No. 09-7042

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,
Plaintiffs-Appellees

v.

DISTRICT OF COLUMBIA, et al.,
Defendants-Appellants.

On Appeal from the United States District Court for the District of Columbia
(R. Urbina)
Civil Action No. 04-1082

BRIEF OF THE SECRETARY OF LABOR, HILDA L. SOLIS, AS AMICUS CURIAE IN SUPPORT OF APPELLANTS

CAROL A. DE DEO
Deputy Solicitor of Labor for
National Operations

TIMOTHY D. HAUSER
Associate Solicitor

NATHANIEL I. SPILLER
Counsel for Appellate and Special Litigation

MELISSA BOWMAN
Attorney
United States Department of Labor
200 Constitution Ave., N.W., Suite N-4611
Washington, DC 20210
Phone: (202) 693-5281

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STATEMENT OF INTEREST

The Secretary of Labor bears primary responsibility for interpreting and enforcing Title I of the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 et seq. In this capacity, she has a strong interest in ensuring that courts correctly apply ERISA's preemption provisions and in expressing her disagreement with the district court's conclusion that ERISA preempts Title II of the District of Columbia Access Rx Act of 2004, D.C. Code § 48-831 et seq. ("D.C. Act"). The Secretary has authority to file this brief under F.R.A.P. Rule 29(a).

STATEMENT OF THE ISSUE

The question presented is:

Whether the D.C. Act, which regulates the relationship between pharmacy benefit managers ("PBMs") and their health benefit provider customers, "relates to" employee benefit plans within the meaning of ERISA section 514(a), 29 U.S.C. § 1144(a), or conflicts with the remedial scheme set forth in ERISA section 502(a), id. § 1132(a), or otherwise conflicts with substantive provisions of ERISA or its regulations, and is, therefore, preempted.

STATEMENT OF FACTS

1. The D.C. Act

The D.C. Act is a consumer protection law that regulates PBMs for the purpose

of making prescription drugs more affordable and increasing the overall health of District of Columbia ("District") residents. D.C. Code § 48-831.01 et seq. (Supp. 2009). The Act defines "pharmacy benefits management" as a "service provided to covered entities to facilitate the provision of prescription drug benefits to covered individuals for dispensation within the District of Columbia, including negotiating pricing and other terms with drug manufacturers and retail pharmacies." D.C. Code § 48-831.02(16). See id. §§ (A)–(E) (listing "pharmacy benefits management" services); see also Pharmaceutical Care Management Ass'n v. Rowe, 429 F.3d 294, 298 (1st Cir. 2005).

The D.C. Act is modeled on the Maine law that the First Circuit upheld in Rowe against an ERISA preemption challenge. Joint Appendix ("JA") 122. Title II of the Act provides that PBMs owe "a fiduciary duty to a covered entity." D.C. Code § 48-832.01(a).[1] This duty must be discharged "in accordance with all applicable laws" and applies "to the practices set forth in [Title II of the D.C. Act]." Id. The specified "practices" require PBMs to transfer to covered entities any financial benefits they receive from pharmaceutical manufacturers based, for example, on volume of sales or

[1] "Covered entity" is defined broadly to include, among other similar entities, "[a]ny hospital or medical service organization, insurer, health coverage plan, or health maintenance organization licensed in the District that contracts with another entity to provide prescription drug benefits for its customers or clients." D.C. Code § 48-831.02(4).

market share. Id. §§ 48-832.01(b)(2) and (d)(3). They also require PBMs to notify covered entities of "any activity, policy or practice" that presents "any conflict of interest" with their fiduciary duties under the Act. Id. § 48-832.01(b)(1)(C). PBMs must also disclose on request "all rebates, discounts and other similar payments," as well as "all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and any prescription drug manufacturer." Id. § 48-832.01(c)(1). A PBM may designate disclosed information as "confidential" and require the covered entity to seek its consent or court approval before release. Id. § 48-832.01(c)(2). The D.C. Act is enforced by "a fine of not more than $10,000 per violation." D.C. Act § 48-832.03.[2]

2. The decision below

The Pharmaceutical Care Management Association ("PCMA"), a trade association representing PBMs, challenged Title II of the D.C. Act on ERISA preemption grounds. JA 119. On March 19, 2009, the district court upheld this challenge. JA 134. While recognizing that this case raises "identical issues

[2] Violations of the D.C. Act constitute violations of the District of Columbia Consumer Protection Procedures Act, D.C. Code § 28-3901 et seq. D.C. Act § 48-832.03. The District maintains that only the Attorney General may bring an enforcement action under the D.C. Act. See Brief for Appellants in No. 09-7042, at 46-47 (Aug. 6, 2009).

pertaining to an almost identical statute" that the First Circuit upheld in Rowe,[3] JA 122, the district court concluded that the D.C. Act, even if it does not bind plan administrators, nevertheless impermissibly seeks to manage the relationship between an ERISA plan and a third-party service provider "instrumental to the administration of the plan." JA 131; compare Rowe, 429 F.3d at 87 n.9. The court focused on "whether the nature of PBM services qualified as ERISA administration," JA 132 n.9, and identified two requirements that it considered to be the regulation of "essential administrative services": the imposition of fiduciary responsibilities on PBMs, and the requirement that PBMs disclose confidential information to customers, including plans. JA 130-31.

