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**Below please find comments from the National Community Pharmacists Association re: the draft guidance document for ERISA Preemption and State PBM Laws.**

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**GUIDANCE DOCUMENT – ERISA PREEMPTION AND STATE PBM LAWS**

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**I. Introduction**

Pharmacy benefit managers (PBMs)<sup>1</sup> play a significant role in the provision of health care in the U.S. PBMs negotiate and contract with pharmacies on reimbursement and pharmacy network terms. PBMs design, negotiate, implement, and manage formulary designs for prescription drugs, including negotiating rebates and drug coverage terms with pharmaceutical manufacturers. Insurance companies and employer groups contract with PBMs for the design and implementation of preferred and non-preferred pharmacy networks, metric-based payment arrangements, and formulary design elements (drug coverage, out-of-pocket responsibilities for patients and utilization management protocols). PBMs engage in the negotiation and financial transactions between pharmaceutical

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manufacturers, health plans, and pharmacies.<sup>2</sup>

In connection with their regulatory authority over health care, including the practice of pharmacy and the business of insurance, states have enacted laws regulating PBMs. However, these laws interact in complex ways with a variety of federal laws (Medicare, Medicaid, Employee Retirement Income Security Act of 1974) that might also apply, depending on the type of benefit plan that the PBM is managing. This has created the

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<sup>1</sup> The alternative form “pharmacy benefits managers” is used in many publications and statutes.

<sup>2</sup> NAIC Health Insurance and Managed Care (B) Committee, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation*, 2023, [https://content.naic.org/sites/default/files/committee\\_related\\_documents/PBM%2520White%2520Paper%2520Draft%2520Adopted%2520B%2520Committee%252011-2-23\\_0.pdf](https://content.naic.org/sites/default/files/committee_related_documents/PBM%2520White%2520Paper%2520Draft%2520Adopted%2520B%2520Committee%252011-2-23_0.pdf)

opportunity for a variety of different federal preemption challenges, which complicate the ability of states to address important health policy issues affecting their citizens.

This guidance paper deals specifically with questions about preemption of state PBM laws under the Employee Retirement Income Security Act of 1974 (ERISA), which regulates employee benefit plans. It does not address potential preemption by other federal laws such as those governing the Medicare Part D prescription drug program.

The leading Supreme Court case on this subject is *Rutledge v. PCMA*, decided in 2020, which held that an Arkansas PBM law was not preempted by ERISA.<sup>3</sup> Per *Rutledge*, ERISA does not preempt state regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage. However, *Rutledge* did not conclusively resolve all questions about the permissible scope of state PBM regulation, so there continue to be disputes over how the principles analyzed in *Rutledge* apply to PBM laws that include different types of provisions. There have been two recent ERISA preemption decisions by federal Courts of Appeals that reached opposing conclusions. The Eighth Circuit upheld North Dakota's law<sup>4</sup> while the Tenth Circuit struck down parts of Oklahoma's law<sup>5</sup>.

This paper provides some guidance related to ERISA preemption by undertaking an analysis of the different types of state PBM laws and considering how appellate courts have applied the reasoning in *Rutledge* to those laws.<sup>6</sup>

## II. ERISA Preemption

The Employee Retirement Income Security Act of 1974 is a complex and comprehensive statute that federalizes the law of employee benefits. ERISA establishes a comprehensive regulatory framework for employee pension benefit plans and also preempts most state laws relating to private-sector "employee welfare benefit plans,"<sup>7</sup> a broad category that includes nearly all employer-sponsored and union-sponsored health plans. However, ERISA does not preempt state insurance law. ERISA's "saving clause" for any state law that

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<sup>3</sup> *Rutledge v. Pharmaceutical Care Management Ass'n*, 592 U.S. 80 (2020). The Court also held that the law was not preempted as applied to Medicare Part D plans.

<sup>4</sup> *Pharmaceutical Care Management Ass'n v. Wehbi*, 18 F.4<sup>th</sup> 956 (8<sup>th</sup> Cir. 2021).

<sup>5</sup> *Pharmaceutical Care Management Ass'n v. Mulready*, 78 F. 4<sup>th</sup> 1183 (10<sup>th</sup> Cir. 2023)

<sup>6</sup> The National Conference of State Legislatures publishes policy reports on various topics. The report titled "State Policy Options and Pharmacy Benefit Managers" places state PBM laws into categories and includes a state-by-state list of laws by category. See, <https://www.ncsl.org/health/state-policy-options-and-pharmacy-benefit-managers>.

