Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

March 25, 1992

ADMINISTRATIVE ORDER
No. 122, s. 1992

Subject: HEPATITIS B SURFACE ANTIGEN (HBsAg) AND HUMAN IMMUNO-DEFICIENCY ANTIBODY (HIV Ab) POSITIVE UNITS OF BLOOD: DOH POLICY, PROCEDURES TO BE FOLLOWED AND SANCTIONS FOR VIOLATIONS.

The Bureau of Research and Laboratories (BRL) is mandated by the Rules and Regulations governing Blood Banks (Administrative Order No. 57, s. 1989) promulgated pursuant to the Blood Bank Law (R. A. 1517) to ensure the safety of the blood that is collected, formulated the "Technical Standards Governing the Collection,
Processing and Operation of Blood Banks in the Philippines (Bur.
Order No. 5, s. 1990) and issued Bur. Circular No. 1, s. 1990
(Disposal of HBsAg and HIV Ab positive Units of Blood) and Bur. Circular No. 2. s. 1990
(Screening of all blood units for HBsAg, HIV Ab, malaria and syphilis).

1., As. stated in the two (2) Bureau Circulars (Nos. 1 and 2, 1999), it is the policy of the Department of Health that:

1.1 All units of blood shall be tested for HBsAg, HIV Ab, malarial parasites, and STS by the blood collecting center (Blood Bank) prior to issuance.
1.2 Only units of blood which are negative for all of the above tests shall be issued by a Blood collecting center (Blood Bank) prior to issuance.

1.3 Any unit of blood found to be positive for HBsAg or HIV Ab by either the Blood bank or hospital laboratory should be reported and submitted to the BRL in Metro Manila or to Regional Health Laboratory in the regions/provinces.

2. To ensure the implementation of these policies, the following procedures are to be followed:

2.1 A blood collecting center/Blood Bank shall test each donor/unit of blood for HBsAg, HIV Ab malarial parasites and scologic test for Syphilis
(STS) prior to issuing the unit of blood.

Although this Administrative Order focuses on laboratory testing of blood, it is understood that all donors shall be screened by history, physical examination and laboratory tests as prescribed in

Section 6, VI Donor Requirements (Screening) in Bureau Order No. 5, s. 1990 (Technical Standards).

2.2 No unit of blood may be issued by a blood bank to a transfusion facility hospital unless it has been tested for the above infectious agents and; found to be negative except when expressly exempted by the BRL under conditions stipulated in Bureau Circular No. 1, s. 1991 (Exemption From The Requirement of Screening of Units of Blood For
Hepatitis B surface Antigen (HBsAg) and Human Immunodeficiency Virus (HIV) Antibody by Blood Banks Prior to Issuance to Hospitals).

2.3 A hospital laboratory MAY retest a unit of blood for HBsAg or HIV Ab in accordance with hospital practice/policy or upon request of the attending physician/consultant.

2.4 If the unit of blood is found to be positive for HBsAg or HIV Ab, the laboratory personnel should:

2.4.1 Inform the blood bank by telephone and issue a written report of the results.

2.4.2 Inform the BRL/Regional Health Laboratory and arrange for its transport to that laboratory.

2.4.3 Store the unit of blood under the proper conditions.

2.5 The issuing blood bank should replace immediately the unit of blood without additional charge.

2.6 If the blood bank desires, it may obtain a segment of donor tubing from the unit of blood together with the written report and retest the blood sample.

2.7 If the blood bank is not satisfied with the hospital laboratory report due to discrepancy with its own testing, it may request in writing the BRL to confirm the proper result of HBsAg/HIV Ab testing. The written request should indicate the method and brand of reagent used by both the blood bank and hospital laboratory.

2.8 Upon submission of the blood bag and written request to the BRL, the appropriate laboratory fee shall be paid by the blood bank.

2.9 If the BRL confirms the unit to be positive for HBsAg/HIV Ab, the blood bag shall be retained by BRL for proper disposal. This incident shall be considered a violation of this policy by the blood bank attributable to the date it was issued to the hospital.

