DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, Maryland 21244 -1850

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MEDICAID DRUG REBATE PROGRAM **Release No. 68**

Bulletin

For Participating Drug Manufacturers

STATE PHARMACY ASSISTANCE PROGRAMS – REVISED CRITERIA

On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). The MMA made historical changes to the Medicare program, and, for the first time since 1965, beneficiaries will be entitled to a comprehensive outpatient drug benefit under Medicare. Given the launch of this new program, we believe it is appropriate to amend the criteria for SPAPs under the Medicaid drug rebate program to ensure consistency and alignment between the Medicare and Medicaid programs.

As added by the MMA, section 1860D-23 of the Social Security Act (the Act) now requires that, in order to meet the definition of a State Pharmaceutical Assistance Program, a State program "in determining eligibility and the amount of assistance to part D eligible individuals under the Program, provides assistance to such individuals in all part D plans and does not discriminate based upon the part D plan in which the individual is enrolled."
§ 1860D-23(b)(2).

On January 28, 2005, we issued a final rule explaining how we interpret the above Congressional language. One commenter, in particular, asked whether State programs could steer their members to a certain Part D plan and still meet the definition of an SPAP. We replied as follows:

> *Comment*: One commenter stated that the States should be able to steer its SPAP enrollees toward the most appropriate plan.
> *Response:* Section 1860D–23(b)(2) of the Act defines an SPAP as a State program which, in determining eligibility and the amount of assistance to a Part D eligible individual

> under the program, provides assistance to such individuals in all Part D plans and does not discriminate based upon the Part D plan in which the individual is enrolled. We further interpreted that provision in the preamble of the proposed regulation such that a SPAP may not designate a preferred PDP, even if the State allows beneficiaries to choose a non-preferred plan and provides for benefits equivalent to that which it also provides for the preferred plan (referred to as wrap-around benefits). We believe that, regardless of whether the SPAP is authorized under State law to make enrollment decisions on behalf of the beneficiary, we interpret using that authority to steer beneficiaries to a preferred PDP or MA-PD plan would be interpreted to violate the non-discrimination provision under section 1860D–23(b)(2) of the Act.

70 Fed. Reg. 4222.

Now that the Medicare statute specifically prohibits a State program from being considered an SPAP under Part D if it steers members to a preferred Part D plan, we believe it is necessary to also amend the criteria for SPAPs under the Medicaid drug rebate program. Congress clearly intended to prohibit State programs from favoring one Part D plan over another, and to ensure that part D plans receive equal assistance from SPAPs. Thus, we believe it would be contrary to Congressional intent to allow State programs that steer their members toward a preferred Part D plan to be excluded from best price (BP) and average manufacturer price (AMP).

In addition, State programs that discriminate under Part D should not continue to reap the benefits of receiving an exemption from BP, especially since some of their manufacturer rebates will likely directly stem from violations of the non-discrimination provisions in section 1860D-23(b)(2). Specifically, it has been brought to our attention that some States are considering directing beneficiaries into State-preferred Part D plans and, in return, either independently or through the preferred Part D plan, would receive rebates and other financial concessions from drug manufacturers. We understand that some States have even begun the process of drafting and enacting legislation that would allow them to act as the authorized representative of their State program enrollees and auto-enroll them into a specific Part D plan.

For these reasons we are amending the criteria described in Medicaid Drug Rebate Manufacturer Release #59 (June 23, 2003) to add a new criterion as described above.

In order for a State only program to qualify as a State pharmacy assistance program, it should generally meet the following criteria:

- The program is a State developed program specifically for the disabled, indigent, low-income elderly of other financially vulnerable persons.
- The program is funded by the State; that is, no Federal dollars are involved.
- The program is set up such that payment is provided directly to providers.
- The program provides either a pharmaceutical benefit only or a pharmaceutical benefit in conjunction with other medical benefits or services.
- The program does not allow for the diversion, resale or transfer of benefits reimbursed under the State pharmacy assistance program to individuals who are not beneficiaries of the State pharmacy assistance program.
- The program does not violate the non-discrimination provisions of section 1860D-23(b)(2) of the Act.

We note that this amended criterion applies only to an SPAP's activities in relation to the new Medicare Part D program. Because the Part D program did not exist prior to the passage of the MMA, this amended criterion does not effect any change with respect to ongoing SPAP activities in relation to non-Part D plans.

The criteria in this release should be applied prospectively as of the date of this release.

THE EFFECTS OF SALES TO HEALTH MAINTENANCE ORGANIZATIONS (HMOs) AND TO OTHER ENTITIES PURCHASING DRUGS FOR DIRECT CONSUMER SALES OR DISTRIBUTION ON THE CALCULATION OF BEST PRICE (*REPACKAGER ISSUE*)

As a result of several inquires from manufacturers and the Office of Inspector General's (OIG) conclusion in Report No. A-06-00-0056: Medicaid Drug Rebates - Sales to Repackagers Excluded from Best Price Determination (March 27, 2001) that there are instances where manufacturers excluded sales to repackagers that are HMOs from their best price determinations, we are reiterating our policy requiring the inclusion of sales to HMOs and other entities purchasing drugs for direct consumer sales or distribution in the calculation of best price.

