DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

July 14, 2016

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 99**

For
Participating Drug Manufacturers

Value Based Purchase Arrangements and Impact on Medicaid

The Centers for Medicare & Medicaid Services (CMS) is releasing this notice to inform manufacturers on how to seek guidance from CMS on their specific value based purchasing (VBP) arrangement, as well as encourage states to consider entering into (VBP) arrangements as a means to address, as well as offset, Medicaid's high cost drug treatments. This guidance also reminds states that they may extend their Medicaid supplemental rebate agreement to some or all of their managed care prescription claims.

Inquiries to CMS Regarding VBP Arrangement's Impact on Best Price

With the introduction of VBP arrangements into the pharmaceutical marketplace, manufacturers have asked CMS if these types of arrangements impact their drug's Medicaid best price. Manufacturers are concerned that the variety of price concessions and services offered to payers in a VBP arrangement may lower the manufacturers' best price and increase their Medicaid rebate obligations, thereby serving as a disincentive to promoting VBP arrangements.

Section 1927(c)(1)(C) of the Social Security Act defines "best price" to mean, for a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for an authorized generic drug), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity in the United States.

In general, prices included in best price include all prices, including applicable discounts, rebates, or other transactions that adjust prices either directly or indirectly to the best price eligible entities, including providers (see 42 CFR 447.505(a)). The regulation defines "provider" at 447.505(a) to mean a hospital, health maintenance organization, including a managed care organization or entity that treats or provides coverage or services to individuals for illnesses or injuries or provides services or items in the provision of health care.

In response to specific requests from manufacturers as to how to reflect their VBP arrangements in calculating best price, CMS has concluded that the impact on a manufacturer's best price will differ depending on the structure of the VBP arrangement. CMS recommends that when manufacturers negotiate such arrangements with entities, they consult both the statute and implementing regulations regarding the determination of best price. In addition, CMS is available to address questions concerning a manufacturer's arrangement, if needed. CMS encourages manufacturers to submit any issues or questions to the CMCS Division of Pharmacy at RxDRUGPolicy@cms.hhs.gov. Based on these inquiries, we will seek to generalize lessons learned regarding common questions and arrangements in subsequent guidance. Manufacturers should continue to document the calculation of best price, including any reasonable assumptions made about the impact of their arrangements on best price (42 CFR 447.510).

Offering State Medicaid Partners Value Based Purchasing Arrangements

CMS encourages innovative approaches to providing health care services, such as VBP arrangements, and encourages manufacturers to consider entering into such arrangements with state Medicaid programs. To the extent a VBP arrangement provides supplemental rebates pursuant to a CMS-approved supplemental rebate agreement with the state Medicaid agency, such rebates would be excluded from best price (see 42 CFR 447.505(c)(7)). Therefore, we encourage states and manufacturers to consider negotiating supplemental rebates as part of VBP arrangements. States should review the September 18, 2002 State Medicaid Director letter regarding supplemental rebates and seek authorization under 1927(a)(1) of the Act from CMS in order to ensure compliance with section 1927 when entering directly into supplemental rebate agreements with manufacturers.

Collecting Supplemental Rebates on Medicaid Managed Care Drug Claims

Regardless of whether states engage in VBP, almost all states collect supplemental manufacturer rebates on Medicaid fee-for-service (FFS) drug claims and some collect these rebates on managed care drug claims. Given that managed care organizations are often the primary mechanism for health care delivery in Medicaid, we urge that states consider negotiating supplemental rebates with manufacturers for some or all of their Medicaid managed care drug claims. Before negotiating supplemental rebates on managed care drug claims, states should determine the impact of their decision to collect supplemental rebates on their contracts with managed care organizations.

States should determine if supplemental rebates in the managed care context will result in better patient outcomes and reduced costs to Medicaid overall. We urge states to work with their supplemental rebate contractors and Medicaid managed care organizations to better understand the impact of this policy.

Alternatively, the state may want to align their FFS preferred drug list and the state's Medicaid managed care organizations' formularies only for certain drug classes and collect supplemental rebates on those drugs dispensed to Medicaid managed care enrollees. A state that already has an approved CMS state plan that allows them to collect supplemental rebates on Medicaid managed care claims will not need to change their approved state plan to implement such an approach.

If you have any questions regarding CMS guidance on value based purchasing or supplemental rebates, please email your questions to RxDRUGPolicy@cms.hhs.gov.

Sincerely,

/s/

Michael Nardone
Director
Disabled and Elderly Health Programs Group