

Pharmaceutical Care Management Association
Testimony to the ERISA Advisory Council

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Thank you for the opportunity to testify to this Council on the issue of whether mandatory disclosure requirements should be imposed on pharmacy benefits managers (PBMs) pursuant to section 408(b)(2) of the Employee Retirement Income Security Act (ERISA).

I am testifying on behalf of the Pharmaceutical Care Management Association (PCMA), the national association representing America's PBMs, which administer prescription drug programs for more than 220 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, and Medicare Part D.

PCMA testified at the previous hearing, on June 19, 2014, and as a result this subsequent testimony will focus only on those topics that the Council has requested be addressed in more detail:

- I. Introduction: Why mandatory disclosure rules are unnecessary, unprecedented, and counterproductive
- II. The PBM-client contracting process:
 - PBM contracts as customized for a particular client
 - Customizing pricing terms
 - Customizing non-price terms
 - The role and compensation of consultants
- III. Post-contracting: The audit process
- IV. URAC's PBM Accreditation Standards and PBM Purchasers Guide
- V. An historical perspective: the early PBM-era consent decrees

I. Introduction: Why mandatory disclosure rules are unnecessary, unprecedented, and counterproductive

Any new regulations under ERISA that would require PBMs to provide detailed disclosures of their proprietary cost structures, including pharmacy discounts and manufacturer rebates, would be unnecessary, unprecedented, and counterproductive for PBM clients, including employers and health plans, which rely on PBMs for efficient processing of pharmaceutical claims.

- *Unnecessary* because there is “no indication that clients of PBMs lack accurate information on the price and quality of the service they intend to purchase,”¹ to quote the Federal Trade Commission;
- *Unprecedented* because no other entity, either in healthcare or in general industry, is required to disclose competitively sensitive, underlying cost information that can be used against them by entities they must bargain with — here, specifically, pharmaceutical manufacturers and retail pharmacies;
- *Counterproductive* because such revelation will reduce or even destroy PBMs’ ability to deliver value for their clients by negotiating discounts with pharmacies and rebates with drug manufacturers, all in the interests of containing drug costs and improving patient outcomes.

In terms of the first point, why enhanced disclosures by PBMs to their clients are *unnecessary*, the fact is that the marketplace already provides health benefit plans and other sponsors with an array of tools to negotiate arrangements that result in payment to their PBM service providers of no more than “reasonable compensation.” In the words of URAC, the independent accrediting agency, transparency has become central to the PBM industry, whose members work hard to be competitive and satisfy market demand of current and potential clients. That demand includes an increased push toward *pricing* transparency, to ensure that the client can “more effectively compare service, evaluate the costs, and determine if the PBM is acting in the plan sponsor’s best interests.”²

No less an authority than the FTC, which has extensively studied PBMs for more than a decade and issued numerous reports and letters to legislators on the subject, believes that health benefit plans need no additional information to contract in their own self-interest with PBMs. And in selecting a PBM, they have a large and varied number of competitors to choose from, with “many examples of aggressive competition when accounts are up for grabs,” in the graphic language of the FTC.³ The agency cites the robust RFP process for PBM business, addressed below, as helping promote such aggressive competition, especially since “employers routinely retain expert consultants to identify potential bidders, develop detailed solicitations, and evaluate the proposals before settling on a winner.”⁴

Second, in terms of the *unprecedented* nature of any such mandatory disclosure obligations, the current legal requirements for PBM disclosure are deliberately

¹ FTC Letter to Rep. Patrick McHenry, U.S. House of Representatives (July 15, 2005), at 13.

² URAC, “PBM Purchasers Guide: A Quality Management Toolkit,” 2009 at 20, available at www.dol.gov/ebsa/pdf/PBM010711.pdf (discussed below).

³ Statement of the FTC Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc., File No. 111-0210, April 2, 2012, at 6. [hereafter FTC 2012 Statement]

⁴ Id. at 7.

limited to assure that any such disclosures do not result in higher prices, and thus harm the very consumers competition law is supposed to protect.⁵ Thus, for example, under the Affordable Care Act (ACA), information is required to be provided to the Secretary of HHS on “qualified health plans” offered through state exchanges, but (a) only aggregated information regarding rebates, discounts, and price concessions, with de-identified data, and (b) under strong confidentiality protections.

