

Medicare Drug Price Reporting and Reimbursement

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February 27, 2004

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National Medicare Prescription Drug Congress



Agenda

- Part B Reimbursement Changes
- Average Sales Price
- Compliance Challenges
- ASP Complexities
- Questions

Part B Reimbursement Changes



Part B Reimbursement Changes

- Some of the most immediate changes to the Medicare Program are in Title III
- Significant Changes as of January 1, 2004
 - Reimbursement for currently covered outpatient drugs and biologicals
 - Reimbursement for infusion drugs furnished through durable medical equipment

Pre-2004 Part B Coverage

- Drugs Covered
 - Drugs and certain vaccines administered incident to a physician service and not usually self-administered
 - Necessary for effective use of covered durable medical equipment
 - Certain self-administered oral anti-cancer and anti-nausea drugs, certain immunosuppressive drugs, self-administered erythropoietin, and hemophilia clotting factors
- Pre-2004 Reimbursement
 - Generally 95% of Average Wholesale Price (AWP)

Payment Reform for Part B

- Two-year transition to new methodology
 - 2004
 - Generally 85% of AWP as of 4/1/03, subject to certain adjustments and exceptions
 - 2005
 - Single source drugs or biologicals reimbursement at 106% of lower of average sales price (ASP) or wholesale acquisition cost (WAC)
 - Multiple source drugs reimbursement at 106% of ASP (volume-weighted average of ASPs)
 - 2006
 - At physician's option – reimbursement under ASP methodology or use of a new competitive acquisition system

Exceptions for 2004

- The following will continue to be reimbursement at 95% of AWP (generally not frozen)
 - Blood clotting factor furnished during 2004
 - New drugs not available for payment as of 4/1/03
 - Certain vaccines (influenza, pneumococcal, and hepatitis B)
 - Separately-billed renal dialysis drugs provided during 2004
 - Infusion drugs provided through DME (as of 10/1/03 frozen until 2007 then replaced by competitive bidding program)
 - Blood and blood products other than clotting factors (frozen as of 10/1/03)
 - No change for radiopharmaceuticals

Adjustments to 2004 Methodology

- CMS published proposed rule for “Payment Reform for Part B Drugs” on August 20, 2003
 - Included “Table 3” averaging and summarizing drug price information for certain drugs analyzed by the OIG and GAO in 2001
 - For the drugs included in Table 3, HHS is to substitute for 85% the percentage determined to be the average of the OIG and GAO data for that drug included in Table 3
- HHS has discretion to use data submitted by manufacturers
 - Effective 1/1/04 (if submitted prior to 10/15/03)
 - Effective 4/1/04 (if submitted after 10/15/03 and before 1/1/04)
- Established a floor of 80% of AWP

ASP Methodology

- Begins in 2005
 - For physicians who do not elect competitive acquisition and for drugs excluded from competitive acquisition
 - Physician purchases drugs and bills patient and Medicare
- Generally, payments for single source drugs or biologicals
 - 106% of lower of ASP or WAC, multiple source drugs at 106% of ASP
- Exceptions
 - Certain vaccines, infusion drugs furnished through DME, blood and blood products (other than clotting factors)

ASP Methodology (cont.)

- HHS required to adjust reimbursement if ASP exceeds “Widely Available Market Price” (WAMP) or Average Manufacturers Price (AMP) by more than a percentage specified by HHS (5% in 2005)
 - Adjusted reimbursement lesser of WAMP or 103% of AMP
 - WAMP: “the price that a prudent physician or supplier would pay for the drug or biological,” taking into account “discounts, rebates, and other price concessions routinely made available to such prudent physicians or suppliers for such drugs or biologicals.”

Competitive Acquisition

- Begins in 2006
- Physician election annually
- Applies to “competitively biddable” drugs
 - Excludes
 - Certain vaccines
 - Certain infusion and inhalation drugs furnished through covered DME
 - Blood and blood products, IV immune globulin, radiopharmaceuticals, and other drugs HHS determines should not be “competitively biddable”

Competitive Acquisition (cont.)

- Contractors will bid to supply categories of drugs for a geographic area (at least two contractors per category in a geographic area)
- Single payment amount for each competitively biddable drug in the area
- Payments to contractors directly
 - Contractors collect beneficiary copayment and deductible amounts

Reimbursement Challenges

- Freezing AWP for 2004 as of 4/1/03
 - Disregards actual changes in pricing, some of which could be significant
- Substituting percentages from “Table 3” disregards actual changes in AWP “spread” since 2001
- HHS discretion to disregard ASP and use WAMP
- HHS broad discretion to determine drugs that are not “competitively biddable”

Average Sales Price



Historical Perspective

- ASP first used in Corporate Integrity Agreement in 2001
- Subsequently used in other CIAs
- Different definition
- “Disclosure approach” vs. “regulatory approach”

Average Sales Price (ASP)

- ASP “means, of a drug or biological for a National Drug Code for a calendar quarter for a manufacturer for a unit -
 - A) Manufacturer’s sales to all purchasers (excluding sales exempted in paragraph (2)) in the United States for such drug or biological in the calendar quarter; divided by
 - B) The total number of such units of such drug or biological sold by the manufacturer in such quarter.”

