State of California—Health and Human Services Agency
Department of Health Care Services

JENNIFER KENT
DIRECTOR

EDMUND G. BROWN JR.
GOVERNOR

Date: June 15, 2015

CCS Information Notice: 15-03

TO: ALL LOCAL COUNTY CALIFORNIA CHILDREN'S SERVICES (CCS) PROGRAM AND GENETICALLY HANDICAPPED PERSONS PROGRAM (GHPP) ADMINISTRATORS, MEDICAL CONSULTANTS, COUNTY MEDICAL STAFF, AND SYSTEMS OF CARE DIVISION STAFF

SUBJECT: PREFERRED USE OF FOOD AND DRUG ADMINISTRATION (FDA) DRUGS OVER COMPOUNDED PRESCRIPTIONS

The purpose of this information notice is to communicate recent information received from Pharmacy Benefits Division regarding use of compounded prescriptions in lieu of FDA approved products.

The FDA and Centers for Medicare and Medicaid Services (CMS) have issued guidance to State Medicaid programs on the issue of Medicaid coverage of compounded alternatives to FDA approved product. In a question and answer statement to the FDA the following guidance is provided::

> ***Should health care professionals prescribe and patients take the FDA-approved drug product rather than the compounded product?***
>
> *If there is an FDA-approved drug that is medically appropriate for a patient, the FDA-approved product should be prescribed and used. Compounded drugs do not undergo the same premarket review (as FDA-approved drugs) and thus lack an FDA finding of safety and efficacy and lack an FDA finding of manufacturing quality. Therefore, when an FDA-approved drug is commercially available, the FDA recommends that practitioners prescribe the FDA-approved drug rather than a compounded drug unless the prescribing practitioner has determined that a compounded product is necessary for the particular patient and would provide a significant difference for the patient as compared to the FDA-approved commercially available drug product.*

The Department of Health Care Services also issued a policy letter (PL 14-002, dated February 19, 2014, attached) informing Medi-Cal managed care plans of existing law and Federal CMS policy requirement to use FDA approved and nationally marketed

drugs. Fee-for-Service Medi-Cal (including CCS and GHPP) services also falls under this policy.

Pharmacy Benefits Division recommends the following:

If there is a FDA approved branded product available in the marketplace, that product must be used. If a compounded product is to be dispensed in place of the FDA approved product, a TAR (or SAR) must be submitted showing the medical (clinical) necessity for the compounded product and documenting why the FDA approved product is not medically adequate or appropriate for the particular case involved. Approval is based solely on clinical justification and not on fiscal concerns or convenience.

If you have any questions, please contact Edan Lum, Pharm D., Pharmaceutical Consultant, at (916) 322-1543 or (510) 286-0708, or via email at edan.lum@dhcs.ca.gov

ORIGINAL SIGNED BY LOUIS R. RICO

Louis R. Rico, Chief
Systems of Care Division

Attachment

State of California—Health and Human Services Agency
Department of Health Care Services

TOBY DOUGLAS
DIRECTOR

EDMUND G. BROWN JR.
GOVERNOR

DATE: February 19, 2014

POLICY LETTER 14-002

TO: ALL MEDI-CAL MANAGED CARE HEALTH PLANS

SUBJECT: REQUIREMENT TO USE FOOD AND DRUG ADMINISTRATION APPROVED DRUGS, RATHER THAN COMPOUNDED ALTERNATIVES

PURPOSE:
The purpose of this Policy Letter (PL) is to inform Medi-Cal managed care health plans (MCPs) that existing law and policy require the use of Food and Drug Administration (FDA) approved and nationally marketed drugs unless a medical necessity can be established requiring the use of a compounded alternative.

BACKGROUND:
There have been recent reports of untoward quality and adverse effects of drugs from compounding pharmacies, including multiple cases of infection. Random testing of compounded products has revealed discrepancies in the percent of active ingredients present in the compound compared to the product's label. Additionally, federal oversight agencies have confirmed that a number of compounding pharmacies have exceeded the limitations placed on the quantity and frequency of distribution of compounded pharmaceuticals particularly when FDA-approved and nationally marketed drug alternatives exist.

In response, the FDA has recently clarified existing policies governing the dispensing of compounded drug products which have not been FDA-approved. The most recent guidance document can be accessed at:

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377052.pdf.

Additionally, on November 27, 2013, President Obama signed the Drug Quality and Security Act that contains important provisions relating to the oversight of compounding of human drugs. This act may be accessed at:

http://beta.congress.gov/bill/113th/house-bill/3204.

FDA guidance related to the passage of this Act may be accessed at:

http://www.fda.gov/drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/.

In a statement issued June 15, 2012, the Centers for Medicare & Medicaid Services (CMS) reminded states "…of their responsibility to cover FDA-approved products… that qualify as covered outpatient drugs under the Medicaid drug rebate program." CMS also noted: "Any prior authorization procedures for such drugs must be administered in accordance with Section 1927(d) of the Social Security Act."

In a Question-and-Answer statement issued on June 29, 2012, the FDA addressed the issue of utilizing a compounded drug alternative as follows:

> ***Should health care professionals prescribe and patients take the FDA-approved drug product rather than the compounded product?***
>
> *If there is an FDA-approved drug that is medically appropriate for a patient, the FDA-approved product should be prescribed and used…Compounded drugs do not undergo the same premarket review (as FDA-approved drugs) and thus lack an FDA finding of safety and efficacy and lack an FDA finding of manufacturing quality. Therefore, when an FDA-approved drug is commercially available, the FDA recommends that practitioners prescribe the FDA-approved drug rather than a compounded drug unless the prescribing practitioner has determined that a compounded product is necessary for the particular patient and would provide a significant difference for the patient as compared to the FDA-approved commercially available drug product.*

REQUIREMENTS:
To ensure the safety and efficacy of drug products provided to all Medi-Cal beneficiaries, the Department of Health Care Services (DHCS) requires the use of FDA-approved and nationally marketed drugs unless a medical necessity can be established requiring the use of a compounded alternative. Additionally, federal law restricts the amount of compounded drugs produced and the frequency of distribution by compounding pharmacies to only that which is needed to provide for a specific, predetermined need.

MCPs must ensure that its providers dispense the FDA-approved product when one is available in the marketplace. Compounded products may be dispensed only when a FDA-approved therapeutic equivalent does not exist in the marketplace or when the FDA-approved product does not meet the medical needs of the patient and a compounded alternative is medically necessary. Routine use of compounded alternatives to FDA-approved drugs not only poses a risk to the patient's health but also places DHCS at risk of actions taken by CMS and/or the FDA.

If you have any questions regarding this PL, please contact Dr. Sarah Royce, Chief, Medical Policy Section, at (916) 650-0113 or Sarah.Royce@dhcs.ca.gov.

Sincerely,

ORIGINAL SIGNED BY MARGARET TATAR

Margaret Tatar
Assistant Deputy Director
Health Care Delivery Systems