PCMA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

February 11, 2008

Via e-mail to e-ORI@dol.gov

Kristen L. Zarenko
Office of Regulations and Interpretations
Employee Benefits Security Administration
Attn: 408(b)(2) Amendment
Room N-5655
U.S. Department of Labor
200 Constitution Avenue, N.W.
Washington, D.C. 20210

Re: Comment Letter on Proposed Regulations: Reasonable Contract or Arrangement Under Section 408(b)(2)—Fee Disclosure

Dear Ms. Zarenko:

The Pharmaceutical Care Management Association ("PCMA")[1] appreciates the opportunity to present comments on the proposed regulations issued by the Employee Benefits Security Administration ("EBSA") of the U.S. Department of Labor ("Department").[2] The proposed regulations would amend the Department's current regulations interpreting the phrase "reasonable contract or arrangement" under Section 408(b)(2) of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"), to provide significantly expanded disclosure requirements on certain service providers that enter into contracts to provide services to ERISA plans.

While commending the Department on its efforts to enhance transparency and efficiency in the selection of service providers to ERISA plans, PCMA urges the Department to reconsider the scope of the proposed regulation to ensure that the effects of the rule, if applied with respect to certain service providers, will not have a negative impact on plan participants and beneficiaries. Specifically, the final regulation should exclude from its coverage Pharmacy Benefit Managers ("PBMs"), as the rationales justifying the proposed regulation are simply inapplicable to PBMs. Absent an express exemption for PBMs, several aspects of the proposed regulation should be changed in order to avoid creating a critical negative effect on the efficient delivery of prescription drug benefits to plan beneficiaries.

[1] PCMA is the national trade association representing Pharmacy Benefit Managers ("PBMs"), which administer prescription drug plans for more than 210 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, and Medicare Part D.

[2] Reasonable Contract or Arrangement Under Section 408(b)(2)—Fee Disclosure, 72 Fed. Reg. 70988 (proposed Dec. 13, 2007) (to be codified at 29 C.F.R. pt. 2550).

EXECUTIVE SUMMARY

PCMA recommends:

A. The application of the regulations should be limited to contracts or arrangements governing the provision of investment services in connection with the management of plan assets, and should not apply to contracts or arrangements involving the provision of administrative services to employee welfare benefit plans, specifically PBM contracts. The Federal Trade Commission ("FTC"), which has comprehensively examined the PBM industry, has repeatedly concluded that a regulatory-induced disclosure regime, like the one set forth in the proposed regulations, is unnecessary in the PBM market as market forces provide plans and plan sponsors with sufficient information to assess the reasonableness of the compensation received by PBMs and whether any conflicts of interest exist. Indeed, the FTC has publicly stated on multiple occasions that such mandatory disclosure may have an unintended anti-competitive effect that would disadvantage consumers by raising the cost of prescription drugs.

B. That incidental services involving contractually delegated named fiduciary status in a narrow scope and only with respect to review of claims appeals should not automatically subject a service provider to the disclosure requirements of the regulations where the services are not a material component of the service relationship.

C. The legal standard utilized in proposed 2550.408(b)(2)(c)(1)(iii) for measuring compliance with the disclosure requirements be a "reasonable good faith knowledge" standard, rather than "best knowledge" standard.

D. The term "compensation or fees", as defined in proposed 2550.408(b)(2)(c)(1)(iii)(A)(1), be clarified to provide that the following items are not "compensation or fees" received by a PBM in connection with its contract to provide administrative services to a welfare benefit plan:

> (i) discounts received by a PBM with respect to its acquisition of goods and services for resale or in connection with services to be rendered by the PBM and any related profits;
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> (ii) income earned by a PBM on the investment of its own assets;
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> (iii) income earned by a service provider with respect to the provision of plan benefits; and
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> (iv) fees received by a service provider for services performed for or on behalf of a third party, provided that the services performed are part of an independent fee for service relationship.

E. That proposed 255.408(b)(2)(c)(1)(v) be revised to provide that a PBM is not obligated to disclose specific information regarding its contracts and arrangements with third parties if the information constitutes a

trade secret or is not generally known to the public and affords the PBM a competitive advantage, provided that (i) with respect to the disclosure of compensation or fees, the PBM discloses sufficient non-protected information to reasonably allow a fiduciary to determine the reasonableness of the service provider's compensation or fees and (ii) with respect to the disclosure of conflicts, the existence of the contract or arrangement is disclosed.

F. That the final regulations clarify the nature and scope of the required disclosure required with respect to a PBM contract taking into account the unique nature of such contracts.

