

Center for Medicaid and CHIP Services

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MEDICAID DRUG REBATE PROGRAM NOTICE

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For State Technical Contacts

Limitations on Coverage of Drugs under the Medicaid Drug Rebate Program

The Centers for Medicare & Medicaid Services (CMS) is providing this guidance to states to remind them of certain limitations on Medicaid Federal Financial Participation (FFP) and manufacturer rebates under the Medicaid Drug Rebate Program (MDRP) for drugs used for cosmetic purposes or hair growth as well as those used to treat sexual dysfunction or erectile dysfunction.

21st Century Cures Act - Limitations on Drugs Used for Cosmetic Purposes or Hair Growth

Effective with respect to drugs dispensed on or after January 1, 2017, Section 5008 of the 21st Century Cures Act (Cures Act) amended Section 1903(i)(21) of the Social Security Act (the Act) to prohibit FFP for agents when used for cosmetic purposes or hair growth, except where medically necessary. The 21st Century Cures Act can be found at this link: <https://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.pdf>.

Section 1927(d)(2) of the Act lists drugs or classes of drugs, or their medical uses, that states may exclude or for which states may restrict coverage under their Medicaid state plan. For drugs dispensed prior to January 1, 2017, state coverage of covered outpatient drugs under this optional coverage provision resulted in these drugs being eligible for both FFP and for rebates under the Medicaid Drug Rebate Program (MDRP), provided the labeler of the drug had entered into a national rebate agreement with the Secretary of the Department of Health and Human Services and the state's Medicaid state plan provided for coverage of the drugs.

As a result of the Cures Act, states will no longer be able to receive FFP or collect rebates for drugs when used for cosmetic purposes or hair growth unless the state has determined that the use of these drugs is medically necessary. Therefore, any reference to these agents currently present on the state plan pages should be removed, including from the "drugs subject to exclusion" listing in the pharmacy coverage section. The following language should be used if the state determines that it will provide coverage for these agents:

"The state will cover agents when used for cosmetic purposes or hair growth only when the state has determined that use to be medically necessary."

It is recommended that states update their prior authorization requirements to ensure that claims for these drugs are medically necessary in order to claim FFP and invoice for manufacturer rebates. The Centers for Medicare & Medicaid Services (CMS) expects states that are required to modify their state plan pages to submit a state plan amendment (SPA) dated no later than March 31, 2017, with appropriate revisions with an effective date of January 1, 2017.

If the state determines it will not provide coverage for these agents, no language regarding these agents should be on the state plan pages.

QI, TMA, and Abstinence Programs Extension and Hurricane Katrina Unemployment Relief Act of 2005 - Limitations on Drugs Used to Treat Sexual Dysfunction or Erectile Dysfunction.

Section 104(a) of the QI, TMA, and Abstinence Programs Extension and Hurricane Katrina Unemployment Relief Act of 2005 (Pub. L. No. 119-91) amended section 1903(i) and section 1927(d)(2)(K) of the Act (which has since been re-designated as subparagraph (H)) to eliminate FFP for drugs "...when used for the treatment of sexual dysfunction or erectile dysfunction, unless such agents are used to treat a condition, other than sexual dysfunction or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration (FDA)." Prior to the enactment of this legislation, FFP was available for covered outpatient drugs used to treat sexual dysfunction or erectile dysfunction under the MDRP. However, with the January 1, 2006 effective date of this provision, drugs approved by FDA solely for the treatment of sexual dysfunction or erectile dysfunction became ineligible for FFP and manufacturer rebates.

CMS reminds states that a State Medicaid Director letter was issued on December 29, 2005 informing states that FFP was not available for covered outpatient drugs when used for the treatment of sexual dysfunction or erectile dysfunction that were dispensed on or after January 1, 2006. At that time, states were asked to review their state plan to determine if their plan referenced this category of drugs and to submit a state plan amendment if necessary. States should review and identify those drugs for which the only FDA-approved indication is the treatment of sexual dysfunction or erectile dysfunction, and should ensure that they are not inappropriately claiming FFP or invoicing manufacturers for rebates for such drugs. If the state's review identifies a drug that is FDA-approved for the treatment of sexual dysfunction or erectile dysfunction in addition to one or more other indications, claims for such drugs are only eligible for FFP and manufacturer rebates if the drug has been used for an FDA-approved indication outside of the treatment of sexual dysfunction or erectile dysfunction.

CMS also notes that while FDA labeling generally references the term "erectile dysfunction" in the indications for drugs used to treat erectile dysfunction, the labeled indications for drugs used to treat sexual dysfunction may not consistently reference the term "sexual dysfunction." Therefore, states may need to closely evaluate the indications for certain drugs to determine if the labeled indications represent sexual dysfunction. If such an evaluation determines that a drug is being used to treat only sexual dysfunction, and the state is covering that drug, the state should not claim FFP nor invoice for manufacturer rebates when they receive claims for that drug. States may utilize methods, such as prior authorization requirements or system edits, to ensure appropriate state coverage of drugs affected by the laws described in this guidance. For

example, states should consider implementing an edit that would always reject a claim for a national drug code (NDC) ineligible for FFP.

Additionally, states should be aware of the potential for future audits which may be initiated to determine if FFP is being inappropriately claimed for drugs affected by these laws. Such audits could lead to the recovery of improperly claimed funds or other penalties; therefore, CMS encourages states to take steps to ensure that the categories of drugs identified in this guidance are covered appropriately.

If you have any questions regarding this guidance, please contact rxdrugpolicy@cms.hhs.gov.

Sincerely,

/s/

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