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EMPLOYEE BENEFITS

ERISA Preemption of State PBM Regulation After *Rutledge*

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In December 2020, the U.S. Supreme Court issued an opinion in the case of *Rutledge v. Pharmaceutical Care Mgmt Ass'n*, holding that an Arkansas statute regulating pharmacy benefit managers (PBMs) was not preempted by ERISA. The Rutledge decision may have narrowed the scope of ERISA preemption of state law in some respects. This article discusses general ERISA preemption concepts, the Rutledge decision and the impact of that decision on other states' regulation of PBMs, looking specifically at a recent 8th Circuit Court of Appeals decision and a law recently enacted in Tennessee.

ERISA Preemption of State Law

ERISA's preemption rule is found in Section 514, the key portions of which provide as follows:

(a) Supersedure; effective date.

Except as provided in subsection (b) of this section, the provisions of this title and title IV shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan described in section 4(a) [29 USC §1003(a)] and not exempt under section 4(b) [29 USC §1003(b)]. This section shall take effect on January 1, 1975.

(b) Construction and application.

(1) This section shall not apply with respect to any cause of action which arose, or any act or omission which occurred, before January 1, 1975.

(2)

- (A) Except as provided in subparagraph (B), nothing in this title shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking, or securities.
- (B) Neither an employee benefit plan described in section 4(a) [29 USC §1003(a)], which is not exempt under section 4(b) [29 USC §1003(b)] (other than a plan established primarily for the purpose of providing death benefits), nor any trust established under such a plan, shall be deemed to be an insurance company or other insurer, bank, trust company, or investment company 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.

Generally speaking, under Section 514, all state laws that "relate to any employee benefit plan" subject to ERISA are preempted other than laws regulating insurance, banking or securities.[1] If a law is preempted, it generally cannot be enforced against the plan, the employer sponsoring the plan or third parties providing services to the plan.

As discussed in the *Rutledge* opinion, the Supreme Court has generally interpreted Section 514 to apply when the state law has a connection with or a reference to an ERISA plan.

1 Section 514 includes other exceptions not relevant here.

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Connection With. When determining whether a state law has a connection with an ERISA plan, the *Rutledge* Court has said 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 . . . or by binding plan administrators to specific rules for determining beneficiary status" or when "economic effects of a state law force an ERISA plan to adopt a certain scheme of substantive coverage." Put another way, a state law generally will be preempted due to its connection with an ERISA plan when it "governs a central matter of plan administration or interferes with nationally uniform plan administration."[2]

Refers To. A state law generally will be considered to "refer to" an ERISA plan if it "acts immediately and exclusively upon ERISA plans or where the existence of an ERISA plan is essential to the law's operation."[3]

The *Rutledge* Decision

In the *Rutledge* case, the Supreme Court considered whether ERISA preempted an Arkansas law regulating PBMs. The law in question (referred to as "Act 900") essentially requires PBMs to reimburse pharmacies at a rate equal to or higher than the rate paid by the pharmacy to acquire the drug. Act 900 contains three key elements: (1) it requires PBMs to timely update their lists of maximum allowable costs (MAC) when wholesale drug prices increase; (2) it requires PBMs to provide administrative appeals to allow pharmacies to challenge MAC reimbursement rates that were lower than the acquisition cost paid by the pharmacy and required PBMs to increase the reimbursement rate if the pharmacy could not obtain the drug at a lower price; and (3) it permits a pharmacy to refuse to sell a drug to someone covered by a plan if the PBM's reimbursement would be less than what the pharmacy paid to acquire the drug. Act 900 was challenged by the Pharmaceutical Care Management Association, which claimed that the law was preempted by ERISA Section 514.

The Supreme Court determined Act 900 is not preempted by ERISA. First, the Court found Act 900 did not have a connection with ERISA plans. The Court held that, although Act 900 has some impact on ERISA plans by affecting the rates such plans must pay for pharmacy benefits, "ERISA does not preempt state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage."

The Court also found Act 900 did not refer to ERISA plans. It determined Act 900 applied to PBMs regardless of whether they were providing services to an ERISA plan and ERISA plans were not essential to the operation of Act 900. Tellingly, the Court wrote that Act 900 " does not directly regulate health benefit plans at all .... It affects plans only insofar as PBMs may pass along higher pharmacy rates to plans with which they contract", which does not result in the law referring to ERISA plans.

Pharmaceutical Care Mgmt Ass'n v. Wehbi

On November 17, 2021, the 8th Circuit Court of Appeals[4] issued a decision in the case of *Pharmaceutical Care Mgmt Ass'n v. Wehbi* addressing the ERISA preemption (in light of the Rutledge decision) of a North Dakota law regulating PBMs. The court held that no provision of North Dakota's PBM law was preempted by ERISA. While there was little question that some of the law's provisions were not preempted in light of Rutledge,[5] the court seemingly could have found the following provisions to have a connection with ERISA plans and therefore preempted[6]:

1. Upon request, a pharmacy benefits manager or third-party payer shall provide a pharmacy or pharmacist with the processor control number, bank identification number and group number for each pharmacy network established or administered by a pharmacy benefits manager to enable the pharmacy to make an informed contracting decision.

