ORAL ARGUMENT NOT YET SCHEDULED

No. 09-7042

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

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Appellee,

v.

DISTRICT OF COLUMBIA and ADRIAN FENTY,
in his official capacity as Mayor of the District of Columbia,

Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA, No. 04-1082,
Honorable Ricardo M. Urbina, United States District Judge

BRIEF FOR AMERICA'S HEALTH INSURANCE PLANS, INC. AND CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF APPELLEE

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RULE 26.1 CORPORATE DISCLOSURE STATEMENT AND CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rules 27(a)(4) and 26.1, *amici* state that America's Health Insurance Plans, Inc. ("AHIP") and the Chamber of Commerce of the United States of America ("the Chamber") are not-for-profit corporations with no parent company; no publicly-held company has a 10% or greater ownership interest in either AHIP or the Chamber.

Pursuant to D.C. Circuit Rules 27(a)(4) and 28(a)(1), *amici* state that, all parties, intervenors, and *amici* appearing before the district court and in this Court are listed in the Brief of Appellee. References to the ruling at issue appear in the Brief of Appellee. This case has previously been before this Court twice previously; *see Pharmaceutical Care Management Association v. District of Columbia*, No. 05-7007, 173 Fed. Appx. 3 (D.C. Cir. 2006), and *Pharmaceutical Care Management Association v. District of Columbia*, No. 07-7062, 522 F.3d 443 (D.C. Cir. 2008). *Amici* are aware of no related cases pending before this Court or any other court in the District of Columbia.

William G. Schiffbauer

Dated: October 13, 2009

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[2] All applicable statutes are contained in the Brief of Appellee.

GLOSSARY

SHORT FORM	DEFINITION
AccessRx Act	AccessRx Act of 2004, D.C. Law 15-164, 51 D.C.R. 3688, 5704, D.C. Code § 48-831.01 *et seq.*
AHIP	America's Health Insurance Plans, Inc.
Chamber of Commerce or Chamber	Chamber of Commerce of the United States of America
DOJ	United States Department of Justice
D.C. or District	District of Columbia
ERISA	Employee Retirement Income Security Act, 29 U.S.C. §§ 1101-1462
FTC	Federal Trade Commission
PBM	Pharmcy Benefit Manager
PCMA	Pharmaceutical Care Management Association
Title II	Title II of the AccessRx Act, § 48-831.01 *et seq.*

INTEREST OF *AMICI CURIAE*

This brief is submitted on behalf of America's Health Insurance Plans, Inc. ("AHIP") and the Chamber of Commerce of the United States of America ("the Chamber") as *amici curiae* in support of appellant Pharmaceutical Care Management Association. *Amici* filed notice for leave to file an amicus brief on June 12, 2009 with the consent of all parties.

AHIP is a national trade association whose membership consists of approximately 1300 companies that administer and/or insure benefits including disability, long-term care, supplemental coverage, health, and pharmaceutical coverage to more than 200 million Americans, the great majority of whom are participants in, or beneficiaries of, employee benefit plans under the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001, *et seq.*

The Chamber is the nation's largest federation of business companies and associations, with an underlying membership of more than 3,000,000 business and professional organizations of every size and in every sector and geographic region of the country. An important function of the Chamber is to represent the interests of its members by filing *amicus curiae* briefs in cases involving issues of national concern to American business. The vast majority of the Chamber's members sponsor employee benefit plans governed by ERISA, many of which employ third parties to provide non-fiduciary but essential services to administer their plans.

Such essential third parties include pharmacy benefit managers employed by many Chamber members to administer prescription drug benefits.

This case is of significant interest to *amici* because the District of Columbia ("District") law at issue has been held invalid by the District Court as preempted by ERISA. *Amici* seek affirmance of that holding, and contend that the District law at issue substantially interferes with the ability of *amici*'s members to establish beneficial terms for the employee prescription drug benefit plans they sponsor and administer, as well as undermining the relationship between employee-benefit plans and the vast network of third-party service providers that facilitate the provision of benefits. Those third-party service providers include PBMs. *Amici* are uniquely positioned to explain the practical effect of the District's law, and thus, file in support of the decision below.

