

--- F.3d ---, 2010 WL 2696524 (C.A.D.C.)
 (Cite as: 2010 WL 2696524 (C.A.D.C.))

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United States Court of Appeals,
 District of Columbia Circuit.
 PHARMACEUTICAL CARE MANAGEMENT ASSO-
 CIATION, Appellee

v.

DISTRICT OF COLUMBIA and Adrian Fenty, In his
 Official Capacity as Mayor of the District of Columbia,
 Appellants.
 No. 09-7042.

Argued Dec. 15, 2009.
 Decided July 9, 2010.

Background: National trade association representing pharmaceutical benefits managers (PBMs) brought action against the District of Columbia and its mayor, challenging validity of provisions of the District of Columbia's Access Rx Act requiring PBMs to act as fiduciaries, pass on discounts, and disclose information concerning conflicts of interest, purchases, and prescription drug substitution. The United States District Court for the District of Columbia granted preliminary injunctive relief, and defendants appealed. The Court of Appeals, [173 Fed.Appx. 3](#), remanded for reconsideration in light of intervening law. On remand, the District Court, [Ricardo M. Urbina, J., 477 F.Supp.2d 86](#), granted summary judgment in favor of defendants. Association appealed. The Court of Appeals, [522 F.3d 443](#), vacated and remanded. On remand, the District Court, Urbina, J., [605 F.Supp.2d 77](#), granted the association's motion for summary judgment in part. Defendants appealed.

Holdings: The Court of Appeals, [Ginsburg](#), Circuit Judge, held that:

(1) Employee Retirement Income Security Act (ERISA) did not preempt Access Rx Act's usage pass back provision and the provision requiring PBMs to disclose the quantity of drugs purchased by a covered entity, the net cost to the covered entity, and the terms and arrangements for remuneration between the PBM and drug manufacturers, but

(2) ERISA preempted provisions requiring PBMs to act as fiduciaries, disclose conflicts of interests, disclose the costs of prescribed drugs and substitute drugs, and transfer any benefit received as the result of prescription drug substitution.

Affirmed in part, reversed in part, and remanded.

West Headnotes

[1] Labor and Employment 231H 

[231H](#) Labor and Employment

Although clearly expansive, ERISA's preemption provision is nonetheless subject to the starting presumption that Congress does not intend to supplant state law, particularly in fields of traditional state regulation, such as health care. Employee Retirement Income Security Act of 1974, § 514(a), [29 U.S.C.A. § 1144\(a\)](#).

[2] Labor and Employment 231H 

[231H](#) Labor and Employment

ERISA did not preempt provisions of the District of Columbia's Access Rx Act directing pharmaceutical benefits managers (PBMs) to pass benefits received from drug manufacturers on to covered entities and requiring PBMs to disclose the quantity of drugs purchased by the covered entity, the net cost to the covered entity, and the terms and arrangements for remuneration between the PBM and drug manufacturers, since the provisions could be waived by an employee benefit plan in its contract with a PBM, and they did not make reference to ERISA plans or create an enforcement mechanism for the rights provided by ERISA. Employee Retirement Income Security Act of 1974, § 514(a), [29 U.S.C.A. § 1144\(a\)](#); [D.C. Official Code, 2001 Ed. § 48-832.01\(b\)\(2\), \(c\)](#).

[3] Labor and Employment 231H 

[231H](#) Labor and Employment

ERISA preempted provisions of the District of Columbia's Access Rx Act requiring pharmaceutical benefits managers (PBMs) under contract with an employee benefit plan to act as fiduciaries, disclose conflicts of interests, disclose the costs of prescribed drugs and substitute drugs, and transfer any benefit received as the result of prescription drug substitution; provisions affected an area of ERISA concern because they touched upon central matter of plan administration, and they constrained benefit plans by forcing them to decide between administering their own pharmaceutical benefits internally or contract-

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ing with a PBM to administer those benefits upon the terms laid down by the Access Rx Act. Employee Retirement Income Security Act of 1974, § 514(a), [29 U.S.C.A. § 1144\(a\)](#); [D.C. Official Code, 2001 Ed. § 48-832.01\(a\), \(b\)\(1\), \(d\)](#).

[4] Labor and Employment 231H

[231H](#) Labor and Employment

A state law relates to an employee benefit plan, within meaning of ERISA's preemption provision, if it (1) has a connection with or (2) reference to such a plan. Employee Retirement Income Security Act of 1974, § 514(a), [29 U.S.C.A. § 1144\(a\)](#).

