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

Center for Medicaid and CHIP Services

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MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 169**

For State Technical Contacts

BIOSIMILARS AND THE MEDICAID DRUG REBATE PROGRAM

As part of this release, we are issuing guidance to states on the classification of biosimilar biological products for rebate purposes and on strategies for states to use these products to reduce costs while improving access in terms of state Medicaid preferred drug lists.

Classification of Products Approved under a Biological License Application

Section 1927(k)(2)(B) of the Social Security Act (the Act) defines a covered outpatient drug to include a biological product, other than a vaccine, which may only be dispensed upon prescription, is licensed under section 351 of the Public Health Service (PHS) Act, and is produced at an establishment licensed to produce such product. The Affordable Care Act (ACA) amended the PHS Act to create an abbreviated pathway for licensure of biological products that are demonstrated to be biosimilar to, or interchangeable[1] with, an FDA-licensed biological product. Generally, both reference biological products and biosimilar biological products are licensed under biological license applications (BLA) under section 351 of the PHS Act.
For purposes of the Medicaid Drug Rebate (MDR) program, the definition of single source drugs found at 42 CFR 447.502 includes covered outpatient drugs licensed under a BLA. Therefore, in light of this provision, biosimilar biological products fall within the definition of single source drugs in the MDR program.

Biosimilars and Preferred Drug Lists

State Medicaid programs should view the launch of biosimilar biological products as a unique opportunity to achieve measurable cost savings and greater beneficiary access to expensive therapeutic treatments for chronic conditions. States and managed care organizations are encouraged to provide biologics that achieve desirable, cost-effective clinical outcomes for beneficiaries using the various drug utilization and cost management tools they

[1] There are two terms used to describe biological products approved under the 351(k) pathway, biosimilar biological products and interchangeable biological products. Biosimilar biological products are highly similar to the reference product and are not significantly different from the reference product in terms of safety, purity and potency. Interchangeable biological products must first be shown to be biosimilar and meet additional standards for interchangeability.

have available (e.g., step therapy, prior authorization, preferred drug lists) to the extent such tools are consistent with the state plan. In addition to the rebates received from manufacturers, cost savings may be achieved through the establishment of supplemental rebate agreements between states and manufacturers. States may consider the total rebates for reference biological products as well as those that have been determined to be biosimilar to, or interchangeable with, reference biological products in their determination of preferred drugs lists consistent with the requirements for prior authorization programs in section 1927(d)(5) of the Act.

We remind states that educating physicians and pharmacists on how to prescribe and dispense cost effective biosimilar biologicals is important to encourage and maximize their use. That is because, in contrast with traditional drugs, a prescriber may not be able to simply write the proprietary name of a reference biological product and expect the pharmacist to substitute it with the biosimilar biological product. The prescriber may have to write the proprietary name of the biosimilar biological product, or the product or proper name of the biosimilar biological product as found in the FDA's Purple Book (http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm) in order for it to be dispensed, or issue a new prescription if a patient is already taking another biological product.

States could also consider encouraging prescribers to determine whether patients for whom treatment with biological products is needed could achieve desired therapeutic outcomes by using the biosimilar biological product if more cost effective than the reference biological product. To ensure safe and efficacious use of these products, we suggest that states could use their drug utilization review (DUR) programs and pharmacy and therapeutics (P&T) committees to inform physicians and pharmacists about the appropriate prescribing and dispensing of biological products, including the use of biosimilar biological products as it relates to the FDA designation of interchangeability with the reference biological product.

States can provide this education through newsletters to prescribers, electronic prescribing messaging, point of sale (POS) edits to pharmacists at the point of dispensing, or a combination of these methods. We refer states to their own drug product selection laws as well as the FDA Purple Book for more information on the biosimilarlity or interchangeability of biosimilar biological products.

Questions regarding biosimilars should be sent to CMS at RxDrugPolicy@cms.hhs.gov.

