

# DRUG BENEFIT NEWS

News, Data and Business Strategies for Health Plans, Employers, PBMs and Pharma Companies

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## PBM Auditing Increases as Rx Costs Rise, But Critics Allege PBMs Are Foiling Audits

Faced with rapidly rising pharmaceutical costs, health plans and employers increasingly are turning to audits to ensure that their PBMs are delivering on contractual promises. While some PBMs willingly open their books, industry critics allege that the auditing process is stymied by PBM gamesmanship, and that clients are losing money as a result. If PBMs would allow better access to their documents, one veteran PBM auditor tells *DBN*, pharmaceutical payers could save up to 10% on their drug spend in some cases.

For their part, PBMs say they recognize the importance of audits and point to an auditing provision that was included by URAC in last year's PBM accreditation standards. And one PBM observer contends that the sheer complexity of the PBM business — with its multiple rebates, fees, discounts and varying pricing formulas — can raise red flags with pharmaceutical payers, even when no wrongdoing exists (see story, p. 7).

But others involved in the PBM auditing process see a pernicious attempt by many PBMs to ensure that full sunshine does not fall on their books. PBMs, they assert, place undue restrictions on the auditing process that skews the audit in favor of the PBM, and can block recoveries of funds due a client. Such practices are enabled by poorly drafted PBM/client contracts and include the following requirements:

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## Medicare Part D 2009 Bids, Premiums Rise; Plans Say Beneficiaries Will Likely Stay Put

The average bid submitted by Medicare Part D sponsors for 2009 is almost 5% higher than it was in 2008, an increase that is estimated to boost premiums for basic drug coverage by roughly \$3 to \$4 per month, according to CMS. While some Part D sponsors could hike premiums significantly more than that, CMS says most beneficiaries will have access to plans with premiums equal to or lower than what they now have. And some Part D stakeholders tell *DBN* that beneficiaries are unlikely to switch plans over modest premium increases.

The findings are part of CMS's Aug. 14 release of average costs for standard Part D coverage next year. Average monthly premiums for basic coverage provided by stand-alone Medicare Prescription Drug Plans (PDPs) will be \$31 in 2009, up from \$27 this year, CMS said. Average monthly premiums for Medicare Advantage prescription drug (MA-PD) plans will be \$21 in 2009, up from \$18 this year, the agency added. The premium figures are based on the national average bid of Part D sponsors, which is \$84.33 in 2009, up 4.7% from \$80.52 in 2008, according to CMS.

CMS did not release premium data for more inclusive Part D plans, which beneficiaries generally select. Individual Part D sponsors also did not release figures, and will not do so until later this fall.

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Patient lack of compliance or adherence to prescribed therapies is emerging as a more costly component of health care than the actual hospitalization or diagnostic portion. Given that most of these conditions are chronic or lifelong, this truly is a significant issue facing a health care system that has traditionally been focused on acute short-term care. As drug therapy and technologies continue to emerge as the new solution to existing chronic medical conditions, this will become our greatest economic and clinically related challenge to overcome. ♦

## PBM Audits Are Under Scrutiny

*continued from p. 1*

- ♦ *The PBM has a right to "mutually approve" any auditor selected by a client, and can veto any auditor that the PBM doesn't find satisfactory;*
- ♦ *The auditor must sign a PBM-drafted "confidentiality agreement" that limits the type of data the auditor may audit, and requires the auditor to provide a draft audit report to the PBM before providing it to the client;*
- ♦ *The auditor cannot disclose certain PBM "proprietary" information to the client, such as types of drug manufacturer rebates and amounts of individual rebates;*
- ♦ *The auditor cannot copy any confidential information in the PBM offices, and may take notes only on broad findings rather than on detailed underlying data; and*
- ♦ *The auditor must pledge not to be involved in any litigation against the PBM, should there be any, nor talk to any news reporters.*

Restrictions, such as the "mutual approval" language, give PBMs undue influence on audits, says Linda Cahn, president of Pharmacy Benefit Consultants and an attorney who has reviewed hundreds of PBM contracts and litigated against PBMs.

"Auditors have to walk a tightrope" she tells *DBN*. "Aware they have obligations to their clients, auditors know they should look for all PBM wrongdoing and disclose all such wrongdoing to their clients. However, aware that PBMs have an almost-universal contract right to 'mutually approve' auditors, many auditors avoid tasks that are likely to result in findings of PBM wrongdoing, and instead conduct audits that are less informative than they should be."

