

655 15th Street, NW Suite 425 Washington, DC 20005 202.628.7837 (Direct) 202.638.1096 (Fax) Stephen J. Northrup Vice President Federal Affairs

February 11, 2008

Ms. 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, DC 20210

RE: 29 CFR Part 2550

Reasonable Contract or Arrangement Under Section 408(b)(2)

Fee Disclosure; Proposed Rule

Dear Ms. Zarenko:

On behalf of WellPoint, Inc., thank you for the opportunity to comment on the proposed rule in 29 CFR Part 2550, Reasonable Contract or Arrangement Under Section 408(b)(2) – Fee Disclosure, published in the *Federal Register* on December 13, 2007 (72 Fed. Reg. 70988).

WellPoint, Inc. is the largest health benefits company in terms of commercial membership in the United States, with medical enrollment of almost 35 million members. Through its nationwide networks, the company delivers a number of leading health benefit plan solutions, along with a wide range of specialty insurance products and services including life and disability, pharmacy benefit management, dental, vision, behavioral health, long term care and flexible spending accounts. Headquartered in Indianapolis, Indiana, WellPoint is an independent licensee of the Blue Cross and Blue Shield Association and serves its members as the Blue Cross licensee in California; the Blue Cross and Blue Shield licensee in Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri (excluding 30 counties in the Kansas City area), Nevada, New Hampshire, New York (as Blue Cross Blue Shield in 10 New York City metropolitan and surrounding counties and as Blue Cross or Blue Cross Blue Shield in selected upstate counties only), Ohio, Virginia (excluding the Northern Virginia suburbs of Washington, D.C.), and Wisconsin; and also serves members across the country through UniCare.

Many of WellPoint's business units and subsidiaries function as "service providers" to ERISA health and welfare plans, providing third party administration, subrogation recovery, pharmacy benefits management, and myriad other services. Based on this experience, we believe our concerns fairly reflect the depth and breadth of WellPoint's involvement in the healthcare benefits industry.

In sum, we are concerned that the proposed rules are overbroad, are attempting to address perceived problems in the industry that may not exist, will have an anticompetitive effect, and grant service providers far too little time for compliance. We have outlined our specific concerns and recommendations in Attachment A.

We appreciate the opportunity to comment on these important issues, and we hope that our comments will assist the Employee Benefits Security Administration in evaluating the impact of these proposed rules on the health and welfare benefits marketplace. Please contact me by phone at (202) 628-7837 or by email at Stephen.Northrup@wellpoint.com with any questions.

Sincerely,

Stephen J. Northrup

Vice President, Federal Affairs

Attachment

WellPoint, Inc. Attachment A

Specific Comments to 29 CFR Part 2550 Reasonable Contract or Arrangement Under Section 408(b)(2) Fee Disclosure; Proposed Rule

General Comment: The proposed rule's new requirements will have a very significant impact on the systems and operations of ERISA health and welfare plan service providers. The new requirement of disclosure of indirect compensation, as well as disclosure of potential conflicts of interest, imposes a substantial new administrative requirement on service providers.

WellPoint cannot overemphasize the impact of the new requirements in this NPRM on the business practices of ERISA health and welfare plan service providers. The NPRM would typically require that service providers do the following, inter alia, to comply: build new IT systems to collect and track indirect compensation and conflict of interest information; create, implement, and maintain new disclosure and conflict of interest policies and procedures; renegotiate and modify thousands of contracts with ERISA plans; conduct training for internal employees and external customers; and more. WellPoint is concerned that the NPRM, as it concerns health benefits plan service providers, has been prematurely issued without sufficient analysis of industry to determine if such an administratively burdensome regulation is warranted.

I. Recommendation: WellPoint strongly urges the Department of Labor to withdraw the proposed rules as to Health and Welfare Benefit Plans. WellPoint urges the Department to conduct a comprehensive study of the welfare benefits industry, to determine whether there are problems that need to be addressed by guidance or by a proposed rule. The Federal Trade Commission has studied one segment of the service provider industry, and has found no abuses.

