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DEPARTMENT OF HEALTH

Pharmacy Benefits Managers Workgroup

Meeting #2

Wednesday, September 17, 2025

Co-Chairs: Mary Kwei, MIA, Associate Commissioner, Market Regulation and Professional Licensing
Athos Alexandrou, MDH, Director, Office of Pharmacy Services

Today's Discussion

Overview of ERISA

- History of ERISA
- ERISA Preemptions and state regulation of pharmacy benefit managers
- ERISA Preemption "savings clause" and "deemer clause"

Examination of Case Law

- Rutledge v. Pharmaceutical Care Management Association ("PCMA")
- PCMA v. Wehbi, 18 F.4th 956 (8th Cir. 2021)
- PCMA v. Mulready, 78 F.4th 1183 (10th Cir. 2023)
- Iowa Ass'n of Business and Industry v. Ommen, Case No. 4:25-cv-00211 (S.D. Iowa)

Discussion

- Questions and Comments from Working Group Member
- Questions and Comments from Public Stakeholders, as time allows

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Overview of The Employee Retirement Income Security Act of 1974 ("ERISA")

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The Employee Retirement Income Security Act of 1974 ("ERISA")

ERISA was enacted by Congress in 1974 to protect the interests of participants in employee benefit plans and their beneficiaries by establishing substantive regulatory requirements for such plans and ensuring "appropriate remedies, sanctions, and ready access to the Federal courts."

ERISA establishes uniform standards and requirements for employee benefit plans, extending its comprehensive regulatory framework to all employer-sponsored benefit plans except those maintained by governmental entities and churches.

The statute's reach encompasses both pension arrangements and employee welfare benefit plans that provide medical, disability, or other specified benefits, including prescription-drug coverage.

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ERISA Preemption and State Regulation of Pharmacy Benefit Managers (PBMs)

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)). A state law "relates to" an employee benefit plan when "it has a connection with or reference to such a plan."

The "connection with" inquiry centers on state laws that dictate the fundamental architecture of employee benefit plans.

- State law has a "connection with" an ERISA Plan if it "governs…a central matter of plan administration," such as reporting, recordkeeping, disclosures, or fiduciary obligations, all of which are specifically addressed within ERISA.
- A state law that "affects an ERISA plan or causes some disuniformity in plan administration" does not entail that the law meets this standard, "especially… if a law merely affects costs."[1]

1. *Rutledge*, 592 U.S. at 87

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ERISA Preemption and State Regulation of Pharmacy Benefit Managers (PBMs)

State Law has an impermissible "reference to" ERISA plans if, and only if, it "acts immediately and exclusively upon ERISA plans" or "the existence of ERISA plans is essential to the law's operation."[2]

- The Supreme Court clarified in *Rutledge* that the existence of ERISA plans is essential to a law's operation only if the law cannot apply to a non-ERISA plan.

2. Rutledge, 592 U.S. at 48

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ERISA Preemption "Savings Clause" and the "Deemer Clause"

Savings Clause

Under the insurance regulation savings clause, states can regulate the terms and conditions of health insurance. "Nothing in [ERISA] shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking or securities."[3]

The Supreme Court has articulated a two-part test for determining whether a State law "regulates insurance" and avoids ERISA preemption:

1. The state law must be specifically directed towards entities engaged in insurance; and
2. The state law must substantially affect a risk pooling arrangement between the insurer and the insured.[4]

Deemer Clause

The ERISA preemption "deemer clause" constrains the authority of the States by providing that no ERISA-covered plan "shall be deemed to be an insurance company" for the purposes of state regulation, thus preventing states from treating self-funded plans as insurance entities subject to state regulation.

3. 29 U.S.C. § 1144(b)(2)(A)

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Examination of Case Law

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Rutledge v. Pharmaceutical Care Management Association ("PCMA")

At issue was an Arkansas law that requires PBMs to reimburse pharmacies at a price no lower than what "a pharmaceutical wholesaler charges" and authorizes pharmacies to decline to dispense a drug if PBM reimbursements are "less than the pharmacy's acquisition cost."

- Pharmaceutical Care Management Association ("PCMA") argued that the statue interferes with "central matters of plan administration" on the theory that allowing pharmacies to decline to dispense a prescription when PBM rates are low effectively denies plan beneficiaries their benefits.
- The Supreme Court unanimously disagreed, arguing that when a pharmacy declines to dispense a prescription, the responsibility lies first with the PBM for offering the pharmacy a below-acquisition reimbursement.
- Not every state law that affects an ERISA plan has an impermissible connection with ERISA plans unless they require provider to structure benefit plans in particular ways, such as requiring payment of specific benefits.

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PCMA v. Wehbi, 18 F.4th 956 (8th Cir. 2021)

At issue was a 2017 North Dakota law that regulated PBMs in part by prohibiting PBMs from conditioning a pharmacy's participation in their network on satisfying accreditation standards more stringent than or in addition to state licensure requirements.

