Teleconference on the Medicaid Drug Rebate Program Proposed Rule

March 6, 2012

Jim Stansel
Hae-Won Min Liao
Meena Datta
Trevor Wear
Agenda

- Recent History of the Medicaid Drug Rebate Program ("MDRP")
- 2012 Medicaid Proposed Rule
  - Economic Impact
  - Review of the Rebate Calculation
  - Proposals on Calculation Fundamentals
    - Definition of “Retail Community Pharmacy,” “Wholesaler,” and “Covered Outpatient Drug”
    - Rejection of Presumed Inclusion Policy
    - Identification of “5i” Drugs
    - Definition of Bona Fide Service Fee ("BFSF”)
    - Codification of “Returned Goods” Exclusion
    - Inclusion of Sales to U.S. Territories
    - Identification of Line Extensions
    - Changes to Best Price
    - Best Price Exclusion of Nominal Sales
  - Overview of Other Changes
- Questions and Answers
Recent History of Medicaid Drug Rebate Program

- Pre-Healthcare Reform
  - Feb. 2006: Congress passes the Deficit Reduction Act of 2005
  - Dec. 2006: CMS releases proposed rule implementing the Act
  - Jul. 2007: CMS issues the Final Rule
  - Nov. 2007: NACDS and NCPA file lawsuit seeking to enjoin select provisions of the 2007 Final Rule
  - Dec. 2007: Court issues preliminary injunction prohibiting CMS from (1) implementing changes to Medicaid reimbursement for retail pharmacies or (2) publishing AMP data

- PPACA and Beyond
  - Mar. 2010: Congress simultaneously passes the Patient Protection and Affordable Care Act & Health Care and Education Reconciliation Act (collectively, “PPACA”)
Recent History of Medicaid Drug Rebate Program (cont’d)

- PPACA requires, among others, several important changes:
  - Increases minimum rebate percentages
  - Extends rebates to Medicaid Managed Care
  - Narrows AMP to sales of retail community pharmacies
  - Adopts a statutory definition of bona fide service fees
  - Revises the enumerated exclusions from AMP
  - Creates an alternative line extension rebate calculation

- Aug. 2010: Congress passes the FAA Air Transportation Modernization and Safety Improvement Act (“FAA Act”) creating the “5i” AMP concept
- Sep. 2010: CMS proposes to withdraw 2007 provisions of Final Rule
- Nov. 2010: CMS withdraws provisions of 2007 Final Rule relating to AMP calculation and FULs
- Feb. 2012: CMS releases proposed rule implementing changes to the MDRP mandated by PPACA and the FAA Act
Recent History of Medicaid Drug Rebate Program

- **Dec. 2006.** Proposed Rule Seeking to Implement DRA Released
- **July 2007.** Final Rule Issued
- **Feb. 2006.** DRA Enacted
- **Nov. 2007.** Suit to Enjoin Parts of 2007 Final Rule
- **Dec. 2007.** Parts of 2007 Final Rule Enjoined
- **Nov. 2007.** Final Rule Issued
- **Feb. 2006.** Proposed Rule Seeking to Implement DRA Released
- **Nov. 2010.** Final Rule Withdrawing AMP Provisions of 2007 Final Rule Issued
- **Aug. 2010.** FAA Act Enacted
- **March 2010.** PPACA Enacted
- **Feb. 2011.** Proposed Rule Seeking to Implement Health Care Reform Released
- **Apr. 2011.** Deadline for Comments to 2012 Proposed Rule

<table>
<thead>
<tr>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
</tr>
</thead>
</table>
Estimated Economic Impact