2.10 If the BRL finds that the unit of blood is negative for HBsAg repeatedly by ELISA, it will be returned to the hospital for disposition. If the BRL finds that the unit of blood is negative for HIV Ab by at least two (2) screening methods the unit shall be discarded as per WHO Guidelines on HIV Testing Strategies and therefore retained by BRL. In both cases, the hospital will be billed for

the unit of blood under question.

2.11 All results of testing for HBsAg/HIV so by BRL shall be recorded on report forms and copies will be sent to the Blood Bank and hospital laboratory.

3. Sanctions for Violations of DOH Policy on contaminated blood:

3.1 Definition: A violation of the policy will include:

1) Issuing a unit of blood that has not been screened for HBsAg/HIV/malaria/syphilis.

2) Issuing a unit of blood that is positive for HBsAg/HIV/malaria/syphilis.

3) Failure to report and submit to BRL or appropriate Regional Health Laboratory by the blood bank or hospital laboratory unit of blood which is found to be positive for HBsAg/HIV Ab. If the report is not done within twenty four (24) hours, this would constitute a violation.

4) when a unit of blood is found to be positive for HBsAg/HIV Ab/malaria/syphilis by the BRL. upon random testing of blood issued by a blood bank or in the inventory of a blood bank stored at a place reserved for units cleared (and labeled for issuance.

3.2 Each act of issuance or failure to report or random testing as stated above (3.1) shall be considered as one violation regardless of the number of units involved.

3.3 Sanctions to be applied for each violation as defined in 3.1 and stipulated in 3.2, resulting in the issuance, non—reporting, or finding at random testing by BRL of HIV positive blood shall be:

1) For the FIRST Violation — the license to operate the blood bank or hospital laboratory shall be suspended for two (2) weeks and the medical technologist shall undergo refresher training if found necessary. The physician—in—charge shall demonstrate that he is competent in HBsAg/HIV Ab testing and promise to adequately supervise the blood bank /hospital laboratory.

2) For the SECOND Violation the license to operate the blood bank or hospital laboratory shall be suspended for one (1) month and the medical technologist and/or physician-in- charge involved shall be reported to the Professional Regulation Commission for negligence and malpractice.

3) For the THIRD Violation — the license to operate the blood bank or hospital laboratory shall be revoked. The medical technologist and physician—in—charge shall be reported to the Professional Regulation Commission for malpractice and recidivism without prejudice to pursuing a criminal court action.

4. Sanctions to be applied for each violation- as defined in 3.1rand stipulated in 3.2 resulting in the issuance of unscreened blood, or issuance, non-reporting or finding on random testing by BRL of

HBsAg/malaria/syphilis positive blood, shall be:

1) For the FIRST Violation - the license to operate the blood bank or hospital laboratory shall be suspended for one (1) week. If the violation was due to a technical error, the medical technologist shall undergo refresher training at the BRL or other training laboratory acceptable to BRL during the period of suspension.

2) For the SECOND Violation 1 the license to operate the blood bank or hospital laboratory shall be suspended for two (2) weeks and the medical technologist shall undergo refresher training if found necessary. The physicians-in—charge shall demonstrate that he is competent in HBsAg/HIV Ab testing and promise to adequately supervise the blood bank /hospital laboratory.

3) For the THIRD Violation — the license to operate the blood bank or hospital laboratory shall be suspended for one (1) month and the medical technologist and/or physician-in—charge involved shall be reported to the Professional Regulation Commission for negligence and malpractice.

4) For the FOURTH Violation - the license to operate the blood bank or hospital laboratory shall be revoked. The medical technologist and physician—in-charge shall be reported to the .Professional Regulation 'Commission for malpractice and recidivism without prejudice to pursuing a criminal court action.

4. The BRL shall monitor the implementation, of this policy, investigate any complaints and recommend to the Undersecretary of Health for Standards and Regulations any sanctions that would be applied to issuing bleed banks or hospital laboratories in accordance to A.O. 57, s. 1989 (Revised Rules and Regulations Governing the Collection, Processing and Provision of Human Blood and the Establishment and Operation of Blood Banks).
5. Any Administrative Order or Circular or provision thereof inconsistent with this Administrative Order is hereby repealed.

6. This 'Administrative order shall be effective two (2) weeks after publication in a newspaper of general circulation.

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