large market share.[24] For example, one PBM demanded drug manufacturers give two years' notice before lowering list prices.[25] This market control results in PBMs securing favorable terms from manufacturers and pharmacies and contributes to higher prices for prescription medications.

Another way PBMs enrich themselves at the expense of consumers and independent pharmacies is through "claw backs." Gag clauses often prohibit

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[22] *Id.*

[23] Neeraj Sood et al., USC Leonard D. Schaeffer Ctr. for Health Pol'y & Econ., *The Association Between Drug Rebates and List Prices*, (Feb. 11, 2020), https://perma.cc/L7GA-SA86.

[24] *Id.*; ND Appx 36.

[25] *Drug Pricing in America: A Prescription for Change, Part III: Hearing Before the* S. *Comm*. *on Finance*, 116th Cong. (2019) (statement of John M. Prince, CEO, OptumRX).

pharmacists from telling consumers a medication's actual cost. In some cases, the cash cost is less than a consumer's copay. PBMs nonetheless require pharmacies to collect the copay from the unwitting consumer. The PBM can then later claw back from the pharmacy the difference between the copay and the actual cost, keeping the difference.[26] For example, a pharmacist collected a $35 copay for an allergy spray, only to have the PBM claw back $30.[27] The consumer would have been better off paying the $5 cash price for the medication, but a PBM gag clause precluded the pharmacist from giving the consumer this information.[28] These types of practices also affect local pharmacies when the reimbursement to the pharmacy is below the acquisition cost. And claw backs inject uncertainty because PBMs can claw back money long after the pharmacy dispenses the prescription.[29]

While the sources of rising drug costs are complex, they should not be beyond the states' traditional police power of protecting the public. States have done the work to identify and regulate problematic facets of the PBM industry that have developed over years, and they play a critically important role in this sphere.

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[26] Julie Appleby, *Filling a Prescription? You Might Be Better Off Paying Cash*, CNN, June 23, 2016, https://perma.cc/M242-ADQL.
[27] *Id.*
[28] *Id.*
[29] Schindelar testimony, *supra* note 20, at 1:53:54.

B. State PBM Regulation Protects the Public from Anti-Competitive and Abusive Practices.

In response to these concerning trends, nearly all states have enacted PBM regulations.[30] Since 2017 forty-eight states have enacted 166 state laws regulating PBMs.[31] In January 2021, eighty-one PBM bills were pending in twenty-nine states.[32] Four categories of legislation are prevalent in state PBM regulations: (1) MAC lists; (2) reimbursements; (3) transparency; and (4) fiduciary duties.[33] State regulation in these and other areas limits the harms discussed above.

1. MAC-list regulations

MAC-list or reimbursement-list regulations ensure fairness and transparency in how drugs are listed. MAC lists are particularly important to PBMs because they essentially control pharmacies' reimbursement rates. All but a few states regulate MAC lists in some form.[34] One common requirement is that PBMs update MAC

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[30] Nat'l Conference of State Legislatures, *State Policy Options and Pharmacy Benefit Managers* (Mar. 17, 2021), https://perma.cc/JVG7-XW2V.
[31] Trish Riley, Nat'l Acad. State Health Pol'y, *Celebrating Five Years of State Action to Lower Drug Prices* (May 18, 2021), https://perma.cc/D9AS-KTR3.
[32] Nat'l Conference of State Legislatures, *Pharmacy Benefit Managers (PBM) and Options for State Legislatures Webinar* (Jan. 28, 2021), https://perma.cc/U9VV-V5TX.
[33] Other types of state regulations are not discussed here because they are neither relevant nor prevalent. For example, while not relevant to the laws before the court, some states require registration or licensure. *E.g.*, Minn. Stat. § 62W.03.
[34] Nat'l Conference of State Legislatures, *supra* note 30.

lists in a timely manner.[35] *See Rutledge*, 141 S. Ct. at 479 (upholding state law requiring PBMs to update MAC lists and allowing pharmacies to appeal MAC reimbursements).

