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September 18, 2025

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

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

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

Dear Co-Chairs Kwei and Alexandrou:

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

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

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

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

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

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

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

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

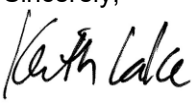
> the effect of dictating the design or provision of substantive benefits of an ERISA-covered plan, it implicates a central matter of plan administration and is preempted by ERISA.[3]

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

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

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

Sincerely,



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

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

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

GROOM LAW GROUP

March 21, 2025

ERISA Preemption of Maryland House Bill 321

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

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

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

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

MD House Bill 321

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

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

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

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