Physician Substitutes (8/15/88)

DATE: 15 August 1988

FROM: Director, Center for Biologics Evaluation and Research

SUBJECT: Physician Substitutes

TO: All Licensed Manufacturers of Source Plasma

This memo updates recommendations of 14 December 1984, for the duties performed by adequately trained physician substitutes approved under provisions of 21 CFR 660.75. Adequately trained physician substitutes may perform some of the routine functions of a physician provided the following requirements are met:

1. The physician substitute must be a graduate of a recognized educational program such as nursing, emergency technician or physician assistant and be currently licensed or certified in the state. The physician substitute must maintain current certification in cardiopulmonary resuscitation (CPR).

2. The establishment must have a training program of at least 5 weeks duration and a job description or statement of responsibilities for the physician substitute. The description of duties should clearly define the limits of authority and provide specific instructions concerning handling medical emergencies and directions for consulting the medical director or plasma center physician. Descriptions of the training program and the job responsibilities must be submitted in writing to the FDA for review and approval prior to the initiation of any person in the training program.

3. After completion of training, the physician who is responsible for the training must evaluate the individual's performance of assigned duties in the plasma center. A copy of the physician's evaluation, and the physician substitute's curriculum vitae, license or certificate, and signed statement of understanding should be submitted to the FDA for approval.

4. The physician substitute's function may include evaluation of normal healthy donors for both manual and automated apheresis procedures, and "disease state donors" when such donors meet the criteria for normal plasma donors. Physician substitutes are not authorized to replace physicians in programs that collect Therapeutic Exchange Plasma (TEP) or plasma from donors who test reactive for HBsAg or positive for antibody to HIV.

5. Physician substitutes may administer or supervise all approved immunizations except red blood cell immunizations, provided they satisfactorily undergo an additional week of training. This training should include procedures relevant to

the approved immunizing agents, knowledge of the hazards of immunizations, so as to obtain appropriate informed donor consent, and details of unexpected adverse donor reactions by the immunizing agents and how to handle them. The plasma center physician continues to be responsible for at least weekly evaluation and review of the donor immunization record and approval of scheduled injections. To facilitate evaluation of specific programs, we recommend keeping the required records of all adverse reactions related to immunization in a format that permits easy retrieval and analysis.

For further information or certification of the procedure, contact Andrea Casper, Division of Blood and Blood Products at (301) 456-0952.

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