G. That given the substantial regulatory and court scrutiny of the relationships between a PBM and its subcontractors, the results of which are widely available in public documents, the final regulations not require further affirmative disclosure of such relationships by PBMs.

H. That the final regulations clarify that multi-year contracts are permitted under Section 408(b)(2) and that upon early termination the recapture of discounts granted in exchange for agreeing to a multi-year contract and other terms designed to put the parties in roughly the same position as they would have been with an annual contract are not penalties for purposes of the current regulation.

I. The final regulations not apply with respect to contracts in effect on the effective date of the final regulations unless the current term of such contract is extended or until there is a material amendment of or modification of the compensation provisions of such contract.

COMMENTS

A. EXCLUSION OF ADMINISTRATIVE SERVICE CONTRACTS WITH WELFARE BENEFIT PLANS

1. Summary

The proposed regulations apply to all contracts or arrangements to provide services to an employee benefit plan entered into by service providers that fall within three separate categories. No distinction is made between services provided to employee pension benefit plans and employee welfare benefit plans or between administrative and investment related services.

2. Recommendation

We recommend that the regulations only apply to contracts or arrangements that provide for the provision of investment related services in connection with the management of plan assets (including bundled administrative services), and that the PBM industry be expressly exempted.

3. Explanation

As the preamble of the proposed regulation makes clear, the proposed regulations are intended to incorporate recommendations made by the

ERISA Advisory Council Working Group regarding the need for plan fiduciaries to have "more comprehensive information about the compensation and fees involved in plan administration and investments, including indirect compensation: 72 Fed. Reg. 70990 (December 13, 2007). However, the regulations as proposed would have much broader application.

The work and findings of the Working Group were expressly limited to studying retirement plan investment related fees and expenses and whether sponsors of retirement plans adequately understood the total fees and expenses that were being paid.[3] The Working Group did not study fees and expenses paid in any other context or whether current levels of disclosure with respect to non-investment related fees and expenses were adequate.

The Working Group's report did not purport to address administrative only service contracts with welfare benefit plans. In fact, the report did not address the adequacy of disclosure in administrative service contracts with respect to retirement plans except where administrative and investment services were bundled and where the fees for both were effectively netted against investment returns.[4] It is important to note that in the majority of cases, unlike the contracts studied by the Working Group, the administrative expenses of a welfare benefit plan are paid out of the general assets of the plan sponsor and such payments have no direct effect on the benefit received by plan participants. As a result, many PBM contracts would not fall under the proposed regulations as the contracts are directly with the plan sponsor, the PBMs are paid out of the general assets of the plan sponsor, and the plan itself has no direct or indirect legal obligation to pay the compensation of the PBM.[5]

The Working Group's report and recommendations were clearly influenced by a number of factors, including (i) the increased prevalence of defined contribution plans over defined benefit plans, (ii) the heavy reliance of retirement plans on pooled investment vehicles, (iii) the "dramatic change" in the way investment fees are charged and their ability to reduce the investment return on plan assets, and (iv) increased revenue sharing arrangements between pooled investment funds and other plan service providers. A major concern reflected in the report was that investment and related administrative fees that are charged against investment returns are effectively paid by, and have a direct impact on the benefits received by, plan participants.

None of the factors cited by the Working Group are involved in, and none are relevant to, the provision of administrative services to welfare benefit plans by PBMs. More importantly, imposition of the Department's proposed regulation in its current form to PBMs would disrupt a system that works well for health plans and their participants who receive the benefit of

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[3] An additional task of the Working Group was to determine whether investment related fees and expenses were being properly reported on Form 5500.

[4] S*ee* ERISA Advisory Council Working Group Report at *http://www.dol.gov/ebsa/publications.*

[5] In such a case, there would be no potential for abuse, no section 406(a) transaction and no need to rely on section 408(b)(2). *See, e.g., Moeckel v. Caremark, Inc.*, 2007 WL 3377831 at 12 (M.D. Tenn. 2007), DOL Reg. §2550.408b-2(a)(section 408(b)(2) exempts "payment by the plan to a party in interest").

lower costs and would likely cause more harm than good, by reducing competition.

Including PBMs within the scope of the proposed regulation is not supported by the particular concerns about the pension consulting industry that animated the Department's action. Indeed, the mandatory disclosure regime that the proposed regulations would impose on PBMs is fundamentally at odds with the conclusions of the FTC that market forces are more than adequately providing purchasers of PBM services with information sufficient to make prudent selections as to which PBM and which drug benefit program would best suit their needs.