<sup>7</sup> Government employee plans are exempt from ERISA. ERISA § 4(b)(1), *codified at* 29 U.S.C. § 1003(b)(1).

“regulates insurance”<sup>8</sup> gives states broad authority to regulate PBMs administering state regulated insurance policies, including fully-insured employee health plans.<sup>9</sup> Although ERISA’s saving clause does not entirely foreclose the possibility of preemption challenges to insurance-specific PBM laws, the focus of recent preemption litigation has been state laws that apply broadly to the PBM industry. Many states have, chosen to address PBM issues through pharmacy regulation rather than insurance regulation because the majority of consumers do not get their medications through state-regulated insurance policies. In particular, almost 2/3 of people with coverage through their employer are covered by self-insured health plans not regulated by state insurance law.<sup>10</sup>

At a high level, when a state contemplates applying a particular regulatory measure to PBMs contracted with self-insured employers, the question policymakers must consider is whether that measure is a permissible exercise of the state’s general powers to regulate the pharmaceutical industry, or whether it encroaches on the exclusive federal power to regulate the employer’s health benefit plan. Under ERISA, if a state PBM law “may now or hereafter relate to any employee benefit plan” and is not a law “which regulates insurance,” that law is preempted.<sup>11</sup>

As the case law discussed below illustrates, it is not a simple task to decide whether a particular provision of state law “relates”, within the meaning of ERISA, to a state-regulated PBM or to its self-insured, federally-protected client.

### III. CASES ADDRESSING ERISA PREEMPTION ANALYSIS OF STATE PBM LAWS

#### ***Rutledge***

To consider the potential impact of ERISA on state PBM laws, it is logical to begin with an analysis of the Supreme Court’s *Rutledge* opinion. In *Rutledge*, the Court upheld an Arkansas law, Act 900, which requires PBMs to reimburse pharmacies at a price equal to or higher than what the pharmacy paid to buy the drug. To accomplish this, Act 900 mandates that PBMs: 1) keep their Minimum Acquisition Cost (MAC) pricing lists current with

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<sup>8</sup> ERISA § 514(b)(2)(A), *codified at* 29 U.S.C. § 1144(b)(2)(A).

<sup>9</sup> The terms “fully-insured employee health plan” and “employer group health insurance policy” are often used interchangeably, and as a practical matter they are functionally identical. However, strictly speaking, the policy is issued by an insurance company, while the fully-insured plan is established by the employer when it buys the policy. This is what the Supreme Court was referring to in *Metropolitan Life Insurance Co. v. Massachusetts*, 471 U.S. 724, 747 (1985), when it explained that the structure of ERISA “results in a distinction between insured and uninsured plans, leaving the former open to indirect regulation while the latter are not.” In other words, by directly regulating the insurer and the insurance policy, the state indirectly regulates the employer that buys the insurance.

<sup>10</sup><https://www.kff.org/health-costs/2024-employer-health-benefits-survey/#e3efa8b3-48d2-458b-a2f7-c4d5add1983b--h-section-10-plan-funding>.

<sup>11</sup> ERISA §§ 514(a) & (b)(2)(A), *codified at* 29 U.S.C. §§ 1144(a) & (b)(2)(A).

wholesale drug price increases;<sup>12</sup> 2) establish an appeal process for pharmacies to challenge PBM MAC pricing lists;<sup>13</sup> 3) increase pharmacy reimbursement rates to cover pharmacy acquisition costs;<sup>14</sup> and 4) allow the pharmacy to adjust any claims<sup>15</sup> affected by the pharmacy's inability to get the drug at a lower price from its usual wholesaler. Act 900 also includes a fifth provision allowing the pharmacy to refuse to fill a prescription if the PBM reimbursement to the pharmacy is less than the pharmacy paid for the drug.

