DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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**Center for Medicaid and CHIP Services**

**March 30, 2015**

**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.

/s/

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**



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# Food and Drug Administration Approval of First Biosimilar Product

## Provider Types Affected

This article is intended for health care professionals who submit claims to Medicare Administrative Contractors (MACs) for Medicare Part B services furnished to Medicare beneficiaries.

## What You Need to Know

The Centers for Medicare & Medicaid Services (CMS) is aware that the Food and Drug Administration (FDA) has approved the first biosimilar product. CMS policies will ensure Medicare beneficiaries will have access to this new product, as it does for other drugs that receive FDA approval. The purpose of this article is to address questions that have arisen regarding biosimilar products.

## Questions and Answers About Biosimilar Products

**Question:**
How will a health care professional that administers this product get reimbursed under Medicare Part B?

**Answer:**
Medicare Part B payment for newly approved drugs and biologicals is available once the product is approved by the FDA. CMS will incorporate biosimilars that are approved under the abbreviated biological approval pathway into the Average Sales Price (ASP) payment methodology, and issue additional guidance as necessary. Initially, once the manufacturer's wholesale acquisition cost (WAC) is available, Medicare will pay 106 percent of the WAC for the product until ASP information is available. Once ASP information is available for this biosimilar product, Medicare payment will equal the ASP for the biosimilar product plus six percent of the ASP for the reference product.

**Question:**
How soon will CMS be releasing coding information related to Part B reimbursement?

**Answer:**
CMS anticipates including the approved biosimilar in the next quarterly Healthcare Common Procedure Coding System (HCPCS) tape release in the coming weeks, appearing in the claims processing system on July 1, 2015, effective retroactively to the FDA approval date.

**Question:**
Will CMS be assigning unique codes to each biosimilar released?

**Answer:**
CMS will create a separate code to distinguish the biosimilar from the reference biological. CMS is considering policy options for coding of additional biosimilars, and will release further guidance in the future.

**Question:**
Will use of a distinguishing identifier to biological products make it harder to achieve Medicare reimbursement?

**Answer:**
Distinguishing identifiers will have no bearing on coding and payment.

**Question:**
How will CMS address providing access to biosimilars through Medicare Part D?

**Answer:**
Although coverage for filgrastim will generally be provided through Part B, it could also be covered under Part D in certain circumstances (for example, nursing homes or Intermediate Care Facilities for Individuals with Intellectual Disabilities ICF/IID)). CMS will be releasing guidance to plans confirming that biosimilars approved by the FDA will be subject to existing rules for prescription drugs under Part D.

## Additional Information

If you have any questions, please contact your MAC at their toll-free number. That number is available at **http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html** under - How Does It Work.

**Seasonal Flu Vaccinations** - For information on coverage and billing of the influenza vaccine and its administration, please refer to **MLN Matters® Article #MM8890**, "Influenza Vaccine Payment Allowances - Annual Update for 2014-2015 Season" and **MLN Matters® Article #SE1431**, "2014-2015 Influenza (Flu) Resources for Health Care Professionals."

Also, check out the following resources from the Centers for Disease Control and Prevention (CDC): **Influenza (Flu)** web page for the latest information on flu including the CDC 2014-2015 recommendations for the prevention and control of influenza, antiviral information, CDC flu mobile app, Q&As, toolkit for long term care employers, and other free resources. Review the CDC's **Antiviral Drugs** website for information about how antiviral medications can be used to prevent or treat influenza when influenza activity is present in your community, and view the updated "Influenza Antiviral Medications: Summary for Clinicians." A CDC Health Update reminding clinicians about the importance of flu antiviral medications was distributed via the CDC Health Alert Network on January 9, 2015, and is available at **http://emergency.cdc.gov/HAN/han00375.asp** on the Internet.

