

P.C.M.A. ERISA Update:
Rutledge and Mulready
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MC A F E E & T A F T

I. ERISA Basics

ERISA's Goals

“It is hereby declared to be the policy of this chapter to protect interstate commerce and the interests of participants in employee benefit plans and their beneficiaries, ... by establishing standards of conduct, responsibility, and obligation for fiduciaries of employee benefit plans, and by providing for appropriate remedies, sanctions, and ready access to the Federal courts.”

ERISA's Definition Of "Fiduciary"

"[A] person is a fiduciary with respect to a plan to the extent (i) he exercises any discretionary authority or discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets, ... or (iii) he has any discretionary authority or discretionary responsibility in the administration of such plan."

29 U.S.C. §1002(21)(A) (emphasis added).

ERISA's Exclusive Benefit Rule

"[A]ll assets of an employee benefit plan shall be held in trust by one or more trustees.

....

the assets of a plan ... shall be held for the **exclusive purposes** of **providing benefits** to participants in the plan and their beneficiaries and **defraying reasonable expenses of administering the plan.**"

29 U.S.C. §1103(a) (emphasis added).

ERISA's "Prudent Person" Standard Of Care

"[A] fiduciary shall discharge his duties with respect to a plan solely in the interest of the participants and beneficiaries and

(A) for the exclusive purpose of:

- (i) **providing benefits** to participants and their beneficiaries; and
- (ii) **defraying reasonable expenses** of administering the plan;

(B) with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent man acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims;

(C) by diversifying the investments of the plan so as to minimize the risk of large losses, unless under the circumstances it is clearly prudent not to do so; and

(D) in accordance with the documents and instruments governing the plan insofar as such documents and instruments are consistent with the provisions of this subchapter and subchapter III [of ERISA]."

29 U.S.C. §1104(a)(1) (emphasis added).

ERISA' Consistency Requirement

"The claims procedures for a plan will be deemed to be reasonable only if ...

The claims procedures contain administrative processes and safeguards designed to ensure and to verify that benefit claim determinations are made in accordance with governing plan documents and that, where appropriate, the plan provisions have been applied consistently with respect to similarly situated claimants."

29 C.F.R. §2560.503-1(b)(5) (emphasis added).

Federal Liability For Plan Losses

“Any person who is a fiduciary with respect to a plan who breaches any of the responsibilities, obligations, or duties imposed upon fiduciaries by this subchapter shall be personally liable to make good to such plan any losses to the plan resulting from each such breach, and to restore to such plan any profits of such fiduciary which have been made through use of assets of the plan by the fiduciary, and shall be subject to such other equitable or remedial relief as the court may deem appropriate, including removal of such fiduciary. A fiduciary may also be removed for a violation of section 1111 of this title.”

29 U.S.C. §1109(a) (emphasis added).

Criminal Penalties Under ERISA

(a) Any person who willfully violates any provision of part 1 of this subtitle [of ERISA], or any regulation or order issued under any such provision, shall upon conviction be fined not more than \$100,000 or imprisoned not more than 10 years, or both; except that in the case of such violation by a person not an individual, the fine imposed upon such person shall be a fine not exceeding \$500,000.

29 U.S.C. §1131(a) (emphasis added).

Federal Civil Actions Against ERISA Fiduciaries

“A civil action may be brought ... by a participant or beneficiary

(1)(b) to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan;

(2) by ... a participant, beneficiary or fiduciary for appropriate relief under section 1109 of this title;

by a participant, beneficiary, or fiduciary (A) to enjoin any act or practice which violates any provision of this subchapter or the terms of the plan, or (B) to obtain other appropriate equitable relief (i) to redress such violations or (ii) to enforce any provisions of this subchapter or the terms of the plan....”

29 U.S.C. §1132(a)(1)(B), (a)(2), (3) (emphasis added).

Federal Fines For ERISA Fiduciaries

“In the case of—

(A) any breach of fiduciary responsibility under (or other violation of) part 4 of this subtitle by a fiduciary, or

(B) any knowing participation in such a breach or violation by any other person,

the Secretary shall assess a civil penalty against such fiduciary or other person in an amount equal to 20 percent of the applicable recovery amount.”

29 U.S.C. §1132(l) (emphasis added).

Federal Regulatory Lawsuits

“A civil action may be brought—...

(2) by the Secretary [of Labor] ... for appropriate relief under section 1109 of this title; ...

