March 3, 2026

Ms. Andria Seip, Chair
ERISA (B) Working Group
NAIC
444 North Capitol Street NW, Suite 700
Washington, DC 20001-1512
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SENT VIA EMAIL

RE: PCMA comments on NAIC's draft *Guidance Document – ERISA Preemption and State PBM Laws*

Dear Chair Seip:

On behalf of our member companies, the Pharmaceutical Care Management Association ("PCMA")[1] appreciates the opportunity to provide feedback on the National Association of Insurance Commissioners' ("NAIC") draft guidance document regarding state regulation of pharmacy benefit managers ("PBMs") and federal preemption under the federal Employee Retirement Income and Security Act ("ERISA") of 1974.

PCMA and its member companies submit these comments to you in your role as Chair of the ERISA and Alternative Health Coverage (B) Working Group's ("Working Group") to provide additional context to the *Guidance Document – ERISA Preemption and State PBM Laws* ("Draft") discussion of ERISA preemption. And we respectfully request that changes be made to the Draft before its finalization.

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BRIEF HISTORICAL CONTEXT

In 1974, Congress enacted ERISA to secure and promote the ability of labor unions and employers (i.e., small and large businesses across the country) to provide a uniform set of benefits to employees across multiple states. ERISA balances certain federal oversight systems and procedures for covered benefits with flexibility for unions and employers sponsoring employee benefit plans to determine the scope and structure of benefits that makes the most sense for the plan's enrollees. This flexibility is particularly important for unions or employers who self-fund health benefits for their enrollees, assuming all the risk of employee benefit claims. Moreover, it is important because it allows unions or employers to offer a similar set of benefits across state lines, when benefit plan enrollees are spread across multiple states.

As confirmed by over 50 years of federal jurisprudence, ERISA generally preempts state laws regulating health plans organized under ERISA. As described in detail below, federal ERISA

[1]PCMA is the national trade association representing the nation's largest PBMs. PCMA's PBM member companies administer drug benefits for more than 289 million Americans, who have health insurance through employer-sponsored health plans – including those organized under federal ERISA law, commercial health plans, union plans, Medicare Part D plans, managed Medicaid plans, state employee health plans, and others.

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preemption is broad. In particular, self-funded health benefits plans are not considered insurance nor subject to the state regulation of insurance. Attempts to extend current or future anti-PBM state laws to ERISA plans is in violation of this federal mandate. Moreover, it is bad public policy, as doing so will likely lead to an explosion of increased prescription drug costs for the residents of any state that attempts to illegally regulate ERISA plans.

Both the organized labor and business communities throughout the country have become increasingly concerned over ERISA preemption issues, understanding that it is health plan sponsors – unions and employers/business (rather than PBMs) and their working beneficiaries (i.e., union members or employees) who ultimately bear the cost of business-restrictive legislation.

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FEDERAL ERISA PREEMPTION GENERALLY

Congress enacted ERISA to provide a "uniform regulatory regime over employee benefit plans." *Aetna Health Inc. v. Davila*, 542 U.S. 200, 248 (2004). "[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). At the same time, Congress understood that reducing the burdens of complying with variable state laws would make employee benefit plans less costly and thus more likely that employers would offer benefits in the first place. *Rutledge v. PCMA*, 141 S. Ct. 474, 480 (2020).

To achieve this objective, Congress included a "comprehensive" express preemption clause in ERISA, *id.*, which was "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). 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).

ERISA preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan" covered by ERISA. 29 U.S.C. §1144(a). Consistent with this Congressional intent, it is well-established under U.S. Supreme Court precedent that state laws may be preempted where they bear an impermissible "connection with" or "reference to" ERISA plans.

State anti-PBM and anti-payor laws frequently implicate the "connection with" line of ERISA preemption doctrine. An impermissible "connection with" ERISA plans may occur where a state law "bind[s] plan administrators to [a] particular choice" concerning the substance of plan benefits. *Rutledge*, 141 S. Ct. at 480. 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. *New York*

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State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co., 514 U.S. 645, 667 (1995). In addition, "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. Finally, 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).

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SPECIFIC DRAFT CONCERNS

Reference and incorporate NAIC ERISA Handbook

At the outset, the Draft should refer to the NAIC's existing *Health and Welfare Plans Under the Employee Retirement Income Security Act: Guidelines for State and Federal Regulation* ("ERISA Handbook"), for a broader view of ERISA preemption and its impact on state efforts to regulate PBMs. It would be more efficient for the NAIC to streamline the Draft by removing issues that are already discussed in the ERISA Handbook. For example, the ERISA Handbook already includes three (3) pages of discussion on the *Rutledge* case.

Furthermore, the Draft should point regulators (i.e., the intended audience) to the Handbook's discussion of *Gobeille*, as it details ERISA preemption of state reporting requirements for ERISA plans. We would also suggest including this in the chart. Recent federal law imposes robust reporting on ERISA plans, further strengthening the *Gobeille* Court's conclusion that states cannot dictate ERISA reporting.