In the preamble to the proposed regulations, the Department acknowledges that the regulations would have the greatest effect on service providers to pension plans, but that some health and welfare plans could also benefit. *id.* at 70994. However, the chief concerns behind the proposed regulation are not applicable to PBM service contracts. The Department has identified the "public policy goals of increased transparency and increased competition in the service provider market" as the justification for its regulatory action. *Id.* at 70995. However, a high level of transparency and competition already exist in the market for PBM services. Indeed, the FTC, which has comprehensively studied the PBM industry, has repeatedly concluded that the operation of competitive market forces provide health benefit plans with sufficient information to assess the reasonableness of compensation received by PBM service providers and whether PBMs have interests that conflict with those of the plans. Critically, the FTC has determined that mandatory disclosures of the type the proposed regulations could impose may have the unintended effect of *limiting* competition and *raising* the cost of providing prescription drugs.

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The FTC has reviewed the PBM industry in two primary contexts: First, the FTC has responded to requests, made by states, for an analysis of the competitive effects of proposed state legislation seeking to regulate the PBM industry through, *inter alia*, a mandatory disclosure regime. Second, the FTC has undertaken its own studies of the issue, either *sua sponte* or in response to congressional request. The FTC's findings are consistent: the current state of the market for PBM services is healthy, and increased regulation, including mandatory disclosures, would have a market-distorting effect.

1. The FTC Has Objected To Proposed State Laws Mandating Disclosures

With respect to the state proposals to more closely regulate PBMs, the FTC in September 2004 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.[6] Among other things, the FTC observed that the proposed legislation might well have an anticompetitive effect:

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[6] Letter from Susan A. Creighton, Director, Bureau of Competition, Luke M. Froeb, Director, Bureau of Economics, Maureen K. Ohlhausen, Acting Director, Office of Policy Planning, and David A. Hyman, Special Counsel, U.S. Federal Trade Commission, to Greg Aghazarian, Assemblyman, California Legislature (Sept. 3, 2004).

> [F]inancial 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.

Id. 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." *Id.* at 10.

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." *Id*. at 11. Indeed, the FTC observed that:

> [V]igorous 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*. . . .

Id. (emphasis added).

Again, in a July 15, 2005 letter[7] 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." *Id*. at 13. 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

[7] Letter from Maureen K. Ohlhausen, Director, Office of Policy Planning, Michael A. Salinger, Director, Bureau of Economics, and Susan A. Creighton, Director, Bureau of Competition, U.S. Federal Trade Commission, to Patrick T. McHenry, U.S. House of Representatives (July 15, 2005).

the price and quality of the service that they intend to purchase." *Id*. 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. *Id*.

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.[8] Again the FTC opposed the legislation, reiterating the points raised in the letters above and further stating:

> [P]lan 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.*

Id. at 14 (emphasis added).

Most recently, the FTC opposed a New Jersey bill that would have required PBMs to disclose sensitive financial information to health benefit plans,[9] noting that "such disclosures may facilitate collusion, raise price, and harm the patients the bill is supposed to protect." *Id*. at 10. The FTC reiterated its consistent concern with mandatory disclosure regimes:

> 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, manufactures 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.

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[8] Letter from Maureen K. Ohlhausen, Director, Office of Policy Planning, Michael A. Salinger, Director, Bureau of Economics, and Jeffrey Schmidt, Director, Bureau of Competition, U.S. Federal Trade Commission, to Terry G. Kilgore, Member, Commonwealth of Virginia House of Delegates (Oct. 2, 2006).

[9] Letter from Maureen K. Ohlhausen, Director, Office of Policy Planning, Michael A. Salinger, Director, Bureau of Economics, and Jeffrey Schmidt, Director, Bureau of Competition, U.S. Federal Trade Commission, to Nellie Pou, Assemblywoman, New Jersey General Assembly (Apr. 17, 2007).

Id. In short, the FTC's position with respect to each state's proposed disclosure regime has been clear and consistent: mandated disclosures are not necessary due to the competitive nature of the market for PBM services and could lead to tacit collusion, which can lead to higher prices. Far from benefiting consumers of prescription drugs, it is the consumers, including plan beneficiaries, who are the ultimate losers in such a scenario.

2. The FTC's Own Studies Indicate That The Market For PBM Services Is Working Efficiently And Effectively

In addition to commenting on proposed state legislation, the FTC has undertaken its own, thorough investigations of the PBM industry—*i.e.*, studies not connected to any specific state request for comments—and has found that the marketplace for PBMs functions well, and that there is no evidence that PBMs have been engaging in abusive practices. For example, in 2004, the FTC and the U.S. Department of Justice ("DOJ") completed a joint two-year project specifically examining the role of competition in the health care industry.[10] 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 of transcripts. 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 (emphasis added).