SUMMARY OF ARGUMENT

The decision of the district court should be affirmed. It held the AccessRx Act of 2004, D.C. Code §§ 48-831.01 *et seq.* ("AccessRx Act"), unconstitutional pursuant to the Supremacy Clause of the U.S. Constitution, as preempted by ERISA § 514(a), 29 U.S.C. §§ 1132(a). More specifically, it held that the District's law, "by regulating the relationship between PBMs and ERISA plans…impermissibly intrudes upon a field exclusively reserved for federal regulation." *PCMA v. District of Columbia*, 605 F. Supp. 2d 77, 78 (D.D.C. 2009).

The district court properly found that PBMs "provide ERISA plans with essential administrative services, which states may not regulate." 605 F. Supp. 2d at 88.

Amici here contend that the District's law, by regulating the conduct of ERISA non-fiduciaries such as PBMs and other plan service providers, interferes with the efficient administration of prescription drug benefit plans governed by ERISA, and is thus preempted by ERISA. As outlined below, *amici* also argue that the District's law undermines the ability of their member employers and health plans to retain service providers like PBMs to administer prescription drug benefits efficiently and uniformly on a nationwide or regional basis. Instead it forces them to both comply with a patchwork of inconsistent state regulations, as well as to forfeit critical flexibility to design pharmaceutical benefits that meet their needs and those of the consumers they serve. The result is a perverse one: a law designed to lower consumers' prescription drug costs will instead inevitably increase those costs.

For these reasons, as well as those articulated by appellee Pharmaceutical Care Management Association (PCMA), the decision below should be affirmed.

ARGUMENT

I. The District's Law Undermines the Ability of Employers and Health Plans to Provide Access to Effective and Affordable Prescription Drug Benefits

Almost all ERISA-governed employee benefit plans that cover prescription drugs relies on a PBM to administer those benefits. Indeed, absent the services PBMs provide, most of the employers *amici* represent would not be financially able to provide access to any meaningful prescription drug benefit at all. PBMs perform a variety of essential functions, virtually all of which result in substantial savings in the costs of covering prescription drugs. *See generally* Federal Trade Commission & U.S. Department of Justice, *Improving Health Care: A Dose of Competition*, ch. 7, at 10-18 (July 2004) ("FTC/DOJ Healthcare Report").

More specifically, PBMs manage drug utilization and costs for their customers—which include health plans, self-insured employer-based plans, Taft Hartley plans, and other third party payers – by processing claims and managing formularies, providing access to retail pharmacy networks, and managing mail-order pharmacy services. By pooling the purchasing power of many different employer- and plan-clients, PBMs can negotiate significant discounts and rebates from drug manufacturers for the drugs their clients will purchase. *Id.* at 11-12. They "assemble networks of retail pharmacies so a plan sponsor's members can fill prescriptions easily and in multiple locations by just paying a co-payment

amount."[3]

In addition, PBMs often work with employers to design benefit structures that provide quality benefits at a reasonable cost. These structures include "formularies" (i.e., lists of prescription drugs approved for coverage under a client's pharmacy benefits plan) and creation of "tiered" copayments (i.e., the assignment of lower co-pay levels for lower-cost but therapeutically equivalent drugs to encourage their use). *Id.* at 12-13. PBMs also strive to assure the safety and efficacy of plan members' drug products by, for example, administering "drug utilization review" programs designed to monitor and deter purchase of dangerous drug combinations. *Id.* at 14.

The District law at issue seeks to alter the contractual relationship between PBMs and their customers by improperly transforming PBMs into "fiduciaries" of employers' ERISA plans and dictating key terms on which PBMs may administer prescription-drug plan benefits. That law – Title II of the AccessRx Act – was enacted in 2004 as an attempt to "take steps to make prescription drugs more affordable for qualified District residents…" D.C. Code § 48-831.01(1).

That legislation, however, directly impedes *amici*'s members' ability to provide prescription-drug benefits to the nation's employee beneficiaries as

[3] Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* (August 2005), at i ("FTC Conflict of Interest Study"), available at http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf (last visited October 5, 2009).

efficiently as possible. Indeed, Title II is an aberration: only two jurisdictions, the District and the State of Maine, Me. Rev. Stat. Ann. Tit. 22 § 2699, have passed legislation imposing fiduciary duties on PBMs in similar misguided attempts to protect the interests of health plans as well as employers and other benefit plan sponsors – all rendered "covered entities" by Title II – from the alleged negative commercial self-interest of PBMs. But, as we explain below, *amici*'s members strongly disclaim any need for the protection of such laws. Indeed, it is the view of *amici* – as well as of the federal government's primary competition authorities – that such laws seriously undermine their ability to make quality prescription drug benefits available at reasonable cost.

