



## Medicare: Today's Issue

April 2, 2004

### *BETTER BENEFITS – MORE CHOICES*

*Good News about the Medicare Prescription Drug, Improvement  
and Modernization Act of 2003!*

#### Changes in the Medicare Modernization Act (MMA) to Part B Payment for Drugs

- ❖ The Medicare Modernization Act, in sections 303, 304 and 305, revises the current payment methodology for Part B covered drugs and biologicals, which are not paid on a cost or prospective payment basis.
- ❖ The types of drugs affected include drugs furnished incident to a physician's service, drugs furnished under the durable medical equipment (DME) benefit, oral anti-cancer drugs, immunosuppressive drugs, and drugs furnished by dialysis facilities that are not included in the end-stage renal disease (ESRD) composite rate payment.
- ❖ In 2004, drugs will be paid at 85 percent of the April 1, 2003 AWP unless they fall under the following exceptions:
  - (1) Specific percentages of the April 1, 2003 AWP for certain high volume drugs based on studies by the GAO or OIG identified in a table in the CMS August 20, 2003 Notice of Proposed Rulemaking (NPRM) on Payment Reform for Part B Drugs. In no case is the percentage less than 80 percent. Four drugs in this table have percentages greater than 85 percent and 24 drugs have percentages between 80 and 84 percent.
  - (2) An exception requested by a manufacturer to the payment at 85 percent of AWP or the alternative percentage identified in the NPRM from the GAO or OIG studies. A manufacturer's exception is based on submission of data and information submitted to CMS. Two exception periods are provided for. The first is for exceptions requested by October 14, 2003 (the close of the comment period on the NPRM) in response to the NPRM. Exceptions granted apply for all of 2004. The second exception period is for requests submitted from October 15, 2003 and before January 1, 2004. Exceptions granted apply for from April through December 2004.
  - (3) The following drugs will be paid 95 percent of AWP during 2004.
    - new drugs (since April 1, 2003);
    - separately billable ESRD drugs; and
    - blood clotting factors.
- ❖ Several other payment rules apply for the following drugs:
  - Vaccines (influenza, pneumococcal, Hepatitis B) furnished on or after January 1, 2004 will be paid 95 percent of AWP.
  - Infusion drugs furnished through a covered item of durable medical equipment will be paid 95 percent of the October 1, 2003 AWP on or after January 1, 2004 and until such drugs are covered in the program for competitive acquisition of durable medical equipment.
  - Blood and blood products will be paid in the same manner as payment was determined on October 1, 2003.

❖ Beginning in 2005, drugs will be paid 106 percent of the average sales price (ASP).

- The ASP is defined to be sales to all purchasers, except for sales exempt from the Medicaid best price determination and nominal sales (using the Medicaid definition), and net of discounts and rebates.
- Discounts and rebates include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on purchase requirements, chargebacks and rebates.
- Manufacturers are required to submit the manufacturer's average sales price as well as volume of sales each quarter for each National Drug Code (NDC). Submissions are due 30 days after the close of a quarter. ASP information is required first to be submitted for the January to March 2004 quarter.
- The Secretary is required to calculate quarterly the Average Sales Price from the manufacturer's submissions.
- The Inspector General (IG) of HHS is required to conduct studies to determine the widely available market price. The IG is required to compare the ASP to both the widely available market price and the Average Manufacturer's Price (AMP). If the ASP exceeds the widely available market price or AMP by a threshold percentage (5 percent in 2005 and a figure determined by the Secretary for 2006 and subsequent years), the Secretary is required to reduce the ASP to the widely available market price or 103 percent of the AMP.
- Civil money penalties can be applied to manufacturers who make a misrepresentation in reporting of ASP information. The False Claims Act also applies to ASP information reported by a manufacturer.

❖ Beginning in 2006, the Secretary is required to establish and implement a competitive acquisition program where each physician is given the opportunity annually to elect to obtain drugs from competitively selected contractors rather than being paid ASP, plus 6 percent and purchasing drugs directly.