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2 Gobeille v. Liberty Mut. Ins. Co., 577 U.S. 312 (2016).
3 Gobeille, 577 U.S., at 319-20.
4 Decisions by the 8th Circuit are binding precedent in the states of Arkansas, Iowa, Minnesota, Missouri, Nebraska, North Dakota, and South Dakota.
5 In fact, after the Court's decision in Rutledge, the party challenging the law conceded that a number of provisions were not preempted by ERISA.
6 The plaintiff in the case did not assert that any of the provisions of the North Dakota law referred to ERISA plans, so that was a not a basis for ERISA preemption in this case.

2. A pharmacy benefits manager or third-party payer may not require pharmacy accreditation standards or recertification requirements to participate in a network that are inconsistent with, more stringent than or in addition to the federal and state requirements for licensure as a pharmacy in this state.

The 8th Circuit ruled the "modest" disclosure requirements imposed under the first provision described above were not preempted because they addressed a noncentral matter of plan administration and had a de minimis impact on the uniformity of plan administration. The 8th Circuit similarly determined the second provision (which it characterized as "merely limiting the accreditation requirements a PBM may impose on pharmacies as a condition for participation in its network") was, "at most, regulation of a noncentral 'matter of plan administration' with de minimis economic effects." It was not preempted because it neither requires payment of specific benefits nor obligates plan administrators to follow specific rules for determining beneficiary status.

Tennessee Public Chapter 569

In May 2021, the state of Tennessee enacted a law known as Public Chapter 569 that regulates the practices of PBMs operating in the State. The law appears to go farther than the Arkansas and North Dakota laws in some respects. Accordingly, a key question is whether any of Public Chapter 569 is preempted by ERISA in light of the Supreme Court's decision in *Rutledge*.

Caution: Ultimately, the ERISA preemption questions discussed below will not have clear answers until the law is challenged in court or the state seeks to enforce the statute against a covered entity. At the time of this writing, we are not aware of any pending litigation related to Public Chapter 569. In the absence of binding court precedent, employers with group health plans providing prescription drug benefits to employees in Tennessee should discuss the implications of the law and the possibility of ERISA preemption with their legal counsel.

Public Chapter 569 contains the following provisions[7]:

1. A health insurance issuer, managed health insurance issuer, pharmacy benefits manager or other third-party payer shall not:
   - Reimburse a 340B entity[8] for pharmacy-dispensed drugs at a rate lower than the rate paid for the same drug by national drug code number to pharmacies that are not 340B entities;
   - Assess a fee, chargeback or adjustment upon a 340B entity that is not equally assessed on non-340B entities;
   - Exclude 340B entities from its network of participating pharmacies based on criteria that are not applied to non-340B entities; or
   - Require a claim for a drug by national drug code number to include a modifier to identify that the drug is a 340B drug.

7 *The provisions of the Public Chapter 569 amend Title 56, Chapter 7 of the Tennessee Code Annotated.*
8 *A 340B entity is one that participates in the federal Drug Pricing Program, along with the Medicaid Drug Rebate Program (MDRP), which is a partnership between the federal government and drug manufacturers to help offset the cost of outpatient prescription drugs, including physician-administered drugs, dispensed to Medicaid enrollees.*

2. A pharmacy benefits manager or a covered entity (which includes self-insured plans)[9] shall not require a person covered under a pharmacy benefit contract that provides coverage for prescription drugs, including specialty drugs, to pay an additional fee, higher copay, higher coinsurance, second copay, second coinsurance or other penalty when obtaining prescription drugs, including specialty drugs from a contracted pharmacy.
3. A pharmacy benefits manager or a covered entity shall not interfere with the patient's right to choose a contracted pharmacy or contracted provider of choice in a manner that violates § 56-7-2359 or by other means, including inducement, steering or offering financial or other incentives.[10]
4. A pharmacy benefits manager or a covered entity shall base the calculation of any coinsurance or deductible for a prescription drug or device on the allowed amount[11] of the drug or device. For purposes of this section, coinsurance or deductible does not mean or include copayments.
5. A pharmacy benefits manager shall not charge a covered entity an amount greater than the reimbursement paid by a pharmacy benefits manager to a contracted pharmacy for the prescription drug or device.
6. A pharmacy benefits manager shall not reimburse a contracted pharmacy for a prescription drug or device an amount that is less than the actual cost to that pharmacy for the prescription drug or device. This requirement does not apply if one of the following conditions is satisfied:
   - The pharmacy benefits manager utilizes a reimbursement methodology that is identical to the methodology provided for in the state plan for medical assistance approved by the federal centers for Medicare and Medicaid services, and the pharmacy benefits manager establishes a process for a pharmacy to appeal a reimbursement paid at average acquisition cost and receive an adjusted payment by providing valid and reliable evidence that the reimbursement does not reflect the actual cost to the pharmacy for the prescription drug or device.
   - The covered entity or pharmacy benefits manager establishes a clearly defined process through which a pharmacy may contest the actual reimbursement received for a particular drug or medical product or device.
7. A pharmacy benefits manager has a responsibility to report to the plan and the patient any benefit percentage that either are entitled to as a benefit as a covered person.
8. A covered entity shall, upon request of an enrollee, enrollee's healthcare provider or authorized third party, furnish certain cost, benefit, and coverage data specified in Public Chapter 569 to the enrollee, the enrollee's healthcare provider or an authorized third party, in accordance with the requirements established in the law.

