The Health Reform Law: Key Changes to Be Implemented in 2010

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It is impossible to overstate the extraordinary range and complexity of the newly enacted health reform law. Taken together, the Patient Protection and Affordable Care Act (PPACA) and the Health Care and Education Reconciliation Act (HCERA) will, for better or for worse, result in thousands of changes to the coverage, financing, regulation, payment, and delivery of healthcare services in the United States. The practical demands of implementation, as well as the mass of rulemaking and other policymaking yet to be, will create an astonishing array of challenges and opportunities for virtually every stakeholder in American healthcare.

Although many of the provisions of the health reform will go into effect in future years—particularly 2014—some key changes are effective on various dates in 2010. The following is a brief rundown of some of the more notable changes for 2010.

Temporary Initiatives to Improve Health Coverage

PPACA provides for several initiatives to help the uninsured and underinsured between now and 2014, when federal subsidies, Medicaid expansion, and state-run health insurance exchanges begin. These are:
• Temporary national high-risk pool to provide healthcare coverage to individuals with preexisting conditions who are unable to buy coverage; this includes $5 billion in federal funding to help subsidize coverage
• Temporary reinsurance program for employers that provide coverage to retirees older than age 55 years who are not eligible for Medicare.

Consumer Protections

In the form of mandates on individual and small group health plans, several consumer protections take effect during 2010:
• Insurers must provide dependent coverage for adult children up to age 26 years
• Insurers may not impose preexisting condition exclusions for children
• Individual and group health plans are prohibited from placing lifetime limits on the dollar value of coverage
• Before 2014, health plans may only impose annual limits on coverage, based on rules to be set by the Secretary of the Department of Health and Human Services (HHS)
• Insurers are prohibited from rescinding coverage, except in cases of fraud.

Tax Credits for Small Employers

Small employers are eligible for a new federal tax credit if they have 25 or fewer employees, have average annual wages of <$50,000, and purchase health insurance for employees.

Health Insurance Rate Regulation

PPACA dramatically changes the landscape for health insurance rate setting. Key provisions include:
• Medical loss ratio (MLR) reporting: health insurers must report the proportion of premium dollars spent on clinical services (provider claims), quality, and other costs (eg, administration, marketing)
• Rebates if MLR exceeds federal minimums: the amount of premium revenues spent on clinical services and quality must be at least 85% for large group plans and 80% for plans in the individual and small group markets; starting from benefit year 2011, if a plan’s MLR falls below the required level, the insurer must rebate the difference to consumers
• New federal-state process for reviewing health plan premium increases: requirement for health plans to justify their premium increases; if a state determines that a plan’s premium increases are unjustified, the state may recommend that the plan be excluded from the exchange market.

Medicare

Changes to Medicare Part D drug benefit:
• Medicare beneficiaries who reach the Part D coverage gap (the so-called doughnut hole) in 2010 will receive a $250 rebate
• Medicare will begin the process of requiring drug manufacturers to provide 50% discounts for drug utilization in the Part D coverage gap; this is part of the new policy to phase out the Medicare Part D doughnut hole by 2020.
In addition, the annual Medicare market basket updates for inpatient hospital, skilled nursing facility, home health, and hospice providers will be reduced.

Congress also banned new physician-owned hospitals in Medicare and limited the future growth of certain existing physician-owned hospitals.

**Medicaid Drug Benefit**

In the Medicaid prescription drug rebate program, PPACA has made the following major changes:

- For most brand-name drugs, minimum rebate increases by 8%, from 15.1% to 23.1% of the average manufacturer price (AMP)
- For clotting factors and brand drugs approved exclusively for pediatric use, minimum rebate increases to 17.1% of the AMP
- Medicaid rebate for generic (noninnovator, multi-source) drugs increases from 11% to 13% of the AMP
- Imposed federal take-back of all rebates applicable to the increased percentages, even if the state was already receiving supplemental rebates; this has the effect of cutting federal Medicaid funding to states
- Extended federal Medicaid rebate to drug utilization in Medicaid health plans; previously, the federally mandated rebates only applied to fee-for-service Medicaid drug utilization.