To increase transparency, many states also require PBMs to disclose their MAC lists to pharmacies.[36] Minnesota is typical in this regard, requiring PBMs to "make the [MAC list] available to a contracted pharmacy in a format that is readily accessible and usable to the network pharmacy." Minn. Stat. § 62W.08(a)(5) (2020). More states also allow pharmacies to appeal MAC prices.[37]

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[35] *See* Alaska Stat. § 21.27.945(a)(4); Ark. Code Ann. § 17-92-507(c)(2); Del. Code Ann. tit. 18, § 3323A(b)(3); Fla. Stat. § 641.314(2)(a); Ga. Code Ann. § 33-64-9(a)(1); 215 Ill. Comp. Stat. 5/513b1(b)(1); Ind. Code § 27-1-24.8-4; Kan. Stat. Ann. § 40-3830(d); Ky. Rev. Stat. Ann. § 304.17A-162(6); La. Stat. Ann. § 22:1864(B)(2); Me. Stat. tit. 24-A, § 4350(4)(C); Md. Code Ann., Ins. § 15-1628.1 (c)(l); Minn. Stat. § 62W.08(a)(2); Miss. Code Ann. § 73-21-155(2); Mo. Rev. Stat. § 376.388(3); Mont. Code Ann. § 33-22-172(2)(a); N.J. Stat. Ann. § 17B:27F-2(a)(2); N.M. Stat. Ann. § 59A-61-4(D)(2); N.C. Gen. Stat. § 58-56A-5(b); N.D. Cent. Code § 19-02.1-14.2(2)(b); Ohio Rev. Code Ann. § 3959.111(A)(1)(a); Okla. Stat. tit. 59, § 360(A)(1); Or. Rev. Stat. § 735.534(2)(f); 40 Pa. Cons. Stat. § 4532(a)(2); 27 R.I. Gen. Laws § 27-41-38.2(b)(1); S.C. Code Ann. § 38-71-2240(B)(2); Tex. Ins. Code Ann. § 1369.355(b); Vt. Stat. Ann. tit. 18, § 9473(c)(2); Wash. Rev. Code § 19.340.100(2)(1); Wis. Stat. § 632.865(2)(1); Wyo. Stat. Ann. § 26-52-104(d)(iv).

[36] Kan. Stat. Ann. § 40-3830(c); Me. Stat. tit. 24-A, § 4350(4)(B); Miss. Code Ann. § 73-21-156(3); Mont. Code Ann. § 33-22-172(2)(c); N.M. Stat. Ann. § 59A-61-4(D)(11); N.D. Cent. Code § 19-02.1-14.2(2)(c); N.J. Stat. Ann. § 17B:27F-2; Ohio Rev. Code Ann. § 3959.111(A)(1)(a); Okla. Stat. tit. 59, § 360(A)(1); S.C. Code Ann. § 38-71-2240(B)(3); Tenn. Code Ann. § 56-7-3107(b)(2); Tex. Ins. Code Ann. § 1369.356; Utah Code Ann. § 31A-46-303(5)(d); Vt. Stat. Ann. tit. 18, § 9473(c)(1).

[37] *See* Alaska Stat. § 21.27.950(a); Ariz. Rev. Stat. Ann. § 20-3331(A)(3); Cal. Bus. & Prof. Code § 4440(f); Colo. Rev. Stat. § 25-37-103.5(3); Del. Code Ann. tit. 18,

(Footnote Continued on Next Page.)

Some states regulate which drugs PBMs can place on MAC lists. For example, Missouri prohibits PBMs from including drugs unless therapeutically equivalent generics are available from multiple sources or wholesalers. Mo. Rev. Stat. § 376.388.[38] These regulations ensure that drugs on MAC lists are available and competitive.