In fact, the joint report noted that "[t]o date, most empirical evidence suggests that PBMs have lowered costs for health plan sponsors," *id.* at Ch. 7, p. 1, and that "consumers with prescription drug insurance administered by a PBM save substantially on their drug costs as compared to cash-paying customers." *Id.* at Ch. 7, p. 11. Panelists consulted during the course of the FTC/DOJ investigation advised that "rebate transparency can be handled through private contracts, because there is no barrier to a plan sponsor negotiating an arrangement providing it with access to the PBM's rebate information." *Id.* at Ch. 7, p. 16.

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 allegations of PBM conflicts of interest. To that end, the FTC examined "differences in payment amounts for pharmacy services provided to enrollees in group health plans that utilize pharmacy benefit managers."[11] The resulting report, released in 2005,

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[10] U.S. Federal Trade Commission and the U.S. Department of Justice, *Improving Health Care: A Dose of Competition* (July 2004) [hereinafter, "FTC/DOJ Report"].

[11] U.S. Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* (Aug. 2005) [hereinafter, "FTC Report"]. The report was requested by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

concluded that there was no merit in the charge that PBMs were 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.").

The FTC's conclusions are solidly backed by other governmental and private sector studies that have also concluded that mandatory disclosures are not necessary and that market forces are working efficiently. For example, the Congressional Budget Office, when examining a potential PBM disclosure requirement as part of the Prescription Drug and Medicare Improvement Act of 2003, concluded that such a requirement would cost taxpayers $40 billion over 10 years.[12] Similarly, a 2007 PricewaterhouseCoopers study determined that legislation requiring disclosure of private PBM terms would increase drug spending by $127 billion over the next decade.[13]

Finally, it cannot be overlooked that larger health benefit plan sponsors regularly retain consultants, sophisticated and knowledgeable about the market, to assist them in contracting with PBMs. As the FTC has put it, there is "no indication that clients of PBMs lack accurate information on the price and quality of the service they intend to purchase." Supra note 5, at 13. Often, health benefit plans are themselves "large, sophisticated repeat-purchasers of health care services, and many use a bidding process to decide which PBM they will contract with." Supra note 4, at 10. Smaller health plans normally receive PBM services through the purchase of insured products and leave the negotiation to the insurer to provide a bundled package of services at a reasonable cost.

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While the approach taken by the proposed regulations may be appropriate with respect to service providers providing investment services and related bundled administrative services to a retirement plan, expanding this approach to other service arrangements, like those involving PBMs, not studied by the Working Group is simply not appropriate.

In these circumstances, the Department should defer to the FTC's determination, backed by persuasive evidence, that the disclosures contemplated in the proposed Section 408(b)(2) regulations are not necessary for the PBM industry and exclude PBMs from the proposed regulations. The marketplace already provides health benefit plans with the tools to negotiate arrangements that pay PBMs no more than "reasonable compensation." And imposing mandatory disclosure obligations on PBMs will likely not be a neutral event: In the FTC's view, additional disclosures may *adversely* affect competition, thereby harming consumers, including participants in ERISA-covered health benefit plans.

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[12] Congressional Budget Office, *Cost Estimate: S1, Prescription Drug and Medicare Improvement Act of 2003*, at 15 (July 22, 2003).

[13] PricewaterhouseCoopers, *Pharmacy Benefit Management Savings and the Commercial Marketplace & the Cost of Proposed PBM Legislation 2008-2017* (Mar. 2007).

B. PARTIAL EXCLUSION OF CERTAIN CONTRACTS INVOLVING FIDUCIARIES

1. Summary

The proposed regulations would make all contracts under which a service provider provides services as an ERISA fiduciary subject to the expanded disclosure requirements of the regulations without regard to the nature or complexity of the service contract.

2. Recommendation

To the extent that the final regulations are applicable to PBM contracts, we recommend that, if a service contract would not otherwise be subject to the regulations pursuant to proposed 2550.408(b)(2)(c)(1)(i)(B) or (C), as such provisions may be modified in the final regulations, the contract would not become subject to the regulations pursuant to proposed 2550.408(b)(2)(c)(1)(i)(A) merely because the service relationship involves contractually delegated named fiduciary status, in a narrow scope and only with respect to the review of claims appeals.

