Impact of Healthcare Reform on Managed Care Drug Benefits and Programs

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Introduction

- Medicaid Prescription Drug Rebates
- Average Manufacturer Price
- Impact on Medicare Part D Plan Sponsors, Members and Manufacturers
- Part D Requirements for and Initiatives Relating to Medication Therapy Management Programs
- PBM Transparency
- Biosimilar Biological Products
- Expanded 340B Drug Program

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Medicaid Prescription Drug Coverage

- **Sec. 2501 Prescription drug rebates – Summary:**
- "Transfers" from pharmaceutical manufacturers to the Medicaid program
- "Shifts" rebate dollars from managed care organizations to the Medicaid program
- Neutral impact on federal funding of Medicaid program

Medicaid Prescription Drug Coverage

- Section 2501 increases the flat rebate for most single source and innovator multiple source outpatient prescription drugs from 15.1% to 23.1%.
- The rebate for clotting factors and outpatient pediatric drugs will increase to 17.1%.
- The provision increases the basic rebate percentage for multi-source, non-innovator drugs from 11% to 13%.
- Total rebate liability would be limited to 100% of the average manufacturer price ("AMP").

Medicaid Prescription Drug Coverage

- Section 2501 requires manufacturers to pay rebates for drugs dispensed to Medicaid beneficiaries who receive care through a Medicaid managed care organization, if the MCO is responsible for coverage of such drugs, effective March 23, 2010.
- Excluded from the extension of rebates for MCO covered drugs are covered outpatient drugs that are dispensed by HMOs and subject to discounts under section 340B of the Public Health Service Act.

Medicaid Prescription Drug Coverage

- The increased rebates to the States are accompanied by a corresponding decrease in federal matching funds.
- Net effect is lower drug costs to the state Medicaid program, with an “echo effect” for the federal financial sharing with state agencies for the cost of Medicaid covered drug benefits.

Medicaid Managed Care Organizations

- The number of Medicaid beneficiaries in managed care nearly doubled in the most recent decade, growing from 17.8 million as of June 30, 1999 to 33.4 million as of June 30, 2008. Over this period, the share of Medicaid enrollees in managed care arrangements also increased substantially, from 56% to 71%.
- Between 2007 and 2008, reflecting major expansions of Medicaid managed care in several states, enrollment grew by nearly 4 million, and the percentage of Medicaid beneficiaries in managed care rose from 64% to 71%.
  - (http://www.kff.org/medicaid/upload/8046.pdf)

Managed Care Provisions

- Section 2501 implements the MCO rebate provisions by adding new conditions for Federal financial participation for contracts between the state agency and MCOs:
  - any covered outpatient drug provided by the MCO is eligible for the rebates authorized under section 1927 of the Act;
  - MCO capitation rates shall be based on actual cost experience related to rebates and subject to Federal regulations at 42 C.F.R. § 438.6 regarding actuarial soundness of capitation payments; and
  - The MCO shall report to the State information on the total number of units of each dosage form, strength and package size by National Drug Code of each covered outpatient drug dispensed to Medicaid MCO enrollees and such other data that the Secretary determines necessary for the State to access the rebates authorized by this provision.

Managed Care Provisions

- On April 22, 2010, Secretary of HHS issued a perfunctory guidance letter on section 2501 and other provisions in Subtitle F.
- The letter provides that, to facilitate the collection of rebates, States must include utilization data reported by each Medicaid MCO to the States when requesting quarterly rebates from manufacturers as well as in their quarterly utilization reports to CMS.
- MCOs will need to coordinate with States to provide segregated data to support State's collection of rebates.

Impact on Managed Care Organizations

- No real clarifying guidance in letter from Secretary on the impact of the rebate provisions beyond sharing utilization data – just a restatement of statutory requirements.
- In States that carve prescription drug benefits out of Medicaid managed care arrangements or cover them through a cost based contract, the impact should be minimal on managed care organizations and arrangements.

Impact on Managed Care Organizations

- For states that cover prescription drugs through a capitated managed care arrangement, section 2501 will almost certainly have the effect of shifting manufacturer rebates from MCOs to the States, depending on the arrangement that is currently in place between the MCO and manufacturers for Medicaid utilization.
- What impact will that have on the contract between the state and the MCO?

Impact on Managed Care Organizations

- Statute incorporates standard of 42 C.F.R. § 438.6 regarding actuarial soundness and provides that capitation rates must be based on "actual cost experience related to rebates."
- 42 C.F.R. § 438.6 defines "actuarially sound capitation rates" as rates that
  - (A) Have been developed in accordance with generally accepted actuarial principles and practices;
  - (B) Are appropriate for the populations to be covered, and the services to be furnished under the contract; and
  - (C) Have been certified by qualified actuaries following practice standards established by the Actuarial Standards Board.

Impact on Managed Care Organizations

- Reasonable to conclude that States must "adjust" capitation rates to reflect increase in "actual costs" that result for MCO in providing pharmacy benefit with decreased rebates.
- State is likely getting more than additional rebate dollars to offset higher payments to MCOs for additional Rx costs.
- But, is there any provision in the current contract – e.g., "change of law" that will enable plan to claim additional payment because of lost rebates?

