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Pharmaceutical Compliance Congress: Pricing Update

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Agenda

- Medicaid Drug Rebate Program
  - OIG Work Plan
  - Draft FULs
  - AMP vs. ASP Comparisons
    - NADAC Survey
- 340B Program
  - GAO Report
- Super-Committee – Potential Impact on Rebates?
- Qui Tam Developments Relating to Pricing

Medicaid Drug Rebate Program

- PPACA changes effective October 1, 2010
  - Change to basic rebate (greater of 23.1% of AMP, or AMP – BP)
  - Changes to AMP definition
  - New Formulations
  - Special rules for "Five I" drugs "not generally dispensed" to retail community pharmacies
- DRA rule withdrawn, but no AMP rule yet!
- But a number of developments of interest
  - OIG Audit Work Plan
  - Retail Pharmacy Survey
  - Draft FULs
  - Qui Tams

Medicaid Drug Rebate Program (Cont'd)

- 2012 OIG Work Plan
  - Will conduct audits of AMP calculations, changes to base date AMP, etc.
  - New concepts in work plan that could bear on health care reform implementation:
    (a) Update of manufacturer compliance with AMP reporting requirements
    (b) Collection of rebates for drugs paid by managed Medicaid Organizations
    (c) Rebates for "new formulations"
    (d) Compare FULs under PPACA methodology to an estimate of pharmacy acquisition costs for selected drugs

Medicaid Drug Rebate Program (Cont'd)

- AMP Reporting
  - DRA required AMP reports on monthly basis starting January 2007
  - Prior OIG reports show that more than ½ of manufacturers untimely or incomplete in filings
  - OIG plans to audit this year to determine percentage of companies that are out of compliance
  - Medicaid rebate statute penalties and FCA penalties may be available for failure to report.

Medicaid Drug Rebate Program (Cont'd)

- Managed Medicaid
  - Historically, manufacturers paid Medicaid rebates solely on FFS Medicaid utilization
  - PPACA extended rebate obligations to managed Medicaid utilization
  - Challenge is that manufacturers do not have access to utilization data, and states may not receive it either
  - OIG review will determine (a) whether states have procedures to determine accuracy of data; (b) whether states are invoicing manufacturers; (c) whether states are collecting rebates; and (d) whether states are able to track utilization

Medicaid Drug Rebate Program (Cont'd)

- New Formulations
  - PPACA amends the Medicaid rebate statute's paragraph on the additional rebate to add the following:

    In the case of a drug that is a line extension of . . . [an innovator drug] that is an oral solid dosage form, the rebate obligation with respect to such drug under this section shall be the amount computed under this section for such new drug or, if greater, the product of:
    - The . . . [AMP] of the line extension of . . . [an innovator drug] that is an oral solid dosage form;
    - The highest additional rebate (calculated as a percentage of . . . [AMP]) under this section for any strength of the original . . . [innovator] drug; and
    - The total number of units of each dosage form and strength of the line extension product paid for under the State [Medicaid] plan in the rebate period . . .

Medicaid Drug Rebate Program (Cont'd)

- "Line Extension" is defined as "a new formulation of the drug, such as an extended release formulation."
- CMS' April 22, 2010 SMDL:
  - Changes for rebates on new formulations are "effective January 1, 2010"
  - Guidance on "the process that will be used to identify . . . line extensions of existing drugs" is forthcoming

Medicaid Drug Rebate Program (Cont'd)

CMS May 24, 2010 email to State Medicaid agencies:

- "The rebate calculation for S/I line extension (i.e., reformulated) drugs in oral solid dosage forms will be calculated as the greater of:
  1. The current unit rebate calculation for S/I drugs as described in Section 1927(c), or
  2. The product of:
     - The highest additional rebate (calculated as described in Section 1927(c)(2)(A) and then converted into a percentage of AMP) for any strength of the original innovator (i.e., S/I Drug Category) drug in an oral solid dosage form and the AMP of each line extension."

Medicaid Drug Rebate Program (Cont'd)

- Manufacturers responsible for calculating URAs according to CMS May 24, 2010 email
- "Labelers that fail to report and pay the increased rebates beginning with first quarter 2010 rebate invoices are responsible for interest in accordance with previous program guidance on any amount of rebate underpayment."

Medicaid Drug Rebate Program (Cont'd)

- No current regulations or guidance on what constitutes a "line extension" or "new formulation."
- Nevertheless, OIG plans to review "drug manufacturers' compliance with Medicaid drug rebate requirements for drugs that are new formulations of existing drugs" and "determine whether manufacturers have correctly identified all of their drugs that are subject to the new provision in law."