(5) ... by the Secretary (A) to enjoin any act or practice which violates any provision of this subchapter, or (B) to obtain other appropriate equitable relief (i) to redress such violation or (ii) to enforce any provision of this subchapter;

(6) by the Secretary to collect any civil penalty ... under subsection (i) or (j)....

29 U.S.C. § 1132(a)(2), (5), (6).”

Federal Plan Audits

The Secretary shall have the power, in order to determine whether any person has violated or is about to violate any provision of this subchapter or any regulation or order thereunder—

(1) to make an investigation, and in connection therewith to require the submission of reports, books, and records, and the filing of data in support of any information required to be filed with the Secretary under this subchapter, and

(2) to enter such places, inspect such books and records and question such persons as he may deem necessary to enable him to determine the facts relative to such investigation, if he has reasonable cause to believe there may exist a violation of this subchapter or any rule or regulation issued thereunder or if the entry is pursuant to an agreement with the plan.

The Secretary may make available to any person actually affected by any matter which is the subject of an investigation under this section, and to any department or agency of the United States, information concerning any matter which may be the subject of such investigation....

For the purposes of any investigation provided for in this subchapter, the provisions of sections 49 and 50 of title 15 (relating to the attendance of witnesses and the production of books, records, and documents) are hereby made applicable (without regard to any limitation in such sections respecting persons, partnerships, banks, or common carriers) to the jurisdiction, powers, and duties of the Secretary or any officers designated by him.

29 U.S.C. § 1134(a), (c).

General Preemption: Supremacy Clause

“This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any thing in the Constitution or Laws of any State to the Contrary notwithstanding.”

U.S. Const., Art. VI, cl. 2 (emphasis added).

ERISA Preemption

General Clause: “[T]he provisions of [ERISA] shall supersede any and all State Laws insofar as they may now or hereafter relate to any employee benefit plan....”

Savings Clause: “[N]othing in [ERISA] shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking, or securities.”

Deemer Clause: “[N]either an employee benefit plan ... nor any trust established under such a plan, shall be deemed to be an insurance company or other insurer, ... or to be engaged in the business of insurance or banking for purposes of any law of any State purporting to regulate insurance companies, insurance contracts, banks, trust companies, or investment companies.”

“State Law” Definition: The term “State law” includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.”

29 U.S.C. § 1144(a), (b)(2)(B), (c)(1) (emphasis added).

The Result

"As a result, **self-funded** ERISA plans are exempt from state regulation insofar as that regulation 'relate[s] to' the plans. State laws **directed toward the plans** are preempted because they relate to an employee benefit plan **but are not 'saved' because they do not regulate insurance**. State laws that directly regulate insurance are 'saved' **but do not reach self-funded employee benefit plans** because the plans may not be deemed to be insurance companies, other insurers, or engaged in the business of insurance for purposes of such state laws. On the other hand, employee benefit **plans that are insured** are subject to indirect state insurance regulation. **An insurance company that insures a plan remains an insurer for purposes of state laws 'purporting to regulate insurance' after application of the deemer clause.** The insurance company is therefore not relieved from state insurance regulation."

FMC Corp. v. Holliday, 498 U.S. 52, 61 (1990).

Stop Loss Insurance

- Stop loss insurance generally doesn't cover "voluntary" payments (payments for things that are excluded under the Plan).
- Fiduciaries can't make the Plan's stop loss insurer pay for things for which it did not agree to pay.
- Result: If fiduciaries make "voluntary" payments the Plan must cover the full amount.
- Result: The fiduciaries have caused a loss to the plan.

Fiduciary Liability Insurance

- Fiduciary liability insurance generally doesn't cover intentional or illegal acts.
- Paying non-covered claims amounts to wasting plan assets. Wasting plan assets is an unlawful act, especially if it is intentional.
- Result: Claims for causing plan losses through such payments are often not covered by fiduciary insurance.

II. *Rutledge v. P.C.M.A.*

Rutledge v. P.C.M.A.

- Arkansas passed Act 900 which regulated Pharmacy Benefits Managers (“PBMs”). It controlled pricing and other things with respect to PBMs.
- The Act established a reimbursement floor by requiring PBMs to reimburse pharmacies at a rate that reflected the pharmacies’ acquisition costs.
- The Act required publication of PBM prices, an appeal process allowing pharmacies to challenge reimbursement rates, and allowing pharmacies to refuse to fill prescriptions if reimbursement fell below acquisition costs.

Rutledge v. P.C.M.A., 141 S. Ct. 474, 479 (2020).