Changes to Part D Include:

- Closing of coverage gap
- Medicare coverage gap discount program
- Requirements for and initiatives relating to Medication Therapy Management Programs ("MTMPs")
- Voluntary *de minimis* policy for LIS eligibles
- Increased authority of CMS to establish formulary requirements

Closing of Coverage Gap

- 2010 - $250 coverage gap rebate
- 2011
  - Medicare Coverage Gap Discount Program
    - Provides for 50% discount on brand name drugs
  - Cost-Sharing Phase-Down begins
    - Cost-sharing for generic drugs phases down to 25% by 2020
- 2012 – 2020
  - Continued closing of coverage gap (brands and generics).
  - By 2020, Part D members will be responsible for 25% of their prescription drug costs in the coverage gap.

Medicare Coverage Gap Discount Program

- Program effective January 1, 2011.
- To be codified at 42 U.S.C. § 1395w-114A.
- Requires drug manufacturer to participate in program as condition for manufacturer's drug to be eligible for coverage under Part D.
- Exception for drugs that Secretary determines drugs' availability is essential to the health of beneficiaries, or the Secretary determines that in the period of January 1, 2011 through December 31, 2011, there were "extenuating circumstances.

Medicare Coverage Gap Discount Program

- Program provides discounts at point of sale to "applicable beneficiaries":
  - individuals enrolled in a Part D plan,
  - are not enrolled in a qualified retiree prescription drug plan,
  - are not entitled to a low-income subsidy under Part D, and
  - who (i) have reached or exceeded the Part D coverage gap during the year and (ii) have not incurred costs equal to the annual out-of-pocket limit under Part D.

Medicare Coverage Gap Discount Program

- CMS Draft Guidance - April 30, 2010
  - Part D sponsors responsible for providing discounts at point-of-sale
  - Part D sponsors must calculate discount amount at time of initial claim adjudication and provide discount amount in the adjudicated response and payment to the pharmacy.
    - Part D prompt payment rules apply.
  - CMS will provide monthly prospective payments to Part D sponsors for manufacturer discounts. Prospective payments based on projections in bid.
    - Prospective payments reduced by discounts amounts invoiced to manufacturers

Medicare Coverage Gap Discount Program

- CMS Draft Guidance - April 30, 2010 (cont'd)
  - CMS will coordinate collection of discount payments from manufacturers and payments to Part D sponsors
    - Coordination will involve standard process for paying Part D sponsors based on new information submitted on prescription drug event ("PDE") data
  - Discount applied after application of supplemental coverage offered by Part D sponsor and any employer group health and waiver plan coverage
  - No discount for in-network pharmacy claims that are not filed electronically
  - Part D sponsors responsible for beneficiary inquiries and complaints

Part D Medication Therapy Management Programs

- Expands on existing MTMP provisions to include required interventions.
- Automatic enrollment with opt-out right.
- Part D sponsor must implement, at a minimum, the following to increase adherence to prescription medications:
  - An annual comprehensive medication review furnished person-to-person or using telehealth technologies by a licensed pharmacist or other qualified provider.
  - Follow-up interventions as warranted based on the findings of the annual medication review or the targeted medication enrollment. May be provided person-to-person or using telehealth technologies

Part D Medication Therapy Management Programs

- Requirements for annual comprehensive medication review:
  - a review of the individual's medications and may result in the creation of a recommended medication action plan or other actions in consultation with the individual and with input from the prescriber to the extent necessary and practicable; and
  - providing the individual with a written or printed summary of the results of the review.
- Part D sponsor shall have a process to assess, at least quarterly, the medication use of individuals who are at risk but not enrolled in the MTMP, including individuals who have experienced a transition in care, if the Part D sponsor has access to that information.

Pharmacy Benefit Managers Transparency Requirements.

- PBMs must provide certain information to the Secretary, including:
  - the percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed, by pharmacy type, that is paid by the health benefits plan or PBM;
  - the aggregate amount, and the type of rebates, discounts, or price concessions that the PBM negotiates that are attributable to patient utilization under the plan, including the concessions that are passed through to the plan sponsor; and
  - the aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.

Biologics Price Competition and Innovation Act of 2009

- Establishes a process under which the Secretary is required to create an approval pathway to license a biological product that is shown to be biosimilar to or interchangeable with a licensed biological product, commonly referred to as a reference product.
- Biosimilar applications will be reviewed by the same FDA division as the reference product. To be approved, the application must satisfy two standards:
  - Biosimilar
  - Interchangeability

Expanded Participation in 340B Program

- Pharmaceutical manufacturers participating in Medicaid must provide discounts on covered outpatient drugs purchased by the types of community providers listed in the statute.
- New provision continues a pattern of extending 340B discounts to a wider range of entities, in this case, to certain children's hospitals, cancer hospitals, critical access and sole community hospitals, and rural referral centers, but only for outpatient drugs.