Moreover, Title II is preempted by ERISA § 514 because it regulates the administration of heath plan benefits. As the district court specifically found, ERISA § 514 preempts any state law that "relates to" ERISA plans, which includes any state law that regulates "employee benefit structures or *their administration*," quoting from *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 658 (1995) (emphasis added). *PCMA v. District of Columbia*, 605 F. Supp. 2d 77, 83 (D.D.C. 2009). The district court was correct in holding that "PBMs provide ERISA plans with essential administrative services, which states may not regulate." 605 F. Supp. 2d at 88. As explained below, the DC law's entire purpose is to regulate the terms on which employers and other

plan sponsors as well as health plans contract with PBMs to administer their prescription drug benefits.

A. Title II Undermines Employers' Ability To Administer Prescription Drug Benefits Efficiently

Title II of the AccessRx Act makes PBMs "fiduciaries" to their customers and requires PBMs: (1) to provide to the health benefit plan sponsor, on request, information about the quantity and cost of drugs purchased by the sponsor, as well as "all financial terms and arrangements for remuneration of any kind" between the PBM and drug manufacturers; (2) to "transfer in full to the covered entity any benefit or payment received in any form by the [PBM] as a result of a prescription drug substitution"; and (3) to "pass . . . on in full to the covered entity" any payment or benefit from a drug manufacturer "based on volume of sales or market share." D.C. Code §§ 48-832.01(a), (b)(2), (c)(1), (c)(2), (d)(3).[4]

In sum, the aim of Title II is to give employers and others who sponsor health benefits in the District a special commercial advantage over PBMs in arms-length negotiations for PBM services, thereby ostensibly setting contract terms and conditions by law in the faint hope of reducing the cost of providing prescription drug benefits. *See id.* § 48.831.01(2). In fact, as we demonstrate below, by interfering with the free – and highly competitive – market for PBM services, laws

[4] Section 48-832.01(b)(2) allows a covered entity to agree by contract to return "*a portion*" of the benefit to the PBM. *Id.* (emphasis added).

such as Title II actually increase the cost of providing prescription drug benefits.

1. *Increasing Prescription Drug Expenditures Strain The Ability Of Employers And Other Plan Funds To Provide Prescription Drug Benefits*

The financial strains on the employer-provided health insurance system in the United States are already widely recognized, and have been the impetus for reform efforts at both federal and state government levels. Despite the improvements in cost containment, growth in national health expenditures is expected to be 6.2 percent a year for the years 2008 through 2018, outpacing average annual growth in the economy.[5]

Increases in prescription drug expenditures have been a critical driver in overall heath care cost increases. While in 1990 prescription drug expenditures in the U.S. were $40.3 billion, by 2006, total expenditures amounted to $216.7 billion, representing over 10 percent of total healthcare expenditures.[6] By 2007,

[5] U.S. Department of Health & Human Services, Centers for Medicare & Medicare Services, *National Health Expenditure Projections 2008-2018* (2009), available online at http://www.cms.hhs.gov/nationalhealthexpenddata/03_nationalhealthaccountsprojected.asp (last visited Oct. 5, 2009) ("*Health Expenditure Projections*"); U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Expenditure Data, NHE Historical and Projections, 1965-2018, also available online at http://www.cms.hhs.gov/nationalhealthexpenddata/03_nationalhealthaccountsprojected.asp (last visited October 5, 2009).

[6] *Id.*, available online at http://www.cms.hhs.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp#TopOfPage (last visited October 5, 2009); Kaiser Family Foundation, *Prescription Drugs Trends Fact Sheet* (September 2008) at 1, available online at http://www.kff.org/rxdrugs/3057.cfm (last visited on October 5, 2009).

according to government actuaries, retail prescription drug spending reached $227.5 billion. *See* M. Hartman, *et al*., *National Health Spending in 2007: Slower Drug Spending Contributes to Lowest Rate of Overall Growth Since 1998,* Health Affairs, Jan/Feb 2009, at 249.

