UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,	:		
Plaintiff,	:	Civil Action No.:	04-1082 (RMU)
v.	:	Document Nos.:	76, 77
DISTRICT OF COLUMBIA *et al.*,	:		
Defendants.	:		

MEMORANDUM OPINION

GRANTING IN PART THE PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT AND DENYING IN PART THE DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT

I. INTRODUCTION

This case comes before the court on the parties' motions for summary judgment. The plaintiff, Pharmaceutical Care Management Association ("PCMA"), is a national trade association representing pharmaceutical benefit management companies ("PBMs"). The plaintiff argues that the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. §§ 1001 *et seq.*, preempts Title II of the District of Columbia's Access Rx Act of 2004 ("Access Rx Act" or "the Act"), D.C. Code §§ 48-831 *et seq.* The defendants, on the other hand, contend that ERISA does not preempt the Access Rx Act because the Act does not regulate ERISA plans and has no connection with ERISA. As discussed in more detail below, by regulating the relationship between PBMs and ERISA plans, the Act impermissibly intrudes upon a field exclusively reserved for federal regulation.

II. BACKGROUND

A. Factual History

At issue in this case is the District of Columbia's attempt to regulate the relationship between PBMs and "covered entities" such as ERISA health plans, government agencies and insurance companies. Compl. ¶ 14. PBMs process claims for pharmaceutical drug benefits for over 200 million Americans. *Id.* As time passed, PBMs began to expand their services to include, *inter alia*, (1) establishing networks of pharmacies that provide discounted drugs to plan members; (2) negotiating rebate arrangements with drug manufacturers; (3) reviewing drug utilization to decrease prices and enhance safety; (4) creating therapeutic drug interchange programs; and (5) establishing generic drug substitution programs. *Id.* ¶ 15.

In response to rising prescription drug prices, the D.C. Council unanimously passed the Access Rx Act, which, in the Council's estimation, would lower the cost of prescription drugs. Mem. Op. (Dec. 21, 2004) at 2. On May 18, 2004, the Access Rx Act took effect. Compl. ¶ 1. Title II of the Act, the only portion that the plaintiff challenges, regulates PBMs by imposing fiduciary duties on them, as well as by requiring disclosure of certain financial information. *Id.* ¶ 3; Mem. Op. (Dec. 21, 2004) at 2. Specifically, Title II dictates that PBMs owe a fiduciary duty to "covered entities," which they must discharge in accordance with all applicable laws. D.C. CODE § 48-832.01(a). Title II also imposes several disclosure requirements on PBMs. For instance, PBMs must disclose to their customers "information showing the quantity of drugs purchased by the covered entity and the net cost to the covered entity for the drugs. This information shall include all rebates, discounts and other similar payments." *Id.* § 48-832.01(c)(1)(A). Furthermore, upon request PBMs must disclose to covered entities "all financial terms and arrangements for remuneration of any kind that apply between the [PBM]

and prescription drug manufacturer or labeler, including, without limitation, formulary management and drug substitution programs, educational support, claims processing and data sales fees." *Id.* § 48-832.01(c)(1)(B).

The Act also provides that when dispensing prescription drugs, a PBM may substitute a lower-priced therapeutically equivalent drug for a higher-priced drug. *Id.* § 48-832.01(d). But, "[i]f the substitute drug costs more than the prescribed drug, the [PBM] shall disclose to the covered entity the cost of both drugs and any benefit or payment directly or indirectly accruing to the [PBM] as a result of the substitution." *Id.* § 48-832.01(d)(2). The PBM must then "transfer in full to the covered entity any benefit or payment received . . . as a result of a prescription drug substitution." *Id.* § 48-832.01(d)(3). Finally, the statute only applies to contracts between PBMs and covered entities "entered into in the District of Columbia or by a covered entity in the District of Columbia." *Id.* § 48-832.02.