- CMS projects that proposed changes would save the federal and state governments a combined $17.7 billion from FY 2010 to FY 2014
- Minimum rebate percentage increase for brand drugs accounts for $3.5 billion and generic drugs accounts for $255 million
- Line extension provision is projected to save the government $1.645 billion
- Cost to manufacturers projected to be $80.9 million through FY 2014, but those include only “administrative and infrastructure” costs
- Projections grossly underestimate the private sector cost of system and procedural changes required by downstream sales tracking, territorial expansion, potential for 340B monitoring, and other issues
- Estimate does not include ancillary effects (e.g., 340B price changes, which are linked to Medicaid rebate calculation)
Determination of the Rebate Amount

- **Single Source/Innovator Multiple Source Drugs (the greater of):**

  \[ \text{AMP} \times 23.1\% + \text{CPI-U Penalty} \]
  
  or
  
  \[(\text{AMP-BP}) + \text{CPI-U Penalty}\]

- **Clotting Factor or Exclusive Pediatric Indicated Drugs:**

  \[ \text{AMP} \times 17.1\% + \text{CPI-U Penalty} \]
  
  or
  
  \[(\text{AMP-BP}) + \text{CPI-U Penalty}\]
Proposed Definition of “Retail Community Pharmacy”

- Retail Community Pharmacy
  - Includes those classes of trade set forth in the statute:
    - “[A]n independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices.”
  - Also includes certain classes of trade that “conduct business as” retail community pharmacies, including, but not limited to:
    - specialty pharmacies
    - home infusion pharmacies
    - home healthcare providers
Proposed Definition of “Retail Community Pharmacy” (cont’d)

- Retail Community Pharmacy (cont’d)
  - Additions are meant to ensure Medicaid rebates for covered outpatient drugs that otherwise would not have an AMP and could not be included in 5i AMP (e.g., oral drugs requiring REMS dispensed through specialty pharmacies)
  - Excludes those classes of trade set forth in the statute, including
    - a mail order pharmacy
    - nursing home pharmacies
    - long-term care facility pharmacies
    - hospital pharmacies
    - clinics, charitable or not-for-profit pharmacies
    - government pharmacies
    - pharmacy benefit managers
Proposed Definition of “Wholesaler”

- Proposes to adopt the statutory definition of “wholesaler”:
  - “A drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including (but not limited to) manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer’s and distributor’s warehouses, chain drug warehouses, and wholesale drug warehouses) independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.”

- CMS specifically seeks comment on further data sources or definitions that could be applied to clarify the definition of wholesaler
Proposed Definition of “Covered Outpatient Drug”

- Proposes to add a regulatory definition of “covered outpatient drug” because there have been “products identified in the drug product data file that do not meet the definition[.]”

- To be considered a covered outpatient drug, must be:
  - approved for safety and effectiveness by the FDA and have received an NDA or ANDA
  - commercially sold in the U.S. before the Drug Amendments of 1962,
  - a drug described under Section 107(c)(3) of the Drug Amendments Act
  - a prescription biologic product, or
  - insulin
Proposed Definition of “Covered Outpatient Drug” (cont’d)

- Drugs, biologics, or insulin would not be a covered outpatient drug when bundled with or incident to:
  - inpatient hospital services
  - hospice services
  - dental services
  - physician services
  - outpatient hospital services
  - nursing facility or intermediate care services for the mentally retarded;
  - other lab or x-ray services, or
  - renal dialysis

- The bundling exception would not apply if the drug is carved out and billed separately from the service.

- Drugs without an NDC or biological use for a medical indication that is not medically accepted are not covered outpatient drugs.
Proposed Rejection of AMP Presumed Inclusion Policy

- Proposes to require that AMP be based upon actual sales to RCPs or wholesalers for drugs distributed to RCPs
  - As opposed to allowing manufacturers to presume that sales should be included in AMP, unless data supports that sales should be excluded
- Acknowledges many arguments for a “top-down” approach in rejecting a presumed inclusion policy
  “We acknowledge that a reasonable approach would be one of presumed inclusion because the statute provides a more structured definition of what is to be included and excluded from AMP. However . . .”
- Sea change for those manufacturers that currently apply a top-down approach to calculating AMP
- Presents a variety of issues, particularly relating to the absence of tracking data for sales through wholesaler
Proposed Identification and Calculation of “5i” Drugs

- Statute requires an alternative AMP calculation for “5i drugs” (i.e., inhaled, infused, injected, implanted, or instilled) that are “not generally dispensed” through a retail community pharmacy.
- Proposal requires manufacturers, and not CMS, to identify 5i drugs using a list of FDA routes of administration that CMS will post on its web site.
- Proposes to define “not generally” as meaning 90 percent or more of sales are not through a retail community pharmacy.