[5] Labor and Employment 231H

[231H](#) Labor and Employment

In addressing whether a state law has a connection with an employee benefit plan and, therefore, relates to a plan within meaning of ERISA's preemption provision, courts must look both to the objectives of the ERISA statute as a guide to the scope of the state law that Congress understood would survive, as well as to the nature of the effect of the state law on ERISA plans. Employee Retirement Income Security Act of 1974, § 514(a), [29 U.S.C.A. § 1144\(a\)](#).

[6] Labor and Employment 231H

[231H](#) Labor and Employment

In the context of assessing whether a state law has a connection with an employee benefit plan and, therefore, relates to a plan within meaning of ERISA's preemption provision, the administration of employee benefits is an area of core ERISA concern. Employee Retirement Income Security Act of 1974, § 514(a), [29 U.S.C.A. § 1144\(a\)](#).

[7] Labor and Employment 231H

[231H](#) Labor and Employment

One of the principal goals of ERISA is to enable employers to establish a uniform administrative scheme, which provides a set of standard procedures to guide processing of claims and disbursement of benefits. Employee Retirement Income Security Act of 1974, § 2 et seq., [29 U.S.C.A. § 1001 et seq.](#)

[8] Labor and Employment 231H

[231H](#) Labor and Employment

The purpose of the title of the District of Columbia's Access Rx Act governing business practices among pharmaceutical benefits managers (PBMs) is to prescribe the way PBMs decide which pharmaceuticals to provide to plan beneficiaries and to prevent PBMs from inflating the price the plan pays for those pharmaceuticals. [D.C. Official Code, 2001 Ed. §§ 48-832.01\(a\), \(b\)\(1\)\(A\), \(b\)\(1\)\(C\), \(b\)\(2\), \(c\)\(1\)\(A\), \(c\)\(1\)\(B\), \(d\)\(2\), \(d\)\(3\)](#).

[9] Labor and Employment 231H

[231H](#) Labor and Employment

The procedure for opting out of a state law may so affect plan administration as not to save the statute from preemption under ERISA. Employee Retirement Income Security Act of 1974, § 514(a), [29 U.S.C.A. § 1144\(a\)](#).

[10] Labor and Employment 231H

[231H](#) Labor and Employment

A law regulating a third party's performance of services on behalf of an employee benefit plan cannot have a connection with an employee benefit plan that would render the law preempted by ERISA unless those services involve an area of ERISA concern and the law has a regulatory effect upon the employee benefit plan. Employee Retirement Income Security Act of 1974, § 514(a), [29 U.S.C.A. § 1144\(a\)](#).

[11] Labor and Employment 231H

[231H](#) Labor and Employment

ERISA does not preempt run-of-the-mill state-law claims such as unpaid rent, failure to pay creditors, or even torts committed by an ERISA plan. Employee Retirement Income Security Act of 1974, § 514(a), [29 U.S.C.A. § 1144\(a\)](#).

[12] Labor and Employment 231H

[231H](#) Labor and Employment

A law makes reference to a plan and, therefore, relates to an employee benefit plan within meaning of ERISA's preemption provision where it acts immediately and exclusively upon ERISA plans or where the existence of ERISA plans is essential to the law's operation. Employee Retirement Income Security Act of 1974, § 514(a), [29 U.S.C.A. § 1144\(a\)](#).

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West Codenotes

Preempted [D.C. Official Code, 2001 Ed. § 48-832.01\(a\), \(b\)\(1\), \(d\)](#)

Appeal from the United States District Court for the District of Columbia (No. 1:04-cv-01082-RMU). James C. McKay, Jr., Senior Assistant Attorney General, argued the cause for appellants. With him on the briefs were [Peter J. Nickles](#), Attorney General, Todd S. Kim, Solicitor General, and [Donna M. Murasky](#), Deputy Solicitor General.

Melissa Bowman, Attorney, U.S. Department of Labor, argued the cause for amicus curiae Secretary of Labor in support of appellants. With her on the briefs were Carol A. De Deo, Deputy Solicitor, Deborah Greenfield, Deputy Solicitor, and [Nathaniel I. Spiller](#), Counsel.

Jan May, [Stacy J. Canan](#), and [Michael Schuster](#) were on the brief for amici curiae AARP et al. in support of appellants.

[Paul J. Ondrasik, Jr.](#) argued the cause for appellee Pharmaceutical Care Management Association. With him on the briefs were [Martin D. Schneiderman](#), [Linda S. Stein](#), and [Eric G. Serron](#). [Alice E. Loughran](#) entered an appearance.