Because of the onerous impact of this NPRM on health and welfare plan service providers, WellPoint strongly urges the DOL to withdraw the NPRM as to non-financial service providers and study the industry of "service providers" to ERISA health and welfare plans to identify and address, in guidance or in a new NPRM, specific, verifiable concerns in the industry.

The Department of Labor's ERISA Advisory Council Working Group included only service providers that are investment advisors in its 2004 study recommending changes to service provider fee disclosure. Hence, the NPRM appears to have been primarily aimed at the financial services industry. Additionally, while two recent GAO Reports evidence that lack of disclosure is a problem in the financial services industry, ¹

¹ Conflicts of Interest Involving High Risk or Terminated Plans Pose Enforcement Challenges, GAO Report to Congressional Requesters (June 2007) (focusing on lack of disclosure by service providers to defined benefit plans); Changes Needed to Provide 401(k) Plan Participants and the Department of Labor Better Information on Fees, GAO Report to the Ranking Minority Member, Committee on Education and the Workforce, House of Representatives (Nov. 2006) (recommending increased service provider

these reports do not address or cite problems in the health and welfare plan industry. The applicability of the NPRM to service providers to health and welfare plans was apparently added without an extensive background study of the industry and its business practices, or any evidence of problems in the industry.

To the best of our knowledge, the Department has not formally studied the service providers to health and welfare plan industry in the context of the NPRM. This is a very complex and broad industry, as further research will bear out. A study might identify potential abuses and allow the Department to target for regulation areas where the competitive marketplace is not working to control those abuses.

We are not aware that there are widespread abuses in this industry that the NPRM would apparently seek to address. If there were systemic abuses in the health and welfare plan service provider industry, one would think they would have manifested themselves, either in frequent requests for the Department to issue Advisory Opinions on this topic, or in litigation. But to the best of our knowledge, there has been very limited cause for the DOL to issue Advisory Opinions or formal litigation to address the reasonableness of health and welfare benefit plan service provider fees.²

In addition to the indirect evidence above, the Department of Labor's sister federal agency, the Federal Trade Commission, at Congress' direction, has extensively studied one type of service provider industry – pharmacy benefit managers, or PBMs.³ The DOL should give the FTC's studies and conclusions significant weight and deference in this NPRM process. We discuss the FTC's findings, as well as its public comments to state legislative leaders, below.

A. Compliance with the NPRM will be far more significant than the Department estimates.

Compliance with the final DOL regulations will increase the cost of health care by means of increased administrative costs, due to the significant cost of compliance for service providers. We disagree with the Department's cost estimate of the impact of the rules on service providers. Because of the breadth and granularity of its requirements on both fee disclosure and conflict of interest identification and disclosure, this NPRM will require service providers to implement entirely new IT tracking and reporting systems for disclosable indirect compensation data and conflicts of interest. Health and welfare plan service providers have had insufficient time to estimate the cost of these IT

disclosure to fiduciaries and increased fee disclosure to plan participants). See also Securities and Exchange Commission, "Staff Report Concerning Examinations of Select Pension Consultants" (May 2005)(concerns with pension consultants' conflicts of interest).

²For a case where a former plan trustee sued a law firm over the reasonableness of the firm's fees, see <u>Rutledge v. Seyfarth, Shaw, Fairweather & Geraldson</u>, 201 F.3d 1212 (9th Cir. 2000), corrected by 208 F.3d 1170, cert. denied 531 U.S. 992 (2000); further proceedings 2005 WL 419673 (Cal. App. 1st Dist. 2005), 2005 WL 419726 (Cal. App. 1st Dist. 2005).

³Federal Trade Commission, "Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies" (August 2005), found at: http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf

modifications, but based upon the breadth of this rule, costs of compliance are anticipated to be significant. Consequently, we respectfully disagree with the Department's cost assumptions set forth in the "Costs to Service Providers" analysis in the preamble to the NPRM (72 Fed. Reg. at 70997).

II. Alternative Recommendation: If the Department of Labor declines to withdraw the proposed rules altogether, WellPoint strongly urges the Department to grant affected entities an extended period of time to comply with the rules.