**Medicaid Coverage Expansion Options**

Although the major nationwide expansion of Medicaid eligibility will take effect in 2014, PPACA provides states with new options to expand Medicaid eligibility through the Medicaid State Plan, without waivers:

- Extend Medicaid coverage to low-income, childless adults
- Through Medicaid’s sister program, the Children’s Health Insurance Program (CHIP), cover children of state employees if certain conditions are met
- Extend Medicaid family planning services coverage to certain low-income individuals.

PPACA also expanded the role of the Medicaid and CHIP Payment and Access Commission to advise Congress on issues affecting adults in Medicaid, including dual-eligibles.

The HHS Secretary is required to create a public comment process for section 1115 Medicare research and demonstration waivers.

**Innovation and Coordination: Medicare and Medicaid**

The health reform law creates a new Center for Medicare & Medicaid Innovation (CMI) in the Centers for Medicare & Medicaid Services (CMS). CMI, which must be established in 2010, is charged with the development and implementation of pilots and demonstrations to improve quality and cost-effectiveness in Medicare and Medicaid. The projects will likely focus on delivery system reforms and payment reforms in Medicare and Medicaid, including joint Medicare-Medicaid initiatives. CMI was given $10 billion to operate the demonstrations, and another $500 million for evaluations and administration.

Congress also created the Federal Coordinated Health Care Office within CMS, with the mission of improving federal and state coordination on issues affecting access, quality, and cost of caring for the 8 million dual-eligible beneficiaries enrolled in Medicare and Medicaid.

**Regulatory Pathway for Biosimilars**

The law authorizes a new regulatory pathway for the US Food and Drug Administration to use in approving biosimilars (or follow-on biologics). The law grants biologics innovators 12 years of exclusive use before a biosimilar version may be developed.

**Comparative Effectiveness Research**

PPACA creates a new nonprofit Patient-Centered Outcomes Research Institute to oversee federal comparative effectiveness research (CER). With a governing board appointed by the US Comptroller General, the institute will set research priorities and contract with federal agencies and research institutions to conduct, assess, translate, and disseminate research on the effectiveness and comparative effectiveness of therapies and technologies.

The institute’s funding will be coming from a mix of Medicare Trust Fund dollars, an assessment on health plans (risk and self-insured plans), and annual congressional appropriations. Once the Medicare and health plan portions of the funding begin in 2013, the institute is expected to have a roughly $500-million annual budget for CER.

These changes are a mere sampling of the many initiatives and activities required under PPACA and HCERA. In addition, HHS, other federal agencies, and states—not to mention employers, healthcare providers, health plans, and other stakeholders—will be extremely busy readying the rules, policies, procedures, staffing, contracting, and infrastructure needed to carry out the far more numerous and complex changes required for 2011 and beyond.

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Federal Drug Price Controls in Medicaid: Expansion of Mandated Rebates under Health Reform Law

Federally mandated rebates for prescription drugs in Medicaid were expanded significantly under the new health reform law, with extraordinary financial, administrative, and compliance implications for pharmaceutical manufacturers, state Medicaid programs, and Medicaid health plans.

Most notably, the Patient Protection and Affordable Care Act (PPACA), as amended by the Health Care and Education Reconciliation Act (HCERA), requires:

1. Higher minimum rebates from drug manufacturers for both brand and generic outpatient drugs dispensed to Medicaid beneficiaries
2. Extension of minimum rebates to drug utilization in Medicaid managed care organizations
3. Diversion of all savings from the higher minimum rebates to federal government, resulting in a significant cut to states.

The new requirements are expected to generate $38 billion in federal savings over the next 10 years, according to a letter dated March 20, 2010, from Douglas W. Elmendorf, Director of the Congressional Budget Office (CBO), to House Speaker, Nancy Pelosi.

This article provides a primer on the Medicaid prescription drug rebate program and the major changes effective for 2010.

Basics of Medicaid Drug Rebate

Two terms are key to understanding the workings of the Medicaid drug rebate program—average manufacturer price (AMP) and best price.

**Average manufacturer price.** The concept of AMP is a creature of federal law, created in 1991 for calculation and administration of mandated rebates on outpatient drugs. AMP is the average price wholesalers pay manufacturers for drugs that are sold to retail pharmacies. To arrive at the actual price paid by wholesalers, AMP is the calculated net of cash discounts, volume discounts, rebates, and other price concessions. Therefore, every drug by every manufacturer has a unique AMP, and AMP figures fluctuate throughout the year. On a monthly or quarterly basis, drug makers must report AMP figures to the Centers for Medicare & Medicaid Services (CMS). PPACA requires CMS to begin to disclose online the weighted average of the most recently reported monthly AMP for multiple-source drugs.

