

# PBM news



## PBMs BEGIN TO EMBRACE TRANSPARENCY

The Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services position on prescription drug rebates is that the full disclosure of contractual obligations about prescription drug rebates offers the least amount of legal liability for the pharmaceutical companies and pharmacy benefit managers (PBMs).

The desire for increased PBM transparency has been communicated to the PBM industry by many of its customers. The desire is for the PBMs to communicate how they make money. The concern, in the absence of this information, is that the business goals of a PBM may not be fully aligned with its customers' goals.

Several PBMs have developed products or business models to respond to the market's increasing desire for transparency. The characteristics common to these products are 1) either the pass-through of all money paid by the client to retail pharmacies (no spread pricing) or the identification of the amount retained by the PBM, 2) the

identification of the rebates received at a drug specific level, and 3) the elimination and or identification of non-rebate monies paid by pharmaceutical manufacturers.

Because transparency may result in the elimination of certain PBM revenue sources, PBMs tend to charge higher administrative fees than those buyers are used to seeing. In theory, the savings generated by the implementation of the transparency characteristics should more than offset the higher administrative costs. Higher rebates paid to the plan sponsor will offset the higher administrative charge.

The PBMs that are embracing transparency today are not doing so as a result of the OIG guidance. In some cases, these practices predate the OIG guidance. PBMI believes these PBMs developed transparency models and increased disclosure of contractual terms to differentiate themselves from their competitors in a market with few opportunities for genuine differentiation.

**Figure: Transparency Model Generates Savings for Plan Sponsor**

	Non-Transparency Model	Transparency Model
<b>Administrative fee paid to PBM</b>	\$0.25 per claim	\$1.00 per claim
<b>Rebates paid to plan sponsor</b>	\$1.50 per claim	\$2.50 per claim
<b>Savings from elimination of spread pricing retained by plan sponsor</b>		\$0.50 per claim
<b>Net amount returned to plan sponsor</b>	\$1.25 per claim	\$2.00 per claim

This figure illustrates a scenario where the transparency business model results in savings for the employer. This figure illustrates some of the factors that need to be considered in a financial analysis of PBM pricing to ascertain the best value for a plan sponsor. Note: This simple illustration is not based on actual market data nor does it represent all of the variables that impact PBM pricing. Each plan sponsor is likely to have a different experience including pricing scenarios where the non-transparency model results in lower net per-claim costs.

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“A key to the transparency model is to know exactly where money is flowing among your PBM and the pharmaceutical manufacturers,” says Tom O’Connor, vice president of SXC. “Transparency is much easier if the entire stream of manufacturer revenue is for rebates only. You can be transparent if you are being paid data fees by the manufacturers, you just have to communicate the amounts to your customers.”

Roderick McKinney, Senior Vice President, Strategic Alliances for Argus Health Systems, echoes this thought and reinforces the value of transparency as part of market differentiation. “What sets us apart? Argus discloses fees upfront, and reports to customers not only the rebates invoiced and collected, but also all administrative fees involved. Further, our customers have the contractual right to audit our process.”

PBMI is aware of several other PBMs that purportedly operate under the principles of transparency. As time passes, PBMI expects market demand for transparency to increase, for more PBMs to adopt this business model, and for more plan sponsors to contract with PBMs using this model. However, change has been slow as the appearance of a higher administrative fee (offset by a higher rebate) makes the financial analysis more complicated.

## **Importance of Disclosure**

Additionally, it is not illegal to pay or collect rebates. Rather, it is the manner in which these rebate payments are made and received that determines suspect activity. The OIG recommends that the PBM fully disclose rebate payments received in writing at least annually.

An area of particular concern to the OIG is drug switching. The primary concern about drug switching relates to the payment of a fee to a PBM for switching a patient’s prescription from one drug to another drug. The use of this type of program for a federal health care program creates clear risks.

Although the Guidance pertains only to federal health care programs (Medicaid and Medicare), the recommendations may eventually impact the commercially insured health care arena. ●

*Note: PBMI does not endorse any PBM identified or not identified in this article. It is important that plan sponsors perform due diligence when entering into a PBM relationship.*

## **OIG COMPLIANCE GUIDELINES TARGETS MANUFACTURERS**

*Guidance is available at [www.oig.hhs.gov](http://www.oig.hhs.gov). Click on the Fraud Prevention & Detection button on the right side of Web page for document issued April 28, 2003.*

The Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services issued a Compliance Program Guidance for Pharmaceutical Manufacturers in April 2003. This guidance is intended to help manufacturers reduce or eliminate their risk of committing unlawful acts while implementing patient compliance programs.

