

Republic of the Philippines Department of Health OFFICE OF THE SECRETARY

July 9, 1973

ADMINISTRATIVE ORDER No. 193 Series of 1973

AMENDMENTS TO SECTIONS 3, II, 13 & 23 of THE REVISED RULES AND REGULATIONS GOVERNING THE COLLECTION, PROCESSING AND SALE OF HUMAN BLOOD AND THE ESTABLISHMENT AND OPERATION OF BLOOD BANKS AND BLOOD PROCESSING LABORATORIES.

SECTION 1 - The provisions of Sections 3, 11, 13 & 23 of the Revised Rules and Regulations Governing the Collection, Processing and sale of Human Blood and Establishment and Operation of Blood Banks and Blood Processing Laboratories are hereby amended to read as follows:

Section 3- Basic License Requirement - Any person, firm, or corporation desiring to establish or operate a blood bank and/or blood processing laboratory, or desiring authority to collect process, and distribute wheter for free or for sale human blood, shall submit to the Secretary of Health, thru the Bureau of Research and Laboratories, a sworn petition/application, said form prepared and adopted therefore, and containing among others the following date: (1) the name of the establishment; (2) the physical location or address; (3) the name and domicile of the head or supervisor of the blood bank; (4) the name, citizenship and domicile of the owner; (5) statement that applocant has complied with all business requirements under other existing laws or ordinances that are necessary in pursuance of the activity for which a license is herein aplied for; (6) a tax clearance for preceding year and tax account clearance for the preceding year and tax account number. A separate certificate as to the character fitness of the owner/s to engage in blood banking, to be issued by responsible government health official, or a member of the Philippine Medical Association or its affiliate societies in the locality, must also be submitted. An inspector of the Bureau of Research and Laboratories shall upon receipt of said application, inspect within 60 days the establishment and verify if the applicant has complied with the requirements prescribed in these regulations. The application will then be forwarded by the Director of the Bureau of Research and Laboratories to the Secretary of Health for approval and signature of the necessary license or for any other appropriate action.

Section 11 - General Requirements for issuance of License - An application for license will be approved if:

(a) The application is for non-profit basis, i.e. blood shall be sold at cost. The regular charge shall not be less or more than that set by the Bureau of Research and Laboratories from time to time in consultation with the appropriate specialty societies.

- (b) The laboratory establishment satisfied the scientific standards as contained in Sections 13 and 14 hereof.
- (c) No material false statement or mistatement of conditions verified on inspection have been made in the application.
- (d) The owner, manager, operator or administrator must not have had any record of illegal operation of blood bank and/or clinical laboratory or the supervisor or physician-in-charge, a record of connection with a blood bank and/or clinical laboratory that has been illegally operating.

Section 13 - Requirement for a Blood Bank and/or Blood Processing Laboratory.

A. Personnel — Blood Banks and Blood Processing Laboratories shall be under the direction and supervision of a licensed and qualified physician with training in Blood processing and operation in a duly accredited Blood Bank. All technical assistants involved in the technical aspect of blood banking, should be either registered physicians or registered Medical Technologist. The Physician-in-charge shall be authorized to head manage or supervise not more than three (3) blood banks centinguously located in the particular area. The physician-in-charge shall be authorized to head, manage or supervise only one blood bank with outlets.

B. Physical Plant:

(7) A reception or waiting room for donors should be provided for which is spacious enough for the confort of the donors. The donors should not be allowed to wait, congregate or loiter outside the blood banks.

Section 23 — Modification and Revocation of License

- a. Any license may be revoked, or suspended in whole or in part, for any material false statement in the application or because of conditions revealed by such application or statement of fact or any report or record of inspection which would warrant the Secretary of Health to refuse to grant a permit on an original application, or for a violation of or failure to observe any of the terms and provisions of these regulations.
- b. Except in cases of willfullness or those in which the public health interest, or safety requires otherwise, no permit shall be suspended or revoked unless, prior to the institution of preceding therefore, facts or conduct which may warrant such action shall have been called to the attention of license in writing and the license shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.
- c. Revocation of license on the ground of illegal operation shall automatically disqualify the owner and Physician-in-charge to open a new blood bank and/or clinical laboratory and to supervise other blood banks and/or clinical laboratories respectively pending the final resolution of the case in

court.

Section 2 - These amendments shall take effect upon approval and required publication.

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Secretary of Health