2. Reimbursement regulations

Closely related to MAC-list regulations are reimbursement regulations. States commonly prohibit below-cost reimbursements to pharmacies or allow pharmacies

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§ 3324A; Ga. Code Ann. § 33-64-9(d); Haw. Rev. Stat. § 328-106(f); 215 Ill. Comp. Stat. 5/513b1(b)(4); Iowa Code § 510B.8(3); Kan. Stat. Ann. § 40-3830(1); Ky. Rev. Stat. Ann. § 304.17A-162(1)(b); La. Stat. Ann. § 22:1865(A); Me. Stat. tit. 24-A, § 4350(5); Md. Code Ann., Ins. § 15-1628.1(f); Minn. Stat. § 62W.08(c); Miss. Code Ann. § 73-21-156(4)(a); Mo. Rev. Stat. § 376.388(5); Mont. Code Ann. § 33-22-l73(1)(a); N.H. Rev. Stat. Ann. § 420-J:8(a)(2); N.J. Stat. Ann. § l7B:27F-4; N.M. Stat. Ann. § 59A-61-4(5); N.Y. Pub. Health Law § 280-a(2); N.D. Cent. Code § 19-02.l-14.2(2)(e); Ohio Rev. Code Ann. § 3959.111(A)(1)(b)(3); Okla. Stat. tit. 59, § 360(A)(4); Or. Rev. Stat. § 735.534(4); 40 Pa. Cons. Stat. § 4533(a); 27 R.I. Gen. Laws § 27-41-38.2(d); S.C. Code Ann. § 38-71-2240(B)(5), (C), (D); Tenn. Code Ann. § 56-7-3108(a); Tex. Ins. Code Ann. § 1369.357(a); Utah Code Ann. § 31A-46-303(5)(c); Vt. Stat. Ann. tit. 18, § 9473(c)(3); Wash. Rev. Code § 19.340.100(3); Wis. Stat. § 632.865(2)(b); Wyo. Stat. Ann. § 26-52-104(e).

[38] *See also* Cal. Bus. & Prof. Code § 4440(d); Colo. Rev. Stat.§ 25-37-103.5(2); Del. Code Ann. tit. 18, § 3323A(a); Ga. Code Ann. § 33-64-9(c); Haw. Rev. Stat. § 328-106(d); 215 Ill. Comp. Stat. 5/513b1(c); La. Stat. Ann. § 22:1864(A); Md. Code Ann., Ins. § 15-1628.l(e); Minn. Stat. § 62W.08(b); Miss. Code Ann. § 73-21-156(2); N.J. Stat. Ann. § 17B:27F-3(a); N.M. Stat. Ann. § 59A-61-4(C); N.C. Gen. Stat. § 58-56A-5(a); N.D. Cent. Code § 19-02.1-14.2(3); Okla. Stat. tit. 59, § 360(B); Or. Rev. Stat. § 735.534(2); 40 Pa. Cons. Stat. § 4531(a)(2); 27 R.I. Gen. Laws § 27-41-38.2(c); S.C. Code Ann. § 38-71-2240(A)(1); Tenn. Code Ann. § 56-7-3106(a); Wash. Rev. Code § 19.340.100(2)(a); Wyo. Stat. Ann. § 26-52-104(a).

to appeal reimbursement rates.[39] Some states allow pharmacies to refuse to dispense medication that will be reimbursed below cost.[40] Consistent with its past decisions, in *Rutledge* the Court upheld both types of provisions in Arkansas law. 141 S. Ct. at 479. When a pharmacy declines to dispense a drug, "the responsibility lies first with the PBM for offering the pharmacy a below-acquisition reimbursement." *Id.* at 482. Another common provision is North Dakota's prohibition on clawing back reimbursements after claims are adjudicated. N.D. Cent. Code § 19-02.1-16.1(4). Many states regulate claw backs, while some states outright ban them.[41]

3. Transparency regulations

The need for transparency cannot seriously be questioned and states have led absent federal action. Efforts to remedy the lack of transparency in the PBM industry can take many forms but two are most common: (1) laws requiring disclosures from