Medicaid Drug Rebate Program (Cont'd)

- FULs
  - PPACA established a new "federal upper limit" for multiple source drugs of no less than 175% of weighted average monthly AMP
  - Multiple source drug = I or N drug in a group with at least two other A rated therapeutic alternatives for which AMPs were calculated
  - CMS published 2 sets of draft FULs (based on July and August monthly AMPs) for comments
  - OIG plans to compare FULs to an "estimate of pharmacy acquisition costs"

OIG Work Plan (Other)

- Other noteworthy items
  - OIG studying whether increases in Part D prices (net of rebates) exceed the rate of inflation (this may relate to super-committee)
  - OIG reviewing CMS payments for off-label and off-compendia use of prescription drugs under Medicare and Medicaid
    - OIG reviewing off-label use of Part B cancer drugs and whether on-label alternative tried first
  - OIG comparing ASP to AMPs (which are now calculated pursuant to PPACA requirements)

ASP vs. AMP Comparisons and Potential Effect On Medicare Part B Drug Payments

- For drugs with Average Sales Price (ASP) ≥ 105% of AMP, CMS may substitute 103% of AMP for 106% of AMP as the Part B payment rate. SSA § 1847A(d)
- CMS has never done this to date, but announced a new policy in the Medicare Physician Fee Schedule Rule for 2012, released November 1, 2011.
- CMS will (as of 2012) replace the 106% of ASP payment rate with 103% of AMP, in cases where three conditions met:
  - ASP was > 105% of AMP for two consecutive quarters or for three of last four quarters (as determined by HHS OIG);

ASP vs. AMP Comparisons and Potential Effect On Medicare Part B Drug Payments (Cont'd)

- ASP vs. AMP comparisons (which are done at HCPCS code level) are based on ASPs and AMPs that reflect same set of NDCs; and
  - → Comparisons based on initially-filed AMPs, not restated AMPs
- 106% of ASP must be > 103% of AMP for the quarter when the substitution would occur (so new policy does not inadvertently increase payment rate)

- If substitution made, it has a <u>one-quarter</u> duration

National Average Drug Acquisition Cost Survey

- August 4, 2011 – CMS held public forum soliciting comments on establishment of an average acquisition cost metric for states to use for Medicaid reimbursement
- Survey conducted monthly by Myers & Stauffer, to include 2000-2500 pharmacies
- Comments submitted as to methodology: (a) include specialty pharmacies in the survey; (b) account for rebates and other off-invoice price concessions; (c) is sample adequate?

GAO Report 340B

- GAO recently issued a new report concerning 340B program
- Report mandated by PPACA
  - PPACA expanded number of covered entities potentially eligible under 340B for discounted pricing
  - PPACA also established enhanced integrity provisions to combat over-charging and drug diversion

GAO Report 340B (cont'd)

- Key findings:
  - Inadequate oversight due to agency reliance on self-policing by covered entities and manufacturers (e.g., reliance on self-policing to ensure covered entity compliance with "patient" definition and ongoing satisfaction of eligibility criteria)
  - Hospitals pose risks: (a) due in part to PPACA, "the number of hospitals participating in the program was nearly three times what it was in 2005, and the number of these organizations, including their affiliated sites, was close to four times what it was in 2005"; (b) in 2005, hospitals were 10% of participants; in 2011, they were 27% of participants; (c) nearly 1/3 of the nation's hospitals participate in 340B; and (d) as Medicaid expands, the number of hospitals eligible as Disproportionate Share Hospitals will likely increase

GAO Report 340B (Cont'd)

- Why is this important?
  - 340B entities are entitled to deeply discounted prices
  - The criteria for eligibility must be satisfied – guidance on eligibility standards not always clear
  - Risk that 340B drugs will be diverted to non-340B patients are far greater in the hospital setting than in other 340B entities
  - In GAO's words: "increasing use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA's reliance on self-policing to oversee the program."

Future Issues

- Many proposals submitted to Deficit Reduction Committee, e.g.:
  - LIS Rebate (Part D)
  - Medicaid rebates on Part B utilization
  - Direct negotiation of pricing in both Part D and Part B
- If no agreement on cuts of at least $1.2 trillion, then sequestration requires 2% reduction of Medicare expenditures

Pricing-Related Qui Tam Developments

- Streck (EDPA): contends that several manufacturers under-reported AMP by treating inventory appreciation adjustments in distribution contracts as discounts
- LaCorte (Boston): alleges that Wyeth failed to account for an arrangement with hospitals in which discounts were contingent on market share and formulary positioning as a bundled sale (pre-DRA)
- Banigan (Boston): alleges failure to account for market share and other performance-based discounts to LTC pharmacies in AMP and BP resulted, thus understating Medicaid rebates (pre-DRA)

Questions?