Third, as many witnesses emphasized to the Council in the June hearing, such mandatory disclosures are *counterproductive*, in that they would adversely impact health benefit plans and other PBM clients, not help them. The FTC has weighed in on many occasions over the last decade with a series of letters and reports warning that it is counterproductive to regulate payments to PBMs and to force disclosure obligations on them. Such disclosure, the agency has bluntly stated, will have a double-barreled negative effect: first, it “may excessively restrict the ability of PBMs and health plans to negotiate efficient, mutually advantageous contracts,” and second, it may “facilitate collusion among third parties” if sensitive business information is made public.⁶

II. The PBM Contracting Process

PBM contracts as customized:

It’s a truism that “when you’ve seen one PBM/plan sponsor contract, you’ve seen one PBM/plan sponsor contract.” The reason is that PBM contracts comprise a highly diverse set of arrangements, depending on the particularized and varying requirements of thousands of PBM customers — the plan sponsors and employers who rely on their services. The accrediting agency URAC seconds the point that there are no “one-size-fits-all” contracts, noting that the “PBM industry has evolved to meet the demand for almost any type of contract that can be imagined by a plan sponsor.”⁷

PBMs are more than just claims administrators: they work to partner with the plan sponsor, their customer, to “drive value.” That includes the ultimate goal — improving member health — and at the same time helping the client lower its healthcare costs by building a strong but cost-effective formulary, increasing the use of generics, increasing the use of mail-order for those with chronic illnesses,

⁵ See Letter from FTC to Nellie Pou, Assemblywoman, N.J. General Assembly (Apr. 17, 2007), available at <http://www.ftc.gov/policy/policy-actions/advocacy-filings/2007/04/ftc-staff-comment-hon-nellie-pou-concerning-new-jersey>, at 10.

⁶ See Letter from FTC to James. L. Seward, Senator, N.Y. Senate, at 5 (Mar. 31, 2009), available at www.ftc.gov/os/2009/04/V090006newyorkpbm.pdf, at 3; see also Letter from FTC Staff to Virginia Delegate Terry G. Kilgore (Oct. 2, 2006).

⁷ URAC, “PBM Purchasers Guide” at 21.

improving medication adherence, monitoring prescription drug interaction, and preventing prescription fraud, waste, and abuse.

As documented in a 2005 FTC Report prepared at the request of Congress, which examined hundreds of plan sponsor contracts, contracting for PBM services involves highly complex, negotiation-driven competition — competition driven by PBM clients.⁸ What was true at the time of that FTC Report is still true today: PBM/plan sponsor arrangements vary widely in terms of not only of multiple price terms, but also significant and many-faceted non-price terms, all at the request of the PBM client. All of those terms negotiated and agreed to by the PBMs and their customers are sold as a package, and thus PBMs do not sell a single product in the classic sense.

Instead, as third-party administrators to benefit plans, they provide multiple and highly variable administrative services for benefit plans. The particular choice of plan design as well as services is customized and chosen by the particular client, including formulary coverage, copayment tiers, utilization management, and pharmacy channel options. In making those choices, plan sponsors weigh many factors, including clinical quality, cost, and member satisfaction.

Thus, for example, sponsors can choose whether to incentivize the use of mail-service pharmacies, and may select strong copay and other incentives to encourage consumers to use cost-effective mail service. PBMs also offer their clients the choices of a host of other services such as generic substitution policies, therapeutic interchange programs, prior authorization programs, specialty pharmacy, and disease management services. All of these services are designed to maximize the value of the plan sponsor's pharmacy benefit as well as balance cost, access, and choice for the plan member.

Customizing pricing terms:

There is no standard PBM compensation model. PBM customers can pay for services in a number of different ways, depending on their unique preferences. They can even mix-and-match payment methods, again based on their particular needs. 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.

Generally, PBM clients have the ability to choose between the two main methods by which PBMs price their services: (1) lock-in pricing, and (2) pass-through pricing.

⁸ FTC, "Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies," (2005), available at <http://www.ftc.gov/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report>. [hereafter FTC 2005 Study].