In further support of its understanding that PBMs provide ERISA plans with essential services that cannot be regulated by a state, the district court cited the Secretary's proposed regulation to impose specific fee disclosure

[3] Applying preemption tests established by Supreme Court precedent, the Rowe court looked to whether the Maine statute had an impermissible "connection with" or "reference to" ERISA plans, and whether it conflicted with ERISA's remedial scheme. Rowe, 429 F.3d at 303. It determined, under the "connection with" test, that the Maine law regulating PBMs did not affect the way in which employee benefit plans administered or structured their plans and thus did not prevent the nationally uniform administration of employee benefit plans. Id. at 302. The court also found that because the Maine law applied equally to a number of non-ERISA entities, it was a law of general application that did not have an improper "reference to" ERISA. Id. at 304. In addition, the court rejected PCMA's argument that the Maine law conflicted with ERISA's remedial scheme. Id. at 305. The court noted that the Maine law did not affect "any of the principal players in the ERISA scenario" since it only regulated service providers, which ERISA does not directly regulate. Id.

requirements on plan service providers, JA 133-34. The court opined that the similarity in scope and focus between the D.C. Act and the Secretary's proposal presented a potential for "the type of conflicting regulation of benefit plans that ERISA pre-emption was intended to prevent." Id.

SUMMARY OF THE ARGUMENT

Consistent with numerous state laws directly affecting ERISA plan service providers, the D.C. Act simply regulates the commercial conduct of PBMs and affords ERISA-covered plans precisely the same protections afforded all other customers of PBM services. Because the D.C. Act regulates PBMs, not as ERISA actors, but in their capacity as commercial actors, it does not impermissibly interfere with uniform plan administration or present the potential for conflicting regulation that is the object of ERISA preemption. The D.C. Act also does not have an improper "reference to" plans, but instead even-handedly imposes the same requirements on PBMs in their commercial relationships with plans and non-plans alike. Nor does the D.C. Act conflict with ERISA's civil enforcement scheme or with any substantive requirement of ERISA. Moreover, the Secretary's proposed regulation of service-provider fee disclosures does not affect whether the D.C. Act is preempted. Therefore, the Court should reject the district court decision and not create a conflict with the First Circuit's Rowe decision.

ARGUMENT

ERISA DOES NOT PREEMPT THE D.C. ACT'S REGULATION OF PHARMACY BENEFIT MANAGERS

A. The ERISA Preemption Standard

In considering whether state law is preempted by ERISA, "the starting presumption [is] that Congress does not intend to supplant state law."[4] New York State Conference of Blue Cross v. Travelers Ins., 514 U.S. 645, 654 (1995). State laws "in fields of traditional state regulation" are afforded an "'assumption that the historical police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" Id. at 655 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)); see id. at 657 ("nothing in the language of [ERISA] or the context of its passage indicates that Congress chose to displace general health care regulation, which historically has been a matter of local concern"); see also Wyeth v. Levine, 129 S. Ct. 1187, 1194-95 (2009); Rush Prudential HMO, Inc. v. Moran, 536 U.S. 355, 381 n.11 (2003); DeBuono v. NYSA-ILA Medical and Clinical Services Fund, 520 U.S. 806, 815 (1997); Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996); Hillsborough County v. Automated Medical Laboratories,

[4] "State law" and "State" are defined terms under ERISA that expressly include laws of the District of Columbia. 29 U.S.C. § 1144(c).

Inc., 471 U. S. 707, 716 (1985); Rowe, 429 F.3d at 301.

