

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



California
Department of
Health Services

SANDRA SHEWRY
Director



ARNOLD SCHWARZENEGGER
Governor

DATE October 26, 2006

MMCD All Plan Letter 06008

TO: ALL MEDI-CAL MANAGED CARE HEALTH PLANS

SUBJECT: CONTRACEPTIVE DEVICES

Purpose:

This letter is to remind all plans that in accordance with California state law and contracts with the California Department of Health Services (CDHS) only Federal Food and Drug Administration (FDA) approved contraceptive drugs, devices and supplies (contraceptives) are provided to beneficiaries enrolled in the Medi-Cal Managed Care Program.

Background:

Through an ongoing investigation by CDHS beginning in 2005, eight physicians participating in the Medi-Cal and Family PACT programs in Southern California have been identified as having obtained intrauterine devices (IUDs) from unlicensed private parties, internet vendors, and other sources in Mexico. The physicians under investigation failed to provide any evidence that they had purchased federally approved IUDs from FDA approved sources. Because these IUDs had not been properly obtained, their safety and effectiveness were unknown. Subsequently, in 2006, CDHS conducted a sample review of records of an additional 100 providers enrolled in Medi-Cal and Family PACT across the state. As of the date of this All Plan Letter, 22 of these 100 providers are suspected of using illegal IUDs. Of these 22 suspected providers, 12 are part of one or more Medi-Cal managed care health plan provider networks, primarily in Southern California.

Standard of Care Policy:

All drugs and medical devices, including IUDs, must be approved by the FDA before they are marketed, distributed or used in the United States. California law requires physicians to provide IUDs that are FDA approved and purchased from a licensed distributor in the United States:

“A health care service plan contract that provides coverage for outpatient prescription drug benefits shall include coverage for a variety of federal Food and Drug Administration approved prescription contraceptive methods designated by the plan. In the event the patient’s participating provider, acting within his or her scope of practice, determines that none of the methods designated by the plan is medically appropriate for the patient’s medical or personal history, the plan shall also provide coverage for another federal Food and Drug Administration approved, medically appropriate prescription contraceptive method prescribed by the patient’s provider” (California Health and Safety Code 1367.25 (1)).”

California and federal laws are the basis for the standards of care and services in providing contraceptive drugs, devices or supplies to enrolled beneficiaries by Medi-Cal managed care plans and their providers. Further, managed care contracts require compliance with applicable state and federal laws.

Discussion:

CDHS has directed the original eight physicians found using illegal IUDs to notify, via certified mail, all patients who received an IUD from January 1, 2005, to the present, and provide to CDHS a copy of each notification sent to Family PACT and Medi-Cal beneficiaries. The letters advise patients that if the IUD has already been removed they do not need to take any action. If the patient still has an IUD, the letter recommends that the patient consult with her physician to consider whether to leave the IUD in place, have it replaced with an FDA approved IUD or have it removed and switch to another method of birth control. For patients still eligible for Family PACT or Medi-Cal services, there is no cost for these services.

Medi-Cal does not pay for drugs or medical devices that are not approved by the FDA or CDHS. Drugs and medical devices must also be purchased from authorized sources. Billing the Medi-Cal program for unapproved drugs or devices may constitute a fraudulent claim. As you are aware, plans are under legal and contractual obligation to report all suspected incidents of fraud. Reports should be made to the MMCD Program Integrity Unit at (916) 449-5000, email at PIUCASES@dhs.ca.gov, or fax at

(916) 440-5287. Investigations regarding this issue will continue. CDHS may be conducting future on-site visits, both announced and unannounced.

We greatly appreciate your cooperation regarding these serious issues. If you have any questions, please contact Dr. Michael Farber, Chief of the Medical Policy Section at (916) 449-5149.

Sincerely,

A handwritten signature in black ink that reads "Vanessa M Baird". The signature is written in a cursive style with a large initial "V" and "B".

Vanessa M. Baird, MPPA, Chief
Medi-Cal Managed Care Division