December 5, 2016

Submitted/filed electronically via email at e-ORI@dol.gov

Office of Regulations and Interpretations, Employee Benefits Security Administration
Attn: RIN 1210–AB63
Annual Reporting and Disclosure, Room N–5655
U.S. Department of Labor
200 Constitution Avenue NW.
Washington, DC 20210

Re: RIN 1210–AB63; Proposed Revisions to Form 5500

Ladies and Gentlemen:

The Pharmaceutical Care Management Association (“PCMA”) appreciates the opportunity to present comments on the proposed revisions to the annual Form 5500 reporting requirements for employee benefit plans that were proposed by the Employee Benefits Security Administration (“EBSA”) of the U.S. Department of Labor (“Department”).

PCMA commends EBSA and the Department for their efforts to improve the information available to EBSA and the public through plans’ annual Form 5500 filings. However, PCMA has a few concerns that it believes EBSA should address when it issues the final Form 5500 reporting package and related guidance.

Background

PCMA is the national association representing America’s pharmacy benefit managers (“PBM”), 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. PBM typically create and maintain networks of retail pharmacies and negotiate with the pharmacies to set rates at which the PBM will reimburse them for prescriptions they dispense to members of PBM’s client plans. Some PBM also operate, directly or through affiliates, their own mail-order, specialty and retail pharmacies, which negotiate directly with pharmaceutical manufacturers, wholesalers and group purchasing organizations to purchase the prescription drugs that they dispense to patients. PBM clients choose from these pharmacies when selecting their pharmacy networks under the terms of their agreements with their PBM.

PBMs are a key driver for reducing healthcare costs and improving patient outcomes. As outlined in the attached report from Visante (Exhibit A), PBMs are projected to save health plans and other consumers almost $2 trillion in prescription drug costs from 2012-2021. The report also found that another $550 billion could be saved if the tools PBMs use to drive down
prescription drug costs for consumers were universally adopted. PBMs improve patient outcomes and provide cost savings in several ways:

- **Negotiating Discounts from Drugstores and Drug Manufacturers.** Retail pharmacies negotiate discounted rates with PBMs for prescription drugs dispensed to members of clients’ plans, and can compete to be in pharmacy networks. In addition, PBMs negotiate rebates from pharmaceutical manufacturers. Rebates are often shared with PBM clients, further reducing clients’ drug costs.

- **Home Delivery of Medicines.** PBMs’ mail-service and specialty pharmacy channels typically offer cost-effective options for clients as well as robust clinical support and convenience for patients.

- **Encouraging Use of Generics and Less Expensive Brands.** PBMs offer clients several tools to encourage the use of generic drugs and preferred brands. These include formularies and tiered cost sharing, prior authorization and step therapy protocols, generic incentives, consumer education, and physician outreach. As PBMs and plan sponsors strive for greater savings, the right drug mix becomes even more important.

- **Using Cutting-Edge Tools to Improve Adherence.** PBMs use drug utilization review to reduce waste such as polypharmacy (i.e., the use of multiple medications to manage coexisting conditions, most often by an older adult) and implement patient adherence programs to help patients stick to their prescription regimens. Both programs improve clinical outcomes and reduce prescription volume and expenditures.

- **Improving Quality and Safety.** PBMs promote the use of technology to improve quality and safety by preventing drug duplication and dangerous drug-to-drug interactions.

Because PBMs are effective in controlling prescription drug costs and maximizing patient outcomes for their clients, including self-insured health plans, governmental entities, insurance companies and others, they are utilized by nearly all such entities either directly or through an intermediary. The alternatives – claims administrators and administrative services-only contracts – typically do no more than process claims and simply lack the tools to control ever-increasing costs or to provide drug safety.

**How PBMs Operate**

By contract with the PBMs, the PBMs’ clients, and, more specifically, the individuals covered by the clients’ prescription drug programs, obtain access to the retail pharmacy networks and mail-order and specialty pharmacies. These arrangements, and the services provided by a PBM to a particular plan, are selected by the plan sponsor.