B. Procedural History

Because Title II imposes fiduciary duties and disclosure requirements on PBMs, as described *supra*, the plaintiff moved this court to enjoin the defendants from enforcing the Access Rx Act. Pl.'s Mot. for Prelim. Inj. The court granted preliminary injunctive relief to the plaintiff on December 21, 2004. *See generally* Mem. Op. (Dec. 21, 2004). The defendants appealed the court's decision to the D.C. Circuit, which remanded the case for this court to determine in the first instance whether the First Circuit's ruling in *PCMA v. Rowe*, 429 F.3d 294 (1st Cir. 2005) precluded the plaintiff from further challenging the validity of the Act under principles of collateral estoppel. *PCMA v. District of Columbia*, 522 F.3d 443 (D.C. Cir. 2008). Accordingly, the court examines the *Rowe* decision and its effect on this case.

1. The First Circuit's Decision in *Rowe*

The First Circuit in *Rowe* addressed the propriety of a statute in Maine that required PBMs to act as fiduciaries for certain covered entities[1] by "disclos[ing] conflicts of interest, disgorg[ing] profits from self-dealing, and disclos[ing] to the covered entities certain of their financial arrangements with third parties." *Rowe*, 429 F.3d at 299. To determine whether ERISA preempted the state statute, the court first analyzed the "high stakes" issue of whether PBMs are fiduciaries under ERISA. *Id.* at 300. The court explained that the state statute's "provisions requiring disclosure of conflicts of interest and payments from drug manufacturers are administrative provisions involving no discretion on the part of the PBMs, . . . are purely ministerial and simply not sufficient . . . to find that the PBMs are acting as fiduciaries under ERISA." *Id.* at 301. With that hurdle behind it, the court applied a two-part test in examining whether ERISA preempts the state statute. The test first probes whether the statute has a "connection with" an employment benefit plan and then asks whether the statute "references" such a plan. *Id.* at 302 (quoting *Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 324 (1997)).

Turning to the first prong, the court acknowledged that a principal concern under the "connection with" prong is "to avoid a multiplicity of regulation in order to permit the nationally uniform administration of employee benefit plans." *Id.* (quoting *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 657 (1995)). With that in mind, the court observed that the state statute left plan administrators with a "free hand" to "administer or

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[1] The Maine statute's definition of "covered entity" is slightly broader than that provided in D.C.'s Access Rx Act. The Maine statute applies to "health plans, labor union plans, association plans, insurance companies, HMOs, medical service organizations, and the state Medicaid program." *PCMA v. Rowe*, 429 F.3d 294, 304 (1st Cir. 2005). The Access Rx Act covers the same groups provided they utilize PBMs. *Compare* ME. REV. STAT. ANN. tit. 22, § 2699(1)(A) *with* D.C. CODE § 48-831.02(4)(A).

structure their plans in Maine precisely as they would elsewhere." *Id.* at 303. The court also noted that "[a]lthough the ERISA plans can re-evaluate their working relationships with the PBMs if they wish in light of the [requirements of the state statute], nothing in the [statute] compels them to do so." *Id.* Therefore, the court concluded that the statute did not have an "impermissible 'connection with' ERISA plans." *Id.*

Moving to the second part of the test, the court explained that an impermissible "reference to" an ERISA plan occurs "[w]here a State's law acts immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to the law's operation." *Id.* (quoting *Dillingham*, 519 U.S. at 325). The court easily determined that the Maine statute did not reference an ERISA plan under this standard because the statute "applies with respect to a broad spectrum of health care institutions and health benefit providers, including but not limited to ERISA plans." *Id.* at 304. In addition, due to the statute's broad application, the court reasoned that "[i]f the reference to employee health plans was deleted from the text of the [statute], [it] would still be operable." *Id.*

Finally, the court addressed a separate ground for ERISA preemption: whether the state statute provides an alternative enforcement mechanism for ERISA claims. *Id.* at 305 (citing *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133 (1990)). Because PBMs are not fiduciaries under ERISA, the court reasoned that the state statute has "no real bearing on the intricate web of relationships among the principal players in the ERISA scenario." *Id.* Accordingly, the court held that the statute did "not provide an alternative enforcement mechanism to ERISA's civil enforcement scheme and [was] not preempted." *Id.*