[Robin S. Conrad](#) and [William G. Schiffbauer](#) were on the brief for amici curiae America's Health Insurance Plans, Inc. and Chamber of Commerce of the United States of America in support of appellee.

Before [GINSBURG](#), [BROWN](#), and [KAVANAUGH](#), Circuit Judges.

Opinion for the Court filed by Circuit Judge [GINSBURG](#).

[GINSBURG](#), Circuit Judge.

*1 The District of Columbia appeals the judgment of the

district court holding Title II of the Access Rx Act of 2004, [D.C. Code § 48-832.01 et seq.](#), is pre-empted by the Employee Retirement Income Security Act, [29 U.S.C. § 1001 et seq.](#) (ERISA). *Pharm. Care Mgmt. Ass'n v. District of Columbia*, 605 F.Supp.2d 77, 84-88 (2009). We agree with the district court that [§§ 48-832.01\(a\), \(b\)\(1\), and \(d\)](#) of Title II are pre-empted by ERISA insofar as they apply to a pharmaceutical benefits manager (PBM) under contract with an employee benefit plan (EBP) because they “relate to” an EBP. [Sections 48-832.01\(b\)\(2\) and \(c\)](#) are not pre-empted by ERISA, however, because each may be waived by an EBP in its contract with a PBM. Accordingly, we affirm in part and reverse in part the judgment of the district court, and remand this matter for the district court to consider the Pharmaceutical Care Management Association's (PCMA) constitutional challenges to the provisions not pre-empted by ERISA.

I. Background

Access to prescription drugs is an increasingly important and expensive-benefit for a health care plan to offer its beneficiaries. Instead of themselves developing a list of covered prescription drugs, purchasing those drugs from pharmaceutical manufacturers, establishing a network of pharmacies to fill prescriptions, and otherwise administering the prescription drug benefit, many health care plans, including many EBPs, contract with a PBM to perform these functions. A PBM offers not just administrative convenience, however; by aggregating the purchasing power of numerous health care plans, a PBM can get greater volume discounts from drug manufacturers and provide access to a larger network of pharmacies than an EBP could do on its own. That the vast majority of insured Americans receive their pharmaceutical benefits through a PBM is, therefore, not surprising.

Title II imposes a number of requirements upon PBMs and, in one respect, upon any health care plan that contracts with a PBM and thus becomes a “covered entity,” [§ 48-831.02\(4\)\(A\)](#). These requirements are summarized in the following table.

Provision	Summary	Requirement
§ 48-832.01(a)	Fiduciary duty	A PBM “owes a fiduciary duty to a covered entity. In performance of that duty [it] shall adhere to the practices in this section.”
§ 48-832.01(b)(1)(A)	Fiduciary standard	A PBM “shall ... Perform its duties ...

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		in accordance with the standards of conduct applicable to a fiduciary.”
§ 48-832.01(b)(1)(B)	NA	Repealed, 53 D.C.Reg. 6899, 6966 (2006).
§ 48-832.01(b)(1)(C)	Disclosure of conflicts	A PBM shall “notify the covered entity in writing of ... any conflict of interest with the duties imposed by” Title II.
§ 48-832.01(b)(2)	Usage pass back	A PBM “that receives from any drug manufacturer or labeler any payment or benefit of any kind in connection with the utilization of prescription drugs” by the beneficiaries of a covered entity “shall pass that payment or benefit on in full to the covered entity. This provision does not prohibit the covered entity from agreeing by contract to ... return [] a portion of the benefit or payment to the [PBM].”
§ 48-832.01(c)(1)(A)	Disclosure of purchases	”Upon request by a covered entity” a PBM shall disclose “the quantity of drugs purchased by the covered entity and the net cost to the covered entity for the drugs.”
§ 48-832.01(c)(1)(B)	Disclosure of terms	”Upon request by a covered entity” a PBM shall disclose the “terms and arrangements for remuneration” between the PBM and a drug manufacturer or labeler.
§ 48-832.01(c)(2)	Confidentiality	”Information designated [by a PBM] may not be disclosed by the covered entity ...”
§ 48-832.01(d)(1)	NA	Repealed, 53 D.C.Reg. 6899, 6966 (2006).
§ 48-832.01(d)(2)	Disclosure of substitution	A PBM that dispenses a substitute drug that “costs more than the prescribed drug shall disclose to the covered entity the cost of both drugs and any benefit or payment ... to the PBM as a result of the substitution.”
§ 48-832.01(d)(3)	Substitution pass back	A PBM “shall transfer in full to the covered entity any benefit or payment received ... as the result of [such] prescription drug substitution.”
§ 48-832.02	Compliance	”Compliance with the requirements of [Title II] is required in all contracts between a[PBM] and a covered entity entered into in the District of Columbia ... executed after May 18, 2004.”
§ 48-832.03	Enforcement	”A violation of [§ 48-832] is a viola-