The NPRM's proposed effective date of 90 days following publication of the final regulation in the Federal Register leaves service providers and plan sponsors/fiduciaries far too little time to prepare for and comply with the new requirements. In fact, service providers to health and welfare plans have had insufficient time since the NPRM was issued on December 13, 2007 to evaluate the full impact of these rules on their business operations. However, it is clear that to meet an effective date 90 days after publication, service providers would need to start renegotiating contracts before the final rules are even published. This would lead to an absurd result: service providers and ERISA plan sponsors or fiduciaries would run substantial risk of entering into noncompliant contracts as they attempt to comply with a rule not yet finalized.

The NPRM will require service providers to renegotiate hundreds, if not thousands, of contracts with plans. According to a recent employer survey, over 3.3 million firms in the U.S. provide health coverage to employees. Frequently, large plans have agreements with multiple service providers related to their health and welfare benefit plans. It is not at all uncommon for a single large plan to retain separate service providers as a third party administrator to administer the plan's medical claims, and a pharmacy benefit manager to administer the plan's pharmacy claims. The Department should be aware of the full magnitude of this undertaking by plan sponsors and service providers, and grant an extended time for compliance.

A. The Department should look to HHS for guidance.

In evaluating whether to permit an extended compliance period, the Department should look to the practice and experience of its sister federal agency Health and Human Services in promulgating and enforcing the HIPAA Administrative Simplification Rules (Transaction Standards and Code Sets, Privacy, Security, and National Provider Identifier). In particular, HHS' experience with the HIPAA Privacy Rules is instructive in showing how a regulated industry needs sufficient time to comply, and assistance in complying, with new, broad, and complex regulatory requirements.

Although the HIPAA statute⁵ enacted in 1996 contained some general privacy requirements, the implementing regulations, issued in December 2000, imposed

⁴ Kaiser Family Foundation/Health Research and Education Trust, *Employee Health Benefits 2007 Annual Survey*, found at: http://www.kff.org/insurance/7672/upload/76723.pdf

⁵ Pub. L. No. 104-191, 42 U.S.C. § 1320d-1, et seq.

extremely detailed and complex information privacy requirements on health plans, healthcare clearinghouses, and healthcare providers. Because HHS realized that the HIPAA Privacy Rules constituted a paradigm shift for the healthcare industry, it allowed affected entities a 24-month period from the date of the issuance of the final rules to comply.⁶ The process of implementing the HIPAA Privacy Rules, affected entities first conducted a gap analysis to compare their existing business practices with the rule's requirements, which gave them a roadmap to compliance.

To ensure that all entities affected by the HIPAA Privacy Rules would understand what was required of them to comply, during the 24-month compliance period HHS, with the assistance of and feedback from industry groups such as WEDI SNIP, issued voluminous materials to assist affected entities with compliance – such as formal guidance, FAQs, model forms, and technical assistance – and conducted nationwide training sessions. Such interpretative materials and training sessions by the regulatory agency created a level compliance playing field for affected entities to prevent unfair competition and help avoid compliance penalties and litigation over differing regulatory interpretation.

The compliance process for this NPRM will be very similar to the compliance process for the HIPAA Privacy Rules. Service providers will first need to conduct gap analyses of their business practices to determine what changes need to be made, and then implement appropriate policies and procedures, and modify existing or build new systems for collecting the indirect compensation and conflict of interest information the NPRM requires service providers to disclose. As with the HIPAA Privacy Rules, this proposed rule constitutes a paradigm shift of existing practices involving the collection and disclosure of new and more detailed information.

Therefore, if the Department declines to withdraw the NPRM for further study and consideration, WellPoint strongly urges the Department to grant the industry at least 24, and preferably 36, months to comply – at least 2 full plan years. If the final rules are promulgated in 2008, then compliance should not be required until plan years beginning on or after January 1, 2011. For multiyear contracts, we also urge the Department to permit plan sponsors and service providers to comply upon the next contract renewal date, so as not to disrupt existing business arrangements. This extended compliance period should also apply to the Proposed Class Exemption, to ensure consistency of treatment.