For example, Cahn says, auditors rarely audit "rebate agreements." And even if they do, PBMs generally restrict the number of rebate agreements that can be audited and redact critical information from the agreements, she adds. "As a result, auditors almost never detect, let alone disclose to their clients, the extent to which

PBMs are depriving their clients of rebates by calling rebates some other name, such as 'administrative fees' or 'health management fees,'" Cahn asserts.

Cahn also blasts PBMs' frequently applied restrictions on note taking and copying of documents. Audits done in virtually every other industry yield boxes of information that auditors thereafter keep confidential, she contends. "But PBMs force auditors to take such slim notes during PBM audits that when PBMs dispute auditors' final reports, auditors are not in a position to demonstrate the accuracy of their findings," Cahn says.

Audit restrictions are costing clients money, asserts Susan Hayes, principal of Pharmacy Outcomes Specialists. "Clients are losing money because they end up hiring auditors that don't press for all of the documents and end up never getting recoveries," she tells *DBN*.

Hayes, who has been blocked by the "mutual approval" provision from auditing certain large PBMs, says that every one of the more than 500 PBM audits her firm has done has uncovered money that was due back to the client. This figure generally ranges from 2% to 3% of drug spending, but can total up to 10% of a client's overall costs, she says.

Examples of audit findings include a PBM that agreed to prior-authorize the expensive rheumatoid arthritis drug Enbrel (etanercept), but never did, she asserts. Or a PBM that agreed to give the client a better price on drugs by increasing the discount on average wholesale price from AWP minus 14% to AWP minus 15%, but never implemented the change. "The client never knows this because they don't know what AWP minus 15% is," Hayes says of the example.

The lack of access to PBM documents often prevents auditors from finding such recoverable monies in the first place, Hayes says. "But once we find it, it is really the clients' desire to pursue the findings that tends to get them recoveries," she adds.

About half of clients get something back, explains Hayes, who estimates the recovery is about 50 cents on the dollar. "Some clients don't fight to get their money back...some take it in a better renewal rate going forward, some change PBMs," she explains. "Then there are those clients that litigate, on the opposite end of the spectrum."

### PBMs Cite Need to Protect Information

Still, even highly transparent PBMs contend that some of their actions are designed to facilitate a smooth auditing process and ensure that information is not improperly used.

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Innoviant, Inc., for example, has used the mutual-approval language not to weed out auditors who take a particularly tough line but to make sure it's dealing with someone who is up to the process, says Mark Campbell, Pharm.D., president and CEO of the pharmacy benefit administrator, which was recently acquired by United-Health Group.

"Because there is a cost to both organizations to doing an audit, you'd like to know it is someone who has done audits before and understands the scope and breadth of what needs to be done, and can do it in an efficient and orderly manner," he says in an interview with *DBN*.

Regarding confidentiality agreements, Campbell says customers should have access to "whatever they need," but at the same time the PBM must ensure it's protecting information to the best of its ability. There is always the danger that information could be used for alternative purposes that would be unsuitable, he says.

"I'm an auditor," Campbell explains as an example. "I'm looking at somebody's contract with a particular

pharmacy, and I go, 'Wow, that's a really great rate. I'm going to go back and make sure that when I'm working on the other side of the house, and doing an RFP [i.e., request for proposal] for somebody, I'm going to try and get that rate for everybody.' That would be an unfortunate use of the information, because it's taken out of context."

Similarly, Innoviant makes efforts to control its manufacturer and pharmacy information. "Sharing it with people so they can verify what's going on — triangulate that information against what's actually occurring — that's our purpose and mission here," he says. "But allowing people to reproduce information would make it difficult if not impossible to control where that information goes, so we do restrict that."

### Audit Procedures Are Established in Contract

How can both sides ensure the audit is fair? Procedures for client audits are part of the negotiations that take place during the RFP and contracting process, according to a PBM trade group spokesman.

"Provisions may include mutual agreement on an auditor, scope, timing and confidentiality," says Charles Coté, spokesman for the Pharmaceutical Care Management Association (PCMA). "The standards for client audits are known to both parties at the time of contracting and are part of the client-PBM relationship during the term of the contract," he says.

Audit standards are included in URAC's PBM accreditation standards, which were developed by a broad cross-section of PBM stakeholders in 2007, Coté adds.