Lock-in pricing: Under this choice, PBMs typically offer clients guaranteed prices, with the PBM's profit or loss depending on how successfully they negotiate price concessions with network pharmacies and drug manufacturers. This form of pricing protects PBM clients from increases in costs and assures them certainty, while the PBM takes more of the risk. As the FTC has noted, lock-in pricing also provides the PBM with a powerful incentive to negotiate aggressively "up the chain" with pharmaceutical manufacturers for the best price, and "down the chain" with pharmacies. Moreover, by earning revenue from the "spread" (the difference between the price guaranteed its client and its actual cost for the prescription) the PBM can offer lower administrative fees to plan sponsors, as well as provide value-added PBM services (such as medication adherence management) at reduced or no cost.

Pass-through pricing also has advantages for the client. In this form of payment, the sponsor pays only actual costs, and the PBM earns revenue based on administrative fees. Under pass-through, the client normally has greater involvement in cost management, and can encourage its enrollees to use more affordable medications (such as generics) as well as more cost-effective distribution channels. Pass-through pricing has become more popular in recent years, as PBMs respond to customer demand in a highly competitive market.

In addition to their choice of the above payment methods, PBM clients in many cases negotiate to receive rebates on drugs. Rebates are not unique to PBM contracting, but are a feature of numerous contractual relationships, both in healthcare and throughout commerce generally. Manufacturers of brand name drugs typically provide rebates to PBMs for placing a drug on the plan's formulary, and may make additional payments for achieving certain volume-based or market share targets. As the FTC has noted, those manufacturer payments are pro-competitive: they assist PBMs in keeping client drug costs down, and incent the PBM to bargain aggressively with pharmaceutical manufacturers.⁹ In some cases, the client negotiates for 100% rebate pass-through, while another client may prefer not to receive all or most of the rebates, and instead choose to pay lower administrative fees.

Whatever form of pricing the customer chooses — in some cases, a combination of both — the PBM customer has multiple means to assure it's obtaining the "benefit of the bargain," including (1) performance-based guarantees included in the contract, enforced through penalties, and (2) the right to audit via an independent, client-selected auditor, as discussed in detail below.

Customizing non-price terms in PBM-plan sponsor contracts:

PBMs have to compete for business on non-price dimensions, including benefit design, the extent of the retail network, and overall customer service.

⁹ FTC 2005 Study at 60.

PBMs also typically provide a wide range of administrative services to their clients in connection with the provision of prescription drug benefits. PBMs also negotiate with customers over such “non-price” features as formulary development, claims processing details, disease management, and drug utilization reviews. In brief, these services may include the following:

- Data management and information reporting
- Formulary management
- Utilization review
- Claims adjudication
- Participant communications

Performance-based guarantees and reporting:

Clients often insist on — and obtain — performance-based guarantees in their contracts with PBMs, including the following:

- Administrative measures contained in contracts and subject to guarantees can include claim processing accuracy, phone service responsiveness, mail-order turn-around time, and timely delivery of management reports.
- Plan design or utilization management guarantees may include targets related to prescription volume, rebates per prescription, or the rate of use of (much more cost-effective) generic drugs.

It is always the client’s choice as to which particular guarantees are most important to it, and hence how to allocate any penalty (should there be one) for failure to meet a particular guarantee. As the FTC has found, most PBM-plan sponsor contracts require the PBM to make specified dollar payments to the plan sponsor if the guarantees are not met.¹⁰ To one client, member satisfaction might be the most important factor, while another client might select a different criterion.

In addition to guarantees, plan sponsors often hold PBMs accountable for performance by asking for reports on a periodic basis (such as monthly or quarterly) on data that can include: the volume of prescriptions, the average payment for prescriptions, and the mix of drugs between brand and generic.

Given the multiple PBMs that compete in the market for plan sponsors’ businesses, it is certain that they will have sufficient alternatives to which they can turn should they find that the performance-based guarantees they contracted for have not been met. It is a fact that plan sponsors can and regularly do change PBMs if they are dissatisfied with performance and/or pricing. Because most PBM contracts are only for relatively short periods (one, two, or three years is common), plan sponsors have the opportunity to and do change PBMs if they are dissatisfied.

¹⁰ FTC 2005 Study at 9.