2. *Rowe's* Effect on the Plaintiff's Claims and Subsequent Proceedings

In light of the First Circuit's ruling addressing identical issues pertaining to an almost identical statute,[2] this court determined that *Rowe* precluded the plaintiff from litigating the validity of the Act, noting that the two cases "are closely aligned in time and subject manner." Mem. Op. (Mar. 6, 2007) at 11 (quoting *Montana v. United States*, 440 U.S. 147, 163 (1979)). On appeal, the Circuit disagreed, explaining that applying collateral estoppel would "freeze the development of the law in an area of substantial public interest." *PCMA*, 522 F.3d at 447. The Circuit also noted that practical considerations counsel against the application of collateral estoppel because eight months after this court issued its decision on collateral estoppel, the Department of Labor ("DOL") proposed a rule implementing ERISA that would require PBMs to "disclose certain financial information to the plans they serve." *Id.* (citing *Reasonable Contract or Arrangement Under § 408(b)(2)—Fee Disclosure*, 72 Fed. Reg. 70,988 (Dec. 13, 2007)). Observing that this proposed rule would require PBMs to disclose information similar to that required under the Act, the Circuit opined that it "may change the legal analysis regarding ERISA preemption," "particularly if the proposed rule is promulgated." *Id.* The Circuit then remanded the case for further consideration on the merits. *Id.*

Shortly thereafter, the court imposed a briefing schedule for the parties to submit cross-motions for summary judgment. Briefing was completed on October 14, 2008,[3] and the court now turns to the pending motions.

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[2] Between the court's first decision granting a preliminary injunction and the D.C. Circuit's remand to determine whether *Rowe* precluded the plaintiff's claims, the District of Columbia amended the Act to "conform the District's law to the Maine law to withstand constitutional and other legal challenges." Access Rx Act Clarification Temporary Amendment Act of 2006 ("Act Am."), 53 D.C. Reg. 40 (2006).

[3] The court appreciates the thoughtful and thorough briefing provided by the parties.

III. ANALYSIS

A. Legal Standard for a Motion for Summary Judgment

Summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Diamond v. Atwood*, 43 F.3d 1538, 1540 (D.C. Cir. 1995). To determine which facts are "material," a court must look to the substantive law on which each claim rests. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A "genuine issue" is one whose resolution could establish an element of a claim or defense and, therefore, affect the outcome of the action. *Celotex*, 477 U.S. at 322; *Anderson*, 477 U.S. at 248.

In ruling on a motion for summary judgment, the court must draw all justifiable inferences in the nonmoving party's favor and accept the nonmoving party's evidence as true. *Anderson*, 477 U.S. at 255. A nonmoving party, however, must establish more than "the mere existence of a scintilla of evidence" in support of its position. *Id.* at 252. To prevail on a motion for summary judgment, the moving party must show that the nonmoving party "fail[ed] to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322. By pointing to the absence of evidence proffered by the nonmoving party, a moving party may succeed on summary judgment. *Id.*

The nonmoving party may defeat summary judgment through factual representations made in a sworn affidavit if he "support[s] his allegations . . . with facts in the record," *Greene v. Dalton*, 164 F.3d 671, 675 (D.C. Cir. 1999) (quoting *Harding v. Gray*, 9 F.3d 150, 154 (D.C. Cir.

1993)), or provides "direct testimonial evidence," *Arrington v. United States*, 473 F.3d 329, 338 (D.C. Cir. 2006). Indeed, for the court to accept anything less "would defeat the central purpose of the summary judgment device, which is to weed out those cases insufficiently meritorious to warrant the expense of a jury trial." *Greene*, 164 F.3d at 675.

B. Legal Standard for Federal Preemption Under ERISA

The preemption doctrine is rooted in the Supremacy Clause of Article VI of the Constitution and stands for the general proposition that courts implement Congress's intent for a federal law to trump, and therefore supersede the enforceability of, a state law. *Fidelity Fed. Sav. & Loan Assoc. v. De La Cuesta*, 458 U.S. 141, 152-53 (1982); *see* U.S. CONST. art. VI, cl. 2.

> In all pre-emption cases, and particularly in those in which Congress has "legislated . . . in a field which the States have traditionally occupied," . . . we "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."

Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

The Court has recognized preemption "by express provision, by implication, or by a conflict between federal and state law." *Travelers*, 514 U.S. at 654. To determine whether a federal statute or regulation preempts state law, the court must evaluate: (1) the congressional intent to occupy the entire field and whether the pervasiveness of the regulatory scheme leaves no room for state supplementation; (2) the level of dominance of the federal interest in preventing state intervention; and (3) the danger of conflict between state laws and the administration of a federal program. *Pennsylvania v. Nelson*, 350 U.S. 497, 502-05 (1956). "Accordingly, 'the purpose of Congress is the ultimate touchstone' of pre-emption analysis."

Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992) (quoting *Malone v. White Motor Corp.*, 331 U.S. 497, 504 (1978)).

To discern Congress's intent the court "examine[s] the explicit statutory language and the structure and purpose of the statute." *Ingersoll-Rand Co.*, 498 U.S. at 138. This inquiry is "considerably simplified," *id.*, under ERISA because the text is "clearly expansive," *Travelers*, 514 U.S. at 655, in that it expressly preempts "any and all State laws insofar as they . . . relate to any employee benefit plan," 29 U.S.C. § 1144(a). The Court has remarked that this provision "indicates Congress's intent to establish the regulation of employee welfare benefit plans 'as exclusively a federal concern.'" *Travelers*, 514 U.S. at 656 (quoting *Alessi v. Raybestos-Manhattan*, 451 U.S. 504, 523 (1981)). In an effort to give meaning to the statutory language of ERISA in light of the presumption against preemption, the Court has explained that "[a] law 'relates to' an employment benefit plan, in the normal sense of the phrase, if it has a *connection with* or *reference to* such a plan." *Shaw v. Delta Air Lines*, 463 U.S. 85, 96-97 (1983) (emphasis added). An additional basis for preemption exists if a state law cause of action "duplicates, supplements, or supplants the ERISA civil enforcement remedy" because the state law cause of action "conflicts with the clear congressional intent to make the ERISA remedy exclusive." *Aetna Health Inc. v. Davila*, 542 U.S. 200, 209 (2004).

C. The Access Rx Act "Relates to" ERISA

1. Legal Standard for Determining Whether a State Law Has a "Connection With" an ERISA Plan

As with the phrase "relate to" the Supreme Court has expressed frustration with the phrase "connection with" because an "uncritical literalism" would lead to "infinite connections" being "the measure of pre-emption." *Travelers*, 514 U.S. at 656. The Court, instead, has instructed courts to assess both "'the objectives of the ERISA statute as a guide to the scope of

the state law that Congress understood would survive,' as well as [] the nature of the effect of the state law on ERISA plans." *Dillingham*, 519 U.S. at 325 (quoting *Travelers*, 514 U.S. at 656, 658-59).

As to Congress's objectives in enacting ERISA, the Court has stated that the "basic thrust" of ERISA's preemption provision is "to avoid a multiplicity of regulation in order to permit the nationally uniform administration of employee benefit plans." *Travelers*, 514 U.S. at 657; *Ingersoll-Rand*, 498 U.S. at 142 (noting that ERISA preemption "was intended to ensure that plans and plan sponsors would be subject to a uniform body of benefits law; the goal was to minimize the administrative and financial burden of complying with conflicting directives among States or between States and the Federal Government"). Indeed, this provision "displace[s] all state laws that fall within its sphere, even including state laws that are consistent with ERISA's substantive requirements." *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 739 (1985). However, "pre-emption does not occur . . . if the state law has only a tenuous, remote or peripheral connection with covered plans, as is the case with many laws of general applicability." *District of Columbia v. Greater Wash. Bd. of Trade*, 506 U.S. 125, 130 n.1 (1992).

To determine the strength of the connection between a state law and an ERISA plan, courts should also consider the effect of the state law on the ERISA plan. The Eighth Circuit has provided the following factors to guide a court's analysis:

> [1] whether the state law negates an ERISA plan provision, [2] whether the state law affects relations between primary ERISA entities, [3] whether the state law impacts the structure of ERISA plans, [4] whether the state law impacts the administration of ERISA plans, [5] whether the state law has an economic impact on ERISA plans, [6] whether preemption of the state law is consistent with other ERISA provisions, and [7] whether the state law is an exercise of traditional state power.