Retail pharmacies in the PBM’s network, and the PBM’s wholly-owned mail order and specialty pharmacies, fill prescriptions with drugs they have purchased directly from wholesalers and
manufacturers. PBMs do not handle or take possession of drugs dispensed at retail pharmacies. When a plan member goes to a retail pharmacy to fill a prescription, the pharmacy will communicate with the PBM regarding the member’s prescription drug coverage and copayment information. After the prescription is dispensed, the PBM reimburses the pharmacy at a contractually-agreed negotiated rate minus the copay collected by the pharmacy. The PBM separately bills the client at the rate contractually negotiated between the PBM and the client.

Under one model (commonly referred to as the “spread” model), the PBM pays the pharmacy the pre-negotiated rate, and bills the plan at the client’s separate pre-negotiated rate (which may be lower or higher than the rate paid by the PBM to the pharmacy). This model provides the client with more cost certainty and generally requires lower administrative fees. Under another model (commonly referred to as the “pass-through” model), the PBM simply passes through the cost of the prescription directly to the client, so the client pays whatever rate was negotiated with the pharmacy that filled the prescription. This model generally has higher administrative costs.

Under either model, the PBM’s obligations to pay the retail pharmacies are not contingent on its receipt of payment from its clients. With respect to mail-order and specialty pharmacy prescriptions, the client’s payment for drugs dispensed is determined under the PBM contract, and the mail order or specialty pharmacy dispenses medications directly to patients in this scenario.

PBM administrative services may include general recordkeeping, data management and information reporting, formulary management, drug utilization review, claims adjudication, member communications, and other services. How PBMs charge for services varies from PBM to PBM and client to client. For example, one client may choose a flat fee for administrative services, while another may prefer variable fees for some services and no fee for other services.

**The PBM Contracting Process**

PBMs compete for business from ERISA plans or their sponsors by submitting bids through a Request for Proposal (“RFP”) process initiated by the plan sponsor. The RFP bidding process allows a plan sponsor to leverage its negotiating ability and purchasing power by creating intense competition among PBMs. The plan sponsors often utilize the services of sophisticated consultants with a deep knowledge of the PBM industry. In other cases, they work in tandem with brokers, third-party administrators and others intimately familiar with how PBMs work. Most PBM contracts are only for a one, two, or three-year period, so plan sponsors have the opportunity to quickly switch PBMs if they are dissatisfied with a PBM’s performance or pricing. Further, many PBM arrangements include market check provisions that allow the plan sponsor to survey the market during the term of the contract and determine whether a lower price is available in the market. If a lower price is available, the incumbent PBM must meet those lower pricing terms – otherwise the plan sponsor may terminate the arrangement and transition its business to the lower-cost PBM.

RFPs often request proposals under both the spread and pass-through pricing models, with various other iterations. The spread model is most often selected by the client because it
provides the PBM a very strong incentive to drive hard bargains with the network pharmacies, which gives the PBM a potential upside and in turn makes the PBM able to offer lower guaranteed rates to their clients than in pass-through arrangements. Because of the potential upside to the PBM, the PBM is willing to offer lower guaranteed rates to the clients, which results in larger cost savings for the client.

The contracting process is highly transparent. The RFP, usually developed by highly experienced consultants or other professionals, includes questions developed to ensure that the plan sponsor receives the suite of services at the price that best meets its needs. RFP requirements include all information deemed relevant by the consultant, including information on rebates and other matters. If the PBM wants to participate in the RFP process, it must answer these questions. Thus, significant disclosures typically are agreed to between the PBM and the client, subject to negotiated confidentiality obligations (and, in general, the stronger the confidentiality protections, the more information may be disclosed). In addition, the financial provisions of PBM contracts are heavily negotiated. For example, under many contracts the PBM shares some or all of the rebates it receives from pharmaceutical manufacturers with the client. In fact, many contracts have minimum rebate guarantees, under which the PBM must pay additional amounts out of its own pocket to the client if the rebates associated with that client’s member utilization fall below the agreed-upon amount.