The Court reviewed each of these provisions in the Arkansas law and concluded that they did not "relate to" ERISA plans and were not preempted. The Court explained that in order to impermissibly "relate to" an ERISA plan, the state law must have a "connection with" or make a "reference to" ERISA plans.<sup>16</sup>

To analyze whether Act 900 had an impermissible "connection with" ERISA plans, after providing some general background on the objectives of ERISA,<sup>17</sup> the Court contrasted three prior cases in which it held laws to be preempted on that ground, stating 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" as in *Shaw v. Delta Air Lines*,<sup>18</sup> or "by binding plan administrators to specific rules for determining beneficiary status," as in *Egelhoff*.<sup>19</sup> In addition, there can be an impermissible connection if "acute, albeit indirect, economic effects of the state law force an ERISA plan to adopt a certain scheme of substantive coverage," citing *Gobeille v. Liberty Mutual*,<sup>20</sup> invalidating a Vermont law establishing an all-payer health claim database and including third-party administrators and self-insurers among the entities subject to mandatory reporting. In summary:

As a shorthand for these considerations, this Court asks  
whether a state law "governs a central matter of plan

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<sup>12</sup> Ark. Code Ann. §17-92-507(c)(2) (Supp. 2019).

<sup>13</sup> Ark. Code Ann. §17-92-507(c)(4)(A)(i)(b) (Supp. 2019)

<sup>14</sup> Ark. Code Ann. §17-92-507(c)(4)(C)(i)(b)

<sup>15</sup> Ark. Code Ann. §17-92-507(c)(4)(C)(iii).

<sup>16</sup> *Rutledge*, 592 U.S. 80 at 86.

<sup>17</sup> *Id.* The Court progressed through its prior jurisprudence by: 1) considering "ERISA's objectives as a guide as to what state laws would survive" (*California Div of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 US 316, 325 (1997)); 2) identifying the objective of ERISA as ensuring the security of employer sponsored benefits "by mandating certain oversight systems and other standard procedures." (*Gobeille*, 577 U.S. 312, 320-321 (2016)); and 3) explaining that Congress, in pursuit of the security of employer sponsored plans, "sought to ensure that plan and plan sponsors would be subject to a uniform body of benefits laws," thereby minimizing the administrative and financial burden of complying with different benefit requirements in multiple jurisdictions. (*Ingersoll-Rand Co. v. McClendon*, 498 US 133, 142 (1990)).

<sup>18</sup> *Id.* at 86-87.

<sup>19</sup> *Id.* at 87.

<sup>20</sup> *Id.*

administration or interferes with nationally uniform plan administration.” If it does, it is preempted.<sup>21</sup>

However, the Court observed:

Crucially, not every state law that affects an ERISA plan or causes some disuniformity in plan administration has an impermissible connection with an ERISA plan. That is especially so if a law merely affects costs.<sup>22</sup>

The Court discussed each of PCMA’s contentions that provisions in Act 900 interfered with central matters of plan administration and impermissibly affected plan design. The Court, in addressing each provision, concluded that the provisions at issue, “do not require plan administrators to structure their benefit plans in any particular manner, nor do they lead to anything more than potential operational inefficiencies....”<sup>23</sup> stating that “ERISA does not preempt a state law that merely increases costs . . . even if plans decide to limit benefits or charge plan members higher rates as a result.”<sup>24</sup> The opinion concludes: “In sum, Act 900 amounts to cost regulation that does not bear an impermissible connection with or reference to ERISA.”

Finally, the Court determined that there was no impermissible “reference to” ERISA plans. Citing *Gobeille*, the Court stated that a law refers to ERISA if it “acts immediately and exclusively upon ERISA plans or where the existence of ERISA plans is essential to the law’s operation.”<sup>25</sup> Applying this reasoning to Act 900, the Court explained that the law does not “refer to” ERISA. It held that the Arkansas law

...does not act immediately and exclusively upon ERISA plans because it applies to PBMs whether or not they manage an ERISA plan. Indeed, the Act does not directly regulate health benefit plans at all, ERISA or otherwise. It affects plans only insofar as PBMs may pass along higher pharmacy rates to plans with which they contract.<sup>26</sup>

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<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> *Id.* at 89, noting in footnote 2 that PCMA does not suggest that Act 900’s enforcement mechanisms overlap with “fundamental components of ERISA’s regulation of plan administration.” *Gobeille*, 577 U. S. at 323.

<sup>24</sup> *Id.* at 91.

<sup>25</sup> *Id.* at 88.

<sup>26</sup> *Id.* at 88-89.