As previously explained in Releases No. 29 and 47, section 1927(c)(1)(C)(i) of the Social Security Act (the Act) specifies that best price is the lowest price available from the manufacturers to any wholesaler, retailer, provider, HMO, nonprofit entity, or governmental entity within the United States. Sections 1927(c)(1)(C)(i)(I)-(IV) of the Act list specific exclusions from the best price calculation. Under these provisions and section 1927(j)(3), it is clear that sales to organized health care settings such as HMOs must be included in best price. The best price provisions in the statute contemplate the inclusion of sales to HMOs without regard to special packaging or labeling.

The Medicaid Drug Rebate Program Manufacturers Releases No. 29 and 47 were issued to reiterate our existing policy regarding the inclusion of sales to HMOs in the calculation of best price, not to implement new policy. Specifically, Program Manufacturer Release No. 29 (June 1997), "Additional Guidance on Average Manufacturer Price (AMP) Calculations" was issued to assist manufacturers in determining the appropriateness of the AMP calculations or proposed calculations and Release No. 47 (July 2000), "The Effect of Sales to Health Maintenance Organizations and Other Entities Purchasing Drugs for Direct Consumer Sales or Distribution on the Calculation of Best Price" was issued to reiterate the existing policy that drug sales to an HMO should not be omitted from a manufacturer's best price calculation on the basis that the purchaser is a drug repackager. Releases No. 29 and 47 did not supersede requirements or change obligations in the rebate agreement or in section 1927 of the Act. Further, no new requirements were imposed on manufacturers and no action was necessary by manufacturers that were not revising or recalculating pricing data.

It is our position that those sales to entities that repackage/relabel under the purchaser's NDC are to be included in best price if that entity also is an HMO or other non-excluded entity. Therefore, if applicable, the best price calculation for quarters prior to the issuance of Release No. 47 (July 2000), as well as any quarter thereafter, must be adjusted to include those sales to

other entities who repackage/relabel (inclusive of private label agreements) under the purchaser's NDC and are HMOs. Additionally, the payment of additional rebates may be due.

As with all pricing data submitted under the Medicaid drug rebate program, if CMS, the Office of Inspector General, or another authorized government agency reviews a manufacturer's pricing data and determines that adjustments or revisions are necessary, irrespective of the quarter, the manufacturer is bound to comply with that determination. Therefore, this determination requiring revised best price pricing data in connection with the repackager issue is not subject to the 3-year timeframe limitation regarding pricing revisions, established January 1, 2004. Consequently, manufacturers will be required to report revisions to best price for a period in excess of 12 quarters prior to the quarter in which the data were due. To obtain instructions regarding the data resubmission process of this determination, please contact Vince Powell, Data and Systems Group at (410) 786-3313.

Edward C. Gendron
Director
Finance, Systems and Budget Group

2 Attachments

cc:
All Regional Administrators
All Associate Regional Administrators, Division of Medicaid

WEEKLY U.S. T-BILL INVESTMENT RATE

weekly 91-day treasury bill auction rates

Date of Auction	Invest. Rate	Date of Auction	Invest. Rate	Date of Auction	Invest. Rate
06-23-03	0.830	02-02-04	0.939	09-13-04	1.671
06-30-03	0.903	02-09-04	0.939	09-20-04	1.716
07-07-03	0.907	02-17-04	0.931	09-27-04	1.741
07-14-03	0.895	02-23-04	0.947	10-04-04	1.716
07-21-03	0.911	03-01-04	0.957	10-12-04	1.711
07-28-03	0.964	03-08-04	0.945	10-18-04	1.803
08-04-03	0.964	03-15-04	0.961	10-25-04	1.890
08-11-03	0.960	03-22-04	0.945	11-01-04	1.987
08-18-03	0.964	03-29-04	0.961	11-08-04	2.084
08-25-03	0.997	04-05-04	0.945	11-15-04	2.115
09-02-03	0.988	04-12-04	0.929	11-22-04	2.197
09-08-03	0.951	04-19-04	0.949	11-29-04	2.380
09-15-03	0.947	04-26-04	0.985	12-06-04	2.253
09-22-03	0.953	05-03-04	1.001	12-13-04	2.243
09-29-03	0.953	05-10-04	1.078	12-20-04	2.223
10-06-03	0.939	05-17-04	1.058	12-27-04	2.269
10-14-03	0.923	05-24-04	1.066	01-03-05	2.320
10-20-03	0.939	05-31-04	1.150	01-10-05	2.376
10-27-03	0.960	06-07-04	1.251	01-18-05	2.407
11-03-03	0.960	06-14-04	1.413	01-24-05	2.366
11-10-03	0.951	06-21-04	1.336	01-31-05	2.525
11-17-03	0.951	06-28-04	1.381	02-07-05	2.530
11-24-03	0.946	07-05-04	1.344	02-14-05	2.592
12-01-03	0.943	07-12-04	1.336	02-21-05	2.669
12-08-03	0.915	07-19-04	1.352	02-28-05	2.772
12-15-03	0.903	07-26-04	1.449	03-07-05	2.767
12-22-03	0.884	08-02-04	1.490	03-14-05	2.792
12-29-03	0.901	08-09-04	1.497	03-21-05	2.859
01-05-04	0.939	08-16-04	1.498	03-28-05	2.839
01-12-04	0.887	08-23-04	1.541		
01-20-04	0.891	08-30-04	1.607		
01-26-04	0.907	09-06-04	1.663		

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