⁶ 42 C.F.R. 164.534(b)(1)

⁷ It should be noted that in two sets of the HIPAA Administrative Simplification rules – the Transaction Standards and Code Sets, and the National Provider Identifier Rules – HHS granted affected entities an additional 12 months' time to comply (called a "contingency plan") to ensure appropriate compliance, based on industry feedback on the difficulty of meeting the original compliance dates.

⁸ See, e.g., the website of HHS Office of Civil Rights, the agency charged with HIPAA Privacy enforcement: http://www.hhs.gov/ocr/hipaa/

III. The compensation disclosure requirement under the proposed rules will have an anticompetitive effect, is overbroad, and gives little guidance to service providers as to what must be disclosed.

A. Disclosure of indirect compensation will have an anticompetitive effect on the industry.

1. Recommendation: The rule should be narrowed to eliminate the requirement that service providers disclose indirect compensation.

The fee disclosure requirement provision in the NPRM will likely have an anticompetitive effect on the pharmacy benefit manager (PBM) industry, and thus it raises substantial antitrust concerns. The proposed rule requires disclosure of proprietary information that can encourage collusion or otherwise undercut vigorous competition on drug pricing. The Federal Trade Commission noted its concerns about the anticompetitive effect of proprietary PBM fee disclosure in its October 2006 comments on Virginia House Bill 945, and has repeatedly advocated that position in communications to several other state legislatures dealing with PBM transparency legislation.⁹

By requiring disclosure of rebates and other manufacturer payments to PBMs, the proposed rule will require PBMs to disclose their cost structure to benefit plans, and in all likelihood, to their benefit consultants also. The more broadly internal and proprietary information on PBM cost structures is disseminated, the more likely that information will become known to competitors in the PBM industry. Knowledge of competitors' cost structures diminishes incentives for PBMs to bid aggressively and fosters tacit collusion. This will likely lead to higher drug costs for benefit plans and for the consumers who participate in them.

As the FTC has pointed out in their comments on the Virginia fee transparency legislation, it is not necessary for a benefit plan to know the underlying price arrangements or cost structures of each PBM; rather, the information required for a plan to make a competitive choice between PBMs is the price that the PBM will make available to the benefit plan. So long as the benefit plan is aware of its agreed-to administrative fee, any percentage in rebates that will be shared, and the price it will pay for medications dispensed, it is unnecessary for a PBM's cost arrangements with manufacturers or retail pharmacies to be revealed to permit the benefit plan to understand the costs of providing a prescription drug benefit. The burden, both in expense and resource allocation, that would be required to track and report on all financial and pricing arrangements, and the calculation of all costs and income streams, will have the anti-competitive effect of discouraging PBMs from developing and negotiating innovative arrangements with its contracted retail pharmacies to control pharmacy prices, and will

⁹ <u>Id.</u> See also the FTC's advocacy letters to Utah and North Dakota legislators on similar PBM transparency legislation: http://www.ftc.gov/be/V060019.pdf and http://www.ftc.gov/os/2005/03/050311northdakotacomnts.pdf

¹⁰ <u>Id.</u> at p. 13.

instead lead to a flat marketplace where PBMs simply administer claims for a higher, flat administrative fee. In addition, the information disclosed by PBMs under this rule to plan fiduciaries will in turn be disclosed to the Department and other federal agencies on Schedule C of the Form 5500, thus compromising the confidentiality of the information and eliminating the competitive advantages that PBMs gain by confidential negotiations. Again, this would hinder the strategies employed by PBMs to drive down the cost of prescription drugs.

More broadly, there will be parallel impacts on the health benefits industry as a whole. The indirect fee disclosure requirement will easily make a service provider's downstream pricing information available to its competitors. Plan sponsors and fiduciaries typically share service provider information with their benefit consultants, who (unlike attorneys) have no ethical or statutory prohibition from freely sharing proprietary or competitive information even with competitors of the service provider. Service providers will have difficulty in identifying information leaks, even if the compensation information is supplied to the plan sponsor under a promise of confidentiality. Service providers will also have difficulty in obtaining an adequate remedy at law for any such breaches. Most importantly, such information sharing will have a permanent anticompetitive effect on the market, ironically making it more difficult for plan sponsors and fiduciaries to obtain better deals on service provider services, since the prices service providers charge will be smoothed out.