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*2 The PCMA, a national trade association representing PBMs, filed suit arguing Title II is pre-empted by ERISA. It also argued Title II is pre-empted by the Commerce Clause, and violates the First Amendment and the Takings Clause of the Fifth Amendment, of the Constitution of the United States. We held in [PCMA v. District of Columbia](#), 522 F.3d 443 (2008), the Association is not collaterally estopped from bringing this suit by the decision of the First Circuit in [PCMA v. Rowe](#), 429 F.3d 294 (2005), which rejected its argument that a similar Maine statute was pre-empted by ERISA. On remand the district court held Title II is pre-empted in its entirety by ERISA, and granted summary judgment for the PCMA, which the District now appeals.

II. Analysis

[1] ERISA expressly pre-empts “any and all State laws insofar as they ... relate to any employee benefit plan.” 29 U.S.C. § 1144(a). Although “clearly expansive,” [N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins.](#), 514 U.S. 645, 655, 115 S.Ct. 1671, 131 L.Ed.2d 695 (1995), this provision is nonetheless subject under the Supreme Court’s ERISA precedents to “the starting presumption that Congress does not intend to supplant state law,” particularly in “fields of traditional state regulation,” such as health care. [Id.](#) at 654-655.

[2][3][4] A state law “relates to” an EBP “if it [1] has a connection with or [2] reference to such a plan.” [Egelhoff v. Egelhoff](#), 532 U.S. 141, 147, 121 S.Ct. 1322, 149 L.Ed.2d 264 (2001) (quoting [Shaw v. Delta Air Lines, Inc.](#), 463 U.S. 85, 97, 103 S.Ct. 2890, 77 L.Ed.2d 490 (1983)). This appeal primarily concerns the “connection with” path to pre-emption because the district court held Title II “has an impermissible connection with ERISA and is therefore pre-empted.” 605 F.Supp.2d at 88. The District challenges that holding on the grounds that Title II does not regulate “relationships among ERISA entities” but merely “giv[es] rights and benefits to plans,” and is “not qualitatively different from [] state laws [regulating lawyers, accountants, and securities dealers].”

A. “Connection with” an EBP

tion of [the **District of Columbia** Consumer Protection Procedures Act], for which a fine of not more than \$10,000 may be adjudged.”

[5] In addressing whether a state law has a “connection with” an EBP, the Supreme Court noted that term “is scarcely more restrictive than [the statutory term] ‘relate to,’ “ and “cautioned against an ‘uncritical literalism’ that would make pre-emption turn on ‘infinite connections.’ “ [Egelhoff](#), 532 U.S. at 147 (quoting [Travelers](#), 514 U.S. at 656). Instead we must “look both to ‘the objectives of the ERISA statute as a guide to the scope of the state law that Congress understood would survive,’ as well as to the nature of the effect of the state law on ERISA plans.” *Id.* (quoting [Cal. Div. of Labor Standards Enforcement v. Dillingham Constr.](#), 519 U.S. 316, 325, 117 S.Ct. 832, 136 L.Ed.2d 791 (1997) (quoting [Travelers](#), 514 U.S. at 656)). Therefore, we consider first whether the provisions of Title II affect an area of ERISA concern, and then evaluate the nature of any such effect.

1. Objectives of ERISA

*3 [6][7] The PCMA argues Title II “intrudes into areas of express ERISA concern” because it regulates a PBM’s administration of benefits on behalf of an EBP. The administration of employee benefits clearly is an “area of core ERISA concern,” [Egelhoff](#), 532 U.S. at 147: “One of the principal goals of ERISA is to enable employers ‘to establish a uniform administrative scheme, which provides a set of standard procedures to guide processing of claims and disbursement of benefits.’ “ *Id.* at 148 (quoting [Fort Halifax Packing Co. v. Coyne](#), 482 U.S. 1, 9, 107 S.Ct. 2211, 96 L.Ed.2d 1 (1987)). Plan administration includes “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.