The role and compensation of consultants:

Competition for clients in the PBM marketplace is “intense,” with at least ten significant players in the industry whose rivalry has driven down prices, according to a 2012 Statement by the FTC.¹¹ Many more PBMs also compete, consisting of both large and small standalone PBMs, as well as health-plan owned PBMs. That aggressive competition is spurred by the “request for proposal” (RFP) process, by which clients seek PBM services. In that process, plan sponsors are almost universally represented by one of the many expert consultants that specialize in PBM RFPs, who first assist in analyzing the various and multiple PBM bids, and then help negotiate the eventual contract with the chosen PBM. RFPs are typically sent to a number of PBMs, ranging from at least four to as many as 12 different companies,¹² so the plan sponsor is assured of a sufficient number of bids to assure that it has adequate selection of both price and non-price terms for its particular needs.

PBM-plan sponsor negotiations today are primarily driven by these consultants, who are chosen by, paid by, and act in the interests of their client health plans. Numerous sophisticated consulting firms have sprung up in the marketplace in the last decade, offering readily available advice on evaluating PBM services. These companies are often household names such as Towers Watson and Aon Hewitt, and are staffed by experts, especially executives who formerly worked for PBMs and/or health plans. The consultants rely on online tools and spread sheets to compare the offerings of multiple PBMs, all competing vigorously for the client’s business, and helping each plan sponsor select what they call the “best possible plan” for its needs by scoring and substantiating the bids from multiple PBMs.¹³

Consultants also know that PBMs, operating in a marketplace where plan sponsors have multiple choices, are interested in designing packages and offering the most competitive price to either obtain or retain business. As a result, consultants can encourage PBMs to “tweak” their offerings to assure they are driving value for that particular client. For one example, PBM bids attempt to be a true reflection of a particular client’s business, based on historical claims detail. Different clients have the need for different mixes of brand vs. generic drugs, for example, or different penetration of more cost-effective mail-order services. As a result, consultants can

¹¹ FTC 2012 Statement at 2.

¹² See the FTC 2012 Statement at 7 (“RFPs are almost always extended to at least four firms, including the incumbent, typically at least two of the Big Three, one or more smaller PBMs, a carve-in proposal from the customer’s health plan provider, and occasionally others on a carve-out basis.”)

¹³ Prominent consulting companies in addition to Towers Watson and Aon Hewitt include: Mercer, Innovative Rx, Horizon, Heritage, Truveris, ARMSRx, DeepView Solutions, Lockton, Willis, Quest Analytics, and Solid Benefits Guidance.

assist the PBM to “price to” the client’s particular needs and (to use the word again) customize the offering for that particular client’s usage.

III. Post-contracting: the Audit Process

Without exception, a PBM client has the right to audit its contractual arrangements with the PBM and assure that the terms of the deal it negotiated are being complied with. The PBM supplies the client and its chosen auditor with all the information necessary to confirm whatever financial arrangement the client has chosen.

The auditor is chosen by the client:

The choice of an auditor is always the client’s, and it can choose among a large group of qualified and readily available auditors. The only condition imposed by the PBM is that the auditor be truly independent, meaning free of conflicts of interest that would create competitive problems. Thus, for example, if a client-selected auditor also has a consulting business helping PBM clients evaluate RFPs, the PBM may ask for a firewall between the two lines of business so that the confidentiality of the PBM’s information is preserved. Another (rare) circumstance when a PBM would reject a client-selected auditor would be when the auditor is assisting a competitor of the PBM to bid on the very same contract at the same time the PBM is bidding. In that case, the client can choose another auditor, or, when the bidding situation causing the conflict has actually been resolved, the auditor can be “cleared” to represent the client.

In an audit, the auditor reviews information either on-site at the PBM’s offices or remotely to confirm the client’s arrangement with the PBM. The auditor has the right to review such materials as invoices and claims records. In a lock-in contract, the auditor is usually auditing to a guaranteed discount, typically off Average Wholesale Price (AWP). The auditor is ensuring the client received the benefit of the bargain, namely the negotiated AWP minus a discount plus a dispensing fee, plus any administrative charges allowed.¹⁴

All audits are conducted under strict rules of confidentiality to preserve the integrity of the pricing and other terms of the PBM-plan sponsor contracts:

- First, every client has a confidentiality provision in its contract with a PBM, providing that it cannot disclosure proprietary information to a third party without the PBM’s written consent.
- Second, the auditing companies have standard non-disclosure agreements (NDAs) with the PBM, and all routinely execute them before they can audit the terms of their client’s deal with the PBM.