Increasing prescription drug costs pose a serious challenge to employers, other plan sponsors, administrators and insurers. *See* Kaiser Family Foundation & Health Research and Educational Trust, *Employer Health Benefits 2007 Annual Survey* 161 (2007) ("*Kaiser 2007 Survey*") ("The factor most often cited by firms as contributing 'a lot' to higher health insurance premiums is higher spending for prescription drugs (66%), followed by higher spending for hospital care (60%) . . . ."). While the rate of premium increases has slowed in recent years, it still greatly exceeds inflation and earnings growth, and premiums for employer-sponsored health insurance increased by a robust 6.1% between 2006 and 2007. *Id*. at 18; *see* P. Ginsburg et al., *Tracking Health Care Costs: Continued Stability But at High Rates in 2005*, Health Affairs Web Exclusive, Oct. 3, 2006, at w488 ("Health care spending outpaced overall economic growth by a wide margin again in 2005, despite a robust increase of 5.4 percent for the U.S. economy . . . ."). Employees are now paying a high percentage of plan costs, as well as larger deductibles and co-payments, *see Kaiser 2007 Survey* at 68, 97-98, 112-14, and the increase of health insurance premiums is clearly linked to the growing ranks of the

uninsured, B. Strunk et al., *Tracking Health Care Costs: Declining Growth Trend Pauses in 2004*, Health Affairs Web Exclusive, June 21, 2005, at W5-294.

2. *PBM Tools Enhance The Efficiency Of Health Benefit Plan Administration While Reducing Sponsors' Cost Of Providing Prescription-Drug Benefits*

More than 216 million Americans – nearly 90% of all those with prescription drug coverage – get their benefits through PBMs, according to the Health Strategies Group.[7] Those enrolled in PBMs include most people with drug coverage sponsored by health insurance plans, labor unions, Fortune 500 employers, and Medicare Part D plans. The cost-saving efficiencies PBMs provide, which are elaborated below, help explain why so many plan sponsors use PBMs.

Although prescription drug expenditures have been rising rapidly, a January 2009 study by the Centers for Medicare and Medicaid Services ("CMS") shows a historic slowdown in drug spending growth, driven largely by the increased use of generic medicines. Increased used of generics is one of the tools pioneered by PBMs. PBMs helped increase generic dispensing from 63 percent of prescriptions in 2006 to fully 67 percent in 2007. *See* Hartman, *et al*., *National Health Drug Spending Contributes to Lowest Rate of Overall Growth Since 1998,* at 250. Generics are critical to reining in drug costs, as they average 30-80 percent less

[7] Health Strategies Group, *PBM Industry Trends,* cited with permission (2009).

than brand-name drugs. *Id*.

Another primary mechanism PBMs use to reduce employers' prescription drug benefit costs is obtaining large-scale discounts and rebates from pharmaceutical manufacturers. PBMs can obtain discounts unavailable to individual employers because PBMs can pool the purchasing power of many different customers simultaneously and provide them with a variety of services.[8] Pharmaceutical manufacturers in turn provide PBMs deep price discounts in exchange for guaranteed volume purchases resulting from inclusion of their drugs on PBM formularies. *See* FTC Conflict of Interest Study at 10. The government has indicated that PBMs obtain discounts amounting to between 5% and 7% on brand name drugs. *See* U.S. Department of Health and Human Services, *Report to the President on Prescription Drug Coverage, Spending, Utilization and Prices* 105 (April 2000) ("HHS Study"). On aggregate, pharmaceutical manufacturer discounts obtained by PBMs reduced total annual drug spending between 3% and 9% from 1998 to 2001. *See* United States General Accounting Office, *Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies* (Jan. 2003) ("GAO Report").