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[39] *See* Alaska Stat. § 21.27.950(c); Colo. Rev. Stat. § 25-37-103.5(3)(d); Ga. Code Ann. § 33-64-9(e); Haw. Rev. Stat. § 328-106(f)(1)(A); Ky. Rev. Stat. Ann. § 304.l 7A-162(1)(b)(4); La. Stat. Ann. § 22:1865(A); Me. Stat. tit. 24-A, § 4350(6)(B); Md. Code Ann., Ins. § 15-1628.1(f)(4)(ii); Minn. Stat. § 62W.08(c)(3); Miss. Code Ann. § 73-21-156(4)(a); Mo. Rev. Stat. § 376.388(6); N.H. Rev. Stat. Ann. § 402-N:3(l)(b)(3)(B); N.M. Stat. Ann. § 59A-61-4(D)(8); N.D. Cent. Code Ann. § 19-02.l-14.2(2)(d), (f); Ohio Rev. Code Ann. § 3959.111(A)(3)(d); Okla. Stat. tit. 59 § 360(A)(5); Or. Rev. Stat. § 735.534(4); 2021 Tenn. Pub. Acts ch. 568, § 3; Utah Code Ann. § 31A-46-303(4); Wis. Stat. § 632.865(2)(b)(4); Wyo. Stat. Ann. § 26-52-104(f).

[40] *See* Ark. Code Ann. § l 7-92-507(e); La. Stat. Ann. § 22:1860.3(B)(l); Miss. Code Ann. § 73-21-155(5)(a); Mont. Code Ann. § 33-22-174(1).

[41] *See State Policy Options*, *supra* note 30 (reflecting twenty-two states regulate claw backs).

PBMs;[42] and (2) laws prohibiting gag clauses on pharmacies.[43] As U.S. Senator Chuck Grassley stated, "More transparency is needed. The current system is so opaque that it is easy to see why there are many questions about PBMs' motives and practices."[44] Such opacity inhibits plans' and consumers' ability to determine whose interests PBMs are furthering.

Here, North Dakota requires PBMs to make disclosures (N.D. Cent. Code §§19-02.1-16.2(2) and 16.1(10)), while allowing pharmacists to disclose information (N.D. Cent. Code § 16.1(5) and (7)). Minnesota similarly requires PBM disclosures to plan sponsors and the state.[45] Robust transparency regulations allow states to properly serve their regulatory function and give consumers data needed to make informed decisions.

4. Fiduciary duties

Absent legislation, courts have generally held that PBMs do not owe a fiduciary duty to the plan sponsors or participants except in limited circumstances. *E.g.*, *In re Express Scripts, Inc. PBM Litig.*, No. 4:05-MD-01672, 2008 WL 2952787, at *3 (E.D. Mo. July 30, 2008). The lack of a fiduciary duty has prevented

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[42] *Id.* (reflecting more than two-thirds of states require disclosures or prohibit gag clauses).
[43] *Id.*
[44] *Drug Pricing in America: A Prescription for Change, Part III: Hearing before the S. Comm.*, 116th Cong. (statement of Sen. Chuck Grassley).
[45] Minn. Dep't of Commerce, *Public Pharmacy Benefit Manager (PBM) Transparency Report* (Dec. 12, 2020), https://perma.cc/QC2C-UGYZ.

plan participants from even litigating whether PBMs contract with drug manufacturers "in ways that enrich [the PBM] to the detriment of the plan." *Moeckel v. Caremark, Inc.*, 622 F. Supp. 2d 663, 667, 692 (M.D. Tenn. 2007).

Some states, like Iowa and South Dakota, expressly impose a duty of good faith and fair dealing on PBMs.[46] While North Dakota prohibits PBMs from owning mail-order specialty pharmacies and patient-assistance programs (section 16.2(3)). other states require PBMs to disclose conflicts of interest.[47] States have properly taken the lead on preventing unfair practices, self-dealing, and conflicts of interest.

