



Center for Medicaid and CHIP Services

CMCS Informational Bulletin

DATE: June 15, 2012

FROM: Cindy Mann, Director
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SUBJECT: Updated FDA Statement on Compounded Versions of hydroxyprogesterone caproate (the active ingredient in Makena)

The U.S. Food and Drug Administration (FDA) updated its statement on compounded versions of hydroxyprogesterone caproate (the active ingredient in Makena) today. Please see <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm308546.htm>. As explained in a November 8, 2011 statement, FDA received information from Makena's sponsor, K-V Pharmaceuticals regarding the potency and purity of samples of bulk hydroxyprogesterone caproate active pharmaceutical ingredients (APIs) and compounded hydroxyprogesterone caproate products. As explained in the updated statement, the FDA has also conducted its own sampling and analysis of compounded hydroxyprogesterone caproate products and the bulk APIs used to make them. FDA states that the analysis of this limited sample of compounded hydroxyprogesterone caproate products and APIs did not identify any major safety problems, but noted that approved drug products, such as Makena, provide a greater assurance of safety and effectiveness than do compounded products. Finally, FDA stated that the compounding of any drug, including hydroxyprogesterone caproate, should not exceed the scope of traditional pharmacy compounding. States may, under appropriate circumstances, cover APIs as incident to another service category or, as a pharmacy service, if such coverage is consistent with the State plan.

We would like to remind States of their responsibility to cover FDA approved products, such as Makena, that qualify as covered outpatient drugs under the Medicaid drug rebate program. Any prior authorization procedures for such drugs must be administered in accordance with Section 1927(d) of the Social Security Act, without imposing unreasonable conditions.