This guidance does not create any new law or legal obligation. It is a starting point for the legal review of pharmaceutical manufacturer marketing practices. Compliance with the guidance does not eliminate all liability. It is, however, a way to minimize risk.

The guidance identifies several activities that could potentially violate federal fraud and abuse statutes and regulations. According to the guideline:

The identification of a given practice or activity as “suspect” or as an area of “risk” does not mean it is necessarily illegal or unlawful, or that it cannot be properly structured to fit in a safe harbor. Nor does it mean that the practice or activity is not beneficial from a clinical, cost, or other perspective. Rather, the areas identified below are those areas of activity that have a potential for abuse based on historical law enforcement experience and that should receive close scrutiny from manufacturers.

Some of the activities at risk for potential abuse include:

- Formularies and formulary placement payments
- Rebate payments
- Drug-switching arrangements

For example, the OIG identified formularies as having a positive potential impact on cost and utilization. The issue that concerns the OIG is the process used to determine how and why certain drugs are included on a particular formulary. For plan sponsors, this could translate into increased scrutiny of the formulary development process employed by their PBMs and managed care organizations. ●

## USE GUIDELINES TO CONTROL HEPATITIS C COSTS

Hepatitis C is a viral infection of the liver that can cause liver scarring, failure, and or cancer. It is the most common, chronic blood-borne illness in the United States, currently affecting about 4 million Americans. The National Institutes of Health has projected a four-fold increase in the number of U.S. adults affected by chronic Hepatitis C from 1990 to 2015.<sup>1</sup>

Hepatitis C often goes undiagnosed because the disease is largely asymptomatic. If symptoms do occur, they include fatigue, occasional stomachaches, and headaches. The disease is difficult to treat because the virus mutates easily. The U.S. Centers for Disease Control guidelines for treatment of chronic hepatitis C suggest that anti-viral drug therapy should be provided to patients with the greatest risk for cirrhosis or hardening and nonfunctioning of the liver. The treatment criteria are:

- Persistently elevated blood levels of the liver enzyme alanine aminotransferase (ALT),
- Detectable levels of the Hepatitis C RNA virus, and
- Liver biopsy indicating fibrosis, moderate degrees of inflammation and or necrosis.

### Treatment Options

Managed care organizations and health plans typically follow protocols consistent with CDC guidelines, implementing prior authorization for the costly medications needed to treat Hepatitis C. Combination therapy of pegylated interferon, an injectable drug, and ribavirin, an oral medication, is the standard of care. The annual cost of these therapies ranges from \$24,000 to \$30,000 per patient per year, based on industry estimates. Table 1 lists the average wholesale price (AWP) of these drugs.

The cost of Peg-Intron® is based on a 75 kg individual for a dose of 120 mcg weekly. Pegasys® is dosed at 180 mcg weekly. The oral component of treatment, ribavirin, is dosed at from 800 mg to 1200 mg daily. The ribavirin costs above are based on an 800 mg dose.

**Table 1: Drug Therapies for Hepatitis C**

Chemical Entity & Strength	Brand Name	Manufacturer	Average Wholesale Price (AWP)* Per Dose	AWP per 48 Weeks of Therapy
<b>Pegylated Interferon (injectable)</b>				
	Peg-intron®** 120 mcg	Schering	\$372.06	\$17,859
	Pegasys® 180 mcg	Roche	\$349.20	\$16,762
<b>Ribavirin (oral medication)</b>				
	Rebetol® 200 mg	Schering	\$11.04	\$14,838
	Copegus® 200 mg	Roche	\$6.33	\$8,508

\*AWP prices from September 2003 Red Book Update, Vol 22 No. 9 & from August 15 Price Alert (by Medi-Span) Vol. 15; No. 8  
\*\*Peg-Intron is dosed by weight and comes in 50, 80, 120, and 150 mcg

The major side effect of the drug treatment is flu-like symptoms including fever, joint and muscle pain, and malaise. In many patients, these side effects are more difficult to tolerate than the disease itself. Interruptions in the drug therapy require a patient to begin the 24-week or longer regimen over again. As a result, effective care for patient with Hepatitis C includes an active case management component to help patients adhere to the drug regimen.

