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before

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,
SUBCOMMITTEE ON FEDERAL WORKFORCE,
POSTAL SERVICE,
AND THE DISTRICT OF COLUMBIA

on

FEHBP's Prescription Drug Benefits: Deal or No Deal?

June 24, 2009

Office of the Medicaid Inspector General

Chairman Lynch, Ranking member Chaffetz, members of the Subcommittee:

I appreciate the opportunity to join my good friend, OPM Inspector General Pat McFarland, in testifying before the Subcommittee today. Inspector General McFarland has long been a leader in the Inspector General community on professional IG standards and on prescription drug issues. I have worked closely with OPM and OPM-IG staff for ten years. I believe that the unique structure of the OPM health plans and members offer a significant opportunity to achieve higher quality health care outcomes for members and lower costs, and that the OPM plans can be a national model for effective, cost-conscious health care. New York's Medicaid experience can provide some helpful advice on how to achieve that result.

Before becoming New York's Medicaid Inspector General in 2007, I was the Associate U.S. Attorney in Eastern Pennsylvania. In that position, I worked with investigative and prosecutive teams for seven years, looking at the business practices of two major pharmacy benefit management (PBM) firms who did business with OPM plans. Medco Health, which handled the mail order contract for OPM's largest contractor, the Blue Cross and Blue Shield Association, and AdvancePCS (now part of Caremark) which handled the Blues' retail contract. These investigations involved allegations of false claims, improper payments from drug companies, and kickbacks to health plans by PBMs to steer business. At the conclusion of those investigations, these two companies paid over $290 million to the United States, and agreed to make significant changes to their business practices. The Eastern Pennsylvania office was also a national leader in investigation of off-label drug promotion, most recently obtaining a $1.4 billion settlement from Eli Lilly for promotion of its antipsychotic drug Zyprexa (olanzapine), and over $400 million from Cephalon for promotion of its drugs.

In the Medco and AdvancePCS cases, federal investigators had the opportunity to interview witnesses and review documents from many companies over a long period of time, and to become educated in how the PBM business works. We also learned the business strategies used by pharmaceutical manufacturers in their relationships with PBMs and health plans.

In my new role as New York's Medicaid Inspector General, the staff in my organization and in New York's Department of Health, which manages the Medicaid program, have educated me on the opportunities for a payor for both cost savings and improved patient outcomes through direct access to integrated patient care information which includes prescription data.

As a federal employee, and now as a federal retiree, participating in the Blue Cross plan for 29 years, I have been exposed to the operation of the OPM drug benefit program as a consumer and parent.

Based upon this experience, I offer the following suggestions for the operation of OPM's prescription drug program:

1) OPM NEEDS ACCESS TO AND A PLAN FOR USE OF INTEGRATED PATIENT CLAIMS DATA

The most important information about prescription drugs is not how much they cost, but what happens to the patients who take them. Do they experience better outcomes? Do they suffer adverse events? What is the cost to the patient and the system of adverse events? Neither community rated plans nor experience rated plans have incentives within the OPM program to address these questions. To be fair, they are not addressed by CMS or the FDA either. But federal employees, and recent federal retirees like me are an ideal population to study for quality improvement, cost saving opportunities, and risks. OPM has access to six-plus years of data for every patient-and we are not leaving the program.

For hospital in-patients, the research from the 1990's suggests that adverse drug reactions leading to death in hospitals are about 106,000 per year in the US, and are between the fourth and sixth leading cause of death.[1] For ambulatory patients (that is, patients not in a hospital or nursing home) the research is also sobering. A 2003 Brigham and Women's study found that "of 661 patients who responded to the survey (response rate, 55 percent), 162 had adverse drug events (25 percent; 95 percent confidence interval, 20 to 29 percent), with a total of 181 events (27 per 100 patients).[2] Twenty-four of the events (13 percent) were serious, 51 (28 percent) were ameliorable, and 20 (11 percent) were preventable. Of the 51 ameliorable events, 32 (63 percent) were attributed to the physician's failure to respond to medication-related symptoms and 19 (37 percent) to the patient's failure to inform the physician of the symptoms."

New York's Medicaid program is a national leader in its data management. The New York state data allows us to determine every reported diagnosis and every Medicaid health care encounter for every Medicaid patient-which allows the state to identify risky, expensive, or inappropriate prescribing, and also allows New York to run an effective supplemental rebate program resulting (for some products) in prices lower than the Medicaid best price. New York's rich and accessible data systems have allowed the Department of Justice and National Association of Attorneys General to investigate and prosecute off-label drug promotion and marketing. The data available to New York as a payor are significantly more comprehensive, and far easier to use, than data available to

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[1] Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-analysis of Prospective Studies *JAMA.* 1998;279:1200-1205, Jason Laxarou et al.

