Coming to Grips with Reform

and its impact on prescription drug coverage

BY BRIAN ANDERSON AND TROY FILIPEK

The smoke has lifted, the politicians and pundits have had their say, and the first provisions of the federal health care reform laws — the Patient Protection and Affordable Care Act (PPACA) combined with the Health Care and Education Reconciliation Act of 2010 — are beginning to take effect. The players in the market, from insurance companies to physicians, are scrambling to figure out what they have to do, how to do it and when it has to be done.

This is no less true in the area of prescription drugs than in other areas of health care. The law calls for new benefits and sets out an array of new regulations affecting all parties involved in the pharmacy arena. The prescription drug regulations will be phased in between now and 2020, with many coming into play within the next 12 months. The more significant changes, such as the changes in Medicaid and Medicare, may result in cost shifting to patients, employers and health plans.

Although it's important to start planning for the longer-term impacts of the reform legislation, it's also crucial to understand the implications of the near-term changes, which, in the case of pharmacy benefits, may be the most significant.

What's happening now: 2010 changes

RDS tax exemption eliminated—The tax exemption to employers that receive the Retiree Drug Subsidy (RDS) for providing qualifying prescription drug coverage for retirees eligible for Medicare has been eliminated. Even though this change does not occur until the beginning of 2013, if plans are currently receiving the RDS, it has the immediate accounting impact of creating a deferred tax liability for their other post-employment benefit obligations. Many large companies have already indicated they anticipate taking an earnings hit as a result of this change. For example, AT&T has disclosed its estimate that the change will cost the company $1 billion, Verizon reported $970 million, Deere & Co. reported $150 million and Caterpillar Inc. reported $100 million. As a result, companies may consider alternate options for providing benefits or they may cut future benefits to offset some portion of the impact.

The Early Retiree Reinsurance Program (ERRP)

This $5 billion fund was created under the PPACA to help employers defray part of the cost of their retiree health insurance. This temporary reinsurance program will reimburse 80 percent of claims between $15,000 and $90,000 for employer-sponsored retiree coverage of individuals 55-64 years old who are not active workers or eligible for Medicare. The program was to be established by June 21 and will sunset on Jan. 1, 2014, or when the funds are exhausted, which many experts anticipate will be before 2014. For employers to take full advantage of the ERRP, they will need to coordinate the merging of pharmacy and medical claims data. Typically, employers use different vendors to adjudicate the two types of claims.

Lifetime limits disallowed

By the end of September, health plans will not be allowed to impose lifetime limits on the dollar amount of coverage provided to their members. This provision extends to prescription drug benefits as well as all other medical benefits.

Medicaid pharmacy changes

Minimum rebates on most brand-name drugs are increasing from 15.1 percent of the average manufactured price (AMP) to 23.1 percent; on generic drugs, minimum rebates are increasing from 11 to 13 percent of AMP. Three formerly excluded pharmaceutical types — barbiturates, benzodiazepines and smoking-cessation drugs — will now be included as covered benefits. Medicaid managed care organizations (MCOs) will be eligible for prescription drug discounts as described in Section 340B of the Public Health Services Act, giving them some of the lowest drug prices in the industry (formerly available only to state and nonprofit Medicaid programs).

Federal upper limit changes

The Federal Upper Limit on pharmacy reimbursement for multiple-source drugs has changed from 250 percent of AMP for the least-expensive therapeutic equivalent drug to 175 percent of the weighted average, as determined by utilization of the most recently reported monthly AMPs of multiple-source drugs available at pharmacies.

Medicare Part D coverage gap rebate checks

As a first step toward gradually eliminating the coverage gap (aka the doughnut hole) in Medicare Part D benefits, Medicare patients whose drug costs reach the coverage gap in 2010 will receive a one-time $250 rebate check from the Centers for Medicare & Medicaid Services (CMS).

Biosimilar products

Another change this year creates an approval pathway for the development of generic products for biological drugs (biosimilar products) that have not previously had generic competition. The Food and Drug Administration will grant the manufacturers of original (brand-name) biological products exclusivity for

12 years, after which biosimilar generics will be allowed to enter the market. This change is meant to open up competition in the biological specialty product area and reduce the long-term costs of many expensive life-sustaining therapies.

These provisions are challenging organizations to move quickly in order to comply with this first wave of required changes.

Just around the corner: 2011-2013

No sooner will the 2010 changes take effect than companies and plans will need to gear up for new requirements starting in 2011.

Manufacturer provisions and coverage gap closure

Pharmaceutical manufacturers will be significantly impacted by two provisions in particular. First, they will be subject to an annual fee. Second, manufacturers of brand-name prescription drugs will subsidize a 50 percent discount to Medicare members who have reached the coverage gap.