Instead, the Court likened Act 900 to the New York law at issue in *Travelers*,<sup>27</sup> a landmark 1995 case limiting the reach of ERISA’s “relate to” clause. That law had imposed surcharges on most hospital bills but not bills for patients who were covered by Medicaid or by nonprofit insurers that offered coverage to all applicants regardless of health status. The law was held not to refer to ERISA plans because the surcharge applied without regard to whether coverage was secured by an ERISA plan or not.<sup>28</sup>

### **Cases Post-Rutledge**

Since the *Rutledge* decision, lower courts have applied the holding and reasoning espoused in *Rutledge* to resolve ERISA preemption challenges to the myriad PBM laws that have been passed in the states.<sup>29</sup> The results have been complicated. Two PBM cases in particular – *Mulready* and *Wehbi* – have risen to the circuit courts and reached opposite conclusions regarding whether ERISA preempted the laws at issue. While the laws being challenged in these cases regulate PBMs, they each include different provisions that were not specifically litigated in *Rutledge*. They cover some of the same topics, (transparency and pharmacy reimbursement), but the North Dakota Law at issue in *Wehbi* includes additional provisions related to pharmacy practices. The Oklahoma law also addresses pharmacy networks. *Mulready* petitioned the Supreme Court for a Writ of Certiorari citing the circuit conflict in these two cases. The Court denied Cert on June 30, 2025, leaving the *Mulready* decision binding law in the 10<sup>th</sup> Circuit.

### **Wehbi**

The United States Court of Appeals for the Eighth Circuit analyzed North Dakota’s PBM laws on remand after the Supreme Court directed the Eighth Circuit to reconsider its decision in light of the reasoning in *Rutledge*. The Eighth Circuit had initially determined that ERISA preempted the contested provisions in 19-02.1-16.1 and 16.2, however, on remand, they reversed their decision and held that the laws were not preempted under ERISA.

Like the Supreme Court in *Rutledge*, the Eighth Circuit Court held that whether a state law “relates to” ERISA plans by analyzing whether there is an impermissible “connection with” or “reference to” ERISA plans.

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<sup>27</sup> *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, (1995).

<sup>28</sup> “...Act 900 regulates PBMs whether or not the plans they service fall within ERISA’s coverage. Act 900 is therefore analogous to the law in *Travelers*, which did not refer to ERISA plans because it imposed surcharges ‘regardless of whether the commercial coverage [was] ultimately secured by an ERISA plan, private purchase, or otherwise.’ 514 U. S., at 656 (footnote omitted).” *Rutledge*, 592 U.S. 80, 89.

<sup>29</sup> All 50 states have laws regulating PBMs. <https://www.ncsl.org/health/prescription-drug-legislation-database>

Considering whether a law has an impermissible “reference to” an ERISA plan, the Court looked to whether the law “acts immediately and exclusively upon ERISA plans” or “the existence of ERISA plans is essential to the law’s operation.”<sup>30</sup> In the case of North Dakota’s PBM laws, they did not make “reference to” ERISA plans because the law applies to PBMs regardless of who they contract with.

The Eighth Circuit reasoned that

A state law has an impermissible ‘connection with’ ERISA plans if and only if (1) it ‘governs . . . a central matter of plan administration’; (2) it ‘interferes with nationally uniform plan administration’; or (3) ‘acute, albeit indirect, economic effects’ of the law ‘force an ERISA plan to adopt a certain scheme of substantive coverage or effectively restrict its choice of insurers.’<sup>31</sup>

The Eighth Circuit, quoting *Rutledge*, softened the emphasis on uniformity in the “connection with” analysis saying, “the mere fact that a state law ‘affects an ERISA plan or causes some disuniformity in plan administration’” does not mean the law meets this standard, “especially...if the law merely affects costs.”<sup>32</sup> The Eighth Circuit further clarified its focus stating that ERISA pre-emption is “primarily concerned with pre-empting 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.”<sup>33</sup>

The Eighth Circuit did not find any “reference to” ERISA plans because the law applies to PBMs regardless of who they have a contract with. The Eighth Circuit Court following the decision in *Rutledge*, holding that the “existence of ERISA plans is essential to a law’s operation only if the law cannot apply to a non-ERISA plan.”<sup>34</sup>

The Court in *Wehbi* also held that the challenged provisions of the North Dakota law did not meet the “connection-with” standard, and therefore, were not preempted under ERISA. The Court reasoned that certain provisions were not preempted because they were “merely *authorizing* pharmacies to do certain things.” Those provisions were:

- Section 16.1(5): disclose certain information to the plan sponsor;
- Section 16.1(7): provide relevant information to a patient;

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<sup>30</sup>*Wehbi*, 18 F.4<sup>th</sup> 956 at 969.