PBMs further reduce drug benefit plan costs by reducing administrative

[8] *See* Letter from Federal Trade Commission to New York Senator James L. Seward, March 31, 2009, at 1 ("FTC Seward Letter"); Letter from Federal Trade Commission to Virginia House of Delegates Member Terry G. Kilgore, Oct. 2, 2006, at 5-6 ("FTC Kilgore Letter"). These letters are available on the FTC's website.

costs in the physical delivery of drugs to plan members. PBMs establish networks of retail pharmacies to deliver prescriptions to plan members. Typically, PBMs contract with 90% to 95% of the retail pharmacies in the geographic regions they serve. *See* FTC Conflict of Interest Study at 4. Retail pharmacies actively compete to join PBM networks by offering discounts on both ingredient cost reimbursements and prescription dispensing fees. *Id.* Health benefit plans and their members directly benefit from this competition through lower drug prices and improved access to pharmacies. For example, the Department of Health and Human Services estimates that PBMs pay retail pharmacies 13% to 15% less than the average wholesale price for brand name drugs. *See* HHS Study at 103.

PBMs also promote the use of less-expensive and more efficient mail-order pharmacies. *See generally* FTC/DOJ Healthcare Report; *see also* FTC Conflict of Interest Study, at vii ("[P]lan sponsors often secure[] more favorable pricing for mail dispensing than for retail"). In a study of the price effects of PBMs on federal employee benefit plans, the Government Accounting Office concluded that PBMs achieved "significant discounts for drugs purchased at retail pharmacies and offered even greater discounts through their mail-order pharmacies." GAO Report at 9. PBM prices for prescription drugs were 18% less than average retail pharmacies and 47% less than average consumer cash prices for four selected generic drugs. *Id.* at 4. Likewise, PBM mail order prices were 27% and 53%

below average retail pharmacy prices for selected brand name and generic drugs, respectively. *Id.* The GAO concluded that these cost savings "were . . . passed on to enrollees in the form of premiums that were less than they otherwise would be." *Id.* at 19. Identifying similar cost-savings generated by mail-order pharmacies, the Department of Health and Human Services attributed the reduction in annual spending growth on prescription drugs from 14.3% in 2000-2002 to 8.2% in 2004 to a shift to greater mail-order dispensing. *See* U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services, *National Health Expenditure Data*, *Highlights* (2004).

Finally, PBMs help lower prescription drug benefit costs for employers and assure safety through a range of intervention techniques and drug utilization review services that identify opportunities to substitute less expensive, but equally effective, drugs to plan members. Other specific intervention techniques include therapeutic interchange (encouraging the substitution of less expensive formulary brand name medications considered safe and effective for more expensive nonformulary drugs within the same drug class) and step therapy (the practice of beginning drug therapy with the most cost-effective and safest therapy and progressing to other, more costly or risky therapy if necessary). GAO has estimated that these programs lower health benefit plan costs between one and nine percent. GAO Report at 12. Moreover, in its analysis of 2005 national health

expenditure data, the Department of Health and Human Services attributed the slowing growth of prescription drug spending in part to "a shift in use toward generic drugs," as well as "the proliferation of tiered-copayment benefit plans." *See* U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services, *National Health Expenditure Data*, *Highlights* (2005). The PBMs' techniques have clearly produced tangible change, and employer-provided ERISA plans' reliance on PBMs to provide and administer prescription drug benefits has reduced the cost of those benefits significantly.

3. *Disclosure And "Transfer" Rules Undercut Many Of The Benefits PBMs Currently Provide To Health Benefit Plans*

Title II makes PBMs "fiduciaries" to ERISA plans, requiring them specifically to disclose to such plans proprietary financial information and to transfer to the plans any benefit of any kind received by the PBM as a result of prescription drug substitution or sales volume. D.C. Code. § 48-832.01(a), (b)(2), (d)(3). In purpose and effect, these requirements statutorily alter the terms of the arms-length contracts that currently exist between plans and PBMs. Laws like Title II are motivated by a perception that PBMs fail to pass on to plans the discounts and rebates they negotiate, and do not adequately disclose to plans the discounts they obtain, thereby denying employers and other plan sponsors all the benefits that might possibly be obtained from PBMs. *See id.* § 48.831.01(2). Title II assumes that employers and other PBM customers like health plans lack

sufficient bargaining power to negotiate adequate disclosures and pass-throughs themselves, thus causing them to pay higher prescription drug benefit prices than they otherwise would.

