Physician Substitutes (12/14/84)

December 14, 1984

FROM: Acting Director, Office of Biologics Research and Review

SUBJECT: Physician Substitutes

TO: All Manufacturers of Source Plasma (Human)

Under the provisions of 21 CFR 640.75, the Office of Biologics Research and Review is now approving adequately trained physician substitutes to perform some of the routine functions of a physician, provided the following requirements are met:

1. The physician substitute must have appropriate basic education in the health care profession and must have formal on-the-job training in plasmapheresis. The physician who is responsible for the training must evaluate the individual's performance of assigned duties in the plasma center at the conclusion of a training period of at least 5 weeks duration. A description of the training program must be submitted along with the curricula vitae for the physician substitute and for the physician responsible for the training program.

2. Submit a copy of the physician substitute job description or statement of responsibilities. The description of duties must clearly define the limits of his or her authority and must provide specific instructions concerning the accessing of medical care and/or consulting a physician in case of emergencies.

3. The substitute's functions must be limited to manual pheresis procedures on healthy donors. The use of physician substitutes for matters related to automated pheresis, therapeutic plasma exchange or "disease state donors" is not approved.

4. Of a physician substitute will be responsible for the administration of tetanus toxoid, a 6 week training period which includes a specific component dealing with the procedures and hazards related to immunization of donors with tetanus toxoid is required. The physician should evaluate and review all immunization records at least weekly.

At the present time, substitutes for physicians are not acceptable in any immunization program except tetanus. All procedures related to donor immunization are under review, and future changes are anticipated. To facilitate evaluation of specific programs, we recommend keeping records of all adverse reactions related to immunization in a format that permits easy

retrieval and analysis.

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