

**[DOH ADMINISTRATIVE ORDER NO. 2005-0002,
January 10, 2005]**

**RULES AND REGULATIONS FOR THE ESTABLISHMENT OF THE
PHILIPPINE NATIONAL BLOOD SERVICES AMENDING
PERTINENT PROVISIONS OF ADMIN. ORDER NO. 9, S. 1995
(RULES AND REGULATIONS IMPLEMENTING R.A. 7719
OTHERWISE KNOWN AS THE NATIONAL BLOOD SERVICES ACT
OF 1994)**

SECTION 1. Rationale - Republic Act 7719 otherwise known as the "National Blood Services Act of 1994" provides that the following are policies of the state:

- a. To promote and encourage voluntary blood donation by the citizenry...;
- b. To provide for adequate, safe, affordable and equitable distribution of blood and blood products;
- c. To mandate the Department of Health to establish and organize a National Blood Transfusion Network in order to rationalize and improve the promotion of adequate and safe supply of blood;"

Pursuant to Section 5. National Voluntary Services Program (NVBSP), of R.A 7719, the Department of Health, in cooperation with the PNRC and PBCC and other agencies and organizations have planned and implemented a NVBSP to meet in an evolutionary manner, the needs for blood transfusion in all regions of the country. One of the goals of the NVBSP Strategic Plan for 2004-2008 is: "2. Strengthening of a nationally coordinated network of Blood Service Facilities to increase efficiency by Centralized Testing and Blood Component Processing as well as improved blood collection and distribution systems."

The Centralization of collection, testing and processing of blood and its components is a global strategy advocated by the WHO in the provision of an adequate supply of safe blood. The high volume of activities, especially in testing and processing of blood promotes efficiency and competency, thus ensuring the quality of blood products. Furthermore, the high volume blood banking procedures make automation cost-effective and can take advantage of discounts in the bulk purchasing of reagents, glassware and supplies.

These Rules and Regulations are promulgated for the establishment of the Philippine National Blood Services (PNBS) pursuant to Section 5. National Voluntary Services Program and Section 6. Upgrading of Services and Facilities, of RA 7719 and amending pertinent provisions of Administrative Order No. 9, s. 1995 entitled the "Rules and Regulations Implementing Republic Act No. 7719 otherwise known as the National Blood Services Act of 1994" specifically the following sections:

- Section 4. Definition of Terms
- Section 5. National Program Committee
- Section 6. Field Representative of National Committee
- Section 7. DOH Program Management
- Section 8. Program Funding
- Section 12. Establishment of Blood Services Network
- Section 14. Monitoring and Evaluation Sub-Committee
- Section 15. DOH Regional Hospitals and Medical Centers
- Section 16. Provincial and District Hospitals
- Section 17. Blood Banks/Center with Special Functions
- Section 25. Operation and Maintenance of Blood Service Facilities
- Section 35. Allowable Service Fees
- Section 38. Standard Operating Manual
- Section 39. Quality Assurance Officer
- Section 40. Confirmation of Voluntary Donors
- Section 41. Emergency Blood Transfusion
- Section 42. Certification of Importation Privileges
- Section 43. Equipment and Materials Covered
- Section 44. Application for Tax Exemption

SECTION II. SCOPE/COVERAGE - These Rules and Regulations shall cover all facilities, both government and private, all over the country that provide blood services.

SECTION III. DEFINITION OF TERMS -

A. BLOOD SERVICE FACILITY (BSF) - a unit, agency or institution providing blood products. The types of BSF, i.e., Blood Station, Blood Collection Unit, Hospital Blood Bank and Blood Center (Regional, Subnational and National) are defined below.

B. BLOOD STATION (BS) - a blood service facility duly authorized by the Department of Health (DOH) Center for Health Development (CHD) pursuant to A.O 101-A s. 2003 with the following service capabilities:

1. Provision of whole blood and packed red cells;
2. Storage, issuance of whole blood and packed red cells;
3. Compatibility testing of red cell units, if hospital-based.

C. BLOOD COLLECTION UNIT (BCU) - a blood service facility duly authorized by the DOH CHD pursuant to A.O. 101-A, s. 2003 with the following service capabilities:

1. Recruitment and retention of voluntary blood donors;
2. Screening and selection of qualified voluntary blood donors;
3. Conduct of health education and counseling services;
4. Collection of blood from qualified voluntary blood donors;
5. Transport of blood units collected to blood center for testing, processing and distribution to hospitals and other health facilities.

D. APHERESIS FACILITY - a blood service facility where blood collection procedure is done in which whole blood is removed, a selected component separated and the remainder returned to the donor.

E. HOSPITAL BLOOD BANK - a blood service facility in a hospital duly licensed by the DOH Bureau of Health Facilities and Services (BHFS) with the following service

capabilities:

1. Storage of whole blood and blood components obtained from a blood center or another hospital
2. Compatibility testing of red cell units
3. Direct Coombs Test
4. Red Cell antibody screening
5. Investigation of transfusion reactions
6. Assist the Hospital Blood Transfusion Committee (HBTC) in the conduct of post-transfusion surveillance (hemovigilance)

F. BLOOD CENTER - a blood service facility licensed by the DOH BHFS with the following service capabilities:

1. Donor recruitment/retention and care of voluntary blood donors,
2. Collection of blood (mobile or facility based) from qualified voluntary blood donors,
3. Processing and provision of blood components
4. Storage, issuance, transport and distribution of units of whole blood and/or blood products to hospitals and other health facilities.
5. For National and Subnational and selected Regional Blood Centers only:

testing of units of blood for 5 infectious disease markers (Anti-HIV 1/2, Anti-HCV, HBsAg, Syphilis, Malaria)

The Blood Centers shall be classified into Regional, Subnational and National whose service capabilities will be determined by the National Council for Blood Services (NCBS).