[8] We also agree with the PCMA, and with the district court, 605 F.Supp.2d at 86-87, that the provisions of Title II regulate a PBM’s administration of benefits on behalf of an EBP. The disclosure and pass back provisions of Title II, §§ 48-832.01(b)(1)(C), (b)(2), (c)(1)(A), (c)(1)(B), (d)(2), and (d)(3), each regulate the administration of employee benefits by requiring a PBM to follow a specific practice in administering pharmaceutical benefits on behalf of an EBP. Likewise, by specifying the standard of conduct to which a PBM must adhere, i.e., that of a fiduciary, §§ 48-832.01(a) and (b)(1)(A) also regulate the

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administration of employee benefits. Indeed, the obvious purpose of Title II, as effectuated through these provisions, is to prescribe the way PBMs decide which pharmaceuticals to provide to plan beneficiaries and to prevent PBMs from inflating the price the plan pays for those pharmaceuticals.

The District does not deny the administration of employee benefits is an area of core ERISA concern or that PBMs administer benefits on behalf of EBPs; indeed at oral argument it conceded as much. Oral arg. at 4:00, 16:55. Rather, the District argues the various provisions of Title II nonetheless fall within the scope of state law the Congress did not intend to pre-empt with ERISA because they do not regulate “relationships among ERISA entities,” such as a plan and an ERISA fiduciary or a plan and its beneficiaries. The District points to no support for this limitation upon pre-emption either in ERISA itself or in any Supreme Court case interpreting it. Instead, the District relies upon decisions of other circuits holding ERISA did not pre-empt breach of contract or professional malpractice claims against third-parties who provided services to an EBP.

As the PCMA points out, in none of the cases cited by the District did the state law regulate a third party who administered employee benefits on behalf of a plan. Those cases therefore suggest only that the relationship among ERISA entities is an area of ERISA concern, not that the objective of uniformity in plan administration is for some reason inapplicable simply because a plan has contracted with a third party to provide administrative services. Indeed, dicta in two cases central to the District's argument suggest a state law regulating a third party's performance of administrative functions on behalf of a plan could be pre-empted. See *Gerosa v. Savasta & Co.*, 329 F.3d 317, 324 (2d Cir.2003) (noting that although courts are “reluctant to find that Congress intended to preempt state laws that do not affect the relationships among [ERISA entities]” they have “typically” held ERISA pre-empts “state laws that would tend to control or supersede central ERISA functions—such as state laws affecting the determination of eligibility for benefits, amounts of benefits, or means of securing unpaid benefits”); *Airparts Co. v. Custom Benefit Servs. of Austin*, 28 F.3d 1062, 1066 (10th Cir.1994) (holding claims for negligence, indemnity, and common-law fraud not pre-empted where defendant “was simply an outside consultant which did not directly perform any administrative act vis-a-vis the plan”). Furthermore, when actually confronted with a malpractice claim challenging a third party's performance of administrative

services on behalf of a plan, the Third Circuit held the claim was pre-empted by ERISA. See *Kollman v. Hewitt Assocs.*, 487 F.3d 139, 148 (2007) (holding ERISA pre-empts malpractice claim against non-fiduciary service provider responsible for plan administration; goal of uniformity reflected in ERISA is “equally applicable to agents of employers ... who undertake and perform administrative duties for and on behalf of ERISA plans”).

*4 In sum, §§ 48-832.01(a), (b)(1)(A), (b)(1)(C), (b)(2), (c)(1)(A), (c)(1)(B), (d)(2), and (d)(3) touch upon “a central matter of plan administration,” *Egelhoff*, 532 U.S. at 148, and are pre-empted if they also have an impermissible effect upon an EBP. Whether § 48-832.01(c)(2), the provision requiring that a covered entity keep certain information confidential, regulates an area of ERISA concern, is not so clear. We need not resolve the question, however, because, as we conclude below, that provision does not have an impermissible effect upon an EBP.

