Health Law Client Advisory: A Win for PBMs: Federal Court Holds D.C.'s Access Rx Act Preempted by ERISA

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In a decision handed down on March 19, 2009, the Pharmaceutical Care Management Association (PCMA) won a multi-year battle in federal court when the United States District Court for the District of Columbia held that the Access Rx Act (the "Act")[1] "impermissibly intrudes upon a field exclusively reserved for federal regulation."[2] This court's holding that the Act is preempted by the Employee Retirement Income Security Act (ERISA) marks a departure from a First Circuit opinion upholding a nearly identical Maine statute in the face of a preemption challenge.[3]

Access Rx Act

The District of Columbia Council passed the Act with the purported goal of lowering prescription drug prices. The challenged portion of the Act imposes fiduciary duties, financial terms, and certain disclosure requirements on pharmacy benefit managers (PBMs) through "covered entities," a term which includes, *inter alia,* insurers, health maintenance organizations, and employers that contract with another entity to provide prescription drug benefits to employees.[4] For example, the Act requires PBMs to pass on to covered entities, in full, any financial benefits the PBM might receive from a drug manufacturer in connection with utilization of prescription drugs by covered individuals. The Act also requires PBMs to provide specific financial and other cost information to covered entities upon request.[5] The Act took effect in 2004, and PCMA brought its ERISA preemption challenge shortly thereafter.

ERISA Preemption

In relevant part, ERISA preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan."[6] According to the Supreme Court, "[a] law 'relate[s] to' a covered employee benefit plan…if it [1] has a connection with or [2] reference to such a plan."[7] The Supreme Court also has found that the goal of ERISA's preemption clause "was to avoid a multiplicity of regulation in order to permit the nationally uniform administration of employee benefit plans."[8] Although two courts analyzing the District of Columbia (D.C.) statute and the Maine statute applied essentially the same test, the courts came to different conclusions regarding ERISA's preemptive scope.

First Circuit Decision

Before the Access Rx Act took effect in D.C., PCMA was already challenging a similar law in Maine; PCMA ultimately lost that challenge. In 2005, the First Circuit affirmed the United States District Court for the District of Maine's dismissal of PCMA's claim that the Maine Unfair Prescription Drug Practices Act (UPDPA)[9] which, like the Access Rx Act, imposes certain fiduciary duties on PBMs and requires specified disclosures and disgorgement of profits to covered entities was preempted by ERISA.

Applying the ERISA "relates to" analysis set forth above, the First Circuit first looked to whether UPDPA has a "connection with" ERISA plans. Citing to the goal of uniformity in administering plans, the First Circuit applied the test by analyzing whether UPDPA "precludes the ability of plan administrators to administer their plans in a uniform fashion."[10] Because UPDPA imposes certain fiduciary and disclosure duties on PBMs, and therefore permits (but does not require) plan administrators to alter their business relationship with the PBMs, the court found no impermissible "connection with" ERISA plans.[11]

Similarly, the First Circuit found that UPDPA did not include sufficient "reference to" an ERISA plan so as to be preempted by ERISA. The court conceded that UPDPA seeks to regulate PBMs that contract with employee health plans, including ERISA plans. However, because UPDPA also "operates upon" insurance companies and the state Medicaid program, the statute would "still be operable" even if any reference to employee health plans were deleted from the statute.[12] Thus, the court found no impermissible reference to ERISA plans. By finding that UPDPA did not meet either prong of the preemption test set forth by the Supreme Court, the court ruled against PCMA's challenge to UPDPA.

PCMA's Successful Challenge in the District of Columbia

Despite the similarity of the Access Rx Act and UPDPA, PCMA had greater success in federal court in the District of Columbia. The District Court for the District of Columbia acknowledged the First Circuit's finding in *Rowe*. Indeed, this same District Court had originally held that PCMA was collaterally estopped from challenging the Act because the case was so similar to the First Circuit case challenging the Maine statute. On appeal, the D.C. Circuit disagreed with the collateral estoppel holding, both because this area of law bears on the public interest, and because the United States Department of Labor (DOL) had recently proposed a regulation that would require PBMs to disclose certain financial information. This regulation, if implemented, could change the ERISA preemption analysis.

