ARNOLD & PORTER LLP

Pricing Issues and Compliance Post-Healthcare Reform

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Agenda

- Medicaid Rebates - - What now?
- Changes in the 340B Program
- Part D Coverage Gap Discounts
- Pharmaceutical Manufacturer Fee

Medicaid Recap

- Major changes to the statutory definition of AMP, including for Five I drugs
- Major changes to the Medicaid rebate calculation, e.g., for
  - Line extensions / new formulations
  - Drugs approved exclusively for pediatric indications
- Many open interpretive issues - - compounded by CMS proposing to pull down the AMP rule, rather than issuing substantive guidance

What Should We Do?

- Medicaid Rebate certification statement provides the answer
  - I hereby certify, to the best of my knowledge, the data being sent to CMS with this submission is complete and accurate at the time of this submission, and was prepared in accordance with the manufacturer's good faith, reasonable efforts based on existing guidance from CMS and the manufacturer's reasonable assumptions [interpreting the Medicaid rebate statute, applicable regulations, and guidance] . . . .

What Should We Do?

- Manufacturers should make "Good faith, reasonable efforts" to
  - Interpret the new requirements
  - Develop and document their approach, including "reasonable assumptions"

- Reasonable Assumptions
  - "In the absence of specific guidance, a manufacturer may make reasonable assumptions in its calculations, consistent with the general requirements and the intent of the Act, Federal regulations, and its customary business practices." 72 Fed. Reg. 39142, 39164 (Jul. 17, 2007).

340B Program Background

- Administered by the Health Resources and Services Administration (HRSA)
- Manufacturer agrees to charge 340B covered entities no more than the 340B ceiling Price for covered drugs used for outpatient purposes, or the States lose Federal Medicaid matching funds for the manufacturer's products
- 340B ceiling price is calculated using Medicaid Rebate data - - AMP and Medicaid Unit Rebate Amount

340B Before Healthcare Reform

- No regulations, and limited subregulatory guidance
- No civil money penalty authority for HRSA
- No requirement to report 340B ceiling prices to the gov't
- No requirement on manufacturers to issue refunds to covered entities, though many voluntarily chose to do so
  - e.g., where systematic errors in AMP or URA calculations were discovered
- Limited categories of entities eligible for ceiling price

340B After Healthcare Reform

- Many changes, including . . .
- Categories of covered entities are expanding
- HRSA
  - Has authority (and is required) to issue regulations and more guidance
  - Has CMP authority
- Manufacturers will report 340B pricing data to the government
- Manufacturers will be required to issue refunds

- What does this mean from a compliance perspective?

340B Expansion

- PPACA expands 340B eligibility to
  - Certain children's hospitals and free standing cancer hospitals excluded from the Medicare prospective payment system;
  - Critical access hospitals;
  - Rural referral centers; and
  - Sole community hospitals.
- Interpretive issue created because certain children's hospitals already were eligible to participate in 340B.

340B Expansion - - Not Retroactive

- PPACA provides that the 340B expansions "shall take effect on January 1, 2010, and shall apply to drugs purchased on or after January 1, 2010."
- HRSA FAQ 2036 provides: "Are the newly enrolled entities entitled to retroactive rebates back to January 1, 2010? No. . . . A newly enrolled covered entity's benefit starts the day the covered entity is listed on the database as eligible."

340B Expansion Cont'd

- The Reconciliation Act
  - Orphan drugs not required to be sold at or below the 340B ceiling price to the new categories of covered entities.
  - Deletes a PPACA provision that would have expanded the 340B program to the hospital inpatient setting
  - Deletes a PPACA provision that would have created exceptions to the statutory prohibition against purchasing 340B drugs through GPOs.

340B Program Integrity Provisions

- PPACA includes 340B "program integrity" provisions that will create extensive new requirements for manufacturers.
- Manufacturers will report 340B ceiling prices to HRSA on a quarterly basis.
- HRSA will:
  - Publish guidance and/or regulations on the "standards and methodology" for calculating 340B ceiling prices; and
  - Establish a process to inquire into any discrepancies between ceiling prices and manufacturer pricing data and take, or require manufacturers to take, corrective action, including issuing refunds to covered entities.

340B Refunds

- HRSA will develop mechanisms under which:
  - Manufacturers will "issue refunds to covered entities in the event there is an overcharge by the manufacturers"
    - "both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered drugs."
  - "[R]ebates . . . by manufacturers to other purchasers subsequent to the sale of covered drugs to covered entities are reported to the Secretary"; and
  - "[A]ppropriate credits and refunds are issued to covered entities if such rebates, discounts, or other price concessions have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved."

340B CMPs

- Current Law
  - No CMPs specific to 340B pricing (but Medicaid rebate CMPs could apply).
- PPACA
  - Requires that HRSA issue CMP regulations
  - CMPs would not exceed $5,000 for each "knowing and intentional" instance "of overcharging a covered entity that may have occurred."
  - HRSA published an ANPRM soliciting comments on 340B CMPs; comments are due by November 19, 2010.