G. END-USER HOSPITAL (EU) - a hospital with a licensed clinical laboratory capable of red cell typing and cross-matching and which does not have any blood service facility but which only receives blood and blood components for blood transfusion as needed.

H. END-USER NON-HOSPITAL HEALTH FACILITY - a licensed/accredited non-hospital health facility without a licensed clinical laboratory but which administers blood transfusion.

I. BLOOD SERVICES NETWORK - an informal organization composed of the designated blood centers and hospital blood banks, blood stations and end-user hospitals established to provide for the blood needs of a specific geographical area.

SECTION IV. Structural Organization and Management of the Philippine National Blood Services -

A. The Blood Services Network shall consist of:

1. National Council for Blood Services and its various committees
2. Philippine National Blood Services (National, Subnational and Regional Blood Centers)
3. Authorized Blood Collection Units and Apheresis Facilities

4. Hospital Blood Banks and Blood Stations, both government and private
5. End-User Hospitals and Non-Hospital Health Facilities, both government and private
6. National Reference Laboratories for Immunology and Immunoematology

B. National Council for Blood Services

1. The National Council for Blood Services shall be the governing body of the Philippine National Blood Services.

2. Composition:

The National Council for Blood Services shall be chaired by the Secretary of Health. It shall be composed of, but not limited to the Heads or Representatives of the following Offices and Associations subject to qualifications:

- 2.1 Philippine National Red Cross
- 2.2 Philippine Blood Coordinating Council
- 2.3 Philippine Society of Pathologists
- 2.4 Philippine Society of Hematology and Blood Transfusion
- 2.5 Director (or Chief Executive Officer) of the Philippine Blood Center

3. The National Council for Blood Services shall establish the following Committees; the functions of which shall be defined in a separate administrative issuance:

- 3.1 Executive Committee
- 3.2 Technical Committee
- 3.3 Committee on Public Education and Advocacy
- 3.4 Committee on Professional Education
- 3.5 Committee on Curriculum Development
- 3.6 Committee on Finance
- 3.7 Committee on Information Technology
- 3.8 Other Committees to be created as necessary

** Annex A* : Organizational Structure

4. The National Council for Blood Services shall establish a Secretariat composed of staff from either the Philippine Blood Center or the DOH National Center for Health Facility Development (NCHFD).

5. The National Council for Blood Services shall meet at least quarterly or as necessary depending upon the discretion of the chairperson. Non-DOH members shall be entitled to per diems for meetings attended.

6. Functions of the National Council for Blood Services:

- 6.1 Approval of Policies governing the operation of the Philippine National Blood Services and the utilization of blood products by hospitals and other health services;
- 6.2 Approval of the Standards, Standard Operating Procedures and Guidelines for the Recruitment of Donors, Collection, Transport, Testing and Processing of Blood, Issuance and Administration of Blood Components and Monitoring of Blood Transfusion Practices;
- 6.3 Approval of Directional/Strategic Plan of the National Voluntary Blood Services Program (NVBSP) from time to time;

- 6.4 Approval of allocation of funds and monitoring of fund utilization;
- 6.5 Develop the capabilities of the Philippines National Blood Services and Blood Services Network as the need arises;
- 6.6 Creation of other standing and special committees as appropriate;
- 6.7 Approval of certification of importation privileges.

C. The Philippine National Blood Services (PNBS) shall operate under the supervision of National Council for Blood Services (NCBS). Under the PNBS are the following Blood Centers:

1. Philippine Blood Center in Metro Manila, shall be designated by the National Council for Blood Services.

1.1 The functions of the Philippine Blood Center are:

- a. Recruitment, retention and care of voluntary blood donors,
- b. Collection of blood (whole blood or component) from qualified voluntary blood donors,
- c. Testing of units of blood for infectious disease markers (HIV1/2-Ab, HBsAg, HCVAb, Syphilis reagin, & Malarial parasites).
- d. Processing of whole blood into blood components.
- e. Pheresis of blood components
- f. Storage, issuance, transport and distribution of whole blood and blood components to end-user hospitals and non-hospital health facilities;
- g. Quality Assurance of Sub-national Blood Centers and selected Regional Blood Centers
- h. Conduct of Training and Research
- i. Performance of special confirmatory and reference immunohematologic examinations such as:

- Resolution of incompatible red cell crossmatches.
- Identification of red cell alloantibodies and autoantibodies
- Phenotyping of patients and donors
- Provision of antigen-negative red cell units.

j. Manufacture and provision of Typing Sera and Panel of reagent red cells

k. Preparation of special plasma derivatives.

l. Ensure that safe supply of blood and blood products to all hospitals and other health facilities are adequate in terms of distribution and delivery.

m. Other functions as may be assigned by the National Council for Blood Services (NCBS).

2. Subnational and Regional Blood Centers for Luzon, Visayas and Mindanao

2.1 The functions are:

- a. Recruitment, retention and care of voluntary blood donors,
- b. Collection of blood from qualified voluntary blood donors,
- c. Testing of units of blood for infectious disease markers (HIV1/2-Ab, HBsAg, HCVAb, Syphilis reagin, & Malarial parasites) for Subnational Blood Centers and selected Regional Blood Centers.
- d. Processing of whole blood into blood components.
- e. Pheresis of blood components