II. ERISA DOES NOT PREEMPT STATE LAWS GOVERNING TRANSACTIONS BETWEEN PBMS AND PHARMACIES.

To protect consumers and address industry abuses, nearly every state regulates PBMs. To protect PBMs' profits, PCMA claims that ERISA broadly preempts these laws because they supposedly dictate plan benefits. The Court should reject this argument. As long recognized and recently reaffirmed by the Supreme Court, ERISA preempts only laws affecting the "who" and "what" of benefits. *Rutledge*, 141 S. Ct. at 480 (recognizing ERISA's primary concern of preempting laws that

[46] Iowa Code § 510B.4(1); S.D. Codified Laws § 58-29E-3; *see also* Cal. Bus. & Prof. Code § 4441(c); La. Stat. Ann. § 40:2864(A); Minn. Stat. § 62W.04(a); Nev. Rev. Stat. § 683A.178(1).

[47] Cal. Bus. & Prof. Code § 4441(d); D.C. Code § 48- 832.01(b)(1)(C); 305 Ill. Comp. Stat. 5/5-36(d); Iowa Code § 510B.4(2); Minn. Stat. § 62W.04(b); Nev. Rev. Stat. § 683A.178(2); 27 R.I. Gen. Laws § 27-29.1-7; Vt. Stat. Ann. tit. 18, § 9472(c)(2).

"determine[e] beneficiary status" or require "specific benefits"). The North Dakota laws at issue largely regulate PBM-*pharmacy* relationships, *not* PBM-*beneficiary* or plan-beneficiary relationships. *See, e.g.*, N.D. Cent. Code §§ 19-02.1-16.1(2)-(3), (5), (7)-(11), -16.2(2)-(5) (2020). Only one challenged provision addresses PBM-beneficiary interactions—and that section is a cost regulation permitted under *Rutledge* and not challenged on appeal. N.D. Cent. Code. § 19-02.1-16.1(4) (2020) (prohibiting copays that exceed medications' costs). Because North Dakota's laws do not affect the structure of benefits plans, ERISA does not preempt them.

A. ERISA Did Not Modify the Presumption that Congress Does Not Intend to Supplant State Law.

ERISA preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C. § 1144(a) (2018). Congress "unequivocally" did not intend to "modify the starting presumption that Congress does not intend to supplant state law." *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 813 (1997). To assert otherwise, PCMA cites the Court's statement in *Puerto Rico v. Franklin California Tax-Free Trust* that, when a statute contains an express preemption clause, the Court focuses on the clause's plain language to determine congressional intent. 136 S. Ct. 1938, 1946 (2016). But this statement—from a non-ERISA case—reflects only the unremarkable proposition that laws within an express preemption clause's scope are preempted. It does not

alter the presumption that if something is *not* within a preemption clause's language—as that language has been interpreted by the Court—it is not preempted.

In *Puerto Rico*, because the Bankruptcy Code "unmistakably" made Puerto Rico a state for preemption purposes, it precluded Puerto Rico from enacting its own code. 136 S. Ct. at 1946. In the ERISA context, in contrast, the Court has repeatedly reinforced the presumption against preemption. *See, e.g.*, *De Buono*, 520 U.S. at 813; *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995).

B. ERISA Preempts Only State Laws Affecting Who Receives Benefits and Which Benefits They Receive.

A state law relates to an ERISA plan if it has a "connection with" or "reference to" a plan. *Travelers*, 514 U.S. at 656. PCMA concedes that *Rutledge* forecloses its "reference to" challenges.[48] This case, therefore, turns on the "connection with" prohibition. In assessing "connections," courts focus on ERISA's goal of avoiding subjecting benefit plans to conflicting state regulation. *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 98–99 (1983); *see also Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 10 (1987). As reflected by a long line of Supreme Court precedent, laws like North Dakota's do not have a connection to a ERISA plans sufficient to invoke preemption.

[48] Appellant's Br. 22. PCMA also correctly concedes that, even if ERISA or Medicare preempts a state law, the law is not invalidated as to non-ERISA or -Part-D plans. *Id.* at 19 n.1.