Federal preemption may be "by express provision, by implication, or by a conflict between federal and state law." Travelers, 514 U.S. at 654. Section 514(a) of ERISA expressly provides that ERISA preempts "any and all State laws insofar as they . . . relate to any employee benefit plan" covered by the statute, 29 U.S.C. § 1144(a). Under ERISA, "[a] law 'relates to' an employee 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, Inc., 463 U.S. 85, 96-97 (1983); accord, e.g., Travelers, 514 U.S. at 656. Because of the "indeterminacy" of "relate to" and "connection with," and the need not "to read the presumption against pre-emption out of the law," however, courts are instructed to eschew "uncritical literalism" of the "unhelpful" statutory text and to "look instead to the objectives of the ERISA statute as a guide to the scope of the state law that Congress understood would survive." Id. at 655-656; accord Egelhoff v. Egelhoff, 532 U.S. 141, 147 (2001); DeBuono, 520 U.S. at 815; Cal. Div. of Labor Standards Enforcement v. Dillingham, 519 U.S. 316, 334 (1997). Generally, state laws that undermine those objectives or address the same subject matter as ERISA are preempted. See Travelers, 514 U.S. at 661; LeBlanc v. Cahill, 153 F.3d 134, 147 (4th Cir. 1998); 29 U.S.C. § 1001(b) (general statement of ERISA policy objectives).

The overall purpose of ERISA's preemption clause 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. Under ERISA "connection with" analysis, ERISA preemption encompasses not only "'state laws dealing with the subject matters covered by ERISA,'" id. at 661 (citing Shaw, 463 U.S. at 98 & n.19), but also state laws that "mandate[] employee benefit structures or their administration," id. at 658, such as by "bind[ing] plan administrators to any particular choice," or by "preclud[ing] uniform administrative practice or the provision of a uniform interstate benefit package if a plan wishes to provide one." Id. at 659-660; see Egelhoff, 532 U.S. at 146-47. Such laws are generally ones that "implicate the relations among the traditional ERISA plan entities, including the principals, the employer, the plan, the plan fiduciaries, and the beneficiaries." LeBlanc, 153 F.3d at 149; see also Sommers Drug Stores Co. Employee Profit Sharing Trust v. Corrigan Enter., Inc., 793 F.2d 1456, 1467 (5th Cir. 1986).

ERISA does not, however, preempt a state law that, through "indirect economic influence," "simply bears on the costs of benefits" or other administrative costs or decisions, since such laws "leave plan administrators right where they would be in any case, with the responsibility to choose the best overall coverage for the money." Travelers, 514 U.S. at 659-660, 662; see

DeBuono, 520 U.S. at 806; Mackey v. Lanier Collection Agency & Service, Inc., 486 U.S. 825, 841 (1988). More generally, state laws having "'only a tenuous, remote, or peripheral connection with covered plans, as is the case with many laws of general applicability,'" are not preempted. Travelers, 514 at 661 (citation omitted).

A "reference to" ERISA plans may also cause a state law to be preempted. Under this analysis, a state law is preempted by ERISA section 514 if an ERISA plan is "essential" to the operation of the law" or the law acts "immediately and exclusively" upon an ERISA plan. Dillingham, 519 U.S. at 325.

The Act's civil enforcement scheme set forth in section 502(a) of ERISA, 29 U.S.C. § 1132(a), also implicitly preempts state-law remedies that duplicate or supplement ERISA claims. See Aetna Health Inc. v. Davila, 542 U.S. 200, 216 (2004); Ingersoll-Rand Co. v. McClendon, 498 U.S. 133, 136 (1990); Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41, 43 (1987). Under section 502(a), however, only the Secretary and fiduciaries, participants and beneficiaries have standing to bring ERISA claims. Non-fiduciary service providers are not among the parties who can bring such a claim.

Finally, state laws that conflict with ERISA statutory or regulatory requirements are preempted. See Boggs v. Boggs, 520 U.S. 833, 841 (1997); cf. Travelers, 541 U.S. at 654. State and federal law conflict when compliance with

both laws is not possible, or when compliance with the state law will frustrate the purpose of the federal law. Boggs, 520 U.S. at 844.

B. The D.C. Act Does Not Have An Impermissible "Connection With" ERISA Plans

The D.C. Act is a consumer protection law enacted under the District's police powers to regulate local commerce and to protect the public in the general area of health-care regulation. Imposing disclosure and cost-saving pass-back requirements on PBMs, it aims to ensure that health care providers doing business with PBMs understand and receive the cost-saving benefit of any deals that the PBMs negotiate with pharmaceutical manufacturers. ERISA-covered plans are affected by the D.C. Act in their capacity as customers of PBM services in exactly the same manner that every other user of the same services is affected. As such, the D.C. Act does not have an impermissible "connection with" employee benefit plans.

The D.C. Act does not interfere with the objectives of the ERISA statute, which act "as a guide to the scope of the state law that Congress understood would survive." Travelers, 514 U.S. at 655-656. Those objectives include safeguarding employees from "'such abuses as self dealing, imprudent investing, and misappropriation of plan funds,'" enabling "'both participants and the Federal Government to monitor the plans' operations,'" and ensuring that employees received benefits from accumulated funds. Dillingham, 519

US at 326-327; Fort Halifax Packing Co. v. Coyne, 482 U.S. 1, 15 (1987) (citing legislative history); see 29 U.S.C. § 1001(b). The D.C. Act does not regulate any of those subject matters.