Shea v. Esensten, 208 F.3d 712, 718 (8th Cir. 2000) (quoting *Wilson v. Zoellner*, 114 F.3d 713, 717 (8th Cir. 1997)).

2. ERISA's Broad Preemptive Sweep Covers the Access Rx Act

The defendants assert that the Act "does not have an impermissible connection with ERISA-covered employee benefit plans, because it does not bind plan administrators to [a] particular choice and thus function as a regulation of an ERISA plan itself, nor does it preclude uniform administrative practice or the provision of uniform interstate benefit package . . . ." Defs.' Mot. at 12 (internal quotation marks omitted). Specifically, the defendants argue that the Act "imposes no restrictions on plans, plan fiduciaries, or plan sponsors." *Id.* According to the defendants, the Act "does not threaten uniformity because it allows plans, fiduciaries, and sponsors to administer or structure their plans in [states] precisely as they would elsewhere," and it "neither forbids a method for calculating benefits that ERISA permits nor requires certain benefits to be included in or excluded from a plan." *Id.* (internal quotation marks omitted).

The plaintiff counters that because "PBMs *administer* prescription drug benefit plans for their customers, [the Act], which imposes mandates on PBM administration of drug benefit plans, falls squarely within the zone of preemption." Pl.'s Mot. at 14. The plaintiff maintains that the Act attempts to "dictate the fiduciary and disclosure duties of persons that perform administrative functions for ERISA plans," and thereby "intrudes into areas of express ERISA concern." *Id.* at 15. For example, the plaintiff cites to the Act's provisions that "mandate PBM standards of conduct; disclosures to customers; and financial arrangements," which it states "create the potential for differing state-by-state requirements that would frustrate Congress's goal of minimizing the costs and burdens associated with ERISA plans." *Id.* at 16-17 (internal citations omitted). Furthermore, the plaintiff notes that the Act's requirement that PBMs

"divulge confidential information" also requires plans to "protect the confidentiality of the information." *Id.* at 17. In sum, the plaintiff believes that by imposing duties and regulating the relationship with an entity that plays "a central role in the administration of ERISA-regulated prescription drug benefit plans," the Act "cross[es] the line into the territory preempted by ERISA." Pl.'s Opp'n at 6.

As to the proposed DOL regulation that may require PBMs to disclose conflicts of interest and certain financial information, the defendants observe that the regulation is not yet in effect, and is, therefore, a nullity. Defs.' Mot. at 21. Furthermore, even if the rule was finalized, the defendants aver that the regulations do not preempt the Act because the rule has "no indicia of express preemption of state law," "so the presumption is that [the] DOL does not intend to abolish the application of valid state laws to administrative service providers simply because they provide services to ERISA plans." *Id.* And, the defendants note that the plaintiff has argued to the DOL that PBMs should be excluded from the proposed regulation. *Id.* at 20-21. The plaintiff protests that the proposed regulation governs key aspects of the relationship between PBMs and ERISA plans, in fact the same aspects that the Access Rx Act addresses. Pl.'s Mot. at 12-13. The plaintiff also clarifies that "it is not the regulation[], nor even the DOL, that preempts [the Act] – it is ERISA." Pl.'s Opp'n at 5.

In weighing the parties' arguments, the court first addresses the scope of ERISA preemption and then turns to the effect, if any, of the DOL proposed regulation. "ERISA makes clear that even indirect state action . . . may encroach upon the area of exclusive federal concern." *Alessi*, 451 U.S. at 525 (quoting ERISA, 29 U.S.C. § 1144(c)(2), defining "State" to include "any political subdivision [], or any agency or instrumentality of either, which purports to regulate, *directly or indirectly*, the terms and conditions of employee benefit plans covered by

this subchapter"). After reviewing ERISA's legislative history, the Supreme Court has observed that the focus of federal concern under ERISA "is on the administrative integrity of benefit plans." *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 15 (1987). Although the Supreme Court has not directly addressed whether state regulation of PBMs falls within the preemptive scope of ERISA, the Court has provided some guidance for courts examining whether a state law intrudes upon the uniform administration of ERISA plans.

