Medicare: Today's Issue

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BETTER BENEFITS – MORE CHOICES

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

Medicaid Prescription Drug Rebates and Best Price Exemptions:

- **Background:** The Medicaid Prescription Drug Rebate Program began in 1991 and was created by the Omnibus Budget Reconciliation Act (OBRA) of 1990. The rebate program was designed to tap Medicaid's purchasing power by giving the program the same kind of volume discounts afforded to other large purchasers of prescription drugs, thus holding down costs. The program requires a drug manufacturer to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services for States to receive federal funding for outpatient drugs dispensed to Medicaid patients.

- The rebate program is an effort to contain costs by attempting to keep drug prices down while still allowing access to drugs for the Medicaid population. Manufacturers that choose to participate in the rebate program will have all FDA approved drugs (with some limited exceptions) covered by Medicaid. States, in turn, will receive rebate dollars from the manufacturers.

- **Terms of the Rebate Programs:**

  - Pharmaceutical Manufacturers sign an agreement with the Federal Government and are required to pay rebates to states as a condition of Medicaid payment for their drug products.
  - State Medicaid Agencies provide the FDA approved drugs (with limited exceptions) of the participating manufacturers to the Medicaid population in their state.
  - Each manufacturer is required to:
    - Submit to CMS a listing of all their drugs;
    - Submit to CMS pricing/sales information for all their drugs; and
    - Pay quarterly rebates to the states based on the state's utilization of their drug products.
  - Each state is required to:
    - Collect Medicaid prescription drug utilization data for their state; and
    - Send utilization data to CMS and the manufacturers.

  - Manufacturers are required to pay state Medicaid programs a basic rebate for single source and innovator multiple source (name brand) drugs. Basic rebates are calculated based on:

    - Brand Drugs:
      The greater of

1. 15.1% of Average Manufacturer's Price (AMP), OR
2. AMP minus Best Price.

- Best Price is used in the calculation of Medicaid drug rebates. Under Section 1927 (c)(1)(C), of the Social Security Act, the term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States.
- For purposes of determining Medicaid rebates, prices paid for drugs by a number of Federal and state entities, such as drugs purchased for the Veterans Administration, are excluded from the definition of "best price."

- Additionally, if the price of a drug increases at a rate faster than CPI from a base year, the manufacturer would owe the state the difference dollar for dollar.

  - Generic Drugs:
    1. 11% of AMP, the average unit price that is paid to a manufacturer for their drug in the United States.
    2. No CPI based rebates on generics

- **New Provision:** The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) includes the following new provisions on Medicaid Best Price Exemptions, effective upon enactment:

  - The Best Price section of title XIX is amended to exclude from definition of best price the following prices:
    - Prices negotiated for the Medicare endorsed discount drug card,
    - Prices negotiated for prescription drug plans under part D,
    - Prices negotiated for prescription drug plans by a MA-PD under part C, and
    - Prices negotiated for qualified retiree prescription drug plans.

  - 340B Best Price Exclusion - MMA also exempts from Medicaid best price calculations purchases of inpatient drugs by public hospitals that qualify under section 340B of the Public Health Service Act. This provision also includes an anti-diversion provision that subjects any drug for inpatient use covered under section 340B to the auditing and record keeping requirements of the 340B program.