Rutledge v. P.C.M.A.

- The national PBM Association challenged the Act as being pre-empted by ERISA.
- The Court held the Act was not pre-empted.
- **First:** the Act is a form of “cost regulation,” the Court which doesn’t have an “impermissible connection” with an ERISA plan. The Act did not “govern[] a central matter of plan administration or interfere[] with nationally uniform plan administration.” State laws that “merely affect the costs” only have an “indirect economic effect” on plan administrators and do not “bind” them to take specified action.
- **Second:** the Act applies generally to PBMs regardless of whether they sometimes manage ERISA plans, so the Act does not “refer to” an ERISA plan. For a state law to “refer to” an ERISA plan (1) it must “act immediately and exclusively” upon the plan or (2) the existence of an ERISA plan must be “essential to the law’s operation.”

Rutledge v. P.C.M.A., 141 S. Ct. 474, 481 (2020).

Rutledge v. P.C.M.A.

General Preemption Rule

- “[A] state law relates to an ERISA plan if it has a **connection with** or **reference to** such a plan.”
- Arkansas Act 900 did not have an impermissible connection with or reference to ERISA plans.

Rutledge v. P.C.M.A., 141 S. Ct. 474, 479 (2020).

Rutledge v. P.C.M.A.

"Connection With"

- State laws have a "connection with" ERISA plans if they "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."
- "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**.' As a shorthand for these considerations, this Court asks whether a state law 'governs a **central matter of plan administration** or interferes with **nationally uniform plan administration**.' If it does, it is pre-empted."

Rutledge v. P.C.M.A., 141 S. Ct. 474, 479-80 (2020).

Rutledge v. P.C.M.A.

"Connection With"

- “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.” *Rutledge*, 141 S. Ct. at 480.
- *Rutledge’s* example: NY’s 13% hospital surcharge for non-Blue Cross insurers. “[S]uch an ‘indirect economic influence’ did not create an impermissible connection between the New York law and ERISA plans because it did not ‘bind plan administrators to any particular choice.’” *NY State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U. S. 645, 659 (1995).
- “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.” *Rutledge*, 141 S. Ct. at 480.

Rutledge v. P.C.M.A. "Connection With"

"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.' Nor is the effect of Act 900 so acute that it will effectively dictate plan choices. 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."

Rutledge v. P.C.M.A., 141 S. Ct. 474, 481 (2020).

Rutledge v. P.C.M.A. *"Reference To"*

"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.'"

"Act 900 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."

Rutledge v. P.C.M.A., 141 S. Ct. 474, 481 (2020).

Rutledge v. P.C.M.A. *"Reference To"*

“ERISA plans are likewise not essential to Act 900’s operation. Act 900 regulates PBMs whether or not the plans they service fall within ERISA’s coverage.”

Rutledge v. P.C.M.A., 141 S. Ct. 474, 481 (2020).

Rutledge v. P.C.M.A.

Conclusion

- *Rutledge* joins a long line of cases holding that states can regulate third-parties who act as **vendors** for ERISA-regulated plans even though the state regulation might have an effect on such plans:
 - **HMOs** (*Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355 (2002));
 - **Insurance Companies** (*KY Ass'n of Health Plans, Inc. v. Miller*, 538 U.S. 329 (2003); *Metro. Life Ins. Co. v. MA*, 471 U.S. 724 (1985));
 - **Hospitals** (*De Buono v. NYSA-ILA Med. & Clinical Serv's Fund*, 520 U.S. 806 (1997); *NY State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U. S. 645 (1995)).
- **BUT ERISA preempts state laws that “relate to” ERISA plans themselves.**

III. *P.C.M.A. v. Mulready*

P.C.M.A. v. Mulready

OPRPCA

- In 2019, the Oklahoma Legislature passed the Oklahoma's Patient's Right to Pharmacy Choice Act, 36 Okla. Stat. §§ 6958, *et seq.* The Act contains:
 - An Any Willing Provider Provision, § 6962(B)(4);
 - A Retail-Only Pharmacy Access Standards, § 6961(A),(B);
 - An Affiliated Pharmacy Prohibition, § 6961(C);
 - A Probation-Based Pharmacy Limitation Prohibition, § 6962(B)(5);
 - A Provider Restriction Prohibition, § 6963(D);
 - A Cost Sharing Discount Provision, § 6963(E); and
 - A Promotional Materials Provision; § 6961(D).