A "connection" for ERISA purposes must be more than a potential, incidental impact. For example, the Court rejected an ERISA-preemption challenge to a state law that required hospitals to collect surcharges from patients who did not have insurance from a particular provider. *Travelers*, 514 U.S. at 649. The Court recognized that providers would pass these costs on to the entities paying for the insurance, i.e., ERISA plans. *Id.* at 659. Nevertheless, the statute did not "bind plan administrators to any particular choice and thus function as a regulation of the ERISA plan itself." *Id.* Such "indirect influences" do not preclude a uniform interstate benefit package. *Id.* at 660.

When the Court has held ERISA preempts a law, it has emphasized the central concern ERISA's preemption clause aims to address: could plan administrators determine a beneficiary's benefits merely by looking at plan documents, or would the administrator need to be familiar with fifty states' laws? *Egelhoff v. Egelhoff*, 532 U.S. 141, 148-49 (2001). Using this standard, the Court struck down a statute that automatically revoked a spouse's beneficiary designation upon divorce. *Id.* at 143. Other types of state regulations that could implicate ERISA preemption are laws that conflict with ERISA's reporting, disclosure, and bookkeeping requirements regarding benefits because they are central to uniform systems of plan administration. *Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 323 (2016).

In *Rutledge*, the Court reaffirmed that ERISA does not preempt regulations that merely "alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage." 141 S. Ct. at 480. In rejecting PCMA's arguments, the Court specifically noted that mandating PBM pricing methodologies does not "require plans to provide any particular *benefit* to any particular *beneficiary* in any particular way." *Id.* at 482 (emphases added). In short, the Court reiterated that ERISA preemption is concerned with the *what* and *who* of benefits. But if a statute affects only transactions ancillary to those questions, then it is not preempted.

C. *Rutledge* Is Not Limited to Cost Regulations.

Despite nearly forty years of the Court holding that ERISA does not preempt state laws unless they affect the who or what of benefits, PCMA attempts to limit *Rutledge*'s holding to cost regulations. PCMA is wrong. *Rutledge* reaffirmed that regulations that do not "for[ce] plans to adopt any particular scheme of substantive coverage" are not preempted. 141 S. Ct. at 480.

In arguing otherwise, PCMA relies on the Court's statement that ERISA preempts laws requiring providers to structure benefit plans in particular ways. *Id.* But after noting this uncontroversial point, the Court discussed how to determine when a law has such requirements. *See id.* at 480-81. Nothing in that discussion suggests that only cost regulations are permissible. Although *Rutledge* considered a cost regulation, the Court held—consistent with its precedent—that a law is not

preempted if it does not force plans to adopt particular coverage. *Id.* Indeed, *Rutledge* rejected PCMA's argument that requiring reimbursement at or above drug-acquisition costs effectively denied beneficiaries benefits. The Court noted that the requirement did not alter the *plan's* benefits; rather, any denial resulted from relations between the PBM and the pharmacy. *Id.* at 482. This confirms that, far from *Rutledge* excluding only cost regulations from preemption, statutes that only alter PBM-pharmacy relations—but have no direct effects on plans or beneficiaries—are likewise not preempted.

D. North Dakota's Laws Do Not Affect the Who or What of Beneficiaries' Benefits.

Despite the limits on ERISA's preemptive scope that were reaffirmed in *Rutledge*, PCMA argues that North Dakota's (and essentially all states') PBM regulations are preempted. PCMA is wrong; because none of North Dakota's statutes alter substantive coverage, they are not preempted.

PCMA first challenges sections 16.1(3), (8), (9), (11) and 16.2(4) as altering "network design." None of these sections dictate who get benefits or what benefits they receive. Sections 16.1(3), (11), and 16.2(4) curtail PBMs' ability to impose accreditation or performance-metric requirements on pharmacies beyond those imposed by unbiased third parties. This does not alter the who or what of benefits. Likewise, sections 16.1(8) and (9) stop PBMs from prohibiting pharmacies from mailing prescriptions or charging a shipping fee for doing so. These provisions do

not require plans to cover shipping as a benefit; instead, they merely provide that, if a particular drug from a particular pharmacy is already covered, PBMs cannot stop pharmacies from mailing that drug (and charging a shipping fee) if the patient so desires.

