Healthcare reform and pharmacy benefits

Changes in benefits and reporting requirements

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The federal healthcare reform law (H.R. 3590, Patient Protection and Affordable Care Act and H.R. 4872, Health Care and Education Reconciliation Act of 2010) contains a number of important changes relating to pharmacy benefits. This article discusses the major provisions of the new law and their implications for healthcare plans, providers, patients, and the government.

The relevant changes are contained primarily in the following sections of the law:

- Pharmacy benefit managers (PBM) transparency requirements (Section 6005)
- Medicaid implications (Sections 2501, 2502, and 2503)
- Approval pathway for biosimilar biological products (Section 7002)
- Physician Payment Sunshine Act (PPSA)
- Prescription drug sample transparency (Section 6004)

This article does not address pharmacy changes related to Medicare Part D, which are covered in a separate article.

TRANSPARENCY IN PHARMACY BENEFIT MANAGERS' OPERATIONS

New reporting requirements and regulations will come into effect for Medicare Part D plans and health plans participating in the state exchanges[1] who have their own PBM or contract with a PBM. These exchanges will emerge in 2014 as part of the healthcare reform act.[2] The time, form, and manner of the new reporting have been loosely defined and have yet to be finalized.

PROVISIONS:

Medicare Advantage Prescription Drug Plans (MA-PDs) and Part D prescription drug plans (PDPs) and health plans participating in exchanges must report:

- The percentage of prescriptions they provide through retail pharmacies compared with mail order pharmacies, as well as the generic dispensing rate by pharmacy type
- Information about rebates, discounts, or price concessions, as well as price concessions that are passed through to the plan sponsor or retained by the PBM, including the financial information and total number of prescriptions
- The difference between the amount the health plan pays the PBM and the amount that the PBM pays its suppliers (this is commonly referred to as the disclosure of *spread pricing*)

IMPLICATIONS:

MA-PDs, PDPs, and health plans that participate in the exchanges will take on an increased administrative burden. They will be obligated to follow an expanded version of reporting processes currently established under Medicare Part D.

Government will take on increasing oversight responsibility for the PBM industry, leading to additional scrutiny at both the state and federal level.

1 The new law requires the creation of state exchanges, which will serve as centralized mechanisms for purchasing individual and small group insurance. All plans that participate will be required to satisfy certain benefit criteria. The exchanges will offer premium and cost sharing credits to individuals/families with income between 133% and 400% of the federal poverty level.

2 On the mechanics of PBM transparency, see Troy Filipek, "PBM transparency could be inevitable," *Managed Healthcare Executive*, Feb. 1, 2009, available online at http://managedhealthcareexecutive.modernmedicine.com/mhe/Exclusives/PBM-transparency-could-be-inevitable/ArticleStandard/Article/detail/577629?contextCategoryId=47310.

MEDICAID IMPLICATIONS

The provisions in Sections 2501, 2502, and 2503 establish parameters with significant changes to the Medicaid drug benefit offering under state Medicaid programs and Medicaid managed care organizations (MCOs).

PROVISIONS:

- Minimum rebates on most brand name drugs increased from 15.1 percent of the average manufacturer price (AMP) to 23.1 percent of AMP.
- Minimum rebates on generic drugs increased from 11 percent of AMP to 13 percent of AMP.
- The federal government will retain a larger portion of the rebates, and as a result, the rebate payments to states will be reduced.
- Three formerly excluded drug types—barbiturates, benzodiazepines, and smoking-cessation drugs—are required to be included in benefits.
- Medicaid MCOs will now be eligible for prescription drug discounts as described in Section 340B of the Public Health Service Act. Previously, these discounts applied only to state Medicaid programs and some nonprofits.
- The new law reiterates and extends AMP as the standard baseline for Medicaid price reporting.

IMPLICATIONS:

Patients will have access to several types of drugs formerly not covered.