<sup>31</sup>18 F.4<sup>th</sup> 956 at 968.

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> *Id.* at 969.

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- Section 16.1(8): mail or deliver drugs to a patient as an ancillary service;
- Section 16.1(9): charge shipping and handling fees to patients requesting prescriptions to be mailed or delivered;<sup>35</sup>

The Eighth Circuit says that “These provisions affect PBMs only insofar as they prevent PBMs from preventing pharmacies/pharmacists from engaging in these practices. This constitutes at most, a regulation of a noncentral ‘matter of plan administration’ with *de minimis* economic effects and impact on the uniformity of plan administration across states.”<sup>36</sup> The *Wehbi* court draws a distinction between allowing pharmacies to decline to dispense a prescription if the reimbursement is too low and “requiring payment of specific benefits.”<sup>37</sup>

The Court explained that Sections 16.1(11) and 16.2(4) of the North Dakota law also did not meet the “connection-with” standard because they “merely limit the accreditation requirements that a PBM may impose on pharmacies as a condition for participation in its network.”<sup>38</sup> The Court said sections 16.1(10) and 16.2(2) also did not meet the “connection-with” standard because these provisions merely “require PBMs to disclose basic information to pharmacies and plan sponsors upon request.”<sup>39</sup> The Court explained that section 16.2(3), which prohibits a PBM from having “an ownership interest in a patient assistance program and a mail order specialty pharmacy,” did not reach the pre-emption threshold because compliance with the law was the responsibility of the PBM, and therefore, the PBM (and not the law) was responsible for any effect on ERISA plans’ beneficiaries.<sup>40</sup>

### **Mulready**

The United States Court of Appeals for the Tenth Circuit reversed the District Court for the Western District of Oklahoma, holding that ERISA and Medicare Part D preempted Oklahoma’s PBM law. Oklahoma enacted legislation in 2019 to “establish minimum and uniform access to a provider and standards and prohibitions on restrictions of a patient’s right to choose a pharmacy provider.”<sup>41</sup>

The Tenth Circuit focused on laws that have a “connection with” an ERISA plan (as opposed to laws that “refer to” an ERISA plan) so as to be preempted under the “relates to” language of ERISA. The Supreme Court in *Rutledge* relied on the “shorthand inquiry” it recited in *Gobeille*: “Does the state law ‘govern a central matter of plan administration or interfere with national uniform plan administration’,”<sup>42</sup> while also clarifying that “ERISA does not preempt

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<sup>35</sup> *Id.* at 968.

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> *Id.* at 968-969.

<sup>40</sup> *Id.* at 969.

<sup>41</sup> Okla. Stat. tit. 36, § 6959 (2019).

<sup>42</sup> *Gobeille*, 577 U.S. at 320.

state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage.”<sup>43</sup>

The Tenth Circuit divided the provisions of the law under review into two categories<sup>44</sup>: 1) “network restrictions,” which includes access standards;<sup>45</sup> discount prohibition;<sup>46</sup> and any willing provider provision<sup>47</sup>; and 2) “integrity and quality restriction,” which is the probation provision that prohibits “PBMs from denying, limiting or terminating a pharmacy’s contract because one of its pharmacists is on probation” with the state pharmacy board.<sup>48</sup> The Tenth Circuit analyzed whether the provisions “govern[] a central matter of plan administration” or “interfere[] with nationally uniform plan administration” so as to be preempted. Emphasizing the importance of uniformity under ERISA, the Tenth Circuit stated that “ERISA’s promise of uniformity is vitally important for employers, who “have large leeway to design plans as they see fit.”<sup>49</sup> The Tenth Circuit concluded in regard to the “network restrictions” “[e]ach provision either directs or forbids an element of plan structure or benefit design” which is a “central matter of plan administration” and therefore preempted under ERISA.<sup>50</sup> Additionally, the Court held the “integrity and quality restriction” provision is preempted under ERISA as it acts similar to the network restrictions, “dictating which pharmacies must be included in a plan’s PBM network.”<sup>51</sup>

As applied to the Oklahoma laws, the Tenth Circuit explains that even though Oklahoma’s law regulates PBMs, not plans, Supreme Court precedent has held that state laws can relate to ERISA plans even if they regulate only third parties, citing *Metropolitan Life*<sup>52</sup> and *Rush Prudential HMO, Inc. v. Moran*.<sup>53</sup>