[2] *Adverse Drug Events in Ambulatory Care* 348:1556-64 New England Journal of Medicine 4/17/03, Gandhi et al. The medication classes most frequently involved in adverse drug events were ssris (10 percent), beta-blockers (9 percent), ACE inhibitors (8 percent), and nonsteroidal anti-inflammatory agents NSAIDs (8 percent). Only the number of medications taken was significantly associated with adverse events.

OPM or Medicare for their programs-because of New York's contractual relationship with its carrier/fiscal agent.

This data has the potential to transform health care over the next ten years, because of the power of data-driven disease management and adverse event identification tools-which are especially significant for FEHBP's older population who are more likely to have chronic conditions. In New York Medicaid, electronic prescribing incentives will provide us with data about every prescription written for our Medicaid patients, at the time it is written. OPM could do the same.

2) A FOCUS ON IDENTIFIED DRUG RISKS-OPM HAS THE OPPORTUNITY TO REVIEW SIGNALS FROM MEDWATCH AND DETERMINE IF THEY ARE VALID AND PATIENTS ARE AT RISK

The FDA's Medwatch program is getting better, but is still not being used to its potential.[3] The Institute for Safe Medication Practices (ISMP) has been reviewing Medwatch data for the past two years. The results of those reviews raise significant concerns:

Chantix (varenicline), a drug to help people stop smoking. Medwatch in one quarter had 227 domestic reports of suicidal acts, thoughts or behaviors, 397 cases of possible psychosis and 525 reports of hostility or aggression. These totals included 28 cases of suicide and 41 mentions of homicidal ideation, 60 cases of paranoia and 55 cases of hallucination.

Digoxin a drug used for heart disease and arrhythmia, Medwatch received more than 1000 patient deaths reported in connection with the recall of 800 million digoxin tablets manufactured in New Jersey by the Actavis Group. The tablets were recalled because of the possibility that the strength of tablets was greater than labeled and might provide a potentially lethal overdose to patients taking the drug to aid failing hearts.

3) FOCUS ON DRUG PRICING

Drug pricing within OPM's health plans was based, during the time period I was involved in reviewing it, upon percentage discounts off Average Wholesale Price negotiated by OPM experience-rated plans with little or no financial interest in the outcome of the negotiations, since the costs were passed through to OPM. The net prices paid by OPM significantly exceed the net prices paid by state Medicaid programs, like New York, who obtain the benefit of the Medicaid best price or better. OPM prices also exceed the prices paid by the Department of Defense under the Federal Supply Schedule. In the mail order pharmacy context, pharmacy benefit managers were able to provide prescriptions based upon the Federal Supply Schedule costs to DoD enrollees in the CHAMPUS program. There is no reason they could not provide the same service to OPM health plans.

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[3] A Medwatch report is based upon association, not causation. It is not proof, but suggests that further review is needed.

At retail, federal employees and OPM need to know what savings can be accomplished by purchasing generics. I found as a consumer that the retail pharmacies were often unwilling to discuss the price charged to the Plan, and when I obtained the price, much of the savings were retained by the PBM-due to the practice of passing through inflated generic prices.

4) COORDINATION OF BENEFITS BETWEEN OPM PLANS AND MEDICARE PART D PLANS

In the past year, New York finally began obtaining access to billing and payment information from PBMs including PBMs that operate private and Medicare Part D plans. The results were troubling-some pharmacies billing and being paid twice for the same prescription, payment for some dual eligible patients being denied by the plans for no apparent good reason and the prescription being billed to Medicaid, some pharmacies not submitting claims to the Part D payor because the Medicaid billing was easier and payment more reliable.

It is important to recognize that many OPM plan entities also manage a Medicare Part D plan. Many federal employees over 65 are enrolled in both plans. Experience-rated plans are not at risk on the OPM side, but are at risk on the Part D side. Audit and oversight are essential to assure that each plan fulfills its responsibilities to beneficiaries and to OPM.

5) CHOICE OF AUDITOR AND ACCESS TO SUBCONTRACTOR PBMs

Auditing PBMs requires experience and sophistication, and avoidance of conflicts of interest. PBMs limit audit access in their contracts with plans to auditors approved by the PBM. OPM and the plans should have the ability to retain auditors who are able to perform these duties effectively.

There are significant opportunities for cost savings on prescription drugs through improvements in OPM operations. As important, there are opportunities for better patient outcomes, more appropriate prescribing, and reduced adverse events through integration of medical claim and diagnostic data with pharmacy data maintained by PBM subcontractors.

Thank you for the opportunity to speak with you today. I am happy to take any questions.