**Best price.** Best price is the lowest manufacturer price paid for a prescription drug by a purchaser or payer, including any retailer, wholesaler, or commercial health plan. Best price, however, excludes prices charged to Medicare Part D drug plans, certain federal agencies, 340B discount program participants, and state pharmaceutical assistance programs.

As with AMP, the intent is for a drug’s best price to be determined net of financial concessions by drug makers, including discounts and rebates. The best price for each drug is reported to CMS and shared with states, but is otherwise confidential.

Federal Rebate Agreements with Drug Manufacturers

To ensure Medicaid coverage of their outpatient prescription drug products, pharmaceutical manufacturers must sign a rebate agreement with CMS. If a manufacturer has a rebate agreement, its drugs are covered nationwide in Medicaid, with a few exceptions. If a drug maker declines to sign a federal rebate agreement, a state Medicaid program may exclude coverage of the nonrebated products.

Rebate agreements apply to brand and generic drugs, orals and biologics, whether dispensed by pharmacies or administered by physicians in any outpatient setting. About 550 pharmaceutical companies have federal rebate agreements. For single-source and multisource innovator (brand-name) drugs dispensed or administered on an outpatient basis, the federal minimum rebate for the drug is the greater of:

1. AMP minus percentage set in statute.
2. Difference between AMP and best price (AMP minus best price).

If a brand drug’s AMP increases faster than inflation, the minimum rebate is increased based on change in AMP compared with Consumer Price Index (CPI).

For noninnovator multisource drugs (generics), the minimum federal rebate is AMP minus percentage set in statute.

Supplemental Rebates and Preferred Drug Lists

In addition to the federal minimum rebates, state Medicaid agencies may negotiate supplemental rebate agreements with drug manufacturers. For bargaining power, states may leverage preferred drug lists (PDLs). Most states use PDLs for some therapeutic classes. Increasingly, states also join in multistate drug purchasing arrangements.

Under these rebate agreements, the drug maker agrees
to pay the state Medicaid program a rebate higher than the minimum required under the federal rebate agreement. Drug makers unwilling to offer supplemental rebates may see their drug placed on a nonpreferred list. Nonpreferred drugs require some prior authorization and, in narrow circumstances, may include a higher beneficiary copayment. Therefore, nonpreferred drugs can expect substantially lower utilization.

**Drug Price and Utilization Reporting**

Drug manufacturers report their best price and AMP figures to CMS, typically on a monthly basis. Using these manufacturer and drug-specific data, CMS calculates and provides states the minimum federal rebate percentage for that quarter for each covered drug. Before PPACA, rebate amounts were increasingly based on the difference between AMP and best price, instead of the “AMP minus X%” minimum. Federal and state officials are concerned about the accuracy and timeliness of manufacturers’ best price and AMP figures. Pricing data are subject to federal and state audits and are often the subject of litigation.

States determine Medicaid drug utilization for the quarter and report the data to drug manufacturers and CMS. States must report utilization data to manufacturers within 60 days after each quarter. States Medicaid utilization data are based on National Drug Codes (NDCs) for all outpatient drugs, including physician-administered drugs. Drug makers may dispute state utilization data.\(^{10}\)

**Changes to Medicaid Drug Rebate**

**New minimum rebates in 2010.** Effective retroactively to January 1, 2010, the health reform law significantly increased minimum rebates on Medicaid drugs:

- **Most brand drugs:** Minimum federal rebate for most single and multisource innovator drugs was increased by 8%, from 15.1% to 23.1% of AMP
- **Generic drugs:** Minimum federal rebate for noninnovator multisource drugs was increased by 2%, from 11% to 13% of AMP
- **Clotting factors and pediatric indication drugs:** Minimum federal rebate for these innovator drugs increased from 15.1% to 17.1% of AMP.

For new line extensions (eg, time-release formulations) of brand oral drugs, the law sets a new method of determining rebate. In addition, Congress capped drug rebates to no more than 100% of AMP, regardless of best price and inflation.