2. Effect upon EBPs

The precise point at which a state law so constrains an ERISA plan's choices as to undermine the goal of uniformity in plan administration is uncertain. *Shaw*, 463 U.S. at 100 n. 21 (“Some state actions may affect employee benefit plans in too tenuous, remote, or peripheral a manner to warrant a finding that the law ‘relates to’ the plan.... [W]e express no views about where it would be appropriate to draw the line.”). For example, in *Travelers* the Supreme Court considered a state law that imposed a larger hospital surcharge upon patients insured by a commercial insurer than upon patients insured by a *Blue Cross/Blue Shield plan*. 514 U.S. at 649-50. The Court held the law was not pre-empted because it did not “force an ERISA plan to adopt a certain scheme of substantive coverage or effectively restrict its choice of insurers,” *id.* at 668, but exerted merely an “indirect economic influence ... that can affect a plan's shopping decisions.” *Id.* at 659-60. “[C]ost uniformity,” the Court held, “was almost certainly not an object of pre-emption.” *Id.* at 662. On the other hand, in *Metropolitan Life Insurance Co. v. Massachusetts*, 471 U.S. 724, 105 S.Ct. 2380, 85 L.Ed.2d 728 (1985), the Court held a state law mandating mental health benefits be covered in certain health insurance contracts related to an EBP notwithstanding the possibility the EBP could self-insure or purchase a policy not affected by the law. The Court noted the law “bears indirectly but substantially on all insured benefit plans, for it requires them to purchase the mental-health benefits specified in the statute when they purchase a certain kind

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of common insurance policy.” *Id.* at 739.

The District argues Title II does not have an impermissible constraining effect upon EBPs because the statute offers “clear benefit[s]” that an EBP may “simply decline.” In this regard the District relies upon *Rowe*, in which the First Circuit held a substantively identical Maine statute was not pre-empted because, “[a]lthough the ERISA plans can re-evaluate their working relationships with the PBMs if they wish in light of the [state law], nothing in [that law] compels them to do so.... The plan administrators here have a free hand to structure the plans as they wish in Maine.” 429 F.3d at 303.

The District's point is well-taken with regard to the usage pass back provision, [§ 48-832.01\(b\)\(2\)](#), because it expressly provides that it “does not prohibit the covered entity from agreeing by contract to compensate the [PBM] by returning a portion of the benefit or payment,” and with regard to [§ 48-832.01\(c\)](#), which requires disclosure (and imposes a corresponding duty of confidentiality) only “[u]pon request by a covered entity.” Those provisions are in essence voluntary provisions for the covered entity.

*5 [\[9\]](#) To be sure, the procedure for opting out of a state law may so affect plan administration as not to save the statute from pre-emption. See *Egelhoff*, 532 U.S. at 150 (“Plan administrators must either follow [the state's] beneficiary designation scheme or alter the terms of their plan so as to indicate that they will not follow it. The statute is not any less of a regulation of the terms of ERISA plans simply because there are two ways of complying with it.”). The procedure for opting out of [§§ 48-832.01\(b\)\(2\)](#) and [\(c\)](#) does not have that untoward effect, however. First, it imposes no meaningful burden at all. Cf. *id.* at 151 (burden was “hardly trivial” because it required plan to maintain familiarity with state law and make ongoing amendments to plan documents). A plan need only include in its contract with a PBM a waiver of those provisions-for which it may be able to obtain something in return, but that is neither here nor there for the purpose of the present analysis. We note also that, because Title II applies only to contracts entered after the effective date of the statute, no EBP has been required either to amend an existing contract or to alter its plan documents. Cf. *id.* at 150-51 (opt out required amendment of already-issued plan documents). Second, negotiating a waiver of those provisions does not itself involve the administration of benefits. Therefore, we conclude [§§ 48-832.01\(b\)\(2\)](#) and [\(c\)](#) do not “relate to” an EBP.

At oral argument the District took the position for the first time that an EBP can also waive the other provisions of Title II. In the supplemental brief we requested, the District backtracked, conceding [§ 48-832.01\(b\)\(1\)\(C\)](#) (disclosure of conflicts of interest) and (d)(2) (disclosure of PBM's gains from substituting drugs) cannot be waived, arguing [§ 48-832.01\(d\)\(3\)](#) (substitution pass back) can be waived, and remaining silent as to whether [§§ 48-832.01\(a\)](#) (fiduciary duty) and (b)(1)(A) (fiduciary standard of conduct) can be waived.

The District's belated interpretation of Title II is inconsistent with both the text and the declared purpose of that statute. As for text, none of the provisions the District now argues may be waived says or implies anything about the possibility of waiver. When contrasted with the provisions that expressly allow for waiver, that silence presumably bespeaks the intent of the D.C. Council to make the other provisions non-waivable. See *Russello v. United States*, 464 U.S. 16, 23, 104 S.Ct. 296, 78 L.Ed.2d 17 (1983) (“Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion” (internal quotation marks omitted)). The District offers nothing with which to rebut that presumption.