P.C.M.A. v. Mulready

P.C.M.A. (the same party in *Rutledge*) sued and argued ERISA and Medicare preemption.

P.C.M.A. v. Mulready, Case No. CIV-19-977-J, Doc. #111 (W.D. Okla. Apr. 4, 2022) (order on summary judgment).

P.C.M.A. v. Mulready

ERISA Preemption

- The Court only addressed the “connection with” prong of the preemption test. *Mulready*, slip op. at 3 n.4.
- The Court examined various OPRPCA provisions and held they are not preempted, (“While these provisions may alter the incentives and limit some of the options that an ERISA plan can use, none of the provisions forces ERISA plans to make any specific choices. This provision therefore does not relate to a central matter of plan administration nor undermine the uniform regulation of ERISA plans. ... these provisions do not impermissibly dictate the design of ERISA plans by forcing the plans into making a specific choice”) *Mulready*, slip op. at 3-5.
- P.C.M.A. lacked standing to challenge the Health Insurer Monitoring Requirement, 36, § 6963(A),(B) because it was not a “health insurer.” *Mulready*, slip op. at 5.

P.C.M.A. v. Mulready

Medicare Preemption

- Medicare Part C and D establish standards which preempt state laws (even non-conflicting ones).
- *Mulready* relied on *Rutledge's* holding in the Eighth Circuit, 891 F.3d at 1113, which was **not** reviewed by the Supreme Court.
- *Mulready* held with respect to Medicare Part D:
 - OPRPCA's Retail-Only Pharmacy Access Standards was preempted;
 - OPRPCA's any willing provider standard is not preempted;
 - OPRPCA's Affiliated Pharmacy Prohibition and Network Provider Restriction are not preempted;
 - OPRPCA's Service Fee Prohibition, Affiliated Pharmacy Price Match, and PostSale Price Reduction Prohibition are preempted;
 - OPRPCA's Probation-Based Pharmacy Limitation Prohibition and Termination Payment Requirement are not preempted;
 - OPRPCA's Contract Approval Rule is not preempted.

P.C.M.A. v. Mulready

Federal Preemption Of State Standards

- Medicare establishes federal standards and it preempts state standards.
- ERISA likewise establishes federal standards for plan fiduciaries and it preempts state standards.
- *Mulready* would ostensibly support fiduciary challenges to state laws that would purport to regulate their conduct.

P.C.M.A. v. Wehbi

The Eighth Circuit, which previously decided the Rutledge case on appeal, followed the Supreme Court's holding and ruled that North Dakota's PBM law:

- Was not preempted by ERISA; but
- Was partially preempted by Medicare Part D.

P.C.M.A. v. Wehbi, 18 F.4d 956 (8th Cir. 2021).

IV. ERISA'S IMPACT ON OKLAHOMA LAWS

Oklahoma's New Insulin Law

“Any **carrier** that provides coverage for insulin pursuant to this section shall cap the total amount that a covered person is required to pay for insulin at an amount not to exceed Thirty Dollars (\$30.00) per thirty-day supply or Ninety Dollars (\$90.00) per ninety-day supply of insulin for each covered insulin prescription, regardless of the amount or type of insulin needed to fill the prescription or prescriptions of the covered person.”

36 O.S. § 6060.2(A)(7) (current).

Oklahoma's New Insulin Law-Amended

“Any **health benefit plan**, as defined pursuant to **Section 6060.4** of this title, that provides coverage for insulin pursuant to this section shall cap the total amount that a covered person is required to pay for insulin at an amount not to exceed Thirty Dollars (\$30.00) per thirty-day supply or Ninety Dollars (\$90.00) per ninety-day supply of insulin for each covered insulin prescription, regardless of the amount or type of insulin needed to fill the prescription or prescriptions of the covered person.”

36 O.S. § 6060.2(A)(7) (effective Nov. 1, 2022).

Oklahoma's Definition of "Health Benefit Plan"

"For purposes of this section, 'health benefit plan' means group hospital or medical insurance coverage, a not-for-profit hospital or medical service or indemnity plan, a prepaid health plan, a health maintenance organization plan, a preferred provider organization plan, the State and Education Employees Group Health Insurance Plan, and coverage provided by a Multiple Employer Welfare Arrangement or **employee self-insured plan as permitted** under Employee Retirement Income Security Act of 1974."