- Third, if there is medical carrier data that must be reviewed as well, the health plan(s) involved will also require NDAs.

Those confidentiality provisions in client contracts and the signing of NDAs in the auditing process are critical to assure that the vigorous, multi-faceted competition in connection with PBM services works — that *clients* have access to information to ensure they received the rebates and discounts they negotiated with the PBM, but that *non-parties* to those contracts cannot gain access to that information and destroy the incentive for competitive discounting.

Auditing in pass-through contracts:

The Council has asked: what information is revealed to a client and its chosen auditor in the pass-through pricing model? In that model, as noted, the PBM charges the client what it pays the pharmacy on every prescription, and all rebates inure to the benefit of the client, while the PBM makes money on administrative fees.

The simple answer is this: the client’s independent auditor can audit “the deal the client got.” That means that the audit will pertain to all financial information relevant to that particular plan sponsor — its claims history, the amounts paid for specific claims, what rebates were passed through (including access rebates and market share rebates), and other material relevant to its contract.

That information could also include transparency of retail pricing, in other words, what the PBM paid the pharmacy for that client’s claims. First, in regard to pricing of brand drugs, usually based on AWP, the PBM provides the auditor with the AWP data since it originates with third parties like First Data Bank; in some cases, the large auditing companies have their own licenses for these pricing data and thus have access. Second, in regard to pricing of generic drugs, the PBM assures that the client obtains generics at the lowest prices in the marketplace by using so-called “maximum allowable cost” (MAC) pricing.¹⁵ Because MAC prices change rapidly, even daily, no fee schedule on generics exists. As a result, PBMs assure the client the “benefit of the bargain” by giving it an overall guarantee on generic pricing that can be audited.

Given the volume of contracts and claims involved in an audit of a large client, the PBM in some cases can give the auditor a choice of the group to review as samples, to assure that the auditor is obtaining an accurate view of how the client’s benefit is being administered by the PBM.

¹⁵ MACs specify the allowable reimbursement by a PBM on behalf of a client for a particular strength and dosage of a generic drug that is available from multiple manufacturers but sold at different prices; it is based on aggregate data that show what pharmacies pay on average for generic drugs. Almost four-fifths of private employer drug plans as well as 45 State Medicaid programs use MAC as a cost management tool.

What no auditor does is insist on obtaining information relevant to other clients' deals. They understand that revelation of the precise details of rebate arrangements or price discounts, for example, would involve undermining the competitive bidding and negotiation process that keeps drug prices low for PBM clients and ultimate consumers. Thus, regardless of the financial terms of the deal, including whether pass-through or lock-in, preserving the competitive nature of the process is critical, and all audits takes place only under terms of strict confidentiality.

IV. URAC's PBM Accreditation Standards and Purchasers Guide

The Council has specifically asked for information regarding URAC, the independent, nonprofit organization that offers a wide range of benchmarking and education programs to assure healthcare quality. Set up to be independent of any particular stakeholder group, it has a governing board that assures input from a wide range of entities, including consumers, providers, employers, regulators, and industry experts. Currently, it has 30 widely respected accreditation programs, which are formally recognized by six federal agencies as well as 48 states and the District of Columbia.¹⁶

In the PBM area, URAC has developed both detailed PBM Accreditation Standards (released in 2007), as well as a useful PBM Purchasers Guide (released in 2009) in conjunction with the National Business Coalition on Health (NBCH).

The Accreditation Standards:

All of PCMA's members are fully accredited under URAC's Pharmacy Benefit Management Standards. Developed by a Standards Advisory Committee over the course of more than a year by 30 stakeholders, they have become the critical quality yardstick for plan sponsors when evaluating pharmacy benefit plans. Because they include standardized definitions and protocols, the Standards allow plan sponsors to make "apples to apples" comparisons when engaging in procurement of PBM services.

The Accreditation Standards cover a wide range of topics, including price and non-price terms, including:

- the PBM's contract terms and pricing structures;
- the PBM's formulary development processes, to assure consumer safety and promote clinically appropriate, safe and effective drug therapy, and provide for a formulary appeals process, including peer clinical review;

¹⁶ URAC's standards cover multiple areas, including Medicare Advantage, provider Credentialing, Dental Plans, Specialty Pharmacy, and others. See <https://www.urac.org/directory/DirectorySearch.aspx>.