Of these provisions, the second, third, fourth and eighth provisions appear to have the best chance to be preempted by ERISA. We will discuss those "potentially preempted" provisions more below. The other provisions of Public Chapter 569 seem likely to withstand an ERISA preemption challenge because they appear to neither have a connection with nor refer to ERISA plans under the *Rutledge* analysis. While those other provisions might impact the costs incurred by ERISA plans to provide prescription drug benefits, under the *Rutledge* analysis, such an impact generally is insufficient to trigger ERISA preemption.

None of the potentially preempted provisions identified above seem to refer to an ERISA plan because they do not act exclusively upon ERISA plans and the existence of an ERISA plan is not essential to their operation. However, there appears to be a strong argument that these potentially preempted provisions have a connection with ERISA plans, in which case they should be preempted when applied to self-insured group medical plans subject to ERISA.

Note: These provisions likely are not preempted by ERISA when applied to insurance carriers and group insurance policies that are part of fully-insured plans due to the exception in ERISA Section 514 allowing states to regulate insurance.

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9 "'Covered entity' means a health insurance issuer, managed health insurance issuer as defined in § 56-32-128(a), nonprofit hospital, medication service organization, insurer, health coverage plan, health maintenance organization licensed to practice pursuant to this title, a health program administered by the state or its political subdivisions, including the TennCare programs administered pursuant to the waivers approved by the United States department of health and human services, nonprofit insurance companies, prepaid plans, self-insured entities, and all other corporations, entities or persons, or an employer, labor union, or other group of persons organized in the state that provides health coverage to covered individuals who are employed or reside in the state. 'Covered entity' does not include a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement, disability income, or other long-term care." TN Code § 56-7-3102.

10 TN Code § 56-7-2359 already requires insurance carriers and HMOs to allow any licensed pharmacies and pharmacists to participate in their networks.

11 Under Public Chapter 569, "'allowed amount' means the cost of a prescription drug or device after applying pharmacy benefits manager or covered entity pricing discounts available at the time of the prescription claim transaction."

The second and fourth provisions place limits on the copays and coinsurance that can be charged by covered entities and dictate the method by which a covered entity's coinsurance and deductible amounts are calculated. As applied to self-insured ERISA plans, these provisions should be preempted because they require plan sponsors to structure their benefit plans in a particular way. In other words, unlike the provisions of the Arkansas law in *Rutledge*, these provisions force ERISA plans to adopt a specific scheme of substantive coverage and do more than merely increase costs or alter incentives for the plans.

The third provision prohibits covered entities from interfering with the patient's right to choose a contracted pharmacy or contracted provider of choice by, among other things, steering or offering financial or other incentives. This provision seems to go further than the provision of the North Dakota law found not to be preempted in the *Wehbi* case, which focused only on the PBM's accreditation and recertification requirements for pharmacies. It requires the plan to structure its benefits in a particular way by prohibiting the plan from having multiple network tiers.[12] As a result, the third provision of Public Chapter 569 should be preempted when applied to self-insured ERISA plans.

The eighth provision imposes disclosure obligations on covered entities, including self-insured plans. ERISA already includes similar transparency requirements. Requiring compliance with such a notice requirement with respect to participants in Tennessee seemingly would interfere with nationally uniform plan administration. This requirement is comparable to the state law requiring plans to provide claims data to state regulators for inclusion in a state health care database addressed by the Supreme Court in the *Gobeille* case. The Court determined the law was preempted because it intrudes on the extensive reporting and disclosure rules integral to ERISA's functioning.[13] Furthermore, these disclosure requirements seem more burdensome than the disclosure requirements in the North Dakota law found to not be preempted by ERISA in the *Wehbi* case.

As mentioned above, whether ERISA actually preempts the provisions of Public Chapter 569 will not be known for certain until the law is challenged in court or the State seeks to enforce the statute against a covered entity. In the absence of binding court precedent, employers with group health plans providing prescription drug benefits to employees in Tennessee should discuss the implications of the law, including whether any portion of it is preempted by ERISA, with their legal counsel.

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12 This provision is similar to "any willing provider" laws states have enacted, which have been found to be preempted if applied to self-insured ERISA plans. See Prudential Ins. Co. of Am. v. Nat'l Park Med. Ctr., Inc., 413 F.3d 897 (8th Cir. 2005).

13 See also DOL Opinion Letter 96-03A (concluding that Minnesota insurance continuation law imposing notice obligations on employers is preempted by ERISA).

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