Government, especially state governments, will spend more because of the newly included drugs but will also benefit from the cost savings resulting from increased rebates. In addition, AMP, generally a lower price than other pharmacy pricing measures, may become the standard government pricing baseline for prescription drugs as average wholesale price (AWP) is phased out during 2011.[3]

Medicaid MCOs will have access to Section 340B pricing, which comprises some of the lowest drug prices in the industry, and will try to make the most of this change to manage costs. The changes will require Medicaid MCOs to report certain items to the states. In turn, the states will set capitation rates paid to the entity based on actual cost experience related to rebates and subject to the federal regulations.

SUNSHINE ACT PROVISIONS: REPORTING REQUIREMENTS FOR GROUP PURCHASING ORGANIZATIONS (GPO), PHARMACEUTICAL MANUFACTURERS, AND PHYSICIANS

The Physician Payment Sunshine Act (PPSA), which had its origins as a standalone bill first introduced in Congress in 2009, was incorporated into the larger act passed in March 2010. The Sunshine Act provisions are designed to shed light on the financial relationships and potential for conflicts of interest between physicians and the pharmaceutical and medical device industries. Some assert that such relationships play a role in physicians' treatment choices and drive up treatment costs.

PROVISIONS:

- Pharmaceutical and medical device companies, as well as GPOs serving physicians and other medical providers, will be required to disclose payments or gifts of value to physicians.
- Also to be reported are any shares of stock that physicians, or groups of physicians, hold in pharmaceutical or medical device companies, or mutual funds that hold stock in the pharmaceutical or medical device industries.

IMPLICATIONS:

Physicians and physician groups will come under government scrutiny aimed at disclosing any possible conflicts of interest in their relationships with pharmaceutical and medical-device manufacturers.

Government will exercise oversight of any such relationships that might suggest conflicts of interest and will investigate investment practices.

Patients will have access to a public website posting information on specific physicians who receive payments from specific manufacturers or GPOs.

[3] On AWP, see Brett Swanson, "The Impact of AWP Litigation on Your PBM Contract," *Milliman Health Perspectives*, August 2009, available at http://www.milliman.com/expertise/healthcare/publications/perspectives/pdfs/health-perspectives-august-2009.pdf.

TRANSPARENCY IN PRESCRIPTION DRUG SAMPLES

Beginning in 2012, manufacturers and distributors of prescription drugs must report information relating to drug samples. The point is to discourage the dispensing of samples by drug manufacturers as a marketing tactic.

PROVISION:

By April 1 of each year, every manufacturer and authorized distributor of an applicable drug shall submit information (still to be defined) to the federal government about samples given to doctors, clinics, hospitals, etc.

IMPLICATIONS:

Government will be able to track and monitor the dispensing of drug samples.

Physicians' offices and other recipients of samples will have to accommodate the tracking requirements. This may result in further use of electronic records to monitor distribution of samples. Physicians' offices may provide fewer samples to patients because of the additional administrative requirements.

Health plans may see changes in prescribing patterns and drug costs, if samples are reduced.

APPROVAL PATHWAY FOR BIOSIMILAR SPECIALTY BIOLOGICAL PRODUCTS

The Food and Drug Administration's (FDA) approval pathway will authorize the FDA to approve generic versions of biologic drugs and grant biologics manufacturers 12 years after the date on which the reference product was first licensed.

PROVISIONS:

- This change allows the development of generic products for biological products that historically have not been allowed to have generic competition. Biological products are typically very expensive specialty medications used to treat high-risk conditions.
- FDA will grant exclusivity for first interchangeable biological product for one year.

IMPLICATIONS:

For patients and plans, these changes will encourage improved price competition in the biological *specialty* product area, while reducing costs of certain high-cost, life-sustaining treatments.

SUMMARY

The new law represents a significant evolution in the pharmacy benefit industry, and, moving forward, it will set the stage for additional disclosures and transparency regulations as the federal government exercises more oversight. Other provisions attempt to address the cost of pharmacy benefits by introducing generic biosimilars and increasing mandatory rebate levels in Medicaid programs. All entities involved in the delivery of pharmacy benefits to patients should prepare to meet increasing compliance requirements.

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