Hepatitis C has three major genotypes (1, 2, and 3) that are strong indicators of how responsive the patient will be to drug therapy and dictate the duration of treatment required as shown in Table 2. Genotype 1, seen in about 75 percent of the population with the disease, typically has the lowest response and cure rates of the three genotypes. The genotype can be ascertained through a blood test which, while expensive, identifies genotype 2 or 3 patients who do not need to continue therapy past 24 weeks

**Table 2: Optimal Treatment Duration for Hepatitis C**

Hepatitis C Genotype	Recommended Drug Therapy Duration
Genotype 1	48 weeks
Genotype 2	24 weeks
Genotype 3	24 weeks

Prior authorization guidelines can be used to ensure drug therapy is continued only when the patient is benefiting and the virus level is declining. After 24 weeks of therapy,

patients must have an undetectable virus level for additional drug therapy to be approved. Most patients with genotypes 2 and 3 do not require additional therapy past 24 weeks. In addition, early viral response at 12 weeks is predictive of the patient's sustained viral response.<sup>2</sup> As a result, many MCOs are exploring the implementation of a blood test for the early viral response at 12 weeks to ensure they are investing in drug therapy that will actually benefit the patient.

Managing Hepatitis C in the next decade requires plan sponsors to work closely with PBMs, specialty pharmacy partners, and disease management organizations. Specialty pharmacy partners can be especially helpful in reducing costs through greater drug price discounts and, more importantly, patient compliance programs. The worst thing for a plan is for a patient to stop therapy because of side effects after significant costs are incurred and then restarting drug therapy from the beginning. An effective specialty pharmacy vendor monitors patient progress through outbound calls from nurses and pharmacists. This methodology helps to manage the side effects of the drug therapy. ●

<sup>1</sup> National Institutes of Health Consensus Development Conference Statement: Management of Hepatitis C 2002, pg.4-5. June 10-12, 2002.

<sup>2</sup> National Institutes of Health Consensus Development Conference Statement: Management of Hepatitis C 2002, pg.15. June 10-12, 2002.

Reed is Vice President of Pharmacy for Preferred Care, a New York HMO with more than 200,000 lives. He is also a member of the New York State Medicaid Pharmacy & Therapeutics Committee.

## REGISTER NOW FOR DISCOUNT ON 9TH ANNUAL DRUG UTILIZATION MANAGEMENT CONFERENCE

PBMI will hold its ninth annual Prescription Drug Utilization Management Conference from April 28-30, 2004, at the Scottsdale Radisson Resort in Scottsdale, Ariz.

“We have invited faculty from organizations nationwide that are employing strategies to manage drug benefit costs,” says Michael H. Deskin, president of PBMI. “Our 2004 faculty includes experts in drug benefit plan design, marketplace trends, pharmacoeconomics, and regulatory issues.”

The conference sells out every year, so register today for the early bird discount on-line at [www.pbmi.com](http://www.pbmi.com) or call PBMI at 480-730-0814. To make hotel reservations at the PBMI conference rate, call the Scottsdale Radisson Resort at 800-333-3333. The Radisson will offer the conference rate until March 26, 2004.

## '03 CUSTOMER SATISFACTION REPORT NOW AVAILABLE

PBMI's 2003 PBM Customer Satisfaction Report is now available. More than 450 employers, representing 10 million drug benefit plan members, provide insights on the performance of PBMs. For the eighth year, the report provides plan sponsors with information to select and manage PBM services. To order a copy, visit [www.pbmi.com](http://www.pbmi.com).

## PBMI FIELDING PLAN DESIGN SURVEY

Fielding has started for PBMI's annual benefit cost and plan design survey. PBMI has conducted this survey of the large U.S. employers to assess the latest trends in pharmacy benefit management, plan design, and cost issues since 1995.

Are you an employer interested in responding to this survey? If so, contact us at [www.pbmi.com](http://www.pbmi.com). You will receive a complimentary copy of the research report for completing the survey. In addition, respondents are automatically entered into the drawing for free conference admission.

## ENJOY REWARDS OF BECOMING A MEMBER OF PHARMACY BENEFIT MANAGEMENT INSTITUTE

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