As to purpose, this interpretation is bolstered by [§ 48-832.03](#), which provides a violation of Title II is a violation of the District of Columbia Consumer Protection Procedures Act, [D.C.Code §§ 28-3901 to -3913](#), enforceable by the Attorney General, [§ 28-3909](#), or by any “person, whether acting for the interests of itself, its members, or the general public,” [§ 28-3905\(k\)\(l\)](#). If [§§ 48-832.01\(a\)](#), [\(b\)\(1\)](#), and [\(d\)](#) could be waived by an EBP, then they would not protect the interests of third parties, such as plan beneficiaries, and it would be anomalous to provide for enforcement by anyone other than the covered entity with which the PBM contracts-let alone by any person whatsoever. We think it obvious the D.C. Council, concerned that contracts between an EBP and a PBM should adequately protect the interests of plan beneficiaries, enacted Title II in order to protect those beneficiaries with rules that, except as expressly provided, could not be waived by contract. This purpose is confirmed in the “Findings and declaration of intent” that begin both the Access Rx Act and the District's statement of facts in its opening brief:

*6 Affordability is critical in providing access to pre-

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scription drugs for District of Columbia residents. Access Rx enables the District to take steps to make prescription drugs more affordable for qualified District residents....

§ 48-831.01(IH2). If Title II could be waived in its entirety by an EBP, then the District would not be able to “take steps” on behalf of plan beneficiaries in precisely those circumstances at which the statute is aimed, i.e., where the contract between the EBP and the PBM is, in its view, insufficiently protective of the beneficiaries.

Although the District argues ambiguity in a state law should be resolved against pre-emption, here the D.C. Council has sounded no “uncertain trumpet,” *Vote Choice, Inc. v. DiStefano*, 4 F.3d 26, 41-42 (1st Cir.1993). Sections 48-832.01(a), (b)(1), and (d) are clearly meant to govern the relationship between a PBM and an EBP regardless whether their contract provides otherwise.

The District argues §§ 48-832.01(a), (b)(1), and (d) nonetheless leave plan administrators with “a free hand to structure the plans as they wish,” *Rowe*, 429 F.3d at 303, because “Title II does not force plans to do anything. Plans remain free to employ PBMs in any manner they see fit.” That is just not so, even as a formality. Title II constrains an EBP by forcing it to decide between administering its pharmaceutical benefits internally upon its own terms or contracting with a PBM to administer those benefits upon the terms laid down in §§ 48-832.01(a), (b)(1), and (d).

The Supreme Court has not prescribed a standard for determining whether a state law sufficiently constrains an EBP's decision-making in an area of ERISA concern that the law is pre-empted, but it has indicated a law that “bind[s] plan administrators to any particular choice” is pre-empted. *Travelers*, 514 U.S. at 659. We need go no further: Sections 48-832.01(a), (b)(1), and (d) bind plan administrators because the “choice” they leave an EBP between self administration and third-party administration of pharmaceutical benefits is in reality no choice at all. For most if not all EBPs, internal administration of beneficiaries' pharmaceutical benefits is a practical impossibility because it would mean forgoing the economies of scale, purchasing leverage, and network of pharmacies only a PBM can offer. By imposing requirements upon third-party service providers that administer pharmaceutical benefits for an EBP, §§ 48-832.01(a), (b)(1), and (d) “function as a regulation of an ERISA plan itself.” *Travelers*, 514 U.S. at 659. Because these provisions also

regulate an area of ERISA concern, they are pre-empted.

[10][11] The District would have us abjure this conclusion on the ground that “the [] standards of conduct, requirements of transparency, and restrictions on self-dealing [imposed upon a PBM by Title II] are not qualitatively different from” laws regulating others who provide services to an EBP, such as accountants, lawyers, and securities dealers; its point is that if Title II is pre-empted by ERISA because it has a “connection with” an EBP, then those implicitly benign regulations of professionals must also be pre-empted. Not to worry: A law regulating a third party's performance of services on behalf of an EBP cannot have a “connection with” an EBP unless those services involve an area of ERISA concern and the law has a regulatory effect upon the EBP. See *De Buono v. NYSA-ILA Med. and Clinical Servs. Fund*, 520 U.S. 806, 808, 117 S.Ct. 1747, 138 L.Ed.2d 21 (1997) (holding state law “imposing a gross receipts tax on the income of medical centers” not pre-empted as applied to centers “operated by ERISA funds”); *Dillingham*, 519 U.S. at 330 (indicating ERISA does not pre-empt state law “in those areas where ERISA has nothing to say”); *Travelers*, 514 U.S. at 661-62 (state law with mere “indirect economic effect” not pre-empted). Thus it is that ERISA does not pre-empt “runof-the-mill state-law claims such as unpaid rent, failure to pay creditors, or even torts committed by an ERISA plan.” *Mackey v. Lanier Collection Agency & Service, Inc.*, 486 U.S. 825,833(1988).