PCMA next challenges sections 16.1(4), (8), (9), and 16.2(5) as affecting "covered drugs and cost sharing." But none of these sections alter drug coverage or costs (except as cost regulations permitted by *Rutledge*). As already discussed, sections 16.1(8) and (9) address only pharmacies' ability to ship drugs, but do not alter benefits. Likewise, section 16.2(5) permits pharmacies to dispense all drugs permitted by their license. This does not mandate coverage, it merely provides PBMs cannot prohibit a pharmacy from dispensing a drug that is *already* covered by a plan. Finally, Section 16.1(4) prohibits PBMs from charging copays that exceed a medication's cost. As in *Rutledge*, this section affects PBM-patient transactions. "ERISA does not pre-empt state rate regulations that merely increase costs . . . ." *Id.* at 480. This is all section 16.1(4) does—it increases PBMs' costs (or rather, decreases entirely unearned profits) by preventing PBMs from charging, for example, $35 for a $5 drug and pocketing the difference.

Next, PCMA, challenges the disclosure requirements of sections 16.1(4), (5), (7), (10), and 16.2(2). Sections 16.1(5) and (7) impose no disclosure requirements on PBMs; they merely prevent PBMs from imposing gag clauses on others. And

section 16.2(2) requires PBMs to disclose information to "plan sponsor contracted payor[s]." But such disclosures are, in effect, disclosures *to ERISA plans*. A disclosure requirement *to* plans cannot be a requirement imposed *on* plans, and therefore cannot implicate ERISA preemption.

This leaves PCMA's disclosure challenges to sections 16.1(4) and 16.1(10). PCMA contests the prohibition on "redacting the adjudicated cost" in section 16.1(4). But as used therein, "redact" means "*reduce* the adjudicated cost;" it does not require any disclosures. (N.D. Appx 30-31.) Section 16.1(10) requires PBMs to provide pharmacies with "the processor control number, bank identification number, and group number for each pharmacy network" the PBM establishes or administers. PCMA relies on *Gobeille* to assert preemption. But *Gobeille* did not hold that ERISA preempts *all* state disclosure requirements. Instead, the Court considered whether disclosure requirements were "central to, and an essential part of, the uniform system of plan administration contemplated by ERISA." *Gobeille*, 577 U.S. at 323. Not all disclosure requirements implicate those concerns.

This leads to a major problem with PCMA's sweeping preemption approach. In contrast to the information sought in *Gobeille* (member eligibility, medical claims, and pharmacy claims), the information required by section 16.1(10) is not "central to uniform plan administration." Instead, North Dakota only requires reporting financial information about PBM pharmacy networks, which is PBM-

business information, *not* plan information. This information is, at best, ancillary to plan administration and therefore the disclosure requirement is not preempted.

Finally, PCMA challenges sections 16.2(2) and (3), which address self-dealing. As with each other challenged section, however, these sections do not alter the who or what of plan benefits. As previously discussed, section 16.2(2) is a disclosure requirement from PBMs to plans. And section 16.2(3) does not alter coverage. It merely ensures that PBMs cannot self-deal when doing so would violate fiduciary duties.

III. MEDICARE PREEMPTS ONLY STATE LAWS THAT CONFLICT WITH A MEDICARE STANDARD.

PCMA also asserts that Medicare Part D preempts North Dakota's PBM laws. Unlike ERISA preemption, Medicare preemption is a much more particularized inquiry depending on the state law and the relevant Medicare standards. Nevertheless, PCMA makes two overarching arguments on Medicare preemption that are so sweeping—and incorrect—that they must be addressed by the amici states.

Medicare's preemption clause states, "[t]he standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to [prescription-drug] plans." 42 U.S.C. § 1395w-26(b)(3) (2018) (Medicare Part C preemption provision); *see also id.* § 1395w-112(g) (2018) (adopting Part C's preemption provision for Part D

prescription-drug plans). If no conflicting Medicare standard on a subject exists, then nothing preempts a state law. *Rutledge*, 891 F.3d at 1113; *see also Uhm v. Humana, Inc.*, 620 F.3d 1134, 1148-49 (9th Cir. 2010).

