



# News Release

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Commissioner

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## **Department of Health and Senior Services Proposes to Amend N.J.A.C. 8:8, the Rules Governing Collection, Processing, Storage and Distribution of Blood**

The Clinical Laboratories Improvement Service of the Division of Public Health and Environmental Laboratories of the Public Health Protection and Emergency Preparedness Branch of the Department of Health and Senior Services is proposing to amend N.J.A.C. 8:8, Collection, Processing, Storage and Distribution of Blood. The notice of proposal appears in the April 21, 2008 issue of the New Jersey Register.

N.J.A.C. 8:8, Collection, Processing, Storage and Distribution of Blood, establishes the requirements for the operation of blood banks in New Jersey. It sets the minimum standards for the collection, processing, storage, and distribution of blood for therapeutic or prophylactic purposes, to protect the health and safety of blood donors and recipients. The Department is proposing technical amendments throughout the chapter.

The Department proposes several substantive amendments at N.J.A.C. 8:8-5.2:

- To establish a new form that blood banks are to use to report transfusion reactions;
- To establish the telephone number blood banks are to use to report fatal transfusion reactions;
- To restate, and provide cross-references to, existing reporting requirements relating to HIV and certain communicable diseases;
- To require blood banks to report certain errors and accidents associated with blood collection, regardless of whether they result in the availability of unsuitable blood and blood components for transfusion or distribution, and to establish a new form to be used to make such reports; and
- To identify the means by which blood banks can obtain the proposed new reporting forms.

A proposed amendment at N.J.A.C. 8:8-5.2 is of special note:

Existing N.J.A.C. 8:8-5.2(c) requires blood banks to report to the Department blood test results of prospective donors that are positive for hepatitis B surface antigen and antibody to hepatitis C virus, and requires blood banks to treat these prospective donors as ineligible for allogeneic donation as long as their names continue to appear on a list the Department supplies of persons who have tested positive for hepatitis. In consultation with the Blood Bank Task Force of New Jersey, the Department proposes to delete the requirement that it distribute the list

of persons with hepatitis who are ineligible to donate, inasmuch as the list no longer serves the purposes for which it was originally intended, as discussed more fully in the notice of proposal.

The Department proposes to repeal existing N.J.A.C. 8:8-6.3, Donor selection, and proposes to establish new N.J.A.C. 8:8-6.3, Donor selection; deferral records; deferral notice to donor. The proposed new rule would eliminate reference in the existing rule to the list of persons with Hepatitis, the dissemination of which the Department proposes to discontinue, as described above, and would articulate more precisely the process by which blood banks are to select and defer donors, maintain records, and as applicable, notify donors who are ineligible to donate of their ineligibility, by identifying the applicable standards to which all blood banks are to adhere.

The proposed new rule at N.J.A.C. 8:8-6.3 would:

- Require trained blood bank staff to screen prospective donors on the date of donation, and to defer those who do not meet the eligibility criteria in the AABB Standards and in applicable Federal regulations;
- Require blood banks to adhere to the recordkeeping requirements the Code of Federal Regulations establishes with respect to the deferral of persons from blood donation; and
- Require blood banks to notify in writing prospective donors that the blood bank determines to permanently defer from donating blood for allogeneic use.

Existing N.J.A.C. 8:8-2.3(d) and 8.8(a) require the presence of a physician or a registered nurse to be present on the premises during blood collection for donor emergency care. In 2006, the Department, in consultation with the Public Health Council, amended N.J.A.C. 8:8-8.2 to establish an exception to this requirement, commonly known as the “RN requirement.” The exception allows blood banks to use “alternative donor emergency care personnel” instead of nurses and physicians, under certain prescribed circumstances. The purpose of this exception is to avoid blood drive cancellations and other missed blood collection opportunities due to the unavailability of physicians or registered nurses.

N.J.A.C. 8:8-8.2(j) establishes March 31, 2008, as the expiration date of the exception. The purpose of this expiration date was to permit the Department to evaluate the effectiveness of this exception in increasing blood collections and maintaining donor safety, and to require the Department to conduct rulemaking if the exception proved effective. The Department proposes to amend N.J.A.C. 8:8-8.2(j) to extend the expiration date to February 1, 2011, to enable the Department to continue its collection of data in the evaluation of the use of alternative donor emergency care personnel.

As stated above, the proposal appears in the April 21, 2008, issue of the New Jersey Register. The public has until June 20, 2008, to comment on the proposal. Persons wishing to comment on the proposal must submit their comments in writing to Ruth Charbonneau, Director, Office of Legal and Regulatory Affairs, NJ Department of Health and Senior Services, P O Box 360, Trenton, NJ 08625-0360. Written comments must be postmarked on or before June 20, 2008, which is the close of the 60-day public comment period.

The Department will convene a public hearing on the notice of proposal, on Monday, May 12, 2008 at 1:00 pm, at the Health and Agriculture Building, First Floor Auditorium, 369 South Warren Street, Trenton, NJ 08608. Persons wishing to comment on the proposal at the public hearing who wish to be placed on the list of speakers are requested to telephone Ms Marks at (609) 984-7923 by Tuesday, May 6, 2008, and to bring an extra written copy of their remarks for submission to the public record.

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