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PRICE REPORTING COMPLIANCE: BEST PRACTICES IN REPORTING MEDICAID DRUG REBATE PROGRAM AND PART B ASP DATA

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Medicaid Drug Rebate Program Compliance

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A. MMA Changes

1. Removes from State Medicaid programs drug coverage obligations for certain dual eligibles.
   a. Therefore, also removes Medicaid drug rebate obligations for this population.
2. Expands scope of exceptions to best price.
   a. Covered drug discount cards.
   b. Part D prescription drug plans.
   c. MA-PD plans.
   d. Inpatient drugs to 340B hospitals.

Medicaid Drug Rebate Program Compliance (cont.)

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B. Continued Congressional interest

1. Nominal Pricing

a. CMS interprets nominal price exception to apply to prices that are less than 10 percent of AMP.

b. Congress is concerned about commercial uses of exception as a "pull-through".

c. Compliance tip – determine whether there are "strings attached" to use of nominal pricing.

2. 340B

a. Congressional concern sparked by OIG findings, such as overpayment in a single month in 2002 of $41 million.

b. Question of HRSA enforcement authority.

Medicaid Drug Rebate Program Compliance (cont.)

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C. OIG Initiatives

1. Work Plan

a. Computation of AMP versus AWP.

1) Includes a determination as to whether manufacturers are circumventing rebate obligations.

b. Computation of AMP and best price.

1) Includes a question regarding consistency in interpreting retail class of trade.

c. Oversight of manufacturer recalculations of rebates.

d. Incorrect classification as a generic.

Medicaid Drug Rebate Program Compliance (cont.)

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C. OIG Initiatives (cont.)

2. Settlements

a) Schering (July, 2004)

1) Alleged to have purchased utilization data it did not need so that it could refund payments to Cigna and Pacificare.

2) In exchange, alleged to have obtained inclusion of Claritin in formularies.

3) Also charged with provision of health management services at below fmv, interest free loans in the form of "prebates", and other discounted services.

4) Value of items not included in best price calculations.

Medicaid Drug Rebate Program Compliance (cont.)

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C. OIG Initiatives (cont.)

2. Settlements (cont.)

b. AstraZeneca (June, 2003)

1) Allegations of under-reporting rebates.

2) Supposed provision of "grants", services, and free goods in exchange for purchases of Zoladex.

3) Value not included in best price calculations.

c. Bayer and GlaxoSmithKline (April, 2003)

1) Allegations of "private labeling" – affixing customer's label and NDC to drug to avoid best price obligations.

Medicaid Drug Rebate Program Compliance (cont.)

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C. OIG Initiatives (cont.)

2. Settlements (cont.)

d. Pfizer (October, 2002)

1) Related to Warner-Lambert and Parke-Davis subsidiaries.

2) Supposed provision of educational grants to an HMO to remain on formulary.

3) Value not included in best price calculations.

e. In each case, manufacturer entered into a CIA that required review of pricing by IRO.

Medicaid Drug Rebate Program Compliance (cont.)

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C. OIG Initiatives (cont.)

3. Compliance lessons

a. Safe harbors don't protect against allegations of best price violations.

b. Scrutinize all items of value to determine if there is any implicit "quid pro quo" involving purchase of drugs.

c. Services offered and services purchased should be at fair market value and serve legitimate business purposes unrelated to the sale of product.

Medicaid Drug Rebate Program Compliance (cont.)

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C. OIG Initiatives (cont.)

3. Compliance lessons

d. Try to comply with OIG Compliance Program Guidance.

1) For instance, separate grant-making functions from sales and marketing functions, and use objective criteria unrelated to purchases.

2) Further, separate research from sales and marketing. Make sure that there is a bona fide need for the research.

Average Sales Price Compliance

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A. In General

1. New payment methodology that applies to drugs covered under Part B
   a. Must meet certain criteria to be covered, including:
      1) Comport with definition of "drug or biological";
      2) Must not be usually self-administered; and
      3) Must be furnished incident to a physician's service.
   b. Exceptions to ASP include:
      1) certain vaccines;
      2) certain infusion therapies; and
      3) blood and blood products.
2. Goes into effect for CY 2005

Average Sales Price Compliance (cont.)

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B. ASP Calculation

1. Measured with respect to each individual NDC code.
2. Divide total amount in sales for a quarter by the total number of units for that quarter.
3. Deduct from sales:
   a. Discounts, including prompt pay, volume, etc.;
   b. Free goods in exchange for purchases; and
   c. Chargebacks and rebates.

Average Sales Price Compliance (cont.)

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B. ASP Calculation (cont.)

4. Must use estimates when there are timing of recognition issues.
   a. Sum all price concessions per NDC over most recent 12-month period and divide by total sales for same period.
   b. Multiply this percentage by the total sales in quarter.
   c. Subtract this amount from total sales for quarter, which is then divided by number of units sold in quarter.

Average Sales Price Compliance (cont.)

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B. ASP Calculation (cont.)

5. Example. The total price concessions over the most recent 12-month period available for a given NDC equal $200,000. The total in dollars for the same period equals $600,000. The price concessions percentage for this period equals .33333 (i.e., 200,000/600,000). The total in dollars for the sales subject to the average sales price reporting requirement for the quarter being reported equals $50,000 for 10,000 units sold. The ASP price calculation for this NDC for this quarter is: $50,000 - (0.33333 x $50,000) = $33,334 (net total sales amount); ASP = $3.33 ($33,334/10,000).

6. Exempt from inclusion are all sales that are exempt from best price calculations.

Average Sales Price Compliance (cont.)

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C. Reporting
   1. Must be submitted within 30 days of the close of every calendar quarter.
   2. Must be certified by either the:
      a. CIO;
      b. CFO; or
      c. Someone delegated by one of the above and reports directly to one of the above.

D. Penalties
   1. CMP of $10,000 per misrepresentation per day.
   2. CMP of $10,000 per day for late filing and "suspension" after 90 days.

Average Sales Price Compliance (cont.)

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E. Calculation of reimbursement amount

1. Sole source drugs
   a. 106% of the ASP; or
   b. If lower, wholesale acquisition cost (WAC).
      1) List price for drugs reported in wholesale price guides.
2. Multi-source drugs
   a. 106% of ASP of weighted average of all drugs described by same HCPCS code.

Average Sales Price Compliance (cont.)

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E. Calculation of reimbursement amount

3. Can be reduced if the widely available market price (WAMP) or AMP is lower by at least a threshold amount.
    a. WAMP is the price a prudent physician or supplier would pay.
    b. Threshold is 5% in 2005.
    c. Determined by OIG.
    d. Can substitute WAMP or 103% of AMP if meets criteria.

Average Sales Price Compliance (cont.)

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F. Financial modeling issues
   1. Increase prices gradually.
   2. Minimize range of price differentials.
   3. Avoid getting WAMPed.

G. Compliance issues
   1. OIG Workplan
      a. Identifies that it will be monitoring ASP data, which is a statutory requirement.
   2. Consider enforcement actions involving Medicaid drug rebates and incorporate into compliance with respect to ASP.

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