- the PBM’s clinical review criteria, including medical protocols and drug treatment guidelines used in evaluating medical necessity and appropriateness for a particular patient;
- the PBM’s drug utilization management, including prospective review (prior to a prescription or service) as well as retrospective review (after prescription services have been rendered);
- a process for PBM outcomes measurement and quality improvement.

URAC’s Standards also require the PBM to disclose to clients specific financial model information, including the following:

- The existence of organizational arrangements that could potentially create a conflict of interest that affects clinical or financial decisions;
- Sources of revenue;
- Pricing structure for PBM services, such as rebate structure and administration fees.

The URAC PBM Standards have essentially become the essential “seal of approval” for consumers, regulators, providers, and employers. Specifically relevant to employers and other plan sponsors seeking PBM services, the Standards supply them with explicit terms and expectations that they can apply to their PBMs, and help them select particular PBM services that meet their particular needs, including formulary coverage, copayment tiers, and pharmacy channel options.

URAC’s PBM Purchasers Guide:

In addition to the Accreditation Standards, URAC in conjunction with the National Business Coalition on Health (NBCH) has issued a useful PBM Purchasers Guide. It is a 90-page document outlining how plan employers — both large and small — can ask the “right questions” when choosing a PBM and negotiating a contract that meets what it calls their “benefit objectives for cost, quality, accessibility, and member satisfaction.”¹⁷ The Guide goes on in detail to outline how plan sponsors should evaluate PBM pricing arrangements and revenue sources, summarizing URAC’s quality standards, outlining questions to ask on the PBM/client audit process, and explaining such concepts as drug utilization management and formulary development.

V. Historical perspective: The PBM consent decrees

PBM emerged in the 1980’s in response to a lack of price competition in the pharmaceutical industry.¹⁸ Plan sponsors of all types retained them to administer

¹⁷ URAC “PBM Purchasers Guide” at 5.

¹⁸ David Dranove, “The Economic Evolution of American Health Care,” Princeton U. Press (2000) at 107.

prescription drug insurance benefits, as their services brought considerable cost savings through “real-time” electronic claims adjudications, which reduced processing costs, as well as a network of pharmacies willing to accept negotiated discounts on both drug prices and dispensing fees. In the 1990’s a number of drug manufacturers purchased PBMs, but since 2003 no PBM with any sizeable market presence has been owned by a drug manufacturer.

The 2003 and 2004 “drug switching” settlements:

The Council has asked about settlements entered into between one PBM, Medco, and state and regulators in 2004. That settlement was directed at “drug switching” while Medco was owned by a large pharmaceutical company, Merck. (Today, Medco no longer exists as a stand-alone PBM). The basic allegation was that this ownership resulted in Medco’s encouragement to prescribers to “switch” patients to more expensive drugs to benefit Merck. The settlements — which are evergreen — prohibited Medco from soliciting such drug switches and put in place requirements to ensure that patients and prescribers were informed, and that incentives to use lower-cost generics were in place.¹⁹

In the decade since that 2004 Medco settlement, a number of factors have made the issue of “drug switching” moot. First, as noted, since 2003 no PBM has been owned by a pharmaceutical manufacturer, thus eliminating any incentive to switch as alleged. Secondly, in terms of promotion of generics, fully 80% of the drugs dispensed in the U.S. today are generics; under PBM contracts, the lowest cost drug to the plan alternative is required to be dispensed unless the physician or other prescriber has specified “dispense as written” for a specific drug. Third, today there are very sophisticated independent pharmacy and therapeutics committees (P&T) at every PBM which review and dictate formulary design with an eye toward appropriateness for the member as well as drug safety, and only secondarily toward cost.²⁰

In addition, there exists an 11-year old Assurance of Voluntary Compliance (AVC) entered into in 2003 by the PBM Express Scripts with a number of state attorneys general that is still in force. Under that AVC, Express Scripts agreed under a “Client Pledge” to:

“Always align its interests with those of its clients and members, develop clinically sound formularies based on evaluations of independent physicians, aggressively promote the use of generic drugs, support the use

¹⁹ In addition, Medco entered into a settlement with the Department of Justice in 2006 pertaining to non-ERISA plans relating to whether it accepted payment from pharmaceutical manufacturers to favor their products on Medco’s published list of drugs in connection with government contracts.

