



Memorandum

Date: June 25, 1993

From: Acting Deputy Assistant Secretary for Population Affairs

Subject: OPA Program Instruction Series, OPA 93-1: Deferred Physical Examinations for Title X Clients

To: Regional Health Administrators
Regions I-X

The issue of deferral of physical examination for clients beginning oral contraceptives was recently addressed by the Food and Drug Administration's (FDA) Fertility and Maternal Health Drugs Advisory Committee. Current FDA labeling criteria for oral contraceptives require a complete medical history and physical examination prior to initiation or commencement of oral contraceptives. The Committee recommended to the FDA that oral contraceptive labeling be revised to permit the provision of oral contraceptives prior to a physical examination, and it is likely that this will be approved by FDA in the near future.

Title X has traditionally taken the position that grantees should conform to current FDA policy as expressed in its labeling standards for contraceptives. OPA continues to be of the view that this policy is appropriate and is, as a general practice, reluctant to waive Guideline criteria which involve conformance with requirements under FDA labeling instructions.

However, it is highly probable that prescription of oral contraceptives prior to physical examination will be regularly allowable in Title X projects in the near future, as it appears likely that the FDA will change its labeling instructions in this regard. The evolution of standards of practice in this area, and the strong support of the FDA Advisory Committee and national reproductive health organizations during the discussion of this issue point to the resultant probability that FDA will indeed change its requirements.

Therefore, until FDA makes a final decision on this issue, the Office of Population Affairs is providing authorization to Regional Health Administrators to waive current policy on the requirement for a physical examination on a case-by-case basis. To ensure patient safety, no request for waiver of current standards should be approved unless the following requirements are met:

- o Physical examination and any blood work should not be delayed for more than 3 months after the initial visit. Substantial justification is warranted for projects that propose as a general practice to defer the examination beyond the 3-month period. In no case may deferral of the physical examination be extended beyond a maximum of 6 months.

- o Counseling regarding contraceptive choice, STD protection and the need for a physical examination (after deferral) must be provided to each client at the initial visit.
- o Written informed consent and medical protocols for delayed examinations must be developed and approved by the project's medical committee.

Informed Consent: Clients must sign an informed consent form describing the special process for the delayed examination and explaining the patient package insert information accompanying oral contraceptives.

Medical Protocols must:

-- Outline what medical, educational and counseling services will be provided at each point leading up to the examination (i.e., initial visit, follow-up counseling, telephone follow-up, visit for physical examination and blood work).

-- Provide for verification through a highly sensitive pregnancy test that the client is not pregnant.

-- Provide that the project will obtain at the initial visit a comprehensive medical history (including menstrual history, pregnancy history, contraceptive history, and sexual history) which demonstrates that the client is healthy and has no contraindications for oral contraceptives.

-- Provide that the project will ensure that clients have no symptoms or reported contact with sexually transmitted diseases (STDs); are provided with information on oral contraceptives and condoms for STD prevention; and have a negative breast examination for women over age 30.

-- Provide that the project will ensure that any medical problems associated with the delayed examinations must be documented.

If you have any questions, please contact me or Dr. Barbara Tausey, OPA Chief Medical Officer.

/s/

Jerry Bennett