*7 A dictum in *Egelhoff* suggests there may be an exception to pre-emption under ERISA for long-standing and widely observed state laws. 532 U.S. at 152 (statutes providing “a murdering heir is not entitled to receive property as a result of the killing” might not be pre-empted because “the principle underlying the statutes-which have been adopted by nearly every State-is well established in the law and has a long historical pedigree predating ERISA”); see also *Custer v. Sweeney*, 89 F.3d 1156, 1167 (4th Cir.1996) (ERISA does not pre-empt malpractice claim against attorney representing EBP because “ERISA does not evince a clear legislative purpose to pre-empt such traditional state-based laws of general applicability”). Such an exception would seem to protect from pre-emption long-accepted laws regulating accountants, lawyers, and dealers in securities, but it would not save Title II because laws regulating PBMs are not the embodiment of long-standing and widely observed principles.

B. PCMA's Other Arguments

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The PCMA raises two alternative statutory grounds for affirming the judgment of the district court as to the provisions of Title II that an EBP can waive, *viz.*, §§ 48-832.01(b)(2) (usage pass back) and (c) (disclosures upon request). Specifically, it argues every part of Title II is pre-empted by ERISA both because Title II has a “reference to” a plan and therefore “relates to” an EBP and because it creates an enforcement mechanism alternative to that provided in ERISA itself. Although the district court did not reach these arguments because it held Title II was pre-empted in its entirety by reason of a “connection with” an EBP, 605 F.Supp.2d at 88, we reach them-as applied to the two provisions we have not already held are pre-empted by ERISA-because the arguments are fully briefed by the parties and their resolution is clear and does not depend upon further factual development. *See EEOC v. Aramark Corp., Inc.*, 208 F.3d 266, 268 (D.C.Cir.2000) (“because we review the district court’s judgment, not its reasoning, we may affirm on any ground properly raised”).

[12] As the Supreme Court has explicated the phrase, a law makes “reference to” a plan “[w]here [it] acts 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. Because Title II applies to any PBM that contracts with a “covered entity,” defined as “[a]ny hospital or medical service organization, insurer, health coverage plan, or [HMO] ... that contracts with another entity to provide prescription drug benefits for its customers or clients,” § 48-831.02(4)(A), sections 48-832.01(b)(2) and (c) do not act exclusively upon EBPs; “the existence of ERISA plans ... is [not] essential to [their] operation,” *Dillingham*, 519 U.S. at 325. Therefore, neither provision has a “reference to” a plan.

Nor does either provision create an enforcement mechanism for the rights provided by ERISA. Rather, each creates an enforceable but “independent legal duty”-to pass back or upon request to disclose certain information-separate from any duty created by ERISA. *Aetna Health Inc. v. Davila*, 542 U.S. 200, 210, 124 S.Ct. 2488, 159 L.Ed.2d 312 (2004). Therefore §§ 48-832.01(b)(2) and (c) are not pre-empted by ERISA.

III. Conclusion

*8 Sections 48-832.01(a), (b)(1), and (d) of Title II require an EBP that outsources the administration of its pharmaceutical benefits in the District of Columbia do so in a particular way. Those provisions have a “connection

with” and therefore “relate to” an EBP and are pre-empted by ERISA. ^{FN*} Because an EBP readily may avoid the default terms of §§ 48-832.01(b)(2) and (c) by contract, and because those provisions do not make “reference to” ERISA plans or create an enforcement mechanism for the rights provided by ERISA, they are not pre-empted by ERISA.

The PCMA raised several constitutional arguments for pre-emption not reached by the district court. Because the parties have not briefed them at any length, we leave those issues, as they relate to the provisions we have held are not pre-empted by ERISA and the application of Title II to covered entities that are not EBPs, for the district court to consider in the first instance. Accordingly, the judgment of the district court is affirmed in part and reversed in part, and this matter is remanded to the district court for further proceedings consistent herewith.

So ordered.

^{FN*} This holding differs from that of the First Circuit in *Rowe*, which held no part of a nearly identical Maine statute was pre-empted by ERISA. *See* 429 F.3d at 303. In our view the uniform administrative scheme encouraged by ERISA includes plan administrative functions performed by a third party on behalf of an EBP.

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