Providing a complete framework on federal preemption

The Draft should provide a complete framework for the regulator-audience. This includes a thorough description of the first steps in determining whether a proposed state law is likely to be federally preempted under ERISA. To do so, we recommend the Draft advise its audience that the starting steps of determining issues related to federal ERISA preemption begins with the question of whether there is a connection with or a reference to ERISA plans. Then the next step requires a Savings Clause analysis. And if a Savings Clause analysis determines that the Savings Clause applies, then move on to an analysis of the Deemer Clause.[2]

Additionally, the Draft states on Page 2, that:

> *…the question policymakers must consider is whether that measure is a permissible exercise of the state's general powers to regulate the pharmaceutical industry…*

This statement is inaccurate for two reasons. First, PBMs are not a part of the "pharmaceutical industry." PBMs administer pharmacy benefits, including on behalf of union or employers (i.e., businesses) that self-fund employee benefits under the framework of federal ERISA law.

[2] In addition to those state laws preempted pursuant to ERISA's express preemption provision, state anti-PBM and anti-payor laws are also subject to the general conflict preemption principles prohibiting any state laws where (1) compliance with both federal and state regulations is impossible, or (2) where the state law stands as an obstacle to the accomplishment and execution of the objectives of Congress. *See Wyeth v. Levine*, 555 U.S. 555, 589 (2009) (stating the standard for conflict preemption).

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Instead, the “pharmaceutical industry” as its commonly known, refers to pharmaceutical manufacturers – which are often foreign or multi-national companies unrelated to the local economies of most states. This is an important distinction for the Draft, as PBMs are administrators for American businesses/employers and unions.

Second, this statement misstates the relevant considerations in assessing whether state laws are preempted. “The purpose of Congress is the ultimate touchstone in every pre-emption case.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 494 (1996) quoting *Cipollone v. Ligget Group*, 505 U.S. 504, 516 (1992). As such, the Draft should clarify that ERISA preemption turns on whether a state law acts on ERISA plans in a manner that Congress sought to preempt. It does not consider the state’s purpose in passing such a restriction.

Finally, but perhaps **most important when taking into consideration decades of federal ERISA preemption jurisprudence**, the Draft should clarify for the audience that federal courts have consistently distinguished between limited instances of state cost regulations imposed upon PBMs (or other health care payors) and state laws that affect health plan design or administration. Federal courts have stated that states may not enact, nor attempt to enforce, laws that affect plan design or administration. Indeed, in considering all of the relevant case law, it is clear that any state attempts to directly regulate ERISA plans or indirectly regulate said plans via the direct regulation of PBMs, are generally prohibited. Despite the contention in the Draft’s section *Lessons for States* that it is not possible to predict how federal courts will ERISA’s preemption provision to particular state laws, federal courts will follow this longstanding jurisprudence.

Additional federal court cases should be discussed

The Draft selects a few cases to address regarding federal ERISA jurisprudence, rather than a comprehensive list of relevant cases. In order to provide a comprehensive and accurate picture of said jurisprudence, it behooves the Working Group to review and understand the over 50 years of federal court decisions regarding ERISA preemption. In addition to the incorporation of the ERISA Handbook by reference, we believe that references and discussions of current relevant federal court cases would provide the Draft with greater accuracy, as well as a more complete perspective on the issue.

For example, federal ERISA preemption cases are ongoing in the Eighth Circuit, including current preliminary injunctions against the states of Iowa and Arkansas are noteworthy. As is an ongoing federal ERISA preemption case in the Sixth Circuit against the State of Tennessee.

The state laws at issue should reflect their text as reviewed by the courts

References throughout the paper to state laws should be narrowed to clarify that the court only reviewed the law as it was enacted at a singular point in time. This will provide regulators with a more accurate reference point if or when these laws are amended. Further, the links at the bottom of the chart should also link to the original Acts.

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Providing accurate summaries of court decisions

The Draft includes misstatements of both law and fact that must be corrected. For example, Footnote #3 on Page 2 of the draft document, misstates the following in reference to the *Rutledge* decision:

> *The Court also held that the law was not preempted as applied to Medicare Part D plans.*

This statement is not true. The issue of federal Medicare preemption was not addressed by the U.S. Supreme Court in the *Rutledge* case. The U.S. Supreme Court's review was limited to whether an Arkansas law regarding reimbursement rates to pharmacies was federally preempted under ERISA . In fact, the Supreme Court's decision "leaves in place [the Eighth Circuit's] judgment that [the Arkansas law] ***is preempted with respect to Medicare Part D*** standards." Order 4, PCMA v. Rutledge, No. 17-1609 (8th Cir. Jan 22, 2021) (emphasis added). That decision remains binding in the Eighth Circuit.

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Finally, we appreciate the Working Group's recognition – including during its February 26, 2026, virtual meeting – of the ongoing federal court cases regarding federal ERISA preemption. That said, if the intent of the Draft is to be a "living document" – one that changes with updates in response to federal court decisions, as well as changing state laws – then we believe that the Draft should state so.

Again, PCMA and its member companies look forward to collaborating with you on the necessary revisions to the Draft. And we appreciate the opportunity to provide these comments.

Please do not hesitate to contact me with any questions or for further discussion.

Sincerely,

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