“However, we continue to have some concerns regarding whether the 90 percent threshold is reasonable because it might result in a portion of drugs eligible for the 5i alternative AMP calculation to be omitted from AMP because the percentage of sales required to classify a drug as ‘not generally dispensed through a retail community pharmacy’ may be too high.”
Proposed Identification and Calculation of “5i” Drugs (cont’d)

- Proposal is for manufacturers to determine 5i drug status monthly and quarterly (i.e., 16 times per year)
  - How does a rejection of a presumed inclusion policy affect this determination?

- Where “5i” drugs are identified, sales and price concessions to the following entities are also included in AMP:
  - (1) Sales to physicians; (2) Sales to PBMs, including mail order purchases; (3) Sales to HMOs, including MCOs; (4) Sales, discounts, or rebates paid directly to insurers; (5) Sales to hospitals; (6) Sales to clinics and outpatient facilities; (7) Sales to mail order pharmacies; (8) Sales to LTC providers; (9) Sales to hospices; and (10) “Sales to other manufacturers who conduct business as wholesalers or retail community pharmacy.”
Proposed Definition of Bona Fide Service Fees

- Proposes a version of the familiar four-part test for BFSFs, and clarifies that such fees “include, but [are] not limited to” the type of fees listed in the statute
  - Proposal also extends exclusions for BFSFs to fees paid to GPOs
- Proposes to not define “fair market value” for purposes of the four-part test
- Proposed language appears to limit the definition of and exclusions for BFSFs to only include fees paid to “wholesalers or retail community pharmacies”
  - This limitation applies equally to AMP and Best Price
- States that price appreciation credits do not meet the definition of BFSFs
Proposed Codification of “Returned Goods” Exclusion

- Proposes to exclude from AMP, reimbursement for recalled, damaged, expired, or “otherwise unsalable returned goods”
  - Exclusion would include “(but not be limited to)” reimbursement for the cost of the goods, costs associated handling and processing the return, reverse logistics, and drug destruction

- Proposal limits the exclusion for reimbursement “only to the extent that such payment covers only those costs”
  - How does this language comport with the “but not be limited to” language?

- Declines to propose definitions for the different terms

“We are not proposing to define the terms recalled, damaged, and expired as we believe they are self-explanatory within the standard industry practice. We likewise are not defining unsalable . . .”
Proposed Inclusion of Sales to U.S. Territories

- Proposes extending the definitions of “States” and “United States” to include U.S. Territories, specifically Puerto Rico, Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa.

- Proposal would likely impact the MDRP calculations and URAs:
  - Would require the examination of an entirely new group of customers.
  - Could raise issues with intercompany transfers to the territories.
  - Potentially high implementation cost relating to system modifications, data requirements, and new policies and procedures.

- Proposal would extend the benefits of the MDRP to the territories:
  - Would increase the volume of Medicaid units on which a rebate is owed.
  - Proposes to allow a one-year delay for the territories to report Medicaid utilization.
Proposed Definition of and Rebate Calculation for Line Extensions

- Effective January 1, 2010, line extensions are subject to an alternate rebate calculation that equals the greater of:
  - The amount calculated under the traditional Medicaid rebate calculation, OR
  - The Alternative URA. This equals the product of –
    - The AMP of “the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form”
    - the highest inflation penalty rebate (calculated as a percentage of AMP) computed under the Medicaid rebate statute “for any strength of the original single source or innovator multiple source drug,” and
    - the total number of units of each dosage form and strength of the line extension