Amici and their members can attest, however, that the core empirical assumption underlying Title II is false: the mandatory disclosure imposed by Title II and similar legislation is both "unneeded and unwanted," in the words of the Federal Trade Commission. FTC Seward Letter at 4. The FTC has noted that "[a]lthough sometimes mandatory disclosures of price and quality information can improve how markets function… health plans do not need them." *Id*. The reason: the market to provide PBM services to plans is already highly competitive, with between 40 and 50 PBMs competing for health plan business. *See* FTC Conflict of Interest Study at 2. That competition, the FTC has noted, "affords health plans substantial tools with which to safeguard their interests." FTC Seward Letter at 4. Employers and other plan sponsors "typically procure PBM service through a bidding process," involving multiple bids submitted in response to requests for proposals. FTC Kilgore Letter at 6; *see* Letter from Federal Trade Commission Bureau of Competition to California Assembly Member Greg Aghazarian, Sept. 7, 2004, at 7 ("FTC Aghazarian Letter"). PBM customers pay close attention to bidders' price guarantees, treatment of rebates, claims-processing fees, customer service promises, and any prior experience with the PBM, including its market

reputation.

The FTC has pointed out that employers have ample power to negotiate concessions from individual PBMs for more extensive disclosures and more extensive discounts, as each individual sponsor sees fit. *See* FTC Kilgore Letter at 7 (competition among PBMs is "vigorous"); FTC Aghazarian Letter at 10 ("There do not appear to be any significant barriers to negotiation between health plan sponsors and PBMs over the terms of their agreement, including how PBMs are to be paid for their services and the disposition of any rebates."). Indeed, PBMs negotiate with their customers over not only the types of services the PBM will provide, but the amount and method for customers to pay for these services; for example, PBMs negotiate with their customers over administrative fee levels, prices for single-source, multiple source, and generic prescription drugs, and the share or dollar amount of manufacturer rebates that are passed through to customers.[9] As the FTC has observed, "some plan sponsors want to receive all payments from manufacturers, while others seek to negotiate deeper discounts on list prices by allowing the PBM to retain these payments – and many plan sponsors fall somewhere in-between." FTC Kilgore Letter at 6. In short, "[m]arket forces are operating to give covered entities the desired disclosures and negotiated terms

[9] Congressional Budget Office, *Prescription Drug Pricing in the Private Sector* (January 2007), at 11, available online at http://www.cbo.gov/ftpdocs/77xx/doc7715/01-03-PrescriptionDrug.pdf (last visited October 5, 2009); *see also* FTC/DOJ Healthcare Report, ch. 7, at 16-17; FTC Conflict of Interest Study at vii.

and conditions for PBM services." William G. Schiffbauer, *PCMA v. Maine, The First Circuit Blesses a 'Shotgun Wedding' Between Business Interests and State Government*, 4 Pharm. L. & Indus. 1, 4 (Jan. 13, 2006).

A recent government study confirms the efficacy of those market forces, showing that 70% to 90% of manufacturers' rebates are already passed along directly to health benefit plans. HHS Study at 105. Even more significant, the federal government's two competition enforcement agencies reviewed the data and concluded unequivocally that the existing competitive market for PBM services works much better to ensure adequate disclosures, sufficient discount pass-throughs and low benefit prices, than interventionist regulations such as Title II:

> Vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of [disclosure] terms. Vigorous competition is also more likely to help ensure that gains from cost savings are passed on to consumers of health-care services, either as lower premiums for health insurance, lower out-of-pocket costs . . . or improved services. . . . Just as competitive forces encourage PBMs to offer their best price and service combination to health plan sponsors to gain access to subscribers, competition also encourages disclosure of the information health plan sponsors require to decide on the PBM with which to contract.

FTC/DOJ Healthcare Report, ch. 7, at 17; *see* FTC Seward Letter at 4 and FTC Aghazarian Letter at 10.

Title II interferes with these properly functioning market forces in ways directly detrimental to the very plan sponsors it is supposed to protect. First, by

requiring PBMs to "transfer in full . . . any benefit or payment received in any form" by the PBM in connection with prescription drug substitution, Title II curtails the flexibility of PBMs and their customers to jointly design products tailored to specific needs and circumstances. As the FTC has found, PBMs already "compete on both price and non-price dimensions to serve . . . varying client needs," considering not just financial terms like administrative fees and manufacturers' payments to plan sponsors based on formulary drugs utilized, but also non-price elements such as benefit design and the quality of mail-order service. FTC Conflict of Interest Study, at 8-9.