In *Travelers*, the Court held that a New York law requiring hospitals to collect surcharges from patients covered by a commercial insurer but not from patients insured by a Blue Cross/Blue Shield plan did not have a sufficient indirect connection with the uniform administrative practice that ERISA was designed to preserve because the law "simply b[ore] on the costs of benefits and the relative costs of competing insurance to provide them." 514 U.S. at 660. And in *Fort Halifax*, the Court included within "ERISA administration" tasks such as "determining the eligibility of claimants, calculating benefit levels, making disbursements, monitoring the availability of funds for benefit payments and keeping appropriate records in order to comply with applicable reporting requirements." 482 U.S. at 9. The Court added that uniformity would be

> difficult to achieve [] if a benefit plan is subject to differing regulatory requirements in differing States. A plan would be required to keep certain records in some States but not in others; to make certain benefits available in some States but not in others; *to 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.

Id. (emphasis added).

With this guidance, the Third Circuit recently concluded that ERISA preempted a state professional malpractice claim against a non-fiduciary[4] administrator, because the claim went to "the essence of the function of an ERISA plan – the calculation and payment of the benefits due to a plan participant." *Kollman v. Hewitt Assocs., LLC*, 487 F.3d 139 (3d Cir. 2007). The Third Circuit explained that the concern of having different standards applicable to the same employer conduct applies to agents of employers "who undertake and perform administrative duties for and on behalf of ERISA plans." *Id.* at 148; *see also Custer v. Sweeney*, 89 F.3d 1156, 1165 (4th Cir. 1996) (concluding that a malpractice claim by a trustee was not preempted because "claims against third-party service providers to an ERISA plan do not implicate the essential functions of an employee benefit plan, such as funding, benefits, reporting and administration").

The defendants acknowledge that PBMs "facilitate the provision of prescription drug benefits to the benefits providers' insured, participants or subscribers." Defs.' Supp. Statement of Facts ¶ 5. Stated differently, PBMs, among other things, process prescription drug claims on behalf of "insurance companies, health maintenance organizations and private and public health plans and programs," including ERISA plans. *Id.* The Act places fiduciary duties on PBMs, D.C. CODE § 48-832.01(b), and requires PBMs to "transfer in full to the covered entity any benefit or payment received in any form by the [PBMs] as a result of a prescription drug

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[4] The parties dispute whether PBMs are fiduciaries under ERISA. Defs.' Mot. 12-15; Pl.'s Response to Defs.' Statement of Undisputed Facts ¶ 2. Circuits are split on whether ERISA preempts state regulation of non-fiduciaries. *Compare Rowe*, 429 F.3d at 305 *and Penny/Ohlmann/Nieman, Inc. v. Miami Valley Pension Corp.*, 399 F.3d 692 (6th Cir. 2004) *and Gerosa v. Savasta & Co.*, 329 F.3d 317, 328-30 (2d Cir. 2003) *with Kollman v. Hewitt Assocs. LLC*, 487 F.3d 139 (3d Cir. 2007) *and Custer v. Pan Am. Life Ins. Co.*, 12 F.3d 410, 419 (4th Cir. 1993) *and Consolidated Beef Indus., Inc. v. N.Y. Life Ins. Co.*, 949 F.2d 960, 964 (8th Cir. 1991) *and Gibson v. Prudential Ins. Co.*, 915 F.2d 414, 417-18 (9th Cir. 1990) *and Howard v. Parisian, Inc.*, 807 F.2d 1560, 1564 (11th Cir. 1987). In this case, even assuming PBMs are non-fiduciaries, the court concludes that ERISA preempts the regulations because, as discussed *infra*, the regulations impede uniform administration of ERISA plans. *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 657 (1995).

substitution,"[5] *id.* § 48-832.01(d)(3). In return, if a PBM discloses confidential information pursuant to one of the Act's many disclosure provisions, an ERISA plan[6] may not disclose that information without the consent of the PBM or order of the court.[7] *Id.* § 48-832(c)(2). By managing the relationship between an ERISA plan and a third-party service provider instrumental to the administration of the plan,[8] the defendants, through the Act, improperly inject