Annual fees

Beginning in 2011, an annual fee will be imposed on pharmaceutical manufacturers and importers of certain branded prescription drugs and biologics for sale to specified government programs, such as Medicare and Medicaid. The aggregate fee imposed starts at $2.5 billion in 2011, climbs to $4.1 billion in 2018 and settles at $2.8 billion thereafter. This fee is shared among individual pharmaceutical manufacturers and importers based on market share.

Coverage gap

Beginning in 2011, brand-name drugs will be discounted by 50 percent for seniors in the doughnut hole through higher pharmaceutical company rebates. This manufacturer coverage gap discount program, in conjunction with yearly changes to coverage for drugs under the standard Part D benefit, will lead to the coverage gap closing entirely by 2020, under the following schedules outlined in the charts above.

Medical account changes

Beginning in 2011, persons using tax-advantaged set-asides such as flexible spending accounts (FSAs), health savings accounts (HSAs) or medical savings accounts will no longer be able to use such accounts to fund over-the-counter (OTC) drug expenditures unless a physician prescribes the drugs. Such plans will only be used to reimburse prescription medications and insulin.

High-income premium surcharge

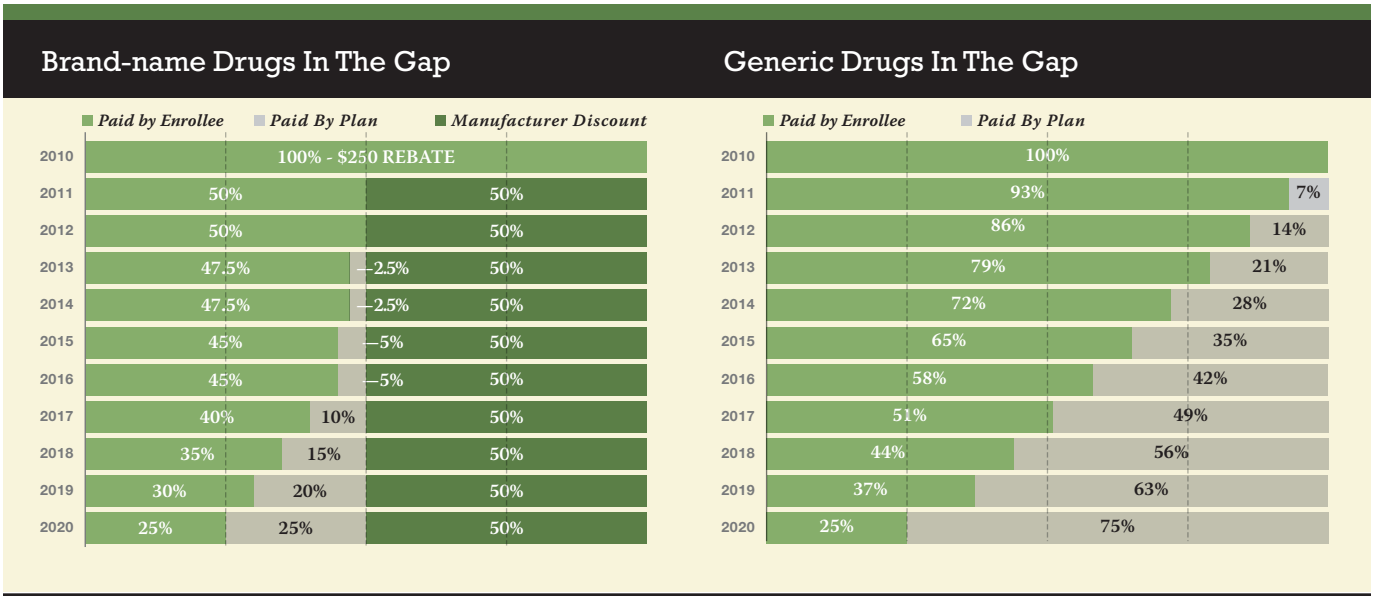
Medicare recipients with an annual income higher than $85,000 (for an individual) or $170,000 (for a married couple) will see their Part D premium subsidies reduced in 2011, in effect raising their premiums.