3. Explanation

PBM service contracts typically cover the provision of multiple services by the PBM and its subcontractors. For example, in addition to providing standard prescription drug benefit services, a PBM contract could provide (i) access to a restricted retail pharmacy network providing favorable prescription pricing, (ii) mail and specialty drug pharmacy programs, (iii) additional benefits offered to plan participants by some or all of the pharmacies in the retail network such as discounts on non-prescription medical products, (iv) clinical and disease management services. In some contracts, the PBM will also agree to limited appeals procedure services where a participant is seeking review of a denied drug claim.

State and federal courts have examined core PBM services and determined that a PBM is not acting as an ERISA fiduciary in providing such services.[14] Nevertheless, in some very limited cases, a PBM may by contract expressly agree to be a named fiduciary, with authority to adjudicate claims appeals in accordance with the terms of the plan document. In such cases, however, the claims appeals procedure services provided by PBMs will likely only represent a small portion of the overall services provided and represent a small portion of the total compensation and fees payable to the PBM.[15] In that circumstance, the compensation received by the PBM for such services would be specifically identified in the contract in a manner consistent with the requirements of 2550.408(b)(2)(c)(1)(iii)(2) of the proposed regulations.

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[14] *See, e.g.,Chicago District Council of Carpenters Welfare Fund v Caremark, Inc.,* 474 F.3rd 463 (7th Cir. 2007) and *Moeckel v. Caremark, Inc.*, 2007 W> 3377831 (M.D. Tenn. 2007).

[15] For example, one large PBM reports that compensation for its services as an ERISA named fiduciary constituted less than one-half of one percent of its PBM service revenue last year.

The mere fact that a PBM agrees to be a named fiduciary for such a limited purpose should not bring the entire PBM contract under the regulation, provided that the disclosure with respect to the compensation to be paid for such named fiduciary services otherwise satisfies the requirements of the regulations. This approach is consistent with the purpose of the regulation and the Department's rationale for creating three categories of service providers that would be subject to the regulations.

C. LEGAL STANDARD FOR MEASURING COMPLIANCE WITH DISCLOSURE REQUIREMENTS

1. Summary

The proposed regulation would require that a service provider disclose required information "to the best of the service provider's knowledge".

2. Recommendation

We recommend that the Department adopt a "reasonable good faith knowledge" standard under the regulations.

3. Explanation

A "best knowledge" standard arguably is among the highest standard that could be applied and could require disclosure of all first hand knowledge known to each employee of the PBM. Under such a standard, any failure, no matter how immaterial, inconsequential, or inadvertent, might violate the disclosure obligation and expose the service provider to liability. Such a strict liability approach is not appropriate. A failure to provide immaterial information should not cause a disclosure to be defective, if the information provided was accurate and reasonably designed under the circumstances to allow responsible plan fiduciaries to satisfy their general fiduciary obligations under ERISA with respect to the selection of a PBM.

It should be sufficient that a PBM disclose the nature of each type of contract generally and the nature and scope, within reasonable ranges, of compensation it will receive. PBMs should be allowed to develop their own disclosure materials that describe their respective business relationships in general terms without the need to disclose the unique features of individual relationships as, arguably, would be required under a "best knowledge" standard. The principal purpose of the proposed regulation is to assure that the responsible plan fiduciary have adequate information to properly discharge its fiduciary obligations. With respect to the compensation of a service provider, this means sufficient material information, not all information, no matter how material.

Consistent with this purpose, the legal standard for compliance should be "reasonable good faith" knowledge.

D. CLARIFICATION OF TERM "COMPENSATION OR FEES"

1. Summary

The proposed regulations require that all service providers that are subject to the regulations disclose in writing all services to be provided, the compensation or fees to be provided by the service provider, and the manner of receipt of such compensation or fees. Compensation and fees subject to disclosure include "money and any other thing of monetary value to be received by the service provider or its affiliates in connection with the services to be provided or because of the service provider's or affiliate's position with the plan." Compensation and fees includes both amounts received directly from the plan or plan sponsor, as well as amounts received from any other source. The proposed regulations also require a service provider to affirmatively certify its compliance with the disclosure requirements.

2. Recommendation

To the extent that the final regulations apply to PBM contracts, we recommend that the regulations make clear that a PBM is only obligated to disclose the direct or indirect compensation received with respect to the provision of services to the plan itself and has no comparable disclosure obligation with respect to the provision of plan benefits to participants or beneficiaries.