- PPACA defined “line extension” as follows:
  “[w]ith respect to a drug, a new formulation of the drug, such as an extended release formulation”

- Legislative history suggests that Congress was focused on products that reflect only “slight alterations” of existing products
Proposed Identification of Line Extensions

- CMS previously clarified that:
  - Both the initial drug and the possible line extension product must be oral solid dosage forms in order for the alternative rebate calculation to apply

- Under the Proposed Rule, CMS sets forth a test to identify “line extension” products
  - Test is based on the FDA-designated “Chemical Type” of the initial brand drug and the possible line extension product
  - CMS states that the test is intended to capture several categories of products other than those expressly designated as new formulations and treat them as line extensions

- Clarifications:
  - New strengths are not line extensions (CMS cites tracking difficulties)
  - Manufacturers are “not responsible” for calculating the Alternative URA if the initial brand drug (i.e., Chemical Type 1) has been terminated
  - The initial brand drug manufacturer and the line extension manufacturer can be two different entities; potential antitrust concerns raised by this proposal
Proposed Identification of Line Extensions (cont’d)

- Five-part Test:
  - (1) line extension must be single source drug or innovator multiple source drug
  - (2) line extension drug must be an oral solid dosage form;
  - (3) line extension is identified based on Drugs@FDA’s application file having a chemical type of 2 (new ester, new salt or other noncovalent derivative), 3 (new formulation), 4 (new combination) or 6 (new indication)
  - (4) line extension is tracked back to a chemical type 1 oral solid dosage form drug (new molecular entity), and
  - (5) manually match FDA active ingredient information to the relevant NDCs for the line extension and initial brand drug

- Products that are not line extensions are: Chemical Type 5 (new manufacturer or a product that duplicates another manufacturer’s already marketed product); Chemical Type 7 (drug already marketed, but without an approved NDA); and Chemical Type 8 (OTC switch)

- CMS proposed to identify line extensions using the five-part test for the first three quarters after the rule is finalized; thereafter, burden is on manufacturers to identify line extension products

- Sample line extension rebate calculation set forth in proposal
Proposed Changes to Best Price

- CMS suggests these changes are not significant, but they could be
- CMS proposes to remove the enumerated list of included prices, leaving only a list of prices excluded from Best Price
- Existing exclusions that CMS proposes to enumerate in the regulations are:
  - Manufacturer vouchers
  - Manufacturer-sponsored patient refund/rebate programs, and
  - Sales outside of the United States (but note potential implications if proposed definition of United States is finalized)
Proposed Best Price Exclusion of Nominal Sales

- CMS proposes two additional categories of entities to which sales may be excluded from Best Price as nominal sales.
- Category 1 criteria requires that an entity:
  - is a 501(c)(3) organization and is tax exempt, or entity is state-owned or operated, and
  - provides the same type of services to the same type of populations as a 340B covered entity, but does not receive funding as such under section 340B.
- Category 2 criteria requires that an entity:
  - is a public or nonprofit entity or an entity based at an institution of higher learning, whose primary purpose is to provide its own students healthcare services, and
  - the entity must provide a service under section 1001(a) of the PHS Act, relating to family planning services.
Proposed Best Price Exclusion of 340B Prices

- Significantly, CMS proposes to limit 340B price exclusions to those cases only where the covered entity meets the conditions set by the PHS Act.

- CMS cites circumstances in which covered entities purchase drugs outside of the 340B program, such as instances when drugs are purchased for inpatient use, drugs that have both inpatient and outpatient uses, and when a covered entity purchases drugs outside the 340B program to dispense to its Medicaid patients.