Low-income benchmark and beneficiary reallocation changes

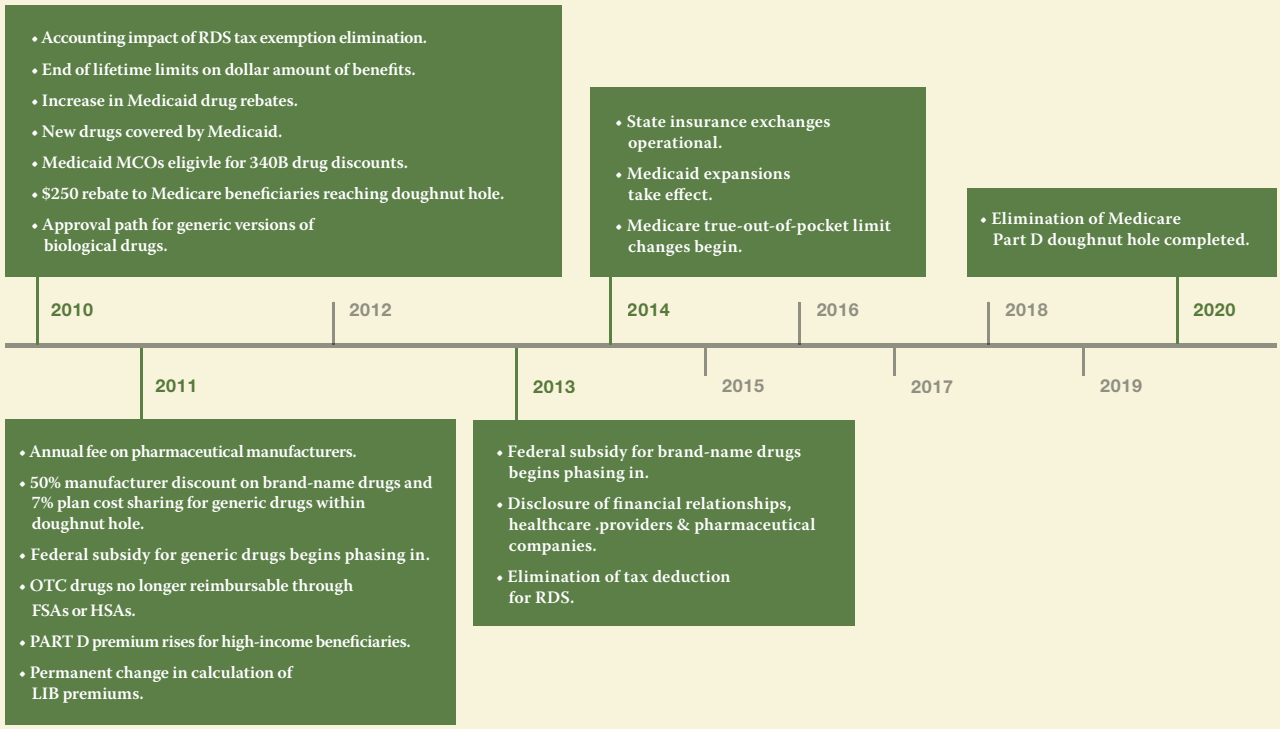
Another Part D-related provision in the law taking effect in 2011 changes the formula for calculating low-income benchmark (LIB) premiums and allows a de minimis amount in which plans can retain auto-assigned members in cases where a plan's bid slightly exceeds the benchmark. (CMS will determine the de minimis premium level each year.) These changes are intended to minimize the movement of low-income enrollees between Part D plans.

Disclosure requirements

The first will require pharmaceutical and medical device companies, as well as group purchasing organizations serving physicians and other medical providers, to disclose payments or gifts of value to physicians, hospitals, pharmacists and other providers. Providers must also report any shares of stock that they hold in pharmaceutical or medical device companies or mutual funds that hold stock in the pharmaceutical or medical device industries. These provisions comprise the Physician Payment Sunshine Act, a piece of the larger health care reform law aimed at exposing any potential conflicts of interest between health care providers and manufacturers.



TIMELINE:
Healthcare Reform Implementation of Prescription Drug Provisions



RDS tax changes

As discussed earlier in this article, the RDS tax exemption officially ends in 2013, although the accounting impact will already be reflected.

2014 and beyond

The changes that take place through 2013 include the most important prescription drug-related provisions. In 2014, it is worth noting that the larger health care changes begin, including the introduction of state health insurance exchanges to support the purchase of health insurance for individuals and small businesses, the expansion of Medicaid, and transparency in pharmacy benefit managers' operations. The 2014 changes will result in new reporting requirements, and regulations will come into effect for Medicare Part D plans and health plans participating in the state exchanges that have their own pharmacy benefits managers (PBMs) or contract with a PBM. These changes will require Medicare Advantage prescription drug plans, Part D prescription drug plans and health plans participating in exchanges to report specific dispensing patterns; information about rebates, discounts or price concessions; and the difference between the amount the health plan pays the PBM and the amount the PBM pays its suppliers.

Government will take on increasing oversight responsibility for the PBM industry, leading to additional scrutiny at both the state and federal levels. Many companies, especially smaller businesses, may be tempted to terminate benefits and instead pay the government-imposed penalty for not providing health care insurance to their employees. If more companies take this route, more people will depend on the state exchanges or Medicaid.

Health care reform will necessitate immediate action as well as constant vigilance and planning over the next five years. The scope of the changes and the increasing compliance requirements present a challenge to all entities involved in the purchase and delivery of prescription drug benefits to patients. INN

***Brian Anderson**, MBA, is a healthcare consultant in the San Diego office of Milliman. Contact Brian at 858.558.8400 or at brian.anderson@milliman.com.*

***Troy Filipek**, FSA, MAAA, is a principal and consulting actuary in the Milwaukee office of Milliman. Contact Troy at 262.784.2250 or at troy.filipek@milliman.com.*