We further recommend that the concepts of "indirect compensation" and compensation received "in connection with the services" or "because of a service provider's position" be clarified, by example, in the regulations such that the following revenues streams that may be received by a PBM or its affiliate are clearly excluded from the definition of "compensation or fees":

> i) discounts received by a PBM with respect to its acquisition of goods for resale or in connection with services to be rendered by the PBM and any related profits;
> (ii) income earned by a PBM on the investment of its own assets;
> (iii) income earned by a PBM with respect to the provision of plan benefits to participants (as opposed to providing services to the plan itself); and
> (iv) fees received by a service provider for services performed for or on behalf of a third party, provided that the services performed are part of an independent fee for service relationship.

3. Explanation

It is critical that a PBM be able to accurately identify "compensation or fees" that are subject to disclosure in order to assure compliance with the regulations. Clear guidance is essential. The concepts of compensation or fees "in connection with" the provision of services to a plan or "because of a service providers position with a plan" are extremely broad

concepts and are not subject to easy application. Further specific guidance is needed to define the scope of such concepts.[16]

Because the proposed regulation is based on a study of fees paid by retirement plans for investment related services, and particularly, fees charged against investment earnings, the current definition of "compensation" in the proposed regulations focuses on the sources of "compensation" received by providers of investment related services.

As the revenue streams received by PBMs differ significantly from those received by investment advisors, the definition of "compensation" as it applies to PBMs under the regulations needs to be clarified. Specifically, the proposed regulations define "compensation or fees" as "money or any other thing of monetary value … received or to be received from the plan or plan sponsor, indirectly (i.e., from any source other than the plan, the plan sponsor …) by the service provider or its affiliates in connection with the services to be provided…." 72 Fed. Reg. 71004. The preamble to the proposed regulation provides a list of examples of indirect compensation or fees, all of which involve sources for the most part unique to retirement plan investments and, more specifically, to mutual funds and other pooled investments that were the focus of the Advisory Group study.

The final regulations should make clear that the term "compensation and fees" is employed in its usual business sense to mean "payments received in return for goods or services provided." It should not include discounts received by a PBM with respect to its acquisition of goods or services for resale, whether or not accounted for as reductions in the "cost of goods sold", or profits realized on such sales by the PBM. For example, "compensation and fees" should not include income realized by PBMs with respect to their sale of prescription drugs to plan participants through PBM owned pharmacies or non-affiliated retail network pharmacies. The FTC has found that there is no "empirical" evidence that health plans need to know a PBM's cost structure in order to negotiate and obtain a competitive price for PBM services. Further, plan sponsors currently are able to negotiate in the market place for varying levels of disclosure regarding such amounts.

Furthermore, the final regulations should also make clear that income earned by a PBM from the investment of its own assets are not part of the PBM's "compensation and fees". The "float income" referred to in the preamble to the proposed regulations refers only to earnings on plan assets held by a service provider, before investment of those assets, as is discussed in Field Assistance Bulletin 2002-3 (November 5, 2002)(e.g., short-term investment income realized on contributions and other plan assets held in the general account of a service provider pending investment direction). Even where the PBM has contractually agreed to share such rebates or discounts with a customer, the existence of such contractual right does not make the rebate or discount plan

[16] Similarly, if a contract involved bundled services, some of which are provided by subcontractors, the final regulation should make clear that the service provider is not required to disclose amounts received by the subcontractor.

assets when received by the PBM. *See, e.g., Chicago District Council of Carpenters Welfare Fund v. Caremark, Inc.*, 474 F.3rd 463, 476 n.6 (7th Cir. 2007).

Finally, the final regulations should make clear that they do not apply to the provision of plan benefits to participants or to transactions with third parties. The preamble to the proposed regulations provide that the regulations only apply to the provision of services to the plan itself and does not apply to the provision of plan benefits to participants. By way of example, it states that a doctor providing medical services to a participant as part of an HMO network that has a contract with the plan is not a service provider subject to the proposed regulations. Similarly, a retail or mail pharmacy owned by or affiliated with a PBM would not be a service provider just because it fills prescriptions of plan participants.

The services provided under a typical PBM contract or arrangement can include both (i) services provided to the plan and also (ii) the provision of plan benefits to plan participants. For example, plan benefits are provided to plan participants where a PBM has a mail order option or the PBM operates, or is otherwise affiliated with, a retail pharmacy that sells prescription drugs to plan participants. In addition, the mail order or affiliated retail pharmacy will also have contractually agreed to accept a specific reimbursement amount with respect to such sales. The preamble to the proposed regulations makes clear that the sales to plan participants and the associated reimbursement arrangements between the PBM and its customers are not subject to the disclosure rules of the proposed regulations. In this instance, the PBM is merely providing prescription benefits to the plan's participants and beneficiaries and should have no obligation to disclose revenue or profits with respect to such transactions. As a result, the regulations should make clear that when such sales are made by a service provider, the sales are not considered made "in connection with" the provision of the covered services to the plan or "because of" the service provider's relationship to the plan.