B. Comment: The definition of "compensation" under the proposed rule is overbroad and goes further than the rule's intent, which is to permit plan sponsors and fiduciaries to assess the reasonableness of contracts with service providers

The definition of "compensation" under the proposed rule is so broad as to sweep in monies received by service providers and affiliates that have no connection to the contracted plan. Moreover, since the intent of the proposed rule's requirement of compensation disclosure is to permit the plan sponsor or fiduciary to determine if its contract with the service provider is reasonable, it makes little sense to require services providers to disclose compensation when they are providing services "at cost." We recommend that the rule be modified to require disclosure of compensation when the service provider retains a margin of profit for its services.

An example of monies that service providers would likely have to disclose to plans under the proposed rule would be an award of attorneys' fees that a service provider was awarded in a lawsuit defending a claims decision. The connection between the plan and the award of attorneys' fees is so tenuous that it can have no bearing on whether the plan's contract with the service provider is reasonable.

Additionally, in the PBM industry, the timing of the compensation disclosure is an issue. In that industry, it is currently commercially reasonable to retroactively disclose the PBM's compensation formula, because the PBM would not know what pharmaceutical manufacturers' rebates would be until the end of the year, when the pharma manufacturer formulates the PBM's annual utilization and calculates the rebate.

It is simply impossible for a PBM to provide prospective compensation disclosure to a plan sponsor in this respect.

C. Comment: The definition of "compensation" under the proposed rule is vague and provides little guidance for service providers.

It is not clear what type of disclosure will satisfy the compensation disclosure requirement of the proposed rules. Do the rules impose a "reasonableness" standard on the type of disclosure required by the service provider? Or must the service provider supply varying levels of disclosure, dependent on the requirements of the responsible plan fiduciary? If different levels of disclosure are provided to different plan fiduciaries, then wouldn't service providers have potential liability to plan fiduciaries? Moreover, it is not clear that transparency is served by disclosing the amount of the service provider's compensation so long as the plan fiduciary is apprised of the actual price the PBM will make available to the benefit plan.

D. Comment: Due to variations in plan sponsor requirements, what is compensation for one plan may not be compensation for another plan.

1. Recommendation: Working with the PBM industry, the Department should establish some benchmarks for compensation within the PBM industry, so all parties meet the same benchmark.

In the PBM industry, it is common for revenues to vary depending on the specific contractual arrangement between a PBM and a particular health benefit plan. Revenues will vary depending on what combination of administration fees, rebate sharing, margin allocation and other arrangements that each benefit plan selects from its contracted PBM. In its opinion letter regarding proposed PBM fee disclosure legislation in Virginia, the FTC noted that plan sponsors' preferences for formulary design and pharmaceutical payment sharing varied considerably. Some plan sponsors want to receive all payments from manufacturers, while others seek to negotiate deeper discounts on list prices by allowing PBMs to retain manufacturer payments — and many plan sponsors fall somewhere in between. As a result, PBMs cannot enumerate a standard list of direct and/or indirect compensation sources for all health benefit plans, making compensation disclosure in the PBM industry a particularly onerous challenge.

Because of the variance in plan sponsor arrangements, we recommend that the Department work with the PBM industry to identify common types of arrangements and to establish benchmark disclosures for those arrangements, which will put the entire PBM industry on a level playing field on this issue.

¹¹ Letter from FTC Staff to Terry G. Kilgore, Member of Commonwealth of Virginia House of Delegates, October 2, 2006, re Virginia House Bill No, 945, p. 6 (found at http://www.ftc.gov/be/V060018.pdf).

- E. Comment: The rule's 30-day timeframe for service providers to disclose material changes is commercially unreasonable.
- 1. Recommendation: WellPoint recommends that the Department extend the timeframe for service providers to disclose material changes to the information required to be disclosed under the NPRM.

The 30-day timeframe for a service provider to disclose material changes to the information required to be disclosed under the NPRM is not commercially reasonable. We suggest that service providers be given 120 days to make such disclosures. As an alternative recommendation, we suggest a phased-in implementation to reflect service providers' compliance efforts: 180 days in the first plan year that compliance is required, 120 in the second plan year, 90 in the third plan year.