Second, the FTC has determined that mandatory PBM disclosure laws are counterproductive, in that they "may increase the cost of pharmaceuticals and health insurance premiums by attenuating competition between pharmaceutical companies." FTC Aghazarian Letter at 12. The FTC believes that "[p]ublic disclosure of proprietary information can . . . undercut vigorous competition on drug pricing," since "[k]nowledge of rivals' prices can dilute incentives to bid aggressively and can facilitate tacit collusion, which increases prices." FTC Kilgore Letter at 13-14.[10] Title II's disclosure requirements undermine healthy

[10] The harm caused by disclosure is not mitigated by the fact that Title II applies only to contracts executed in the District or with covered entities who are in the District, *see* D.C. Code § 48.832.02. The information, once released, will spread, not least because many of the covered entities operate regionally or nationally.

competition among pharmaceutical manufacturers, as manufacturers are likely to respond to the new law by reducing price concessions to any particular PBM, thereby preventing employers from obtaining lower individually negotiated prices. Letter from Federal Trade Commission Bureau of Competition to North Carolina Rep. Patrick McHenry, July 15, 2005.

In short, PBMs "achieve the best cost efficiencies in the prescription drug industry when left unregulated." Thomas P. O'Donnell & Mark K. Fendler, *Prescription or Proscription? The General Failure of Attempts to Litigate and Legislate Against PBMs as "Fiduciaries," and the Role of Market Forces Allowing PBMs To Contain Private-Sector Prescription Drug Prices*, 40 J. Health L. 205, 235 (Spring 2007); *see also id.* (collecting economic data to that effect, including a study concluding that "PBMs save the State of Texas an estimated $180 million per year in prescription drug costs" and that Title II-like regulation of PBMs "would result in a decrease in spending in the Texas economy by almost $1.6 billion per year"). Of course, an increased cost of benefits "could be passed on to plan sponsors and individual health plan consumers in the form of higher prices…" FTC Seward Letter at 10. And "when costs are high, people who cannot afford something find substitutes or do without. . . . The higher the cost of pharmaceuticals, the more people skip doses or do not fill their prescriptions." FTC Kilgore Letter at 15 (quoting William Sage et al., *Why Competition Law*

Matters to Health Care Quality, 22 Health Affairs 31, 35 (Mar./Apr. 2003)).

In addition to these specific consequences, Title II will create a general upward pressure on prescription-drug benefit costs. This is so for at least two reasons. First, the law imposes general fiduciary duties on PBMs, and creates a cause of action for money damages by making a violation of Title II a violation of the District's consumer protection laws. *See* D.C. Code §§ 48-832.01(a), 48-832.03. This new litigation threat will increase PBMs' cost of doing business with District employers and other plan sponsors exponentially – costs that are inevitably passed on to sponsors through prices for PBM services. Not only does Title II create a damages action where none existed before, but that action brings with it the added cost of significant uncertainty. As the FTC noted in commenting on a New York Senate proposal to regulate the contractual relationships between PBMs and health plans, the uncertainty created "may suggest significant and costly risks, including forms of liability beyond those contemplated under contract law or health regulations." FTC Seward Letter at 3. It is impossible for PBMs, given the vague language of the statute, to determine how to avoid commercial actions that will create monetary liability, and may be forced to increase prices generally to insure against the possibility that a given decision will result in significant

monetary payout.[11]

Moreover, benefit costs will be adversely affected by the law's interference with the efficient market forces already governing PBM services. As noted above, there is no evidence whatsoever of any failure in the market for PBM services. Government regulation of that highly competitive market thus can have only one effect – increased prices or reduced output, in terms of either the quantity or quality of the services provided. Title II may mandate that District benefit plans receive something they currently must bargain for, but the law cannot mandate that plans receive these gains for nothing. Because bargaining in this market is otherwise unimpeded, plans' legally mandated gains will necessarily come at some price elsewhere in the economic relationship. That price will either be more expensive benefits, less attractive benefits, or no benefits at all.