In addition to the provision of administrative services to welfare plans and the sale of prescription drugs to welfare plan participants, some PBMs may also provide direct services to or on behalf of drug manufacturers or retail pharmacies for which they are compensated. For example, a PBM may be retained by a drug manufacturer to offer educational programs or clinical consulting programs for health care professionals, patients, or payers. In some cases, the PBM may also provide administrative services to drug manufacturers with respect to rebate contracts across its book of business. A PBM that is engaged in the PBM business is a natural provider of such services. However, the provision of such services is pursuant to a separate fee for service relationship. In most instances, the party receiving the services could retain a number of independent service providers to render such services. As a result, the regulations should make clear that when such services are provided to third-parties by a service provider under such conditions, the service fees are not considered received "in connection with" the provision of covered services to the plan or "because of" the service provider's relationship to any plan.

E. PROTECTION OF TRADE SECRETS

1. Summary

The proposed regulations set uniform standards of disclosure for all contracts subject to the regulations. The preamble to the proposed regulations makes clear that the service provider must provide all relevant information and certify that it has made complete and accurate disclosure.

2. Recommendation

We recommend that the regulations clarify that a service provider is not required to disclose information with respect to contracts or arrangements to which the service provider is a party to the extent the terms of such contracts are not generally known to the public and provide a competitive advantage to the service provider.

3. Explanation

The Department has an interest in ensuring that fiduciaries have sufficient information to reasonably determine the reasonableness of compensation and fees with respect to service contracts and arrangements. Where reasonable information exists to make such determination, however, fiduciaries do not require access to all compensation and fee information that exists with respect to the service provider and its affiliates. This is especially true where the disclosure of additional protected information would cause legal and financial harm to the service provider.

As the FTC has made clear, the PBM market is highly competitive because PBMs are not required to disclose the details of their strategic contracts or arrangements. The FTC, in comments on proposed legislation in numerous states that would have required PBMs to disclose confidential information, has consistently imposed such legislation as unnecessary and anti-competitive. In doing so, the FTC has stated:

> 'Therefore, the Bill's disclosure requirements are analogous to a requirement that a firm reveal its cost structure to its customers. Moreover, while consumers need accurate information on price and quality to make efficient purchasing decisions, there is no reason that consumers require the seller's underlying cost information for markets to achieve competitive outcomes. FTC Staff Letter to Greg Aghazarian (September 7, 2004).

Consistent with the FTC's findings, the regulations should make it clear that a PBM should not be obligated to disclose protected information to customers because non-protected information sufficient to allow the responsible fiduciary to fulfill its fiduciary obligations is disclosed in the marketplace.

With respect to the obligation to disclose potential conflicts, the disclosure obligation should be satisfied where the PBM merely discloses the nature of the contractual relationship.

F. THE PROPOSED REGULATIONS NEED TO PROVIDE GREATER FLEXIBILITY REGARDING THE DISCLOSURE OF COMPENSATION AND FEES.

1. Summary

The proposed regulations require that if a service provider cannot disclose compensation in a specific monetary amount, if may satisfy the disclosure requirement by "using a formula, a percentage of plan assets, or a per capita charge per participant or beneficiary." 72 Fed. Reg. 70990.

2. Recommendation

To the extent the final regulations are applicable to PBMs, we recommend that the final regulations clarify the nature and scope of disclosure required with respect to a PBM contract, taking into account the unique nature of such contracts.

3. Explanation

As in other areas, the discussion in the proposed regulations of alternative methods for disclosing compensation was clearly influenced by the Working Group's report and its focus on pooled investment vehicles. If the regulations are to be expanded to include PBMs, any alternative disclosure methods need to reflect the unique aspects of the PBM business.

PBMs do not normally charge for services based on a percentage of plan assets or on a per capita basis. Rather, in most cases, the compensation received by the PBM is directly tied to future utilization (e.g., the number of prescriptions filled) and other related factors such as whether the drugs dispensed are branded or generic.

Providing plans with a "formula or estimate" of the amount of the actual compensation or fee the plan will pay *prospectively* will, by definition, be so speculative or general, given the multiple factors involved, that it will not to provide plans or plan sponsors with information that is sufficient to evaluate the reasonableness of the PBM's compensation.