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**CENTER FOR MEDICARE**

TO: Part D Sponsors

FROM: Amy K. Larrick
Acting Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Part D Requirements for Biosimilar Follow-On Biological Products

DATE: March 30, 2015

The Affordable Care Act amends section 351 of the Public Health Service Act (PHS Act) adding a subsection (k) to create an abbreviated licensure pathway for follow-on biological products that are demonstrated to be either "biosimilar" to or "interchangeable" with a Food and Drug Administration (FDA) licensed reference biological product.[1] This memorandum clarifies the application of Part D formulary review policies, low-income subsidy (LIS) and catastrophic cost sharing rules, and Coverage Gap Discount Program (Discount Program) requirements regarding "biosimilar" follow-on biological products covered under Medicare Part D. Additional guidance may be issued for "interchangeable" biological products at a later date.

**Medicare Part D Formulary Review Policies**

Biosimilars may provide Part D sponsors with new products that create formulary design options to help control costs while still ensuring beneficiaries have access to the medications they need. Our existing formulary review and formulary change policies provide Part D sponsors with the flexibility to promote the appropriate use of biosimilars through their formulary and drug utilization management strategies when designing their Part D benefits. CMS will evaluate formulary change requests involving biosimilars on an individual basis and will determine if they meet the requirements of our formulary review and approval process based on information in the FDA-approved label and statutory compendia. However, the reference and biosimilar products will not be considered as different drugs for the purposes of satisfying the two distinct drugs requirement for each of the submitted categories and classes, except as provided in 42 CFR § 423.120(b)(2)(ii).

Biosimilars may be added to plan formularies at any time as a formulary enhancement. Formulary changes involving the addition of the biosimilar and removal of the reference biological product will generally be considered a non-maintenance change. These formulary

[1] Follow-on biological products approved under subsection (k) will be listed in the FDA's new *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*, available at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm. Part D sponsors are also encouraged to monitor the FDA's website for new BLA approvals at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu.

changes will be evaluated, as are all non-maintenance changes, on a case-by-case basis, and allowed if the formulary continues to meet the formulary review standards with the corresponding addition of the biosimilar. Because biosimilars are not interchangeable with the reference biological product, CMS expects that Part D sponsors' Pharmacy and Therapeutics (P&T) committees will review newly approved biosimilars in accordance with section 30.1.5 of Chapter 6 of the Medicare Prescription Drug Benefit Manual.

For the purposes of Part D transition supply and notice requirements, biosimilars and the reference biological product should be treated like different products. Part D enrollees taking the reference biological product should receive a transition supply when only a biosimilar is available on the formulary. Similarly, Part D enrollees taking the biosimilar should receive a transition supply when the reference biological product is the only formulary product.

**Low Income Subsidy (LIS) and Catastrophic Cost Sharing**

Section 1860D-14(a) of the Social Security Act specifies lower maximum copayments for LIS eligible individuals for generic drugs and preferred drugs that are multiple source drugs (as defined in §1927(k)(7)(A)(i) of the Social Security Act) than available for all other Part D drugs. Biosimilars do not meet the CMS definition of a generic drug in 42 CFR §423.4 or the §1927(k)(7) definition of a multiple source drug. Consequently, biosimilars are subject to the higher maximum copayments for LIS eligible individuals applicable to all other Part D drugs. In 2015, the maximum copayment would be either $3.60 or $6.60 depending upon the individual's subsidy level.

Similarly, lower minimum copayments specified in §1860D-2(b)(4) for non-LIS individuals in the catastrophic coverage portion under the standard Part D benefit for generic drugs and preferred drugs that are multiple source drugs would not apply to biosimilars. Nevertheless, CMS generally expects that non-LIS individuals will pay the 5% coinsurance for biosimilars in the catastrophic portion of the standard Part D benefit in accordance with§1860D-2(b)(4) requirements.

**Applicability to the Medicare Part D Coverage Gap Discount Program**

The Affordable Care act established the Discount Program by adding sections 1860D-43 and 1860D-14A of the Social Security Act. When defining "applicable drugs" that are discounted under the Discount Program, the statute specifically excludes follow-on biological products receiving FDA approval under subsection (k) of section 351 of the PHS Act. Consequently, biosimilars are non-applicable drugs for purposes of establishing coverage gap cost sharing under the basic Part D benefit, and are not discounted or otherwise subject to Discount Program requirements.

If you have any questions regarding this memorandum, please contact Stephanie Hammonds at Stephanie.Hammonds@cms.hhs.gov or (410) 786-1646.