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

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MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 102**

For

Participating Drug Manufacturers

Excluding Abuse-Deterrent Formulations From the Definition of Line Extension

The purpose of this guidance is to clarify how the Centers for Medicare & Medicaid Services (CMS) intends to verify if a drug is an abuse-deterrent formulation, and thus be excluded from the definition of line extension for purposes of the Medicaid Drug Rebate (MDR) program.

On July 22, 2016, the Comprehensive Addiction and Recovery Act of 2016 (CARA) (Pub. L. 114-98) was enacted into law. The Act contains language that is intended to exempt certain abuse-deterrent formulations of a drug from the definition of line extension for purposes of the MDR program. In particular, section 705(a) of CARA amends §1927(c)(2)(C) of the Social Security Act so that the definition of the term "line extension" now means, "with respect to a drug, a new formulation of the drug, such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation". The effective date for this provision is October 1, 2016.

CMS intends to use information provided on the Drug Details page for the drug on Drugs@FDA: FDA Approved Drug Products to perform our verification process for determining whether a drug is an abuse-deterrent formulation, and thus excluded from the definition of line extension for the purposes of the MDR program.

If a drug meets the requirements provided in the April 2015 Food and Drug Administration's (FDA's) Guidance for Industry titled "Abuse-Deterrent Opioids- Evaluation and Labeling" (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm334743.pdf), then FDA permits the labeling of that drug to include language that the drug has demonstrated abuse-deterrent properties. Further, the approved labeling will include information about abuse-deterrent properties in section 9.2 of the Drug Abuse and Dependence section. In addition to language within the drug's labeling, for a drug approved with abuse-deterrent properties, FDA also includes a statement on the Drug Details page for the drug on Drugs@FDA: FDA Approved Drug Products that provides: "FDA has determined that this product has abuse-deterrent properties."

We recommend that manufacturers also utilize this informational statement on the Drug Details page for the drug on Drugs@FDA: FDA Approved Drug Products to determine if a drug would be excluded from the definition of line extension in section 1927(c)(2)(C) of the Act, as amended by section 705(a) of CARA. If a manufacturer has questions regarding the information that appears on Drugs@FDA: FDA Approved Drug Products or that the abuse-deterrent properties is not indicated on Drugs@FDA: FDA Approved Drug Products, it should contact FDA's Regulatory Project Manager for the application or via email to CDER-OPQ-Inquiries at CDER-OPQ-Inquiries@fda.hhs.gov, or using the Contact Us link on Drugs@FDA: FDA Approved Drug Products.

In the above referenced 2015 Guidance for Industry, FDA notes that the science of abuse deterrence is relatively new and that the methods for developing and evaluating the technologies are rapidly evolving. The guidance also states that because of the evolving nature of the field, FDA intends to take a flexible, adaptive approach to the evaluation and labeling of potentially abuse-deterrent products. Therefore, any changes implemented by FDA may potentially impact how CMS verifies whether a drug is an abuse-deterrent formulation. Additionally, FDA states in its guidance that certain circumstances may lead to a determination that labeling revisions are needed. If those circumstances lead to an FDA determination that the abuse-deterrent labeling is no longer appropriate, we clarify in this release that for the purpose of the definition of line extension, CMS intends to consider such drug as a line extension drug as of the date of the FDA re-determination.

If you have any questions regarding CMS guidance on excluding abuse-deterrent formulations from the definition of line extension, please email your questions to RxDRUGPolicy@cms.hhs.gov.

Sincerely,

/s/

Michael Nardone
Director
Disabled and Elderly Health Programs Group