ALLOWING ZERO AS A VALID VALUE FOR MEDICAID AMOUNT REIMBURSED & TOTAL AMOUNT REIMBURSED FIELDS ON MCO UTILIZATION RECORDS

CMS previously issued guidance to manufacturers (Manufacturer Release #84, July 19, 2012), responding to inquiries that were received regarding whether manufacturer rebates are required to be paid to states in instances when managed care organization (MCO) data do not reflect a paid amount for a drug the MCO covered for a Medicaid beneficiary enrolled in its plan. In accordance with section 1927(b)(1)(A) of the Social Security Act (the Act), the manufacturer is responsible for payment of rebates for covered outpatient drugs dispensed to Medicaid

beneficiaries enrolled in MCOs, regardless of the payment terms negotiated as part of the contract between the MCO and its participating pharmacies to provide Medicaid coverage.

When a drug is dispensed to a Medicaid beneficiary under a managed care arrangement, the state may have paid for the drug in advance, via a capitated payment to the MCO. In these instances, MCO data will generally not reflect a paid amount for the drug that was dispensed. Previously, CMS's Medicaid Drug Rebate (MDR) system rejected any state utilization (either fee-for-service (FFS) or MCO) record in which the Medicaid Amount Reimbursed or Total Amount Reimbursed Fields were zero. However, in light of the capitated payment arrangements that are generally utilized by states and MCOs, a zero value in these fields could be appropriate for MCO data. As a result, we have updated the MDR system to accept a zero value for MCO utilization records for the Medicaid Amount Reimbursed and Total Amount Reimbursed fields. This change is applicable to all future MCO utilization data submissions, as well as to all prior quarterly submissions back to first quarter 2010, since that is the first quarter in which MCO utilization data reporting was available to the states. Consequently, any state that submits an update to previously reported MCO utilization data back to first quarter 2010 will be able to submit a zero value in the Medicaid Amount Reimbursed and Total Amount Reimbursed fields. FFS utilization records will continue to reject if either of these fields are reported with a value of zero. If a state previously reported MCO utilization data incorrectly by including a value greater than zero in the Medicaid Amount Reimbursed or Total Amount Reimbursed fields, or if a state's previous MCO utilization submission was rejected due to a zero value in either of those fields, the state has the option to resubmit the utilization data to CMS as soon as possible. As a reminder, states must submit all rebate utilization for which rebates were billed within 60 days of the end of the rebate period, including any adjustments or corrections to previous rebate periods.

Questions regarding the submission of utilization data should be sent to CMS at MDRUtilization@cms.hhs.gov.

BRANDED PRESCRIPTION DRUG (BPD) PROGRAM AND ZERO REIMBURSEMENT AMOUNT MCO UTILIZATION VALUES

Currently, the Medicaid sales formula for each quarter of the BPD program determines the percentage of the Total Amount Reimbursed that is the Medicaid portion. However, per above guidance "Allowing Zero as a Valid Value for Medicaid Amount Reimbursed...", this determination did not take into account that zero may be a valid value in the MCO Medicaid Amount Reimbursed and Total Amount Reimbursed Fields. This being the case, in order to facilitate the calculation of the BPD sales fee, MCO records received from states with zero reimbursement values will be calculated with a proxy amount of .01 in both the Medicaid Amount Reimbursed and the Total Amount Reimbursed fields. This proxy amount will not be reflected in DDR or Medicaid.gov, but will be used in the methodology to derive each manufacturer's calculated fee. For more information, please visit the BPD website at http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Branded-Prescription-Drug.html.

Questions regarding the BPD program for Medicaid should be sent to MedicaidBPD@cms.hhs.gov.

CLARIFICATION OF POSTMARK DATES WHEN USING SECURE WEBSITES

This is a follow-up to clarify the guidance provided in State Release No.166 (March 10, 2014), pertaining to what qualifies as a postmark date for secure websites. Specifically, that release noted that the postmark date for states that opt to use a secure website for invoice transmission should be equal to the date of an email notification that a web invoice is ready to be downloaded. In addition, the release stated that such email notifications should include the invoice within the body of the email or, at minimum, information on the number of units paid by national drug code (NDC).

While the postmark date for purposes of determining when interest is due is still equal to the date of an email notification that a web invoice is ready to be downloaded, after further consideration, the invoice or unit information is no longer required to be included in the email notification since it would be redundant. States may continue to include the information if they so choose. If you have any questions, please contact MDRUtilization@cms.hhs.gov.

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Alissa Mooney DeBoy
Acting Director
Disabled & Elderly Health Programs Group