340B CMPs

- "HRSA believes that 'instance' [for purposes of calculating per "instance" CMPs] . . . could potentially be defined either as a per unit of drug and/or per commercial transaction. If an entity purchases 100 units of a particular drug in a single transaction, should this constitute 100 instances or a single instance?"
  - HRSA ANPRN, 75 Fed. Reg. 57230
- E.G. $5,000 * 100 * 14,000 covered entities = **$7 BILLION DOLLARS!!**

More Health Reform Changes to 340B

- Each agreement between HHS and a manufacturer "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price <u>if such drug is made available to any other purchaser at any price.</u>"

- HRSA to issue dispute resolution regulations

Medicare Part D

- Private sector model, with benefits delivered by private insurers (Part D plans) that contract with the government
- Pre-health reform
  - Many Part D enrollees had 100% cost-sharing during the "coverage gap" (aka "doughnut hole")
- Post health reform
  - Beginning 2011, drug manufacturers that sign a coverage gap agreement will owe discounts on applicable drugs dispensed to applicable individuals in the coverage gap, significantly reducing beneficiary cost sharing.
  - Failure to sign generally will result in Part D denying coverage for the manufacturer's drugs.
  - Coverage gap will be gradually phased out

Part D Background - - Negotiated Price

- Drug payments by Part D beneficiaries generally depend on a drug's "negotiated price" and the portion of the negotiated price paid by a beneficiary
  - E.G. in the doughnut hole, often beneficiaries pay 100% of the negotiated price for brand name drugs
- Part D plans must charge patients no more than the "negotiated price" for on-formulary drugs (even if the beneficiary is in the "doughnut hole")
- Negotiated price is a point-of-sale price (including dispensing fee) and must "take into account" discounts, rebates, other price concessions obtained by plan

Part D Background - - Structure of Standard Part D Benefit

- "Standard" Part D benefit has following cost-sharing parameters for 2010:
  - Initial benefit: Beneficiary pays (on average) 25% for drug spending between $310 and $2,830 "initial coverage limit"
  - Donut hole: After initial coverage limit, beneficiary pays 100% until obtains catastrophic coverage (this requires $4,550/yr in "true-out-of-pocket" - - TrOOP - - spending)
  - Catastrophic coverage: Beneficiary pays (on average) $2.50 for generic/preferred multiple source drugs, $6.30 for other drugs
- Part D plans can offer "alternative" coverage (either basic or enhanced) that varies these parameters in certain ways

Coverage Gap Discount Program

- Manufacturers must enter agreements with HHS and with a "Third Party Administrator"
  - Beginning January 1, 2011, manufacturers will pay 50% of the negotiated price (less dispensing fees) for brand name drugs dispensed to beneficiaries in the coverage gap who do not receive low income subsidies
  - The TPA will send manufacturers quarterly discount invoices and supporting data
  - Manufacturer will generally pay each Part D plan sponsor the invoiced amount in full within 38 days of receiving invoice
  - Manufacturer has the right to dispute invoice (after payment) and audit TPA data
  - Manufacturers subject to audit, CMPs, and termination

Key Compliance Issues

- Build computer systems, staffing, policies, and SOPs to allow prompt payment, analysis of data provided by TPA, and disputes
- Be careful with coverage gap program data
  - "[T]he Manufacturer agrees 1) to ensure the integrity, security, and confidentiality of the data by complying with the terms of this Agreement and applicable law . . . ; and 2) to use the prescription or claim-level data only for purposes of evaluating the accuracy of claimed discounts and resolving disputes concerning the Manufacturer's payment obligations under the Discount Program as described in the applicable statutes, regulations, and this Agreement."
  - Agreement includes additional, detailed, limitations regarding data use and disclosure
- Watch the CMS web site for further guidance

Drug Manufacturer Fee

- Beginning in 2011, PPACA, as amended by the Reconciliation Act, will impose annual fees on domestic and foreign drug manufacturers and importers with gross receipts above $5 million from branded prescription drug sales.
- Branded prescription drugs
  - Drugs "for which a new drug application was submitted to FDA" and any biologic licensed under section 351(a) of the Public Health Service Act (PHSA), which includes reference biologics but excludes follow-on biologics.
  - Fees will not be assessed on sales of certain orphan drugs

Drug Manufacturer Fee

- The aggregate annual fee - - across the industry - - will equal $2.5 billion in 2011, increase to $4.1 billion by 2018, and decrease to $2.8 billion for 2019 and beyond.
- The Department of Treasury will split the aggregate fee among manufacturers each year based on their relative share of “branded prescription drug sales” in the preceding calendar year.
  - Sales made to or “pursuant to coverage under” Medicare Parts D and B, Medicaid, VA procurements, DoD procurements, and TRRx will count
  - Sales generally will be net of rebates that the manufacturers paid to these programs.
  - Sales will be reported by CMS, VA, and DoD to Treasury

Drug Manufacturer Fee

- Guidance is forthcoming, but has not yet been issued
  - CMS "shall establish a process for determining the units and the allocated price for purposes of this section for those branded prescription drugs that are not separately payable or for which National Drug Codes are not reported."
  - "Treasury shall publish guidance necessary to carry out the purposes of this section."

Questions?

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