Upon analyzing PCMA's case on the merits, the District Court found the Act to fall within ERISA's preemptive scope. Although the District Court noted the "connection with" and "relates to" standards, and also cited to a seven-part test set forth by the Eighth Circuit to determine whether a state law is connected to an ERISA plan, the court's analysis focused more on the purpose of ERISA preemption: promotion of national uniformity in administering employee benefit plans.[13] The District Court also relied heavily on another Supreme Court case, *Fort Halifax Packing Co. v. Coyne,* 483 U.S. 1 (1987), that expressly addresses the goal of uniformity by finding that it would be difficult to achieve such uniformity if a plan must, *inter alia,* "process

claims in a certain way in some States but not in others; and to comply with certain fiduciary standards in some States but not others."[14] Claims processing is a key function of a PBM, and the Act imposes certain reporting requirements on prescription drug claims, as well as imposing fiduciary duties on PBMs. According to the District Court, "[b]y managing the relationship between an ERISA plan and a third-party service provider instrumental to the administration of the plan, the defendants, through the Act, improperly inject state regulation into an area exclusively controlled by ERISA."[15]

Moreover, although the DOL's proposed regulation is not yet in effect, the District Court found that it would, if anything, support the holding in this case. Similar to the Act, the proposed regulation would require PBMs to disclose information to plans, including compensation it will receive and conflicts of interested that may arise. The fact that the DOL believes that ERISA's scope includes the contractual relationship between PBMs and ERISA plans further supports the District Court holding (and possibly cuts against the First Circuit's holding to the contrary) that state laws attempting to govern the relationship between PBMs and ERISA plans are preempted by ERISA.[16]

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More than half of the states in the nation have proposed and rejected legislation similar to D.C.'s Access Rx Act and Maine's UPDPA. In fact, only a small handful of states[17] have enacted laws subjecting PBMs to fiduciary duties and other disclosure requirements. Given the holding of the recent case considering D.C.'s Access Rx Act, PBMs have reason to be hopeful that states will continue to refrain from passing similar legislation.

Endnotes

[1]D.C. Code §§ 48-831 *et seq.*

[2]*Pharmaceutical Care Management Ass'n. v. District of Columbia, et. al,* 2009 WL 711771 (D.D.C. Mar. 19, 2009).

[3]*See Pharmaceutical Care Management Ass'n. v. Rowe,* 429 F.3d 294 (1st Cir. 2005)

[4]D.C. Code § 48-831.02.

[5]D.C. Code § 48-832.01.

[6]29 U.S.C. 1144(a).

[7]*California Div. of Labor Standards Enforcement v. Dillingham Constr. N.A., Inc.,* 519 U.S. 316, 324 (1997) (internal citations omitted).

[8]*New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.,* 514 U.S. 645, 657 (1995).

[9]Me. Rev. Stat. Ann. tit. 22, § 2699.

[10]*Rowe,* 429 F.3d. at 302 (emphasis added).

[11]*Id.* at 303.

[12]*Id.* at 304.

[13]*PCMA v. District of Columbia,* 2009 WL at *6.

[14]*Id.* at *8, citing Fort Halifax Packing Co. v. Coyne, 483 U.S. 1, 9 (1987).

[15]*Id.*

[16]*Id.* at 9.

[17]*See, e.g.,* S.D. Codif. Laws § 58-29E-4 (requiring PBMs to make certain disclosures upon the request of a covered entity), and Vt. Stat. Ann. tit. 18, § 9472 (imposing fiduciary duties and requiring certain financial disclosures to health plans upon request, "unless the contract provides otherwise").

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