

DEPARTMENT OF COMMUNITY HEALTH

COMMUNITY PUBLIC HEALTH AGENCY

BLOOD BANKS

(By authority conferred on the director of public health by section 9133 of Act No. 368 of the Public Acts of 1978, being S333.9133 of the Michigan Compiled Laws)

R 325.2941 Definitions.

Rule 1. As used in these rules:

(a) "Act" means Act No. 368 of the Public Acts of 1978, being S333.1101 et seq. of the Michigan Compiled Laws.

(b) "Blood bank" means a facility which provides through its ownership or operation a system for the collection of blood from donors for the purpose of transfusion or for the preparation of a component or product intended for transfusion.

(c) "Department" means the department of public health.

(d) "Director" means the director of the department of public health.

(e) "Physician" means a person licensed to practice medicine or osteopathic medicine under the laws of this state.

History: 1979 AC.

R 325.2942 Federal standards; adoption by reference.

Rule 2. The standards of the bureau of biologics, food and drug administration, being 21 C.F.R. SS600 to 680, dated April 1, 1978, are adopted by reference. Copies of the adopted standards may be obtained from the Superintendent of Documents, U.S. Government Printing Office, 710 North Capitol Street N.W., Washington, D.C. 20402, and from the Department of Public Health, Bureau of Disease Control and Laboratory Services, P.O. Box 30035, Lansing, Michigan 48909, at a cost of \$4.25.

History: 1979 AC.

R 325.2943 Annual report; inspections.

Rule 3. (1) A blood bank collecting blood in this state or preparing components or products intended for transfusion shall file with the director an annual report as designated by the director.

(2) A representative of the director of public health may inspect a blood bank at any reasonable time.

History: 1979 AC.

R 325.2944 Performance of tests in licensed laboratories required; exceptions.

Rule 4. Clinical laboratory tests performed in or for a blood bank subject to these rules shall be performed in a clinical laboratory licensed under sections 20501 to 20554 of Act No. 368 of the Public Acts of 1978, being SS333.20501 to 333.20554 of the Michigan Compiled laws. This rule does not apply to laboratory tests performed in any of the following when part of routine blood bank procedures:

(a) A blood bank operated exclusively as a donor center by the American red cross or other community-sponsored program holding a U.S. federal license issued by the bureau of biologics, food and drug administration.

(b) A plasmapheresis center holding a U.S. federal license issued by the bureau of biologics, food and drug administration.

(c) A clinical laboratory in another state holding an interstate clinical laboratory license in immunohematology issued by the federal government.

(d) A laboratory operated by the federal government.

History: 1979 AC.

R 325.2945 Rescission.

Rule 5. R 325.2901 to R 325.2936 of the Michigan Administrative Code, appearing on pages 6611 to 6620 of the 1973 Annual Supplement to the Code and page 8563 of the 1976 Annual Supplement to the Code, are rescinded.

History: 1979 AC.