- The 8th Circuit said these laws "constitute, at most, regulation of a noncentral 'matter of plan administration' with *de minimis* economic effects."
- While the laws may cause "disuniformity," they do not require payment of specific benefits or bind plan administrators to specific rules
- Other provisions that authorize pharmacies to do certain things–disclose certain information to patients; mail or deliver drugs to a patient as an ancillary service; charge shipping and handling fees when a prescription is mailed or delivered–were all also upheld.

The Court also considered Medicare Part D preemption and found that some provisions were not preempted by Medicare while others were.

- Those that were preempted required PBMs to utilize an electronic quality improvement platform for plans and pharmacies and limits performance based fees that PBMs can charge pharmacies, and a prohibition on retroactive fees (which are contemplated by federal regulations).

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PCMA v. Mulready, 78 F.4th 1183 (10th Cir. 2023)

Oklahoma's Patient's Right to Pharmacy Choice Act included "network restrictions" that:

1. Prohibited PBMs from cutting off rural patient's access to in-network pharmacies;
2. Forbade PBMs from steering patients to favored pharmacies by offering discounts at those pharmacies (and not others); and
3. an "any willing provider provision" that required PBMs to accept into their network all pharmacies willing to accept the network terms and condition.

Additionally, a fourth provision of the Act prohibited PBMs from terminating contract with a pharmacy based on a pharmacist's active probation status.

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PCMA v. Mulready, 78 F.4th 1183 (10th Cir. 2023) Ruling

The 10th Circuit Court ruled that:

1. all three "network restrictions" were all impermissibly connected with ERISA plans because they operate to winnow the PBM-network-design options available to benefit plans; and
2. the probation prohibition implicated a central matter of plan administration and was therefore preempted.

The 10th Circuit expressly disagreed with the 8th Circuit when it noted that the North Dakota laws resembled the Oklahoma Probation Prohibition, but found that the law dictated which pharmacies must be included in the plan's PBM network.

The 10th Circuit also found that Medicare Part D preempted the any willing provider provision as applied to Part D plans.

A petition for writ of certiorari to the Supreme Court was denied.

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Iowa Ass'n of Business and Industry v. Ommen, Case No. 4:25-cv-00211 (S.D. Iowa)

Recently, a coalition of Iowa employers and employee benefit plans, filed suit against the Iowa Insurance Commissioner, with regard to Iowa Senate File 383 ("SF 383"), which went into effect on June 11, 2025.

Senate File 383:

- prohibits discrimination against pharmacies by PBMs, health carriers, health benefit plans and third-party payors
- requires identical treatment regarding "participation, referral reimbursement of covered service or indemnification
- establishes mandatory reimbursement standards, as well as what the court described as extensive transparency and contractual requirements
  - PBMs must reimburse at no less than the published national average drug acquisition cost and must pay a minimum dispensing fee of $10.68 per prescription
- restricts communications between plans and participants
- prohibits PBMs from promotion of one participating pharmacy over another and bar, and bars disclosures comparing the reimbursement rates between pharmacies and mail-order options that might affect a person's choice of pharmacy provider

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Iowa Ass'n of Business and Industry v. Ommen, Case No. 4:25-cv-00211 (S.D. Iowa)

On July 21, 2025, the Southern District of Iowa issued an 87 page order granting a preliminary injunction as to several provisions of the bill, echoing the Plaintiffs' claim that cost regulations under Rutledge are permissible but those provisions that dictate the structure and administration of employee benefit plans are not.

20 distinct provisions were challenged, but 7 were found to be preempted by ERISA:

1. the anti-discrimination requirements;
2. The any-willing provider standards;
3. Open access standard for specialty drugs;
4. Mail order pharmacy and cost-sharing provisions;
5. Deductible credit requirements;
6. Mandatory contract terms and supersession provisions; and
7. The general enforcement provision.

Other provisions such as the limitation on guidance to preferred pharmacies, the dispensing fee provision, and various reporting and transparency provisions were found not to be preempted by ERISA.

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Applications of ERISA Preemption

The application of ERISA preemption is not clear cut, but some general rules of thumb can be gleaned:

1. Courts have generally upheld provisions that reflect permissible exercises of state authority over processional licensing, cost regulation, and commercial relationships outside of ERISA's scope.
2. Each bill seeking to regulate PBMs will require a careful case-by-case analysis with respect to ERISA preemption, Medicare, and the First Amendment.
3. Other provisions may be permitted by the courts depending on which U.S. Federal Court Circuit jurisdiction the enacted bills are in

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Questions and/or Comments from Workgroup Members

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Questions and/or Comments from Public Stakeholders

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Written Comments

Written comments will be accepted though EOD Wednesday, October 1, 2025, on the topics covered in today's meeting. Those can be submitted via email to:

pharmacyservicesworkgroup.mia@maryland.gov

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Thank you!

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Contact Information

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