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

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MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 103**

For

Participating Drug Manufacturers

Biosimilar Biologics Treated as Authorized Generics

On March 30, 2015, the Centers for Medicare & Medicaid Services (CMS) issued a manufacturer release regarding treatment of biosimilar biologics for the purpose of the Medicaid Drug Rebate (MDR) program. In that release, we indicated that for purposes of the MDR program the definition of single source drugs found at 42 CFR 447.502 includes covered outpatient drugs licensed under a biologics license application (BLA). We stated that in light of this provision, biosimilar biological products fall within the definition of single source drugs in the MDR program, consistent with the 2016 Final Rule. See 81 FR 5195. Therefore, such drugs should be reported as single source or "S" in our MDR system.

In this release, we want to further clarify that a biosimilar biological product would not qualify as an authorized generic drug as it is defined by our regulation at 42 CFR 447.502. An authorized generic drug is defined as any drug sold, licensed, or marketed under a new drug application (NDA) approved by the Food and Drug Administration (FDA) under section 505(c) of the Federal Food, Drug and Cosmetic Act (FFDCA) that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark or packaging (other than repackaging the listed drug for use in institutions) than the brand name drug. Further, authorized generic drugs are classified as innovator multiple source or "I" drugs in the MDR system. A biosimilar biological product approved under a BLA should not be treated as an authorized generic for the purpose of the MDR program nor included in the sales of the manufacturer of the reference biological product to the manufacturer of the biosimilar biological product when calculating AMP because it is neither marketed under an NDA nor able to be classified as an I drug. In addition, because biosimilar biologics are single source drugs, the best price of the reference biologic and the

biosimilar biologic should be determined separately as the lowest price available from each manufacturer.

Please contact RxDRUGPolicy@cms.hhs.gov if you have any questions.

Sincerely,

/s/

Michael Nardone
Director
Disabled and Elderly Health Programs Group