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[5] The plaintiff argues that the Act converts PBMs into ERISA fiduciaries, Pl.'s Mot. at 19 n.22, an argument rejected by the First Circuit in *Rowe*, 429 F.3d at 300-01. The First Circuit reasoned that PBMs were not ERISA fiduciaries because they "do not exercise discretionary authority or control in the management and administration of the plan." *Id.* at 301 (internal quotation marks omitted). But this Circuit's decision in *Chao v. Day* held that a fiduciary under ERISA, as defined in the disposition clause, "contains no 'discretion' requirement," thus, providing the plaintiff a strong argument that the Act would convert PBMs into ERISA fiduciaries by giving them "authority or control" over plan assets. 436 F.3d 234, 236-38 (D.C. Cir. 2006); 29 U.S.C. § 1002(21)(A)(i) (defining a fiduciary as one who "exercises any authority or control respecting management or disposition of its assets"). Because determining whether PBMs are ERISA fiduciaries does not control the outcome in this case, the court leaves the issue for another day.

[6] PBMs contract with entities other than ERISA plans, and therefore, the Act does not affect ERISA plans exclusively. But "even if a state law does not expressly concern an employee benefit plan, it will still be preempted insofar as the law applies to a benefit plan in particular cases." *Bd. of Trustees of Hotel & Restaurant Employees Local 25 v. Madison Hotel, Inc.*, 97 F.3d 1479, 1487 (D.C. Cir. 1996) (quoting *Boren v. N.L. Indus., Inc.*, 889 F.2d 1463, 1466 (5th Cir. 1989)).

[7] The parties disagree about the economic impact the Act will have on ERISA plans. Defs.' Mot. at 2 (stating that the Act was "designed to slow down rising pharmaceutical costs"); Pl.'s Opp'n at 2; Pl.'s Statement of Facts ¶¶ 8-9 (noting that the "Directors of the Bureau of Competition, Bureau of Economics and Office of Policy Planning of the FTC have concluded that disclosure requirements in state legislative proposals similar to [the Act] are likely to increase rather than decrease the costs of PBM services").

[8] The court notes that although "the field of health care [is] a subject of traditional state regulation," *Pegram v. Herdrich*, 530 U.S. 211, 237 (2000), the preemption clause displaces "all state laws that fall within its sphere, even including state laws that are consistent with ERISA's substantive requirements," *Mackey*, 486 U.S. at 829.

state regulation into an area exclusively controlled by ERISA.[9] *Fort Halifax*, 482 U.S. at 9 (stating that ERISA administration includes the "process[ing] [of] claims"); *Travelers,* 514 U.S. at 661 (explaining that ERISA preemption "was meant to sweep more broadly than 'state laws dealing with the subject matters covered by ERISA[,] reporting, disclosure, fiduciary responsibility, and the like'" (quoting *Shaw*, 463 U.S. at 98)); *E.I. DuPont de Nemours & Co. v. Sawyer*, 517 F.3d 785, 800 (5th Cir. 2008) (observing that "[f]or purposes of ERISA preemption the critical distinction is not whether the parties to a claim are traditional ERISA entities in some capacity, but instead whether the state law affects an aspect of the relationship that is comprehensively regulated by ERISA"); *Kollman,* 487 F.3d at 150 (recognizing that the "calculation and payment of the benefit due to a plan participant" is an essential administrative function of ERISA plans); *but see Sommers Drug Stores Co. Employee Profit Sharing Trust v. Corrigan Enters., Inc.*, 793 F.2d 1456, 1467-68 (5th Cir. 1986) (stating that "courts are more likely to find that a state law relates to a benefit plan if it affects relations among the principal ERISA entities – the employer, the plan, the plan fiduciaries, and the beneficiaries – than if it affects relations between one of these entities and an outside party, or between two outside parties with only an incidental effect on the plan").