B. Title II Is Preempted By ERISA § 514 Because It Regulates The Administration Of Health Benefit Plans

The district court properly held that Title II has a "connection with" ERISA plans and so is preempted by ERISA § 514(a), 29 U.S.C. § 1144(a). Citing *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 657 (1995), the district court stressed that the goal of ERISA's preemption

[11] By allowing a private action for damages by any person injured by a Title II violation (damages that will ultimately be borne by the plans), Title II impermissibly supplements the remedies already provided by ERISA § 502(a) and is preempted for that reason. *See Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004). *Amici* discuss why Title II is preempted by ERISA § 514 in Part B, *infra*.

provision is "to avoid a multiplicity of regulation in order to permit the nationally uniform administration of employee benefit plans." *PCMA*, 605 F. Supp. 2d. at 83. As discussed above, there can be no doubt that Title II specifically "impedes uniform administration of ERISA plans". 605 F. Supp. 2d at 85, n. 4. It regulates the terms on which plans may contract with PBMs to provide and administer prescription drug benefits. Under the District law, for example, the requirement that benefits of drug substitution be passed along to the covered entity will limit plan sponsors' flexibility to design pharmaceutical benefits to meet their needs and those of their beneficiaries, including limiting the ability to negotiate for other contractual concessions.

Thus, as the district court held, Title II is preempted as improperly "managing the relationship between an ERISA plan and a third-party service provider instrumental to the administration of the plan, the defendants, through the Act, improperly inject state regulation into an area exclusively controlled by ERISA." 605 F. Supp. 2d at 87. Those third-party service providers which the court called "instrumental to the administration of the plan" include not just PBMs, but also, for example, behavioral health service providers as well as entities providing dental or vision coverage to a plan. The services they provide include

core ERISA concerns such as claims adjudication and processing.[12] As such, they thus may be "part[ies] in interest" under ERISA. *See* 29 U.S.C. § 1002(14)(B) (defining a "party in interest" to include "a person providing services to an ERISA plan"). Those parties in interest, for example, cannot engage in certain transactions with an ERISA plan, such as the sale of real property, 29 U.S.C. § 1106(a); *see also* 29 U.S.C. § 1108(b)(2), and must disgorge assets and profits obtained through participation as parties in interest in those transactions. As the district court held, PBMs are parties in interest which provide a service "necessary to the establishment or operation of the plan." 29 U.S.C. § 1108(b)(2). This led to the district court's core conclusion: "PBMs provide ERISA plans with essential administrative services, which states may not regulate." *PCMA*, 605 F. Supp. 2d at 88.

The district court directly rejected the contrary logic of the First Circuit's ruling in *PCMA v. Rowe*, 429 F.3d 294 (First Cir. 2005), by noting that the First Circuit "simply did not address the issue of whether the nature of PBM services qualified as ERISA administration." 605 F. Supp. 2d at 87, n. 9. The answer to that question is that those PBM services clearly do, and that a law such as Title II cannot impose state law fiduciary duties on an ERISA plan service provider. The

[12] The Department of Labor concedes as much in its amicus brief, that PBMs perform "ERISA administration" services for ERISA plans. Those services include processing and payment of claims. Brief of the Secretary of Labor as *Amicus Curiae* Supporting Appellants, *Pharmaceutical Care Management Association v. District of Columbia,* et al., No. 09-7042 (September 2009).

First Circuit's reasoning would allow each jurisdiction to impose burdensome (and potentially contradictory) restrictions of all kinds on the benefit-plan-related administrative functions of third-party providers. And because burdens on the third party provider services plan sponsors receive are effectively burdens on the plan sponsors themselves, the decision to uphold the District's restrictions on PBM service activities could have much broader negative consequences for welfare benefit plans nationwide, and for the employers, unions, and other plan sponsors who establish them in this time of rising health care costs.

Amici respectfully suggest that the Court should then decide that Title II is, as a matter of law, preempted by ERISA.

CONCLUSION

For the foregoing reasons, and those stated by appellee, the judgment of the district court should be affirmed.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 5,568 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2007 in 14-point Times New Roman.

Dated: October 13, 2009

William G. Schiffbauer

CERTIFICATE OF SERVICE

I, William Schiffbauer, an attorney for *amici*, hereby certify that on October 13, 2009, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the D.C. Circuit by using the CM/ECF system.

Participants in the case who are registered CM/ECF users will be served by the CM/ECF system. I further certify that some of the counsel in the case are not CM/ECF users. I have mailed the foregoing document by First-Class Mail, postage prepaid to the following non-CM/ECF participants:

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