

Center for Medicaid, CHIP and Survey & Certification

CMCS Informational Bulletin

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SUBJECT: Makena

CMCS would like to bring to the States attention the FDA news release dated March 30, 2011 concerning the status of compounded hydroxyprogesterone caproate- please see <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm249025.htm> . FDA has announced that it does not intend to take enforcement action against pharmacies that compound hydroxyprogesterone caproate based on a valid prescription for an individually identified patient unless the compounded products are unsafe, of substandard quality, or are not being compounded in accordance with appropriate standards for compounding sterile products.

Therefore, we would like States to be aware that they can choose to pay for the extemporaneously compounded hydroxyprogesterone caproate as an active pharmaceutical ingredient (API) and this can be covered under the “medical supplies, equipment and appliances suitable for use in the home” portion of home health. Because we do not require States to list all of the items they cover under this section in the Medicaid State plan, States can cover hydroxyprogesterone caproate under their current State plan and do not need to submit a State plan amendment to provide for such coverage.

If you have any questions please send them to the Medicaid Drug Policy email box at RxDRUGPolicy@cms.hhs.gov.

I hope you will find this information helpful. Thank you for your continued commitment to Medicaid and CHIP.