# GIBSON, DUNN & CRUTCHER LLP

LAWYERS

A REGISTERED LIMITED LIABILITY PARTNERSHIP
INCLUDING PROFESSIONAL CORPORATIONS

1050 Connecticut Avenue, N.W. Washington, D.C. 20036-5306
(202) 955-8500
www.gibsondunn.com

WKilberg@gibsondunn.com


April 21, 2008


Direct Dial
(202) 955-8573
Fax No.
(202) 530-9559


Client No.
L 26493-00010

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: *Supplemental submission with respect to Proposed Regulations: Reasonable Contract or Arrangement Under Section 408(b)(2)—Fee Disclosure*

Dear Ms. Zarenko:

The Pharmaceutical Care Management Association ("PCMA") commends the Department of Labor ("Department") for the substantial amount of effort that it has put into the rulemaking process in order to ensure that the views of interested parties have been aired. Specifically, the PCMA applauds the Department for having conducted two full days of hearings on this matter and for leaving the rulemaking record open for an additional 21 days in order to allow for supplemental submissions. The PCMA also appreciated its opportunity to have oral testimony presented on its behalf. By this letter, we would like to take the opportunity to elaborate on some of the issues about Pharmacy Benefit Manager ("PBM") services and disclosures that were raised during the question-and-answer session following my formal testimony.

## I. The Proposed PBM Disclosure Requirement In The 2003 Medicare Prescription Drug Reform Legislation

During the question-and-answer session, a question was raised about the PBM disclosure requirement proposed to be included in the 2003 legislation that added an extensive prescription drug benefit to Medicare. Although the PCMA's comment letter and my testimony briefly addressed this issue, it is worthy of some additional discussion.

The PCMA's comment letter noted that 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."[1] The proposed disclosure requirement analyzed by the Congressional Budget Office ("CBO") was added by amendment to S. 1, the version of the bill then pending in the U.S. Senate. This amendment, referred to as the "Cantwell-Lincoln Prescription drug transparency amendment," stated (in applicable part):

> (a) **PROHIBITION**.--
>
> (1) **IN GENERAL.**--Notwithstanding any other provision of law, an eligible entity offering a Medicare Prescription Drug plan . . . shall not enter into a contract with any pharmacy benefit manager . . . that is owned by a pharmaceutical manufacturing company.
>
> (2) **PROVISION OF INFORMATION.**--A PBM that manages prescription drug coverage under this part . . . shall provide the following information, on an annual basis, to the Assistant Attorney General for Antitrust of the Department of Justice and the Inspector General of the Health and Human Services Department:
>
> > (A) The aggregate amount of any and all rebates, discounts, administrative fees, promotional allowances, and other payments received or recovered from each pharmaceutical manufacturer.
> >
> > (B) The amount of payments received or recovered from each pharmaceutical manufacturer for each of the top 50 drugs as measured by volume (as determined by the Secretary).

---

[1] Letter from Barbara Levy, Vice President & General Counsel, Pharmaceutical Care Management Association, to Kristin L. Zarenko, U.S. Department of Labor (Feb. 11, 2008), at 9 & n.12.

> (C) The percentage differential between the price the PBM pays pharmacies for a drug described in subparagraph (B) and the price the PBM charges a Medicare Prescription Drug plan . . . for such drug.
>
> . . . .

*See* 149 Cong. Rec. S8612-13 (daily ed. June 26, 2003) (S. Amdt. 942 to S. 1). The amendment was adopted as Section 133 of S. 1, *id.* at S8617, and the bill as modified was passed by the Senate. *Id.* at S8707. The companion bill in the House of Representatives, H.R. 1, passed the following morning and did not include a disclosure mandate. *Id.* at H6255-56.

