

NEW YORK STATE DEPARTMENT OF HEALTH
WADSWORTH CENTER
ALBANY, NY

COUNCIL ON HUMAN BLOOD AND TRANSFUSION SERVICES

Thursday, April 3, 2025

MINUTES

Members Present: Joanne Becker, MD
Rachel Elder, MD
Timothy Hilbert, MD, PhD, JD, Chair
Jessica Jacobson, MD
Philip McCarthy, MD
Beverly Rauch, Commissioner's Designee
Amy Schmidt, MD, PhD (remote)

DOH Staff Present: Maribeth Dooley
Matthew Kohn, PhD, Secretary
Alexa Nagy, JD (via Webex)
Jason Riegert, JD (via Webex)

Members of the Public:
(via Webex) Ruth Espinoza
Betsy Jett
Maria Locher
Sarai Paradiso
Heather Pratt
Gracemarie Sullivan

Meeting Called to Order

Shortly after 10:00 am, Dr. Hilbert called the meeting to order and welcomed the participants. Council members introduced themselves. Dr. Schmidt joined from a non-publicly accessible location and was not counted for purposes of quorum. DOH staff introduced themselves and Dr. Kohn identified the additional registered observers. Council members attended from four publicly accessible sites in New York City, Albany, Buffalo and Syracuse. All members of the public attended virtually via Webex.

Prior to proceeding to the first order of business, Dr. Kohn noted that the public comment portion of the agenda would precede discussion of proposed rulemaking.

Approval of Minutes of September 6, 2024 meeting

Dr. Hilbert requested discussion of the minutes of the September 6, 2024, Council meeting, and as there was none, requested a motion to approve the minutes as presented. Dr. Elder motioned to approve the minutes as presented, Dr. Jacobson seconded the motion. The motion was approved unanimously.

Public Comments

Dr. Kohn invited comments from the public. Betsy Jett, representing the New York Blood Center, provided comments related to proposed rulemaking, noting draft regulations regarding visual inspection of blood products in storage went beyond the requirements of the US FDA and suggested that the proposed rulemaking should be reconsidered. Maria Locher, representing the American Red Cross, seconded Betsy Jett's comments.

Discussion of Proposed Rulemaking, Subpart 58-2 of Title 10 NYCRR

As the public comments pertained directly to the proposed rulemaking, discussion segued directly into the proposed rulemaking. Ms. Rauch described proposed amendments to sections 58-2.6, 58-2.10, 58-2.25 and 58-2.27, and noted the changes were intended to be consensus rulemaking to conform with existing statutes and regulations. She went on to note that the Department had already responded to informal comments previously received that aligned with suggestions put forth during the public comment period. Accordingly, revisions to the proposed rulemaking were presented to withdraw the contemplated changes that would be more stringent than the US FDA requirements.

During the discussion, additional comments were provided by members of the Council and by the public.

Ms. Rauch and Dr. Kohn described the process of rulemaking and public comment, noting that any substantive changes made to the proposed rulemaking based upon feedback received from the public would require subsequent opportunities for public comment.

Dr. Hilbert requested a motion to consider the proposed rulemaking. Ms. Rauch motioned that the proposed rulemaking, as provided to the Council, including amendments to 58-2.6 to require visual inspection for only whole blood and red cell components, section 58-2.10 to extend record retention for blood components and derivatives released for transfusion to 10 years from seven, sections 58-2.25 and 58-2.27 to extend record retention requirements from seven to 10 years, and to repeal section 58-2.20 as previously approved at the September 6, 2024 Council meeting. Dr. Jacobson seconded the motion and it was approved unanimously.

Public Comments

Dr. Kohn invited additional public comments or questions, but there were none.

Adjournment

At approximately 10:50, Dr. Hilbert requested a motion to adjourn. Dr. Elder so motioned, Dr. Jacobson seconded the motion, and following a unanimous vote, the meeting was adjourned.