*Mulready* petitioned the United State Supreme Court for a Writ of Certiorari, citing a conflict between the Eighth and Tenth Circuit decisions. Amicus briefs were filed by numerous parties. Of note is the brief for the United States arguing that the petition for a Writ of Certiorari should be denied. In the brief, the U.S. argued that the decision in *Mulready* did not conflict with the Supreme Court’s decision in *Rutledge* or with the Eighth Circuit’s decision in *Wehbi*. The brief argued that:

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<sup>43</sup> *Rutledge*, 592 U.S. 80, 88.

<sup>44</sup> *Mulready*, 78 F.4<sup>th</sup> 1183 at 1196.

<sup>45</sup> Okla.Stat. tit. 36 § 6961 (a)-(B) (2019).

<sup>46</sup> Okla.Stat. tit. 36 § 6963.

<sup>47</sup> Okla.Stat. tit. 36 § 6962 (B)(4).

<sup>48</sup> Okla.Stat. tit. 36 § 6962 (B)(5);

<sup>49</sup> *Mulready*, 78 F.4<sup>th</sup> 1183 at 1193.

<sup>50</sup> *Id.* at 1198.

<sup>51</sup> *Id.* at 1203.

<sup>52</sup> *Metropolitan Life Insurance Co. v. Massachusetts*, 471 U.S. 724, 734 (1985).

<sup>53</sup> *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 359 (2002).

The Tenth Circuit faithfully adhered to this Court's precedent, and the Eighth Circuit's decision in *Wehbi* does not necessarily indicate any divergence of approach to ERISA preemption. In addition, this case would be a suboptimal vehicle for addressing ERISA preemption because neither the Tenth Circuit nor the district court addressed whether the challenged provisions of the Oklahoma law are exempt from preemption in some applications under ERISA's savings and deemer clauses.<sup>54</sup>

The Supreme Court denied the Writ of Certiorari in *Mulready* on June 30, 2025.

#### IV. LESSONS FOR STATES

As a threshold matter, states should recognize that it is not possible to predict with any degree of certainty how federal courts will apply ERISA's preemption provisions to a particular state's law. While decisions of the U.S. Supreme Court constitute binding authority, variations in state laws must be carefully considered in any analysis. While appellate decisions can serve as persuasive authority, they are only binding on states within that circuit court's jurisdiction. This is especially true with respect to questions of ERISA's preemption of state PBM laws since the *Rutledge* decision.

As the beginning of this paper notes, PBMs play a critical role in the current health care ecosystem, and as a result, states have an interest in regulating their activities for the benefit of consumers. Every state has enacted PBM legislation, and the scope and focus of those laws differ. Also, states continue to consider enacting new PBM legislation to address PBM practices as the market evolves.<sup>55</sup>

When states evaluate existing PBM statutes or contemplate new legislative measures, it is important to carefully consider both the entities to which the legislation will apply and the content and focus of its specific provisions. For new legislation, make sure severability language is included.

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<sup>54</sup> Brief for the United States as Amicus Curiae, p. 10, *Pharmaceutical Care Management Ass'n, v. Mulready*, No.23-1213, *cert. denied*.

<sup>55</sup> See, NAIC Health Insurance and Managed Care (B) Committee, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 28

***Principles to apply to the question of whether ERISA may preempt the state law at issue:***

Step 1 – To whom does the law apply?

- a. **State laws as applied to PBM contracts with insurers issuing individual health coverage regulated by the state.** These applications will not raise ERISA preemption concerns because they do not apply to ERISA covered health plans.
- b. **State laws limited to PBM contracts with state-regulated insurers who may be issuing both individual health coverage and fully insured ERISA plans.** These laws are likely to fall under ERISA’s “saving clause” as state laws that “regulate insurance” and therefore would not be preempted under ERISA. It bears repeating that there have not been any challenges to insurance-specific PBM laws; the focus of recent preemption litigation has been state laws that apply broadly to the PBM industry.
- c. **State laws that apply to PBM contracts both for state regulated insurance and for other state-regulated health plans.** Only private employers are protected by ERISA’s deemer clause when they self-insure. In addition to individual plans and fully-insured employer plans, ERISA gives states broad authority to regulate self-insured plans maintained by state and local governments and by other public employers such as state universities. However, to the extent a state law regulating non-Federal governmental plans prevents the application of a Federal law, the state law would be preempted.