PBM-client contracts typically include significant audit rights for the client, and clients frequently take advantage of these rights to confirm that the services are being provided in accordance with the contract and that the client is receiving the financial benefits it bargained for in the arrangement. Audits may examine claims processing, rebate sharing, and other aspects of the contractual relationship. Many professional firms, including the largest accounting firms, provide PBM auditing services at a reasonable cost. PBM contracts typically have an annual audit right covering at least two years of data at the PBM’s cost.

In addition, several firms offer software programs to manage and analyze PBM bills on a “real-time” basis and also offer processes to manage RFPs, either directly or through consultants and brokers. These programs are becoming increasingly popular with plan sponsors and other purchasers of PBM services.

Ultimately, the plan sponsor chooses the arrangement that best suits its needs. With the vigorous competition in the industry to obtain and retain clients and the significant voluntary, mutually agreed-to disclosures that provide for significant transparency, clients can ensure that they are paying competitive rates for the services the PBMs provide and the health care their covered members receive.¹

¹ Some parties with interests adverse to plan participants, such as pharmacies, allege that PBM compensation arrangements create conflicts of interest, such as being incentivized to structure formularies to encourage the use of brand name drugs with higher rebates or spread. This argument is false. Formularies are developed with clinical safety as the paramount consideration. Once clinicians have determined which drugs must be on the formulary and which drugs may compete with others in their therapeutic class, PBMs leverage competition within the therapeutic classes to create cost savings that are shared with clients. In addition, the FTC Report (discussed below) concluded that there are no problematic conflicts of interest.
FTC and DOJ Evaluation of the Industry

In 2004, the Federal Trade Commission (the “FTC”) and the U.S. Department of Justice completed a joint two-year project examining the role of competition in the health care industry. The findings of this study were reached after 27 days of joint hearings, including testimony from 250 panelists, which produced a transcript of almost 6,000 pages. With respect to PBMs, the joint FTC/DOJ Report stated that, “[i]n general, vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation. Just as competitive forces encourage PBMs to offer their best price and service combination to health plan sponsors to gain access to subscribers, competition should also encourage disclosure of the information health plan sponsors require to decide with which PBM to contract.” FTC/DOJ Report at Executive Summary, p. 28.

While collecting information with respect to the joint FTC/DOJ Report, the FTC was also conducting a separate study of the PBM industry pursuant to a Congressional request that it investigate “differences in payment amounts for pharmacy services provided to enrollees in group health plans that utilize pharmacy benefit managers.” The resulting report, released in 2005, concluded that PBMs were not engaging in self-dealing by both administering a health plan’s pharmacy benefits program and directly selling prescription drugs to plan participants via the PBM’s own mail-order pharmacy. FTC Report at vi. (“The actual data from study participants on the business practices Congress requested the FTC to study revealed that these allegations are without merit.”).

In addition, on April 2, 2012, the FTC issued a closing statement in connection with the acquisition of Medco Health Solutions, Inc. by Express Scripts, Inc., two of the largest PBMs in the United States. The FTC conducted an intensive eight-month investigation of the transaction:

The evidence we examined was the product of a comprehensive investigation. Our staff interviewed over 200 market participants, including customers, other PBMs, retail and specialty pharmacies, pharmacy trade groups, pharmaceutical manufacturers, and healthcare benefit consulting firms. Millions of documents produced by the merging parties and numerous market participants were reviewed. Staff economists performed detailed analyses of historical sales, cost, and bid data obtained from the parties and other industry participants. We also considered numerous advocacy letters and white papers submitted by a variety of consumer organizations. Our investigation was conducted in cooperation with, and the assistance of, a working group of 32 state attorneys general.

4 U.S. Federal Trade Commission, Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc. (the “Medco/Express Scripts Report”)
The FTC concluded as follows:

Our investigation revealed a competitive market for PBM services characterized by numerous, vigorous competitors who are expanding and winning business from traditional market leaders. The acquisition of Medco by Express Scripts will likely not change these dynamics: the merging parties are not particularly close competitors, the market today is not conducive to coordinated interaction, and there is little risk of the merged company exercising monopsony power. Under these circumstances, we lack a reason to believe that a violation of Section 7 of the Clayton Act has occurred or is likely to occur by means of Express Scripts’ acquisition of Medco.