The D.C. Act also does not interfere with the principal purpose of ERISA preemption, which 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. Uniformity is threatened when "an employer's administrative scheme would be subject to conflicting requirements." Fort Halifax, 482 U.S. at 10. Interference with such uniformity occurs when a state law "mandate[s] employee benefit structures or their administration," "bind[s] plan administrators to any particular choice," or "precludes uniform administrative practice." Travelers, 514 U.S. at 658-660. The D.C. Act, however, does not mandate plan terms or otherwise restrict the plan fiduciaries' administration of plans or the plan sponsors' flexibility to design their plans. Unlike ERISA, which is focused on protecting the interests of participants and beneficiaries by establishing requirements for the conduct of plan fiduciaries, see 29 U.S.C. §§ 1104, 1109, the D.C. Act is focused on the commercial activities of a particular kind of service provider. For this reason, the First Circuit found the virtually identical Maine law not to be preempted. See Rowe, 429 F.3d at 303.

The district court thus erred in concluding, contrary to Rowe's analysis, that the D.C. Act's imposition of fiduciary obligations on PBMs in their relationship to their customers, and placement of restrictions on the information those customers can disclose, runs afoul of ERISA's goal of promoting uniform plan administration. The D.C. Act simply requires that PBMs meet state-law fiduciary standards in their dealings with all their customers, plan and non-plan alike. Nothing in the D.C. Act alters the scope of fiduciary duties owed to participants under ERISA or expands the scope of persons who are regulated as "fiduciaries" under ERISA. See 29 U.S.C. §§1002(21)(A), 1104. Rather, the PBMs' fiduciary duty is "owed . . . to a covered entity," shall be "discharge[d] . . . in accordance with applicable law," and pertains only "to the practices set forth in [Title II of the D.C. Act]." D.C. Act § 48-832.01(a). It does not pertain to other practices not regulated by Title II, such as those listed in the definition of "pharmacy benefits management" but not the subject of any Title II requirement. Id. §§ 48-831.02(16)(A)–(E).[5] The Act contains no requirements relating to the key obligations and functions of employee benefit plans or plan fiduciaries

[5] For instance, "[p]harmacy benefits management" includes "[c]laims processing," "[c]linical formulary development," "c]ertain patient compliance, therapeutic intervention, . . . [and d]isease management programs." Id. This definition appears in Title I and applies to all titles of the D.C. Act. Title II, however, contains no requirements pertaining to these services.

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." Fort Halifax, 482 U.S. at 9. Nor does it intrude upon or conflict with any disclosure obligation mandated by ERISA. See Rowe, 429 F.3d at 303; see generally 29 U.S.C. §§ 1021-1025 (reporting and disclosure requirements). ERISA's purposes are in no way threatened by a general requirement that PBMs act as fiduciaries to their customers, including plans, and disclose their financial arrangements and conflicts of interest.[6] Thus, like the Maine Act, the D.C. Act avoids preemption by not regulating plan administration.[7] See Rowe, 429 F.3d at 301.

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[6] There may be circumstances where a PBM functions as an ERISA fiduciary by engaging, for instance, in claims management and adjudication. See, e.g., Varity Corp. v. Howe, 516 U.S. 489, 511 (1996). Under ERISA, however, a person is a fiduciary only "to the extent" he engages in certain discretionary management or administrative control, or provides investment advice, "with respect to a plan." 29 U.S.C. § 1002(21)(A). Thus, a fiduciary with respect to one function is not necessarily a fiduciary with respect to all functions. Here, the District is not regulating PBMs' conduct as ERISA fiduciaries, but merely their conduct as service providers. See E.I. Dupont de Nemours, & Co. v. Sawyer, 517 F.3d 785, 800 (5th Cir. 2008) ("[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 relevant state law affects an aspect of the relationship that is comprehensively regulated by ERISA").

[7] The D.C. Act's requirement that covered entities must protect the confidentiality of information from PBMs, which is the only provision that can be viewed as limiting actions permitted by ERISA, "does not provide an

Quite simply, the D.C. Act focuses on the relationship between PBMs and their customers, not on the relationships between any of the principal entities involved in the administration of employee benefit plans – plans, fiduciaries, participants and beneficiaries, and employers or employee organizations that sponsor plans. See LeBlanc, 153 F.3d at 149. Such purely commercial relationships between service providers and plans do not bear on ERISA's core concerns. See Paulsen v. CNF, Inc., 559 F.3d 1061, 1083 (9th Cir. 2009); United Wire, Metal & Mach. Health & Welfare Fund v. Morristown Memorial Hosp., 995 F.2d 1179, 1193 (3d Cir. 1993); Sommers Drug Stores, 793 F.2d at 1467. Rather, the D.C. Act is simply one of "myriad state laws in areas traditionally subject to local regulation, which Congress could not possibly have intended to eliminate." Travelers, 514 U.S. at 668.