This determination is bolstered by ERISA's statutory framework and by the DOL's proposed regulation. First as to the statute, ERISA allows fiduciaries to contract with a "party in

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[9] The First Circuit, in *Rowe*, ended its "connection" analysis after determining that the Maine statute "[i]n no way [] circumscribe[s] the ability of plan administrators to structure or administer their ERISA plans." 429 F.3d at 303. Although determining whether a state law binds plan administrators may be an important factor, *Cal. Division of Labor Stds. Enforcement v. Dillingham Constr. N.A.*, 519 U.S. 316, 332 (1997) (concluding that ERISA did not preempt a California state law in part because the law "does not bind ERISA plans to anything"), analyzing whether a state law "affect[s] the uniform administrative *practice*" of ERISA is also important, *Travelers*, 514 U.S. at 660 (emphasis added). And the First Circuit simply did not address whether the nature of PBM services qualified as ERISA administration.

interest"[10] for "services necessary for the establishment or operation of the plan, if no more than reasonable compensation is paid therefore." 29 U.S.C. § 1108(b)(2).[11] Because PBMs are "parties in interest," to contract with an ERISA fiduciary, PBMs must provide a service "necessary for the establishment or operation of the plan." *Id.* This provision conforms with the court's understanding, discussed *supra*, that PBMs provide ERISA plans with essential administrative services, which states may not regulate.[12] *Ingersoll-Rand*, 498 U.S. at 142 (opining that ERISA's preemption clause is designed to foreclose states from subjecting ERISA administration "to the peculiarities of the laws of each jurisdiction").

Second, the proposed DOL regulation supports this reading of ERISA by clarifying the meaning of "reasonable" in § 1108(b)(2). 72 Fed. Reg. 70988 (stating that the regulation "will ensure the disclosure of information to assist plan fiduciaries in assessing the reasonableness of the compensation or fees paid for services that are rendered to the plan and the potential for conflicts of interest that may affect a service provider's performance"). The proposed regulation would require a PBM to disclose to the plan "the compensation it will receive, directly or indirectly, and any conflicts of interest that may arise in connection with its services to the plan." *Id.* at 70,989. The DOL's initial interpretation of ERISA's scope, as demonstrated in the

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[10] ERISA defines "'party in interest,' as to an employee benefit plan [as] . . . a person providing services to such a plan." 29 U.S.C. § 1002(14)(B).

[11] ERISA prevents a plan fiduciary from engaging in a transaction, "if he knows or should know that such transaction constitutes a direct or indirect . . . transfer to, or use by or for the benefit of, a party in interest, of any assets of the plan" except as provided in 29 U.S.C. § 1108. 29 U.S.C. § 1106(a)(1).

[12] The defendants argue that this would lead to the preemption of regulations pertaining to "*every* entity with whom an ERISA plan contracts." Defs.' Opp'n at 8. The court disagrees because the "ERISA administration," as described in *Fort Halifax*, does not reach as far as the defendants' fear. *See Painters of Phila. Dist. Council No. 21 Welfare Fund v. Price Waterhouse*, 879 F.2d 1146, 1153 n.7 (3d Cir. 1989) (holding that ERISA "does not generally preempt state professional malpractice actions").

proposed regulation, includes PBM's contractual relationship with ERISA plans and confirms the court's reading of ERISA. *Id.* (explaining that "a pharmacy benefit manager that contracts with an employee benefit plan to manage the plan's prescription drug program would be covered as a service provider to the plan providing third party administration or recordkeeping, and possibly consulting, services"); *Wyeth v. Levine*, 2009 WL 529172, at *11 (Mar. 4, 2009) (recognizing that "[w]hile agencies have no special authority to pronounce on pre-emption absent delegation by Congress, they do have a unique understanding of the statutes they administer"). Because the Access Rx Act "creates the potential for the type of conflicting regulation of benefit plans that ERISA pre-emption was intended to prevent," the Act must yield to ERISA's preemptive force. *Fort Halifax*, 482 U.S. at 14. Having concluded that the Act has an impermissible connection with ERISA and is therefore preempted, the court need not traverse the parties' remaining preemption arguments.

IV. CONCLUSION

For the foregoing reasons, the court grants in part the plaintiff's motion for partial summary judgment and denying the defendants' motion for partial summary judgment. An Order consistent with this Memorandum Opinion is separately and contemporaneously issued this 19th day of March, 2009.

RICARDO M. URBINA
United States District Judge