**Extension of rebates to Medicaid health plan utilization.** Since its inception in 1991, the Medicaid drug rebate program applied only to Medicaid fee-for-service (FFS) drug utilization. Therefore, states were unable to collect the federally mandated rebates on drugs dispensed to Medicaid beneficiaries enrolled in Medicaid plans. Although Medicaid plans were able to negotiate rebates similar to commercial plans and pharmacy benefit managers, the rebates were far from those mandated for Medicaid FFS.

PPACA extended Medicaid drug rebate to Medicaid health plan drug utilization starting March 23, 2010. State Medicaid programs will receive federal minimum rebates on all Medicaid-covered outpatient drugs dispensed or administered to Medicaid beneficiaries, excluding drugs already discounted under the federal 340B program.

States will include Medicaid health plan drug utilization in their quarterly reports to drug manufacturers and CMS. To support Medicaid-wide (FFS and managed care) drug utilization by states, Medicaid health plans must report covered drug utilization by Medicaid beneficiaries using full 11-digit NDCs to identify utilization by manufacturer, dosage form, strength, and package size. Since Medicaid rebates also apply to drugs and biologics administered by physicians in physician offices, clinics, and outpatient hospitals, Medicaid health plans must also report utilization of physician-administered drugs.

Federal law requires that state capitation rates for Medicaid health plans are actuarially sound, with the drug portion of rates based on actual cost related to rebates.

**Federal retention of savings from increased rebates.** Much to the frustration of state leaders, PPACA includes a controversial provision for the federal government to retain all the savings associated with the new, higher minimum rebate percentages. Therefore, CMS is taking the entire rebate amount between 15.1% and 23.1%—for both FFS and MCOs. CMS is taking the difference between 11% and 13% on generics. This represents a multibillion-dollar budget hit to states, as well as an added administrative complication.

The following allocation of rebate savings start in 2010:

- **Brand drugs in Medicaid FFS:** states will lose the state share of savings of all existing supplemental rebates between 15.1% and 23.1%. That is, states will lose their share of 8% in brand drug price concessions previously received via best price, state-negotiated supplemental rebates, or multistate group purchasing
- **Generic drugs in Medicaid FFS:** states lose 2% (ie, the difference between the old 11% and new 13% minimum federal rebate) on generics
- **Brand drugs dispensed in Medicaid managed care:** states and CMS will share rebate savings between 0% and 15.1%, CMS gets everything from 15.1% to 23.1%, then states and the federal government share any supplemental rebate above 23.1%

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Generic drugs through Medicaid managed care: states and CMS will share between 0% and 11%, then CMS gets everything from 11% to 13%, then states and the federal government share anything above 13%.

Where states and CMS still share minimum and supplemental rebate receipts, the split is based on the state’s federal Medicaid matching rate (federal medical assistance percentage) applicable to the fiscal year when the rebate payment is received.

Conclusions

The Medicaid drug rebate program has generated substantial federal and state budget savings. The newly expanded rebates will generate an estimated $38 billion to help finance the federal health insurance reform. The extension of federal minimum rebates to Medicaid managed care utilization will generate federal and state savings and remove the incentive for states to carve out pharmacy benefits and disrupt care management for managed care enrollees. States will be able to leverage managed care utilization to negotiate higher supplemental rebates, particularly for therapy classes used more by the younger populations who are more likely enrolled in Medicaid health plans.

However, the PPACA changes create an array of fiscal and administrative challenges. State Medicaid directors have raised a number of questions for CMS.11 States will lose a large portion of savings from supplemental rebates.

Drug makers will see lower margins and higher compliance risks. States and Medicaid health plans will need to navigate and adapt to changes likely to dramatically change rebate negotiations and utilization management practices. Changes to utilization reporting necessary to capture health plan–associated rebates will present technical and compliance challenges for both plans and states.

Long-term, the future expansion of federal price controls under the health reform law raises serious concerns. Policymakers, eager to finance the costs of coverage expansion and ongoing Medicaid costs, are legislating short-term cuts in unit prices at the long-term expense of value-based benefit designs, medication therapy management, innovation, and patient access.

Disclosure Statement

Mr. Piper is a Consultant to Fleishman-Hillard, GlaxoSmithKline, Philips Healthcare, and TogoRun.

References