- III. The conflict of interest requirements in the rule are problematic. Requiring service providers to disclose potential conflicts of interest is unrealistic and unworkable. Further, there is no evidence of service providers' conflicts of interest harming plan sponsors, but in the PBM industry, there is evidence to the contrary.
- A. Comment: The requirement that service providers disclose potential conflicts of interest is vague, subjective, and rife for misinterpretation.
- 1. Recommendation: WellPoint recommends that the rule be modified to require service providers to disclose only actual conflicts of interest.

The NPRM requires service providers to disclose a relationship that "may" create a conflict of interest with the plan. Such a subjective standard is fraught with problems, and is unrealistic and unworkable. The potential conflict standard essentially requires a service provider to speculate as to what may possibly be a conflict of interest. Not only will service providers be prone to disclose too much information to plan sponsors out of an abundance of caution, but the information disclosed is likely not to be useful to the plan sponsor or fiduciary. The standard may also require service providers to divulge their business arrangements with such specificity as to require disclosure of proprietary information, with consequent anticompetitive effect. Thus, with respect to potential conflicts of interest, we urge the Department to develop a better understanding of what potential conflicts might be, so as to provide useful information to plan sponsors and fiduciaries.

B. Comment and Recommendation: The FTC found no conflict of interest when it studied a potential conflict in the PBM industry. The issue of actual conflicts of interest of service providers to welfare benefit plans should be further studied by the Department to identify whether conflicts exist, and if so, if they harm plans.

The complexity of relationships in the service provider industry makes the conflict of interest provisions impracticable and unworkable. For example, a large organization such as WellPoint could have a healthcare provider in its provider network

(and reimburse the provider for healthcare services to members), yet also provide third-party administration (TPA) services to the provider's self-insured health plan. Although one would imagine that in this situation the provider would be fully aware of the conflict, the NPRM as drafted would require the TPA-service provider to disclose the conflict. We recommend that the NPRM be amended so as not to require a service provider to disclose to the plan sponsor the service provider's existing relationship with the plan.

At the request of Congress, the FTC studied a potential conflict of interest issue in the PBM industry in the Medicare context, and issued a report of its findings in August 2005, entitled "Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies." The FTC examined whether a conflict of interest arises when a PBM both administers the pharmacy benefits for a plan sponsor and sells drugs to a plan sponsor's members via the PBMs' owned mail-order pharmacy. Such "self-dealing" arrangements, the argument went, could provide PBMs with an opportunity to manipulate drug dispensing and enhance their own profits at the expense of plan sponsors and their members. However, the report concluded that the prescription drug plan sponsors generally paid lower prices for drugs purchased through PBM-owned mail-order pharmacies, and that the data suggested that competition in this industry can afford plan sponsors with sufficient tools to safeguard their interests. ¹³

Similarly, it may very well be that competition among other types of service providers also permits plan sponsors to protect their plans' interests. The Department should further study this issue.

C. Comment and Recommendation: The rules' requirement that the service provider identify and disclose to the plan its relationship with another service provider to the plan creates an impossible standard for service providers to meet, and should be omitted from the rule.

Requiring a service provider to identify whether it has any relationships with other service providers to the plan imposes an unrealistic burden on the service provider and does not seem to identify a material conflict of interest. For example, Plan A may retain a law firm to provide it with legal and compliance advice, and may also hire a PBM to manage Plan A's pharmacy benefits. Further, the PBM may manage the pharmacy benefits for the law firm's self-funded health and welfare plan. If the PBM is unaware of the law firm's arrangement with Plan A, the PBM could not possibly identify or disclose that relationship to Plan A. Moreover, the fact that the PBM also manages the law firm's plan's pharmacy benefits does not appear to raise any conflict of interest for Plan A.

This provision will also require plans to periodically and frequently inform their service providers about all of their other service providers. If plans do not assume this duty, service providers will not be able to fully comply with this provision.

 $^{^{12}\ \}underline{\text{http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf}}$

 $^{^{13}\ \}underline{http://www.ftc.gov/opa/2005/09/pharmbenefit.shtm}$