Likewise, state Medicaid plans and other publicly funded benefit programs are outside the scope of ERISA. Though states will need to ensure that any Medicaid PBM requirements are consistent with federal Medicaid law and any relevant terms and conditions of the federally-approved state Medicaid plan.

- d. **State laws that apply to all PBM contracts regardless of the type of health plan involved.** Insofar as the law applies to contracts with self-insured private employers (directly or through a third-party administrator), it is necessary to analyze the specifics of these laws to determine if they improperly "relate to" an ERISA plan so as to be preempted.
- e. **State laws mandating requirements for PBM contracts with state-regulated fully insured health plans, with an opportunity for self-funded group health plans to voluntarily participate (“opt-in”) in state regulatory structure.**<sup>56</sup> Including an opt-in

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<sup>56</sup> Washington state law authorizes self-funded group health plans to opt into their PBM law beginning January 1, 2026. See [RCW 48.200.330](#). This approach has been incorporated into state balance billing protections in several states. In Washington state, over 300 self-funded group health plans have opted into the Balance Billing Protection

for self-funded plans should not, in and of itself, cause the law to be preempted under ERISA.<sup>57</sup>

**Step 2** – If a state law applies to contracts between PBMs and ERISA plans (either fully insured or self-funded), states should consider the content and focus of the specific provisions in the state PBM law and the analysis in the chart that follows:

- a. Does the state law “relate to” an ERISA plan – Shorthand inquiry asks whether the law makes “reference to” or has a “connection with” an ERISA plan.
- b. A state law “makes reference” to an ERISA plan if it “acts immediately and exclusively upon ERISA plans or where the existence of ERISA plans is essential to the law's operation.”<sup>58</sup>
- c. The law will have a “connection with” a state law if it ‘govern(s) a **central matter of plan administration or interfere(s) with nationally uniform plan administration.**’<sup>59</sup> That test is satisfied when, for example, a state law “require[s] providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits,” or when state law “bind[s] plan administrators to specific rules for determining beneficiary status.”<sup>60</sup>
- d. In contrast, state laws “that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage” are not preempted.<sup>61</sup> “[N]ot every state law that affects an ERISA plan or causes some disuniformity in plan administration has an impermissible connection” and “[t]hat is especially so when a law merely affects costs.”<sup>62</sup>

It is important to recognize that the application of Supreme Court decisions leaves considerable room for interpretation. As evidenced in the chart below, there are inconsistencies in how each circuit understood what is a “central matter of plan administration.” In *Wehbi*, the Court determined that ERISA did not preempt the provision in North Dakota’s statute prohibiting PBMs from imposing accreditation or recertification

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Act. To give an opportunity for local and governmental self-funded group health plans to opt in, whether or not governed by or exempt from ERISA, see [RCW 48.49.130](#).

<sup>57</sup>The Supreme Court made clear in *Gobeille* that more than mentioning an ERISA plan is required create a “reference to” ERISA such that the law “relates to” an ERISA plan and is preempted. (*See infra* p.12 n. 49)

<sup>58</sup> *Gobeille*, 577 U.S. at 319–320

<sup>59</sup> *Rutledge*, 592 U.S. at 87.

<sup>60</sup> *Id.* at 86-87.

<sup>61</sup> *Id.* at 88.

<sup>62</sup> *Id.* at 87

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standards that exceed those required by state or federal licensure. This provision may arguably pertain to pharmacy network development or maintenance. Conversely, in *Mulready*, the Court adopted a broader perspective, classifying network development and maintenance provisions as central matters of plan administration subject to ERISA preemption. Legal challenges to state PBM regulations continue, and varying court interpretations are expected.

