

UPDATED INFORMATION

Medi-Cal Bulletin

September 2006

Clinics and Hospitals
General Medicine

Consolidated Inpatient and Outpatient Services
Obstetrics

IUD Investigation Alert

This is to remind providers that the Federal Food and Drug Administration (FDA) must approve all drugs and medical devices, including IUDs, before they are marketed, distributed or used in the United States. Medi-Cal and Family PACT do not pay for drugs or medical devices that are not approved by the FDA or the California Department of Health Services (CDHS). Drugs and medical devices are also required to be purchased from authorized sources. Billing the Medi-Cal or Family PACT program for unapproved drugs or devices may constitute a fraudulent claim.

An ongoing investigation by CDHS has identified eight southern California physicians participating in Medi-Cal and Family PACT, who have obtained IUDs from unlicensed private parties, Internet vendors, and sources in Mexico. CDHS is reviewing records of these physicians and will recover Medi-Cal and Family PACT funds paid for providing IUDs that were not approved by the FDA or not purchased from sources authorized under state and federal law. CDHS is conducting a wider review of the records of providers across the state enrolled in Family PACT and Medi-Cal. Results of this review will be shared with the FDA.

The patients of the eight physicians were sent a letter advising them to consult with their doctor, or another Family PACT or Medi-Cal doctor to discuss their choices. The risk of harm to these patients is unknown. A copy of the letter sent to these patients is attached for your reference.

Today's date

Ms. Jane Doe
1234 Main Street
Frostbite Falls, MN

Dear Ms. Doe;

I am writing to tell you about the birth control device that you had inserted at this office. When your IUD, or intrauterine device, was inserted, some of the IUDs that were used may have been purchased in violation of state and federal law.

You may not have had any problems with your IUD and there may be no reason for concern. However, the safety and effectiveness of your IUD is unknown. Therefore, I recommend that you schedule an appointment with this office or any other Medi-Cal or Family PACT doctor or clinic to discuss these choices:

1. If your IUD has already been removed you don't need to do anything.
2. If you still have your IUD, you should discuss your options with me or another doctor. These options include:
 - Do nothing. You may have the IUD removed as originally scheduled.
 - Have your IUD removed and replaced.
 - Have your IUD removed and pick another method of birth control.

The doctor you talk to may wish to do an examination and test before discussing your options with you. There will be no cost to you for any of the choices you pick if you are eligible for the Medi-Cal or Family PACT program.

I can work with you to help decide the best choice for you. If you are interested in discussing any of these options, or if you have more questions, please schedule an office visit by calling, xxx-xxx-xxxx.

To contact the Medi-Cal or Family PACT program to ask questions or to locate another nearby Medi-Cal or Family PACT doctor or clinic for services, please call 1-866-781-0330. If you visit another Medi-Cal or Family PACT doctor or clinic, please show them this letter to explain the reason for your visit. If you no longer have Medi-Cal or Family PACT eligibility, you can discuss the situation with me.

I regret any inconvenience that this may cause you. Thank you for your prompt attention to this letter.

Sincerely,

Dr. Smith

Note to Medi-Cal or Family PACT Providers: if a Medi-Cal or Family PACT patient presents this letter and you wish to receive more background information, please call **1-866-781-0330**.