Preemption of the D.C. Act would, however, undermine ERISA's protective purposes by depriving plans and their participants of the protections

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adequate basis to sustain a facial challenge." Chicanos Por La Causa, Inc. v. Napolitano, 558 F.3d 856, 866 (9th Cir. 2009). The requirement applies only to information that the covered entity requests for which the PBM denies consent to disclose. Under the D.C. Act, a PBM's compliance with a disclosure request and invocation of confidentiality must be "in accordance with all applicable laws," necessarily including ERISA. D.C. Act.§ 48-832.01(a), (c). Therefore, any potential conflict with ERISA's reporting or disclosure obligations is currently merely "a speculative, hypothetical possibility." Chicanos Por La Causa, 558 F.3d at 866; accord Rice v. Norman Williams Co., 458 U.S. 654, 659 (1982).

the District has deemed necessary for all other similarly-situated customers. Indeed, if the District had excluded PBMs insofar as they service ERISA plans from the Act's coverage, that itself could have triggered ERISA preemption under the "reference to" prong discussed below. The inclusion in the D.C. Act of PBMs providing services to ERISA plans on an equal basis with PBMs servicing all other covered entities does not. See, e.g., Mackey, 486 U.S. at 841 (preempting state law that exempted only ERISA plans from generally applicable state garnishment procedures but not preempting general garnishment statute as applied to ERISA plans). Placing plans in a less protective position than other entities dealing with service providers is not consistent with Congress' intent in enacting ERISA.

For this reason, the line the district court drew between the regulation of essential and non-essential administrative services provided to plans by service providers is analytically flawed. Employee benefit plans necessarily transact with a wide range of service providers, encompassing a vast array of critical services, including insurance, banking, and securities brokerage; and legal, accounting, actuarial, and medical and related ancillary services. ERISA was not intended to supplant the body of state law regulating these transactions and services or place ERISA plans in a "fully insulated legal world." United Wire, 995 F.2d at 1193. In fact, ERISA clearly contemplates plans being subject to the

same state-law protections and duties as other non-ERISA parties by providing that ERISA plans may "sue and be sued." 29 U.S.C. § 1132(d)(1).[8]

If plans as a rule are not immune from generally applicable state laws that do not regulate the ERISA-covered operations of the plan itself, the same is surely true of service providers who contract with plans. It does not make sense to base the determination of whether a state law governing service provider conduct is preempted on an ad hoc, largely subjective assessment of how essential or nonessential the services are. For example, the services attorneys and accountants provide to plans are surely essential to proper plan administration, but it has widely been established that ERISA does not displace state malpractice claims. See, e.g., Custer v. Sweeney, 89 F.3d 1156, 1167 (4th Cir. 1996); Airparts Co. v. Custom Benefit Servs. of Austin, 28 F.3d 1062, 1064 (10th Cir. 1994); Harmon City, Inc. v. Nielsen & Senior, 907 P.2d 1162, 1169 (Utah 1995) (listing cases). Accordingly, service providers to plans must abide

[8] In Mackey, the Supreme Court relied on the ERISA "sue or be sued" clause to conclude that plan assets may be garnished just like the assets of other entities. 486 U.S. at 825-26. As construed in Mackey, the clause provides textual support for the principle that ERISA plans acting in a commercial capacity are not generally immune from the laws that apply to other commercial actors. The inference to be drawn here from this principle is that the commercial relationship between ERISA plans and pharmaceutical companies, or between ERISA plans and the intermediary PBMs, should be subject to the same generally applicable state laws that affect the commercial relationship between any entity and PBMs or pharmaceutical companies.

by state contract law, tort law, malpractice law, professional standards, and all the other obligations that govern marketplace and professional conduct generally.

Since the D.C. Act is well within the District's traditional regulatory authority in the area of health care and commercial market regulation, does not implicate ERISA relationships or concerns and does not mandate particular benefit structures or bind administrators to particular choices, it is analogous to the state laws upheld by the Supreme Court in Travelers and its progeny (see, e.g., Dillingham and DeBuono). Therefore, the D.C. Act has no impermissible "connection with" ERISA plans.