In addition, as particularly relevant here, the FTC has consistently opposed efforts to mandate disclosures by PBMs. For example, in September 2004, the FTC objected to a proposed California law that would have required PBMs to make specific disclosures to their health plan clients regarding revenue (including rebates from drug manufacturers), administrative fees, and arrangements to encourage formulary compliance or manage benefits. Among other things, the FTC observed that the proposed legislation might well have an anticompetitive effect:

Financial information disclosed by PBMs to [health plans] may become public and a knowledgeable pharmaceutical manufacturer might well be able to use this information to calculate the rebate a competitor was offering. If pharmaceutical manufacturers learn the exact amount of the rebates offered by competitors . . . then tacit collusion among manufacturers is more feasible. Consequently, the required disclosures may lead to higher prices for PBM services and pharmaceuticals.

Although acknowledging that “[i]t is possible that [the bill] may provide some additional information to these plan sponsors about the revenue streams obtained by PBMs,” the FTC emphasized that “it does not necessarily follow that this would make the PBMs compete more aggressively to do business with this plan sponsor. Indeed, to the extent [the bill] makes tacit collusion more likely, these plan sponsors may end up with ‘worse’ contractual terms.”

The FTC also found that “[t]here do not appear to be any significant barriers to negotiation between health plan sponsors and PBMs over all the terms of their agreement, including how PBMs are to be paid for their services and the disposition of any rebates.” Indeed, the FTC observed that:

Vigorous competition in the marketplace for PBMs is more likely to arrive at an economically efficient level of transparency than regulation of those terms. Just as competitive forces encourage PBMs to offer their best price and service combinations to health plan sponsors in order to gain access to subscribers, competition also encourages disclosure of the information group health plan sponsors require to decide which PBM to contract with[.]
Then, in a July 15, 2005 letter regarding a North Carolina bill that would have mandated certain financial disclosures by PBMs—including with respect to “rebates, discounts, disbursements, or any other similar financial program or arrangement relating to income or consideration received, directly or indirectly, with any pharmaceutical company”—the FTC concluded that, while “[c]onsumers need accurate information on price and quality to make informed purchasing decisions,” “there is no theoretical or empirical reason to assume that consumers require a producer’s underlying cost information for markets to achieve competitive outcomes.” In other words, there is no need for health benefit plans to know what it costs PBMs to purchase drugs from manufacturers in order to achieve a competitive price for the PBM’s service. Indeed, because most health benefit plans select PBMs via a sealed bidding process, there is “no indication that clients of PBMs lack accurate information on the price and quality of the service that they intend to purchase.” The FTC did not agree that “requiring PBMs to reveal information related to rebates received from pharmaceutical companies would improve market outcomes.” On the contrary, it was the agency’s view that “increased disclosure of financially sensitive information may pose a risk to healthy competition between pharmaceutical manufacturers” by increasing the risk of tacit collusion.

In October 2006, the FTC again submitted comments, regarding proposed legislation in Virginia that would have regulated the contractual relationship between PBMs and health benefit plans, including mandatory disclosure of proprietary information. Again, the FTC opposed the legislation, reiterating the points raised in the letters above and further stating:

[Plan sponsors generally appear able to negotiate contract terms—including terms regarding information disclosure—to protect themselves from conflicts of interest. Press reports suggest that, as a result of competition to provide the best mix of price and quality, many PBMs offer contracts that provide both full disclosure and rebate sharing to their clients. Further, it is common for contracts to provide for audit rights, so that [health plans] can verify that pharmaceutical payments are being shared as per agreement. Thus, there is no reason to suppose that competition between PBMs is less likely than government regulation to produce efficient levels of information disclosure.

The FTC also opposed a New Jersey bill that would have required PBMs to disclose sensitive financial information to health benefit plans, noting that “such disclosures may facilitate collusion, raise price, and harm the patients the bill is supposed to protect.” The FTC reiterated its consistent concern with mandatory disclosure regimes:

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If pharmaceutical manufacturers know the precise details of rebate arrangement offered by their competitors, then tacit collusion among them may be more feasible. Absent such knowledge, manufacturers have powerful incentives to bid aggressively for formulary position, because preferential formulary treatment offers the prospect of substantially increased sales. Unprotected disclosures thus may raise the price that New Jersey consumers pay for pharmaceutical coverage by softening competition among pharmaceutical companies for preferred formulary treatment.