***Laws at issue in Rutledge, Wehbi and Mulready***

<b><u>CATEGORIES OF STATE LAW</u></b>	UPHELD (SCOTUS)	UPHELD (8 <sup>th</sup> Cir. Court of Appeals)	<b>NOT</b> UPHELD (10 <sup>th</sup> Cir. Court of Appeals)
<b>PBM PAYMENT TO PHARMACIES</b>			
Requires PBMs to reimburse pharmacies at a price equal to or higher than the pharmacy's wholesale cost.	Rutledge (Act 900)		
Pharmacies may refuse to sell a drug if the PBM's reimbursement rate is lower than its acquisition cost.	Rutledge: Ark.Code Ann. §17-92-507(e)		
If a consumer pays a copayment, it is retained by pharmacy; cannot be 'clawed back' by PBM.		*Wehbi (19-02.1-16.1(4))	
<b>PBM OVERSIGHT OF PHARMACY OPERATIONS</b>			
PBM 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.		*Wehbi (19-02.1-16.1(3))	
PBM is limited to applying a fee to the professional dispensing fee outlined in the pharmacy contract.		*Wehbi (19-02.1-16.1(3))	
PBM may not impose a fee relating to performance metrics on the cost of goods sold by a pharmacy.		*Wehbi (19-02.1-16.1(3))	
PBM may not prohibit a pharmacy from disclosing certain health information to the plan sponsor or patient.		Wehbi (19-02.1-16.1(5))	
Gag Orders prohibited: PBM may not prevent a pharmacy from providing relevant drug pricing & efficacy information to a patient.		Wehbi (19-02.1-16.1(7))	
PBM may not prevent mail or delivery of drugs to a patient as a pharmacy's ancillary service.		Wehbi (19-02.1-16.1(8))	
PBM may not prevent a pharmacy from charging shipping and handling fees to patients requesting prescriptions to be mailed or delivered.		Wehbi (19-02.1-16.1(9))	
PBM may be required to provide pharmacists information about each pharmacy network established or administered by a PBM.		<u>Wehbi (19-02.1-16.1(10))</u>	

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PBM may not require accreditation or recertification requirements that are more stringent than federal & state licensure requirements ( <i>for network participation</i> ).		Wehbi (19-02.1-16.1(11) & 16.2(4))	
PBM may not prohibit pharmacy from dispensing any drug allowed under its license.		*Wehbi (19-02.1-16.2(5))	
AWP Provision. Any willing pharmacy that is already in the PBM/plan's network must be allowed to be part of a preferred network if it is willing to accept the contractual terms.			Mulready: Okla. Stat. tit. 36, § 6962(B)(4).
Probation Prohibition: PBM may not deny or terminate a pharmacy license based on the license status of a pharmacy employee (being on probation with the State Pharmacy Board).			Mulready: Okla. Stat. tit. 36, § 6962(B)(5).
<b>TRANSPARENCY IN PBM OPERATIONS</b>			
PBMs must timely update their MAC lists when drug wholesale prices increase.	Rutledge: Ark. Code Ann. §17-92-507(c)(2)		
PBMs must have an appeal procedure for pharmacies to challenge MAC reimbursement rates.	Rutledge: Ark. Code Ann. §17-92-507(c)(4)(A)(i)(b)		
PBM may not charge or hold a pharmacy responsible for fees that it does not disclose to the pharmacy.		*Wehbi (19-02.1-16.1(2))	
Disclosing Spread Pricing: If requested, a PBM (or third-party payer) that has an ownership interest in a pharmacy, must disclose the difference between PBM's pharmacy payments and what is charged to the plan.		Wehbi (19-02.1-16.2(2))	
If a patient pays a copayment, PBM may not redact the adjudicated cost paid.		*Wehbi (19-02.1-16.1(4))	
A PBM may not have ownership interest in a patient assistance program or mail order specialty pharmacy unless it agrees to NOT participate in a transaction that would benefit the PBM.		Wehbi (19-02.1-16.2(3))	
Access Standards: PBM must meet certain network adequacy requirements for retail pharmacies (that do not include mail order pharmacies).			Mulready: Okla. Stat. tit. 36, § 6961((A)-(B).

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Discount Prohibition: A PBM shall not using any discounts in cost-sharing or a reduction in copay for individuals to receive prescription drugs from an individual’s choice of in-network pharmacy.			Mulready: Okla. Stat. tit. 36, § 6963(E).
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\* PCMA at appeal withdrew its claims that ERISA preempts section 16.1(2), section 16.1(3), the challenged portions of section 16.1(4), and section 16.2(5).

*Rutledge* (SCOTUS): Arkansas State law at: [A.C.A sec. 17-92-507](#)

*Wehbi* (8<sup>th</sup> Circuit): North Dakota State law at: <https://ndlegis.gov/cencode/t19c02-1.pdf>

*Mulready* (10<sup>th</sup> Circuit): Oklahoma State law (Patient’s Right to Pharmacy Choice Act) at:

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