C. The D.C. Act Does Not Have An Impermissible "Reference To" ERISA Plans

The Supreme Court has held that state laws impermissibly "refer[] to" plans, and thus are preempted, when they act "immediately and exclusively upon ERISA plans" or "where the existence of ERISA plans is essential to the law's operation." Dillingham, 519 U.S. at 325. The D.C. Act does not "refer[] to" ERISA plans in this relevant sense. As the First Circuit held with respect to its Maine counterpart: "The existence of ERISA plans is not at all essential to the operation of [the law]. The [law] applies regardless of whether PBMs are serving ERISA plans. The law applies with respect to a broad spectrum of health care institutions and health benefit providers, including but not limited to

ERISA plans." Rowe, 429 F.3d at 304; see n.1 supra (D.C. Act's definition of "covered entity"). The district court in this case agreed with this aspect of the Rowe decision. JA 131 n.6. For the reasons stated in Rowe, this conclusion is completely correct.

D. The D.C. Act Falls Outside the Scope Of ERISA's Exclusive Civil Enforcement Scheme

Because the ERISA civil enforcement scheme is exclusive, claims for violations of ERISA cannot be duplicated or supplemented by state-law remedies. Aetna Health, 542 U.S. at 216; Ingersoll-Rand, 498 U.S. at 136; Pilot Life, 481 U.S. at 43. The D.C. Act does not conflict with ERISA's exclusive civil enforcement scheme because it sets forth a distinct legal regime that does not duplicate or supplement ERISA's remedies for ERISA violations. Predicated on a completely different set of duties, rights and relationships, the Act does not regulate the relationships between ERISA actors as ERISA actors. See Rowe, 429 F.3d at 305 ("PBMs are outside of the 'intricate web of relationships among the principal players in the ERISA scenario'") (citation omitted). Therefore, the D.C. Act's remedies do not duplicate or supplement the ones provided in ERISA's civil enforcement scheme.

Claims under the D.C. Act involve violations of legal duties that are independent of ERISA. A claim against PBMs under the Act is not a claim that could be recast and brought as an ERISA claim. The Act does not

provide a cause of action against a plan, its fiduciaries or third parties for any violation of ERISA or the terms of an ERISA plan. Claims under the Act would not require consideration of the plan or the actions of its fiduciaries. D.C. Act claims are therefore similar to claims under the numerous cases that have held that state-law claims against non-ERISA fiduciary service providers, such as accountants, attorneys, plan advisors and consultants, are not preempted. See, e.g., Gerosa v. Savasta & Co., 329 F.3d 317, 325-29 (2d Cir. 2003); Trustees of the AFTRA Health Fund v. Biondi, 303 F.3d 765, 777-79 (7th Cir. 2002), LeBlanc, 153 F.3d at 147; Ariz. State Carpenters Trust Fund v. Citibank, 125 F.3d 715, 717-18 (9th Cir. 1997); Custer, 89 F.3d at 1167 ; Painters of Philadelphia Dist. Council No. 21 Welfare Fund v. Price Waterhouse, 879 F.2d 1146, 1152-53 (3d Cir. 1989); Harmon City, 907 P.2d at 1169.

Unlike the numerous cases permitting lawsuits against service providers under state law because they did not implicate ERISA claims or ERISA actors, the cases cited by the district court in support of its preemption holding involved the precise conduct regulated by ERISA. See Ingersoll-Rand, 498 U.S. at 142 (plaintiff's claim that he had been fired so that the employer could avoid contributing to the benefit plan was in direct conflict with a cause of action for discrimination under section 510 of

ERISA); Kollman v. Hewitt Associates, LLC, 487 F.3d 139 (3d Cir. 2007) (plan participant brought a claim for benefits that should have been brought under ERISA).[9] In contrast, the D.C. Act does not provide a cause of action against a plan, its fiduciaries or its service providers for any violation of ERISA or the terms of the plan. An adjudication of a claim under the D.C. Act would solely involve adjudication of the actions of the PBM and a determination of whether the PBM failed to provide the plans with the disclosures and financial benefits required by the Act.[10]

E. The D.C. Act Does Not Conflict With Substantive ERISA Requirements

Applying conflict preemption analysis, see, e.g., Boggs, 520 U.S. at 841, 844, the district court separately held that the D.C. Act impermissibly interferes

[9] E.I. Dupont de Nemours, & Co. v. Sawyer, 517 F.3d 785, 800 (5th Cir. 2008) , contradicts the court's conclusion to the extent it held that the employees' fraud and fraudulent inducement claims against their employer "simply do not intrude into federal matters respecting the duties and standards of conduct for an ERISA plan administrator" and do not "create a relationship between the plaintiff and defendant that is so intertwined with an ERISA plan that it cannot be separated."