Then, in 2009, a proposed New York statute would have required PBMs to make substantial disclosures to health plans during contract negotiations and annually thereafter. Disclosures would have included extensive details of the PBM’s cost structure and business strategies, and the bill also would have required PBMs to provide physicians with financial and clinical information upon request. The FTC strongly objected to the proposed bill, noting that “health plans appear able to protect themselves . . . through arms-length contracts.” The FTC concluded that “[a]llowing competition among PBMs is more likely to yield efficient levels of payment sharing, disclosure, and price than contract terms regulated by government regulation.”

In short, the FTC’s longstanding position with respect to each state’s proposed PBM disclosure regime has been clear and consistent: mandated disclosures can lead to tacit collusion, which can lead to higher prices. Far from benefiting ERISA plans and consumers of prescription drugs, it is the consumers, including health plan participants and beneficiaries, who are the ultimate losers in such a scenario.

**The 2009 Form 5500 Revisions**

When it issued the most-recent revisions for Form 5500, EBSA recognized the concerns raised by the FTC with respect to public disclosure of rebate-related information of PBMs. Schedule C of Form 5500 requires disclosure of compensation paid to plan service providers. Interpreting these requirements, the following FAQs were issued:

**Q26: Pharmacy Benefit Managers (PBMs) provide services to plans and are compensated for these services in various ways. How should this compensation be reported?**

PBMs often act as third party administrators for ERISA plan prescription drug programs and perform many activities to manage their clients’ prescription drug insurance coverage. They are generally engaged to be responsible for processing and paying prescription drug claims. They can also be engaged to develop and maintain the plan’s formulary and assemble networks of retail pharmacies that a plan sponsor’s members can use to fill prescriptions. PBMs receive fees for these services that are reportable compensation for Schedule C purposes. For example, dispensing fees charged by the PBM for each

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8 Letter from James Cooper, Acting Director, Office of Policy Planning, Pauline M. Ippolito, Acting Director, Bureau of Economics, and David P. Wales, Acting Director, Bureau of Competition, U.S. Federal Trade Commission, to James L. Seward, New York Senate (March 31, 2009).
prescription filled by its mail-order pharmacy, specialty pharmacy, or a pharmacy that is a member of the PBM’s retail network and paid with plan assets would be reportable as direct compensation. Likewise, administrative fees paid with plan assets, whether or not reflected as part of the dispensing fee, would be reportable direct compensation on the Schedule C. Payments by the plan or payments by the plan sponsor that are reimbursed by the plan for ancillary administrative services such as recordkeeping, data management and information reporting, formulary management, participant health desk service, benefit education, utilization review, claims adjudication, participant communications, reporting services, Website services, prior authorization, clinical programs, pharmacy audits, and other services would also be reportable direct compensation.

**Q27: PBMs may receive rebates or discounts from the pharmaceutical manufacturers based on the amount of drugs a PBM purchases or other factors. Do such rebates and discounts need to be reported as indirect compensation on Schedule C?**

Because formulary listings will affect a drug’s sales, pharmaceutical manufacturers compete to ensure that their products are included on PBM formularies. For example, PBMs often negotiate discounts and rebates with drug manufacturers based on the drugs bought and sold by PBMs or dispensed under ERISA plans administered by a PBM. These discounts and rebates go under various names, for example, “formulary payments” to obtain formulary status and “market-share payments” to encourage PBMs to dispense particular drugs. The Department is currently considering the extent to which PBM discount and rebate revenue attributable to a PBM’s business with ERISA plans may properly be classified as compensation related to services provided to the plans. Thus, in the absence of further guidance from the Department, discount and rebate revenue received by PBMs from pharmaceutical companies generally do not need to be treated as reportable indirect compensation for Schedule C purposes, even if the discount or rebate may be based in part of the quantity of drugs dispensed under ERISA plans administered by the PBM. If, however, the plan and the PBM agree that such rebates or discounts (or earnings on rebates and discounts held by the PBM) would be used to compensate the PBM for managing the plan’s prescription drug coverage, dispensing prescriptions or other administrative and ancillary services, that revenue would be reportable indirect compensation notwithstanding that the funds were derived from rebates or discounts.