- This proposal could impose significant and burdensome verification requirements on manufacturers.
Proposed Restating of Reported Prices

- CMS proposes significant limitations on restatements outside the 12-quarter rule
- Under the proposal, restatements outside the 12-quarters will be permitted only if the change is:
  - a result of a drug category or market date change
  - an initial submission for the product
  - due to a manufacturer’s termination from the MDRP because of failure to submit timely pricing data and thus must submit pricing data to reenter the program
  - due to a technical correction (e.g., keying error) not based on any changes in sales transactions or pricing adjustments, or
  - to address specific underpayments to states or possible liability regarding underpayments
- CMS is also considering a “good cause” option
Proposed Pharmacy Reimbursement Rates

- Proposes to replace the definition of “estimated acquisition cost” with the term “actual acquisition cost” ("AAC")
  - AAC is the state Medicaid agency’s determination of the actual prices paid by pharmacy providers to acquire drug products marketed or sold by specific manufacturers
  - Goal is to let states develop payment methodologies that will be “more reflective of actual prices paid, as opposed to estimates based on unreliable published compendia pricing”

- Proposes to calculate Federal Upper Limits ("FULs") at 175 percent of the weighted average of monthly AMPs to pharmaceutically and therapeutically equivalent multiple source drugs (innovator and non-innovator)
  - Applies FULs only in cases where the FDA has rated at least three drug products as pharmaceutically and therapeutically equivalent
  - Raises the issue of FUL smoothing, but no specific proposal on methodology
Overview of Other Proposed Changes

- **Recalculation of Base Date AMP:** Proposes to give manufacturers the option to recalculate and report a revised base date AMP (reflecting the revised definition) for four full calendar quarters, following publication of the final rule.

- **Penalties: Limitations on Re-reporting:** Proposes penalties for failure to timely report quarterly AMP of up to $10,000 per day per drug; also considering suspension or termination of a manufacturer for (1) failure to report quarterly AMP on a timely basis or (2) being otherwise out of compliance with rebate requirements. CMS specifically seeks comment on this proposal.
Select Questions and Responses
Is the “conducts itself as” rule limited to REMS products?
How does CMS’ proposal to expand the classes of trade included in the determination of AMP to include sales to entities that “conduct business as” retail community pharmacies impact the Agency’s proposal for the identification of 5i drugs?
Is the Best Price exclusion for bona fide service fees limited to those entities that qualify as RCPs and wholesalers?
My returned goods policy does not require that the product is unsalable. Will that affect my treatment of such returns for purposes of calculating AMP? Best Price?
Does the Proposed Rule’s treatment of authorized generics, including the adoption of the statutory definition of wholesaler, substantially change a manufacturer’s treatment of authorized generics?
Can I revise my AMP methodology past the 12-quarter cut-off under the new proposed rule?
Does the proposed rule affect how my company calculates Best Price? I thought the proposed rule was focused on changes to AMP only.
Does the Proposed Rule affect how mail order sales are treated in AMP?
How would manufacturers know if an entity is a 340B covered entity?
My company doesn’t have any reformulated products. Do we need to worry about CMS’ line extension provision?
The Proposed Rule uses the phrase “not passed on” in several instances to describe transactions that can be excluded from AMP. How should a manufacturer interpret this requirement?
Does the Proposed Rule contain drafting errors?
Does the Proposed Rule have implications for my company’s managed care contracting strategy?
How does the methodology for smoothing in the Proposed Rule compare with the methodology in the ASP regulations?
How do you handle transfer payments that include lagging royalty payments?
**Pricing used for 340B in 3Q**

**AG transfer sale**

**4Q AMP / BP deadline**

**340B price available**

**AMP**

**Best Price w/o AG**

**AG Net Price**

**AG Transfer Price**
When will the proposed rule be finalized?
Questions?

Jim Stansel  
Washington, DC  
(202) 736-8092  
jstansel@sidley.com

Meena Datta  
Chicago  
(312) 853-7169  
mdatta@sidley.com

Hae-Won Min Liao  
San Francisco  
(415) 772-1227  
hminliao@sidley.com

Trevor Wear  
Chicago  
(312) 853-7101  
twear@sidley.com