Statutory Exemptions

- The following sales shall be excluded:
 - (A) Sales exempt from the inclusion in the determination of “best price” under the Medicaid Rebate Statute; and
 - (B) Such other sales as the Secretary identifies as sales to an entity that are merely nominal in amount (as applied for purposes of the Medicaid Rebate Statute) except as the Secretary may otherwise provide.

Net Prices

- ASP shall include:
 - Volume discounts
 - Prompt pay discounts
 - Cash discounts
 - Free goods contingent on any purchase requirement
 - Rebates (except Medicaid Rebates)
 - For years after 2004, Secretary may include other price concessions based on recommendations of the HHS OIG that result in a reduction of the cost to the purchaser

Reporting-Special Rules

- Reported on a quarterly basis
- If there is a lag in the reporting of rebates or chargebacks so that adequate data are not available on a timely basis, manufacturer shall apply a methodology based on a 12-month rolling average for the manufacturer to estimate costs attributable to rebates and chargebacks
- For years after 2004, Secretary may establish a uniform methodology to estimate and apply such costs

Exceptional Calculations

- WAC

- The manufacturer's list price for the drugs or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

- WAMP

- The price that a prudent physician or supplier would pay for a drug or biological. In determining such price, the OIG shall take into account discounts, rebates and other price concessions routinely made available to such prudent physicians or suppliers. The OIG shall consider information from manufacturers, wholesalers, distributors, physician supply houses, specialty pharmacies, GPOs, surveys of physicians, survey of suppliers, information from suppliers, information from insurers, and information from private health plans.

Special Issues:

- “...sales to all purchasers” - net of managed care rebates?
- “...in the United States” - exclusively for foreign distribution?
- “in the calendar quarter” - based on request, shipment, or payment?

Special Issues (cont.)

- Statutory exemptions
 - Limited to HIS, VA, certain state homes, DoD, PHS; FSS; SPAPs; and depot prices and single award prices
- “Nominal”

Special Issues (cont.)

- Net of price reductions in addition to those identified in the Medicaid Rebate Statute
 - “Prompt pay discounts” and “chargebacks”
 - Other price reductions identified by the OIG

Compliance Challenges



Compliance Challenges

- Civil Monetary Penalty and False Claims Act
 - Civil monetary penalty up to \$10,000 per occurrence & \$10,000 per day for each price misrepresentation in connection with reporting of ASP
 - Conference Committee intent that false ASP information be subject to False Claims Act liability
- CAP contracting and distribution structure created without OIG clarification on application of fraud and abuse laws
 - Manufacturers should consider conducting a comprehensive review of corporate compliance policies and contracting practices

ASP Complexities



Calculating ASP is Complex

- Multitude of systems from which to pull data
 - Gather data from all transactional systems
 - Data sources may include third party processors (e.g. joint ventures, partnerships, etc.)
 - Certain data (i.e., rebates and chargebacks) will be applied utilizing a 12-month average process



The Nature and Type of Data Increases the Complexity of the ASP Calculation

- Some data sources are not likely to be integrated into the sales and contracting systems
 - Sales and marketing incentives
 - Free goods and/or grants, donations that may constitute price discounts
- Other data may be provided by third-parties and the amount/type of data may pose calculation challenges
 - Product distributed through consignment processes (i.e., mail order)
 - Returned expired product
- Certain transactions will need to be evaluated to determine whether they represent price discounts (i.e., administrative fees)

The Nature and Type of Data Increases the Complexity of the ASP Calculation (cont.)

- Processes will need to be designed for identifying and excluding “nominal sales”
- Rebate and chargeback data will need to be integrated into the ASP price reporting system
 - Proper identification of rebates to be included (all COT except those excluded from Medicaid Best Price)
 - Timing issues and the need to apply a 12-month average estimation process
 - How to design?
 - How to apply at the NDC level?
 - What to do with new rebate programs/products before 12-months of data are available?

Correcting Previously Reported ASP

- Other government programs have processes in place for correcting previously reported price information:
 - In the Medicaid Program, manufacturers routinely adjust prior quarters for changes to AMP, BP, and URA
 - The VA program also has a process for adjusting prior period price reports
- Modifying previously reported ASP poses numerous problems:
 - ASP is used as the basis for reimbursement between parties that do not include the manufacturer
 - Any adjustments to previously reported ASP cannot be corrected by simply refilling a corrected report and recalculating the benefit/liability
 - Clarification is needed regarding how modifications to previously reported ASPs will be handled in terms of the impact on historical reimbursement transactions

Questions?



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