Because the type of information and timing of when it is provided may vary from contract to contract, PBMs and health plans should be permitted to bargain over the type of information to be provided and the timing of its disclosure, so that a health plan may seek the information most useful to that plan. In a highly competitive market, which is what the FTC has found the market for PBM services to be, a market based solution is superior to a one-size fits all regulatory approach.

G. ARRANGEMENTS NOT INVOLVING AN ACTUAL CONFLICT SHOULD NOT HAVE TO BE DISCLOSED

1. Summary

The proposed regulations would require a service provider to disclose relationships or interests that may give rise to a conflict of interest related to the proposed service relationship.

2. Recommendation

To the extent that the final regulations are applicable to PBMs, we recommend that given the substantial regulatory and court scrutiny of the relationships between a PBM and its subcontractors, the results of which are widely available in public documents, the final regulations not require further affirmative disclosure of such relationships by PBMs.

3. Explanation

Over the past few years, both the federal courts and the FTC have closely examined the various relationships which a PBM needs to create in order to provide PBM related services. A focus of these inquiries, particularly a series of class action lawsuits brought against individual PBMs, were alleged self-dealing or other conflicts of interest. In addition, as discussed below, Congress also directed the FTC to study potential conflicts related to vertical integration in the PBM industry (e.g., ownership of a PBM of a mail order pharmacy service).

No case has found that the challenged relationships were problematic and the FTC determined, after an exhaustive study, that the challenged vertical integration reduced costs to consumers.

Given the substantial regulatory and court scrutiny of the relationships between a PBM and its subcontractors, the results of which are widely available in public documents, the final regulations should not require further affirmative disclosure of such relationship by PBMs.

H. TERMINATIONS OF CONTRACTS OR ARRANGEMENTS

1. Summary

The proposed regulations invite comment as to any “practical issues” relating to the current regulation’s requirements concerning contract termination.

2. Recommendation

To the extent that the final regulations are applicable to PBM contracts, we recommend that the current regulation be clarified to make clear that multi-year contracts are allowed and that the recapture of discounts granted

in exchange for a multi-year contract is not a penalty for purposes of the current regulation.

3. Explanation

PBMs offer multi-year contracts with lower fees than single year contracts. The ability of a PBM to offer lower fees is directly related to the fact that it takes time to fully implement various cost savings components that over time reduce the cost to the health plan and allow the PBM to make a reasonable profit. Thus, under multi-year contract pricing, the PBM's ability to earn a reasonable profit depends on the contract being in effect for its entire term. For that reason, PBMs cannot offer similar pricing for single year contracts.

The final regulation should clarify that multi-year contracts other than leases are allowed under the regulation. The final regulation should also include additional examples of the types of recoupment provisions that do not constitute penalties. For example, if a plan sponsor elects to terminate a multi-year contract prior to the end of the term, the PBM should be allowed to recoup a reasonable fee (e.g., the difference between the fees paid by the plan sponsor under the multi-year contract and the fees that would have been paid had the contract been for a single year).

I. EFFECT OF REGULATIONS ON PRE-EXISTING CONTRACTS OR ARRANGEMENTS

1. Summary

The proposed regulations provide that the final regulations shall become effective 90 days after publication in the Federal Register. 72 Fed. Reg. 70994.

2. Recommendation

We recommend that the regulations specify that contracts which are in effect on the day the final regulations are published are not subject to the final regulations, until the earlier of the date there is (i) an extension of current term of the contract by amendment or (ii) a material amendment or modification of the compensation provisions of the contract without changing its term. In addition, the final regulation should provide further clarification regarding the effective date with respect to contracts with automatic renewal provisions as well as short term extensions of existing terms.

3. Explanation

The proposed regulations provide no transition rule explaining how the effectiveness of the final regulations impacts existing contracts. Disclosure under the final regulations should not be required where the parties to an existing service contract have not entered into negotiations regarding the terms of such contract.

The regulations should provide that they are effective with respect to contracts entered into after the effective date of the regulations and to contracts entered into before the effective date if and when the current term of the contract is extended by amendment or the compensation provisions of the contract are amended or modified in a material respect without changing its term. The final regulations should also provide specific guidance regarding contracts who terms are subject to automatic renewal and to short term extensions of contracts.

The final regulations should reflect the principal purpose of the proposed regulations of assuring that responsible fiduciaries have adequate disclosure when making fiduciary decisions.

On behalf of PCMA, we appreciate your consideration of our comments on this proposed rule, and look forward to continuing to work with the Department as it looks to issue final regulations.

Sincerely,

Barbara A. Levy
Vice President and General Counsel