[10] The District has construed the D.C. Act to give only its Attorney General standing to sue under that Act, as opposed to the private parties (fiduciaries, participants and beneficiaries) that have standing to sue under ERISA. The D.C. Act could conceivably be the subject of an "as applied" preemption challenge if it were construed to give participants and beneficiaries a private right of action and a participant or beneficiary sued a PBM for its violation of duties owed to the plan. On its face, however, the D.C. Act's enforcement provision is not subject to a preemption challenge.

with ERISA's statutory framework governing the reasonableness of service provider compensation under the Act's prohibited transaction rules, specifically the statutory exception in section 408(b)(2), 29 U.S.C. §1108(b)(2), and the Secretary's proposed regulation under that provision requiring service providers to make certain disclosures about compensation to their ERISA plan clients. But no such conflict exists since the D.C. Act in no way impairs enforcement of the prohibited transaction rules or any regulations implementing those rules. Indeed, the proposed rule at issue has yet to be made final, making actual conflict an impossibility.

1. Sections 406 and 408(b)(2)

Section 406 of ERISA, 29 U.S.C. § 1106, prohibits transactions between plans and "parties in interest" to the plan, including service providers, to prevent the potential for abuse by individuals and entities associated with the plan. See 29 U.S.C. § 1002(14) (defining "party in interest"); Lockheed Corp. v. Spink, 517 U.S. 882, 888 (1990); Rutledge v. Seyfarth Shaw, 201 F.3d 1212, 1222 (9th Cir. 2000). Such transactions are not prohibited, however, if they qualify for one of the exemptions from liability set forth in ERISA section 408, 29 U.S.C. § 1108. Section 408(b)(2) of ERISA exempts from the prohibitions of section 406(a) "any contract or reasonable arrangement with a party in interest, including a fiduciary, for . . . services necessary for the establishment or operation of the

plan, if no more than reasonable compensation is paid therefore." Id. § 1108(b)(2).

According to the district court, the existence of the 408(b)(2) exemption signaled that ERISA already regulates the relationship between plans and service providers and that additional state regulation of the same relationship would interfere with the administration of employee benefit plans under ERISA. The D.C. Act, however, does not implicate ERISA's prohibited transaction provisions or the 408(b)(2) exemption any more than the numerous state laws regulating the conduct of the other businesses and professionals that contract with ERISA-covered plans. It does not render a prohibited transaction permissible, nor add to or subtract from ERISA's list of prohibited transactions; and it does not purport to redefine what "reasonable compensation" means under ERISA or regulate the fees paid by the plans for a PBM's services. Its imposition of financial integrity and transparency standards on PBMs in their dealings with covered entities poses no threat to implementation of the 408(b)(2) exception to the prohibited transaction rules.

In Abraham v. Norcal Waste, 265 F.3d 811, 821 (9th Cir. 2001), the Ninth Circuit addressed whether ERISA preempted plaintiffs' state law fraud, fiduciary breach and negligence claims against company officers and

directors for their failure to advise plaintiff note holders, including some plan participants, of a transaction that caused the company to default on note payments. Similar to the district court's ruling here, the defendants argued that ERISA preempted the plaintiffs' state law claims because ERISA's prohibited transaction provisions regarding the "lending of money or other extension of credit between the plan and a party in interest" comprehensively governed the sale of stock and extension of credit between parties-in-interest and the plan. Rejecting the defendants' argument, the court noted that the lending parties' status as parties-in-interest was irrelevant because none of the state law claims asserted in the complaint implicated ERISA's prohibited transaction provisions. Congress, the court held, understood that state laws that fell outside the details of those provisions and exemptions would "survive to govern such transactions in all aspects unrelated to the objectives and administration of ERISA." Id. at 821.

Similarly, other courts have repeatedly recognized that state laws can regulate service providers if they do not conflict with ERISA, mandate particular benefit structures, or depend on the existence of plans for their operation. See, e.g., Custer, 89 F.3d at 1167; Airparts Co., 28 F.3d at 1064 .

Thus, while it is true that the section 408 exceptions apply to one aspect of the relationship between plans and certain service providers, they

do not purport to comprehensively regulate the service providers in all their conduct. Nothing in the prohibited transaction rules or their exceptions, merely by requiring ERISA fiduciaries to enter into "reasonable arrangements" with service providers, leads to a conclusion that states are ousted from this field to the disadvantage of ERISA-covered plans. ERISA, therefore, plainly does not occupy this field to the exclusion of non-conflicting state business practices law and other laws generally applicable to service providers, including state malpractice, tort, contract, and business ethics or professional responsibility laws.

2. The proposed disclosure regulation

The proposed Department of Labor regulation that the district court relies on intends to clarify what constitutes "a reasonable contract or arrangement" by amending and expanding the current definition of "reasonable" to include disclosure in such contract of specific information to plan fiduciaries about compensation related to a service provider's service to the plan and potential conflicts of interest. See Reasonable Contract or Arrangement under § 408(b)(2)-Fee Disclosure, 72 Fed. Reg. 70, 988 (2007). The district court was concerned that, given the Department's intention to regulate in this area, the D.C. Act should be preempted by ERISA because it presents the potential for conflicting regulation and thus prevents the uniform administration of benefit

plans. Cf. Pharmaceutical Care Management Ass'n v. District of Columbia, 522 F.3d 443, 447 (D.C. Cir. 2008) (noting that the preemption analysis might change "if the proposed rule is promulgated," but expressing no opinion on the issue).