**The Proposed Revisions to Schedule C and New Schedule J**

We do not believe that the proposed revisions to Schedule C should impact the guidance in the FAQs quoted above. The same concerns that EBSA considered with respect to disclosure of PBM information continue to apply. However, in order to avoid any confusion between PBMs and their clients as to whether the revisions to Schedule C impact this analysis, we respectfully request that EBSA specifically confirm that those FAQs continue to apply to revised Schedule C.

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9 PBMs do not buy and sell drugs; rather, the rebates and discounts are based upon prescription drugs dispensed by the pharmacies within a PBM’s network.
The proposal also adds a new Schedule J to Form 5500 for group health plans. The proposal indicates that there are several reasons for mandating new Schedule J. First, the information to be reported will assist the Department in its reporting obligations under the Affordable Care Act. Second, sections 2715A and 2717 of the Public Health Service Act, as amended by the Affordable Care Act (“ACA”), added various new reporting requirements for group health plans regarding claims and appeals and certain other information. Third, in order to “collect and provide high value data to participants, beneficiaries, and regulators,” the rulemaking proposes “transparency and quality reporting” group health plans.

As applicable to PBMs, the proposed Schedule J would require disclosure of rebates paid by PBMs to the plan. PCMA respectfully submits that none of the reasons EBSA provided for new Schedule J support requiring public disclosure of rebates paid by a PBM to the plan.

First, the ACA includes reporting rules applicable to PBMs. Specifically, section 6005 of the ACA requires entities that provide PBM services to a prescription drug plan or a “qualified health plan” offered through a state exchange to provide certain information to the Secretary of the Department of Health and Human Services. The information must be aggregated, with de-identified data, so that the PBM and plan names are not disclosed to anyone other than the Secretary. In addition, the Secretary may only disclose the information she received if (i) it is in a form that does not disclose the identity of the PBM, plan or prices charged for drugs, and (ii) the disclosure is either necessary to carry out the requirements of the ACA or Medicare Part D, for review by the Comptroller General, for review by the Congressional Budget Office, or to enable states to carry out the health exchange provisions of the ACA. The limited nature and strong confidentiality protections for these disclosures was an intentional decision of Congress, following input from the FTC, because of the negative impact such disclosures would have on the marketplace. Thus, Congress’ intent in the ACA strongly counsels against requiring public disclosure of PBM rebates through Form 5500 reporting.

Second, when Congress enacted sections 2715A and 2717 of the Public Health Service Act, it listed several specific types of information that group health plans are required to disclose. Rebates are not included in the list. The fact that PBM-specific reporting provisions were included in other provisions of the ACA, as summarized above, is further evidence that Congress did not support public disclosure of PBM rebates through Form 5500 reporting or otherwise.

Third, we do not believe that public disclosure of rebates paid by a PBM to a group health plan has any value to participants, beneficiaries or regulators. EBSA and other regulators can always request this information in the course of a plan audit if desired, without requiring the type of public disclosures that the FTC has consistently opposed.

In sum, required disclosures of rebates on Form 5500 are inconsistent with the structure of the ACA, would have no real benefits for participants, beneficiaries or regulators, and would implicate the concerns raised by the FTC many times in the past 15 years. EBSA recognized these concerns when it issued the FAQs for current Schedule C of Form 5500. Thus, we respectfully request that neither Schedule C nor Schedule J of the revised Form 5500 require disclosure of rebate-related amounts received by PBMs or paid by PBMS to plans.
PCMA appreciates the opportunity to file these comments on the proposed revisions to Form 5500. Please let us know if we can provide you with any further information.

Sincerely,

[Signature]

Barbara Levy
Vice President and General Counsel
Pharmaceutical Care Management Association