36 O.S. § 6060.4(C)(1) (effective Nov. 1, 2022).

Oklahoma's New Insulin Law

- Applies to government plans, church plans, etc., which are expressly exempt from ERISA's coverage. 29 U.S.C. § 1003(b).
- Applies to private sector fully-insured plans under the "Savings Clause" of ERISA, 29 U.S.C. § 1003(b)(2)(A).
- Is preempted with respect to self-funded private sector plans under the General, Deemer, and definitional provisions of ERISA's preemption section, 29 U.S.C. § 1144(a), (b)(2)(B), (c)(1).

OID's Position

- “[T]he provisions of 36 O.S. § 6060.2(A)(7) are not pre-empted by [ERISA] pursuant to ... *Rutledge* ... which finds in part that ‘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.**’ It is therefore the position of the Department that the insulin cost-sharing caps created by 36 O.S. § 6060.2(A)(7) are applicable to any health plan . . . to the extent permitted by [ERISA],’ **including, but not limited to, self-funded ERISA plans.**”
- Okla. Ins. Dep’t. LH Bulletin No. 2021-04 (Second Revision) (emphasis added, quoting *Rutledge*)

Oklahoma Legislative Background

The Oklahoma insulin law was proposed by Oklahoma state Senator Carri Hicks, who ostensibly recognized that because state laws are preempted as to self-funded plans “only 10 percent of [Oklahoma’s] insulin-using population would be addressed by her proposed copay cap....”

<https://www.healthline.com/diabetesmine/state-insulin-copay-caps-not-enough>.

General Position

“That federal law [ERISA] sets minimum standards for most of the employer provided health and retirement plans. These are ‘self-funded’ plans governed by ERISA, meaning the employer takes on some of the financial responsibility for the plans it offers.

As a result, [people with diabetes] with these ubiquitous ERISA-governed plans are not able to take advantage of the insulin copay cap within their particular state.”

[https://www.healthline.com/diabetesmine/state-insulin-copay-caps-not-enough.](https://www.healthline.com/diabetesmine/state-insulin-copay-caps-not-enough)

Georgia

“Moreover, despite what some parties may claim, the recent *Rutledge v. PCMA* decision by the U.S. Supreme Court does not permit this office to regulate ERISA plans. Instead, the *Rutledge* decision merely found that an Arkansas law dealing with cost regulation was not pre-empted by ERISA under longstanding Supreme Court precedent. Accordingly, my office will continue to enforce those laws in Georgia which are not pre-empted by ERISA. However, this also means my administration cannot and will not enforce Georgia’s laws against ERISA plans until such time as it is permitted expressly by the U.S. Congress or a court of competent jurisdiction.”

Letter from GA Commissioner of Insurance & Safety Fire
(Mar. 7, 2022).

New York

Insulin Cost-Sharing Limit Q&A Guidance

“Q-4. Does the [New York] law limiting cost-sharing for prescription insulin apply to self funded ERISA plans?”

No. The law does not apply to self-funded ERISA plans.”

NY Dep’t. of Financial Serv’s. Insulin Cost-Sharing Limit Q&A Guidance

[https://www.dfs.ny.gov/apps_and_licensing/health_insurers/insulin_cost_sharing_qa_guidance.](https://www.dfs.ny.gov/apps_and_licensing/health_insurers/insulin_cost_sharing_qa_guidance)

Hobson's Choice

If the OID is correct, then ERISA fiduciaries must either:

1. Follow federal standards (pay insulin benefits as mandated by the plan) and violate state law; or
2. Follow state law and violate federal law; or
3. Restructure their plans to avoid violating either set of laws (re-structuring = preemption).

Federal law preempts state law.

Conflict Preemption

- Conflict preemption occurs when compliance with both federal and state regulations is a physical impossibility (“impossibility preemption”), *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963);
- Or when state law creates an “obstacle” to the accomplishment of the “full purposes and objectives” of Congress (“obstacle preemption”), *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

Fiduciary Remedies

- Fiduciaries could possibly file federal lawsuits under ERISA, 29 U.S.C. § 1132(a)(3) to enjoin OHA (or other) plaintiffs from proceeding, notwithstanding the Anti-Injunction Act, 28 U.S.C. § 2283.
- Fiduciaries could file lawsuits under 28 U.S.C. §§ 2201, 2202; and/or 29 U.S.C. § 1132(a)(3) against state officials, who seek to impose preempted state statutes on self-funded plans, for a judgment that the “state action” is preempted by ERISA, 29 U.S.C. § 1144(a), (c).
- Anyone who “willfully” violates ERISA—including its preemption provisions—can be prosecuted under 29 U.S.C. § 1131.