Under URAC's standards, PBMs will disclose to clients — if the disclosures are required by the PBM/client contract — various financial model information upon request, including:

- ◆ *Existence of organizational arrangements that could potentially create a conflict of interest that affects clinical or financial decisions,*
- ◆ *Sources of revenue, and*
- ◆ *Pricing structure for PBM services, such as rebate structures and administration fees (DBN 8/17/07, p. 7).*

But getting these points written into the contract can be tricky, some say. Clients and their consultants should focus on a client's audit rights during the RFP process, and before a PBM is selected, says Kevin M. Nagle, president and CEO of Envision Pharmaceutical Services. Unfortunately, many consultants reverse the process, and start the contract negotiation phase after a PBM finalist has been selected in an RFP, he tells *DBN*.

"And what they'll find out is that some of the things they wanted to accomplish in their RFP, they may in fact not be able to, because the PBM has negotiated certain

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clauses which prohibit them from doing the kind of auditing to ultimately get to that transparency component," he says.

The issue also caught the attention of the Texas State Auditor's Office, which issued a report Aug. 20 recommending that state agencies have greater power to audit their PBMs (see brief, p. 8).

Meanwhile, some clients choose not to pursue their audit rights more fully, says Hayes. Most benefit managers would like to find an auditor who is not controversial, and some just want a clean bill of health, she asserts. Hayes recalls the reaction of a large Pennsylvania company after she told them how much money they were losing under the PBM. "They said, 'Oh well, it's a rounding error. Let's move on,'" Hayes says.

But others say PBM auditing is expected to increase as an important business process as pharmaceutical spending continues to balloon the coming years.

Innoviant's Campbell points out that in 2000, the U.S. spent roughly \$129 billion on prescription drugs. That figure is expected to grow to \$540 billion by 2014, he adds. "That got people scrambling a little bit to try and figure out what's driving these expenses," Campbell says.

He also notes the PBM audit process is still relatively new, and lacks standardization within the industry. "The overall process is good," he says. "It's just going to take a little while before there is a bit more commonality in how the process works and what's expected of both parties."

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### *PBM Complexity Presents Moving Target for Auditors*

The complexity of the PBM industry and how PBMs price products and services can lead to confusion and consternation during the auditing process, says Jon Warren, director of PBM product management at UMR, the nation's largest third-party administrator, which was acquired last year by UnitedHealthcare.

"People go into it thinking that an audit is going to be very similar to audits that are done in other portions of health care," he tells *DBN*. "It's not. It's very, very complex. This is definitely a moving target. There are lots of pieces of the puzzle that leave it open to gamesmanship."

What clients of PBMs need to understand is that essentially they are buying services for a fee, Warren explains. "But that fee is oftentimes spread over a half a dozen or more pricing components, which may in turn have the fee spread over additional pricing components," he says. "At the end of the day, you have an extremely confusing, complex pricing mechanism. And PBMs are jealous of that information and how they do business — jealous of how much money they're making as they do business."

"That complexity, confusion and hesitancy to release that information has resulted in an industry that is not really trusted by their clients," Warren continues. "The result is the requirement for audits."

The complexity, however, does not necessarily mean that PBMs are engaged in any wrongdoing, Warren adds. Public PBMs have responsibilities to their shareholders, he notes. "If there is an oppor-

tunity built into this complex pricing model for me to make more money for my shareholders, it is my obligation to do that," he says as an example.

Mark Pastin, chairman and president of the Council of Ethical Organizations, says any business that runs on rebates, such as the PBM industry, creates a lack of transparency.

"Rebates are given to incentivize," he tells *DBN* of rebates from drug manufacturers to PBMs that accrue when products are sold. "And whether those incentives are in the interest of the patients or the clients is highly subject to debate."

There is a lot of distrust and confusion around pharmaceutical pricing, he says. The honest PBMs naturally do not want to be accused of wrongdoing because of the way pharmaceutical companies manage their rebate programs, he adds. The movement toward transparency in pharmaceutical pricing is great right now, Pastin says, adding that the market is "migrating to an environment in which the rebate model will no longer be tolerated."

In the end, however, pharmaceutical prices are still governed by market factors, Pastin adds. And he doubts there would be huge amounts of money to be recovered if the rebate model goes away. "The appearance of wrongness is probably greater than the underlying wrongness," he adds. "That's all the more reason to get rid of the appearance as well."

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