²⁰ See discussion in FTC 2005 Study at p. 11; see also URAC, “PBM Purchasers Guide,” at 71.

of clinically appropriate, lower-cost brand-name drugs, never recommend switching a member to a higher-cost drug, provide its clients with a detailed disclosure of its sources of revenue and financial relationships with drug manufacturers, and always respect the physician’s prescribing authority.”

While that AVC is still in place, none of the participating states has felt the need to undertake enforcement action for one primary reason: the market for PBM services has changed radically in the 11 years since the AVC. First, importantly, the terms of that decade-old AVC are perfectly mirrored in the URAC Accreditation Standards that all PCMA members currently comply with. Second, the economics today are different; for one example, the need to assure that there are incentives in place for dispensation of much-cheaper generic drugs is moot. The reason is that generics are more profitable to pharmacies and PBMs than brand drugs, and the vast majority of drugs dispensed are generic — thus aligning incentives perfectly between PBMs and their plan sponsor customers.

Conclusion:

In its decade-plus of experience studying PBMs, the FTC has concluded over and over that operation of competitive market forces afford plan sponsors sufficient information to assess the reasonableness of compensation received by PBMs.²¹ It has also repeatedly condemned any proposed legislation or regulation that interferes with PBMs’ flexibility to work with their customers to design customized drug benefits that lower costs and expand access. As the FTC has stated, “[t]here is no theoretical or empirical reason to assume that consumers require sellers’ underlying cost information for markets to achieve competitive outcomes.”²² Exactly that same definition — whether the customer needs or can use the information being disclosed — applies in many different healthcare contexts, as the Department of Health & Human Services, the FTC, and other federal entities have noted.²³

Obtaining that type of “underlying cost information” is detrimental to competition, since it would invite price-matching by other firms, thereby eliminating all the advantages to consumers that PBMs bring through vigorous negotiation of

²¹ See FTC 2005 Study; S. Kanwit, “FTC ‘Conflict of Interest Report:’ Implications for the Competitive Marketplace in Prescription Drugs,” *American Bar Ass’n Antitrust Bulletin* (2005).

²² FTC Letter to Sen. James L. Seward, N.Y. Senate (March 31, 2009), at 6, available at www.ftc.gov/os/2009/04/V090006newyorkpbm.pdf.

²³ See the HHS Value Driven Health Care Initiatives, www.cms.hhs.gov/QualityInitiativesGenInfo (discussing CMS’s transparency initiative); www.cms.hhs.gov/pgri (discussing CMS’s physician quality reporting program); FTC and Dept. of Justice, *Improving Health Care: A Dose of Competition*, Executive Summary at 21 (2004).

discounts. Thus, for one example, the General Accountability Office (GAO) has stressed the importance of confidentiality of rebate negotiations under the Medicare drug benefit, since such confidentiality “makes it difficult for manufacturers to monitor one another’s behavior and thus impedes collusive activity.” Revelation of those rebates “would tend to increase costs for both the Medicare program and for enrollees.”²⁴

PBMs compete vigorously in the marketplace not only with each other, but also with retail pharmacies, large health plans, employers which may choose to administer their own drug benefit plans, and with pharmaceutical manufacturers. The basic tool is freely negotiated contracts, dictated by sophisticated consultants, that involve multiple terms, both price and non-price. The PBM customer — the health plan or employer which retains a PBM to administer its drug benefits — has all the tools necessary to compare services and evaluate costs on the *front end*, as well as assure it has obtained the “benefit of the bargain” on the *back-end* through audits, performance guarantees, and the ability to change to one of multiple competing PBMs if it chooses.

As economists would phrase it, basic market discipline is provided by the fact that unsatisfied PBM clients can (and do) easily “vote with their feet” and seek alternative terms from competing PBMs. Additional disclosure rules would severely inhibit rather than enhance the efficiency of the PBM market, which are projected to save consumers and both private and public payers an estimated two trillion dollars on prescription drug costs between 2012 and 2021.²⁵

²⁴ CBO, “Potential Effects of Disclosing Price Rebates on the Medicare Drug Benefit,” Letter to the Hon. Joe Barton and the Hon. Jim McCrery, March 12, 2007.

²⁵ Visante, “Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers,” at 3, (2011).