PCMA's preemption analysis conflicts with the plain language of the law and aims to eradicate states' traditional police powers. First, PCMA suggests virtually all state regulation of PBM-pharmacy contracts is preempted because Medicare requires that plans permit participation of "any pharmacy that meets the terms and conditions under the plan" and that plan contracts have "reasonable and relevant terms and conditions of participation." 42 U.S.C. § 1395w-104(b)(1)(A) (2018); 42 C.F.R. § 423.505(b)(18) (2020). But the Centers for Medicare & Medicaid Services (CMS), the federal agency responsible for administering Medicare, has considered and rejected this position. During a rulemaking process, for example, CMS responded to concerns about a North Dakota PBM law by stating CMS "continue[s] to believe state pharmacy practice acts represent a reasonably consistent minimum practice." *Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-For Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program*, 83 Fed. Reg. 16,440, 16,598 (Apr. 16, 2018).

If CMS's standards preempted such laws, CMS would have said so; but it did not. PCMA argues CMS addressed only state standards as regulatory floors, not

PBMs' ability to impose additional requirements. But this misses a necessary premise underlying CMS's position—if some state regulation is permissible, then the any-willing-pharmacy and reasonable-and-relevant requirements do not generally preempt state laws regulation of PBM-pharmacy relations. Otherwise, even regulatory-floor laws would be preempted.

Such a broad view of Medicare preemption also belies the historic balance between Medicare and adjacent state regulations. *Cf. Med. Soc'y of State of N.Y. v. Cuomo*, 976 F.2d 812, 816 (2d Cir. 1992) (recognizing that regulating public health and medical-care costs "are virtual paradigms of matters traditionally within the police powers of the state"). Indeed, states sometimes lead the way, with federal laws eventually catching up. For example, Congress amended Medicare in 1997 to require marketing-material review. Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251, 285-86 (1997). Before 1997, some states had laws to prevent fraudulent solicitations, deceptive advertising, and misrepresentations in the enrollment process. *See, e.g.*, *Solorzano v. Superior Court*, 13 Cal. Rptr. 2d 161, 167-70 (Cal. Ct. App. 1992). While the federal law then preempted conflicting state laws in this area, states were the leaders. *E.g.*, *Uhm*, 620 F.3d at 1157. Here, the lack of CMS standards necessarily means that PCMA's preemption claims fail. Although CMS could theoretically promulgate standards that may, in some

circumstances, preempt states' PBM regulations, unless CMS does so, states are free to continue protecting their consumers by prohibiting unscrupulous actions.

Second, PCMA asserts preemption because Medicare prohibits states from interfering in negotiations between pharmacies and PBMs. Although this Court endorsed this view in *Rutledge*, 891 F.3d at 1113, respectfully, the argument has no basis in Medicare's text, which prohibits only "the Secretary [of Health and Human Services]" from interfering in negotiations or requiring particular formularies or price structures. 42 U.S.C. § 1395w-111(i) (2018). And even if it applied to the states, it applies only to "negotiations or disputes involving payment related contractual terms." 83 Fed. Reg. at 16,590. It does not apply to regulations that "promote competition," "increas[e] the transparency of prices," or "minimiz[e] barriers to entry." *Id.* North Dakota's PBM regulations, and many state regulations, squarely fall into these categories, and as a result, they are not preempted.

CONCLUSION

PBMs market abuses have caused numerous harms, which states are attempting to curtail by placing reasonable restrictions on PBM-pharmacy contracts that increase transparency, discourage rent-seeking behavior, and reduce self-dealing. State laws to this effect do not alter substantive coverage of ERISA plans, and therefore they are not preempted. PCMA's arguments in favor of broad

Medicare preemption of state laws are similarly misplaced. Accordingly, the Court should affirm the district court.

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CERTIFICATE OF COMPLIANCE
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The undersigned, on behalf of the party filing and serving this brief, certifies that the brief has been scanned for viruses and that the brief is virus-free.

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