On July 22, 2003, the CBO released its report on the expected fiscal impact of S. 1 and H.R. 1. *See* Congressional Budget Office, *Cost Estimate: S1, Prescription Drug and Medicare Improvement Act of 2003* (July 22, 2003) [hereinafter, CBO Report]. Separately reporting on the forced impact of Section 133 of the Senate Bill, the CBO found that:

> [P]rivate firms would perceive a significant risk of public disclosure of the detailed information on drug pricing that this provision would require them to compile and provide to the federal government. That risk arises partly because the information would be in a more accessible form than other data on drug prices that is currently collected by HHS for the Medicaid program or that would be collected under other provisions of S. 1, and partly because more stringent limits on disclosure apply to those other data. Consequently, PBMs operating as part of the Medicare prescription drug plan would find it more difficult to obtain significant price concessions and rebates from drug manufacturers, who would be concerned that the terms of those favorable deals could be determined by competitors or other purchasers. Consequently, CBO estimates that, with this amendment, the degree of drug-cost management under S. 1 would decline and would no longer exceed the levels of cost management seen in the current employer market. The greater difficulty of using price discounts as a way to control drug spending would also reduce the likelihood of having risk-bearing drug plans deliver the Part D benefit, and thus would increase the share of beneficiaries in less tightly managed fallback plans.
>
> As a result, CBO estimates that section 133 would increase the estimated costs of S. 1 over the 2004-2013 period by $40 billion. (At the request of Senate conferees, that impact is not reflected in the estimated cost of S. 1.) In addition to raising federal costs of providing the Part D benefit, the smaller reductions in drug prices under section 133 would translate into higher monthly premiums for Part D ($36 per month in 2006, instead of $34). Beneficiaries' cost-sharing obligations generally also would be higher because they would be paying the same percentage of a higher cost for prescriptions.

CBO Report, at 15 (emphasis added). The CBO Report makes clear that the type of disclosure required under Section 133, while seemingly helpful, is anything but. Rather than preventing collusion, the disclosure mandate would facilitate collusion. Rather than saving the federal government money, the disclosure mandate would have added 10% to the overall cost of the prescription drug program. Rather than decreasing prices for seniors, the disclosure mandate would have raised their out-of-pocket costs.

Section 133 was omitted from the final bill during conference. *See* H. Rpt. 108-391, Conference Report to Accompany H.R. 1, *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, at 522-23, 108th Cong. Nov. 21, 2003. In lieu of any specific disclosure provision, the conferees required the Federal Trade Commission ("FTC") to conduct a study, which would examine "differences in costs incurred by such enrollees and plans for drugs dispensed by mail order pharmacies owned by PBMs compared to those not owned by PBMs, and community pharmacies" and "whether such plans are acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees." H.R. Rpt. 108-391, at 519. This congressional direction produced the FTC study—U.S. Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* (Aug. 2005)—cited in footnote 12 of the PCMA's comment letter, discussed during my testimony, and a copy of which was provided to the Department. That study concluded that ownership of mail order pharmacies by PBM's was supportive of competition and lower prices. The CBO's findings and the FTC's findings are consistent: the PBM market currently operates efficiently and in a pro-competitive way.

## II. The Benefits Achievable By PBMs Are Considerable

A recent study by yet another government agency, the Government Accountability Office ("GAO"), has concluded that the PBM model is an effective way to save money for plans and plan sponsors. *See* U.S. Government Accountability Office, *DOD Pharmacy Program: Continued Efforts Needed to Reduce Growth in Spending at Retail Pharmacies* (April 2008). In this study, the GAO examined two steps recently taken by the Department of Defense's TRICARE health care program to curb pharmacy spending. First, it has encouraged participants to use the TRICARE Mail Order Pharmacy, where the DOD has used its pricing power and formulary placement to induce drug manufacturers to provide prices of between 30% and 50% savings compared to retail pharmacy costs. Second, the DOD has created a rebate program for retail pharmacies. In the conclusion of the GAO, these actions have "saved the agency hundreds of millions of dollars." Notably, these steps are the exact same strategies that commercial PBMs use to produce savings for plans and plan sponsors.

* * *

The findings of the CBO, the FTC, and the GAO serve to underscore the key points from my testimony: the current market for PBMs is efficient and produces extensive benefits for

plans, plan sponsors, and plan participants, and disclosure mandates would disrupt this market by enabling tacit collusion among drug manufacturers. Because there is no evidence that there is a problem in the current market for PBM services—and evidence that disclosure mandates interfere with, rather than assist, competition in that efficient market—the Department should not apply the proposed regulation to PBMs.

Again, we thank you for the opportunity to provide testimony and to answer some of your questions on these important issues. Please let us know if we can be of any further assistance.

Very truly yours,

William J. Kilberg, P.C.

WJK/jcc

cc: Bradford P. Campbell, U.S. Department of Labor
Mary M. Rosado, Esq., Express Scripts, Inc.
Barbara A. Levy, Esq., Pharmaceutical Care Management Association