The district court's reliance on this proposed regulation was misplaced. Simply put, a proposed regulation has no legal effect. See Commodity Futures Trading Comm'n v. Schor, 478 U.S. 833, 845 (1986). So long as it remains an unfinalized proposal, it is no more than a policy statement of future intent to act based on a current understanding of existing legal authority. While issuance of the proposal represents a legal judgment that the Secretary has authority to regulate in this area, that alone cannot form the basis for preempting a state law on a conflict preemption theory.

The timing and scope of the final rule the Secretary may issue, including which arrangements are to be covered, are uncertain. Moreover, as presently contemplated, such rule would not, as the district court concluded, present the potential for the "type of conflicting regulation of benefit plans that ERISA pre-emption was intended to prevent." JA 134. The D.C. Act and the proposed regulation do not conflict since the intent, structure, claims and remedies provided for in the D.C. Act and in ERISA are distinct, and indeed are complementary.

In short, the Department's authority over plans' contractual arrangements with service providers does not occupy the field to the exclusion of state regulation of these same service providers. State regulation like the D.C. Act is peripheral to such core (and exclusively federal) ERISA concerns as plan fiduciary conduct, including the management of plan assets, claims administration, and the enforcement of plan terms. Although the Department and the District have distinct but overlapping authorities to regulate the same relationship, the Department has not promulgated a final regulation. In any event, as long as a regulated entity can comply with both sets of requirements, ERISA does not require preemption of state laws aimed at the same practices that would also be addressed by the federal regulation. See Boggs, 520 U.S. at 844; see also John Hancock Mut. Life Ins. Co. v. Harris Trust, 510 U.S. 86, 100 (1993) (citing with approval Government's argument that "dual regulation [of group annuity insurance contracts] under ERISA and state law is not an impossibility [;] [m]any requirements are complementary, and in the case of a direct conflict federal supremacy principles require that state law yield"). There is, accordingly, no conflict between the D.C. Act and any statutory or regulatory requirements governing the "reasonable compensation" exception to ERISA's prohibited transaction rules that would trigger preemption.

CONCLUSION

For the foregoing reasons, ERISA does not preempt Title II of the D.C. Act.

Respectfully submitted,

CAROL A. DEDEO
Deputy Solicitor of Labor for
National Operations

TIMOTHY D. HAUSER
Associate Solicitor

/s/ Nathaniel I. Spiller

NATHANIEL I. SPILLER
Counsel for Appellate and Special Litigation

MELISSA BOWMAN
Attorney
United States Department of Labor
Plan Benefits Security Division
200 Constitution Ave., N.W., Suite N-4611
Washington, DC 20210
Phone: (202) 693-5281

CERTIFICATE OF COMPLIANCE

Pursuant to the September 17, 2009 order of the Court denying the Secretary's motion to exceed the word limitation for her amicus brief originally filed by the Secretary on August 21, 2009, and requiring the brief to conform to the 7,000 word limit for amicus briefs, I certify that the foregoing brief complies with the type volume limitation set forth in Fed. R. App. P. 32(a)(7)(B)(i). The brief contains 6,219 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). The brief was prepared by using Microsoft Office Word, 2003 edition.

_/s/ Nathaniel I. Spiller__
Nathaniel I. Spiller
Counsel for Appellate and Special Litigation
United States Department of Labor

Dated: September 24, 2009

CERTIFICATE OF SERVICE

I hereby certify that I have served a copy of this brief upon all counsel of record, by mailing same, postage prepaid and addressed as follows, on this the 24th day of September, 2009:

Jan Allen May
AARP Foundation
601 E. Street, NW
Washington, DC 20049

Stacy J. Canan
AARP Foundation
601 E. Street, NW
Washington, DC 20049

Martin D. Schneiderman
Steptoe & Johnson LLP
1330 Connecticut Avenue, NW
Washington, DC 20036-1795

William Gene Schiffbauer
Law Office of William Schiffbauer
1300 Pennsylvania Ave.,NW
Suite 700
Washington, DC 20004

Michael R. Schuster
AARP Foundation
601 E. Street, NW
Montgomery, Alabama 36104

Peter J. Nickles
Office of the Attorney General for the District of Columbia
Office of the Solicitor General
441 4th Street, NW
One Judiciary Square, Sixth Floor
Washington, DC 20001-2714

/s/ Nathaniel I. Spiller
_____
Attorney
United States Department of Labor