

NEW YORK STATE DEPARTMENT OF HEALTH
WADSWORTH CENTER
ALBANY, NY

COUNCIL ON HUMAN BLOOD AND TRANSFUSION SERVICES

Friday, February 5, 2021
(by Webex Video Call)

MINUTES

Members Present: Joseph Chiofolo, D.O.
Rachel Elder, M.D.
Timothy Hilbert, M.D.
David Huskie, R.N.
Phillip McCarthy, M.D.
Beverly Rauch, Commissioner's Designee

DOH Staff Present: Andrea Garavelli
Matthew Kohn, Ph.D.
Danuta Olkowska, M.D.
Jason Riegert, J.D.
Derek Symula, Ph.D.

Members of the Public: Allen, Laura
Battle, Michele
Brinser, Roger
Cherny, Nelli
Clifford, Celia
Clifford, Karen
Dalheim, Amy
Driscoll, Christine
Espinoza, Ruth
Farallo, Marianne
Fialkow, Lawrence
Frei, Cristin
Hakes, Vlasta
Jacobson, Jessica
Jett, Betsy
Kramer, Kristin
Locher, Maria
O'Rourke, Mark
Pratt, Heather
Rempola Occiano, Marietta
Sachais, Bruce
Schmidt, Amy
Spier, Bill
Sullivan, Gracemarie
Ustin, Mark
Vandervort, Margaret
Vandervort, Todd

White, Karla

Meeting Called to Order

Dr. Chiofalo called the meeting to order at 11:05 a.m. and welcomed the participants. Council members introduced themselves, Dr. Kohn identified the additional observers, then additional DOH staff introduced themselves.

Approval of Minutes of December 2, 2020 meeting

Dr. Chiofalo requested discussion of the minutes of the December 2, 2020, Council meeting, and as there was none, requested a motion to approve the minutes as presented. Dr. McCarthy motioned to approve them as presented, Dr. Elder seconded the motion. The motion was approved unanimously.

Proposed Changes to Regulations

Dr. Symula provided a recap of the timeline pertaining to changes to sections 58-2.14 and 58-2.15, and addition of 58-2.28, and the rulemaking process. He stated that the Department is requesting the Council approve revisions to the emergency regulation, based on the public comments in response to proposed changes to the permanent regulation. He informed the Council that once is approves the emergency regulation, the Department will publish the revised permanent regulation in the State Register, subject to a 45-day public comment period. He then indicated the Council should expect to meet in late March or early April to re-approve the revised emergency regulation, and again by early June to discuss the permanent rule.

Dr. Symula then went on to summarize the public comments to the permanent rule proposed at the September 4, 2020, Council meeting, and the Department's responses.

Comment: amendments to Sections 58-2.14(d) and 58-2.15(d)(3), requiring certain licensed healthcare personnel to be on-site during procedures, are not necessary, are more stringent than federal requirements, and might draw healthcare personnel away from other responsibilities.

Response: the Department revised the proposed regulation to remove any reference to specific healthcare personnel being on-site. The revised rule instead requires on-site personnel to be trained to recognize and respond to health issues related to the procedure, consistent with federal requirements.

Comment: amendments to Sections 58-2.14(c) and 58-2.15(c) requiring certain licensed healthcare personnel to explain the hazards of the procedure to prospective donors as part of the informed consent process, are not necessary, are more stringent than federal requirements, and might draw healthcare personnel away from other responsibilities.

Response: The Department revised the proposed regulation to require information provided to the prospective donor be approved by the blood bank director or responsible physician and prohibit delegation of the approval cannot to other staff. In addition, certain language in the proposed rule was deleted to minimize redundancy with federal regulations.

Comment: section 58-2.14 of the proposed rule does not explicitly address infrequent plasma donation.

Response: the Department did not revise the proposed rule in response to this comment.

Comment: section 58-2.15(e)(3)(i) does not take into consideration a federal requirement for first time platelet donors.

Response: the Department has revised the proposed regulation to account for first time platelet donors by amending the regulation to limit the number of platelets that can be collected from such donors.

Comment: the revised section 58-2.14(b), prohibiting a blood bank director from delegating approval of new or revised standard operating procedure manuals or other procedural guides, is inconsistent with other New York State requirements related to blood banks, clinical laboratories and the delegation of authority.

Response: the Department has revised this requirement and the equivalent requirement in Section 58-2.15(b). The revised rule allows the blood bank director to delegate the review and approval of most procedures and is now consistent with other New York State requirements.

Comment: the requirements in Sections 58-2.14(b) and 58-2.15(b) that the responsible physician be licensed in the state or jurisdiction where the blood bank is located and either hold a Certificate of Qualification (CQ) in transfusion, or be board certified in clinical pathology or in clinical pathology/laboratory medicine, is not necessary and is more stringent than federal requirements.

Response: the Department has revised this requirement and the proposed regulation no longer requires a CQ or board certification. The regulation has also been revised to clarify that the responsible physician must be licensed as a physician in New York State.

Comment: the requirements in Sections 58-2.14(b) and 58-2.15(b) that would require blood bank directors to hold a CQ in Blood Banking Collection – Comprehensive, is not necessary and is more stringent than federal requirements.

Response: the Department did not revise the proposed rule in response to this comment.

Following Dr. Symula's descriptions of the comments and the Department's responses, Dr. Chiofolo invited questions and discussion from the members. Dr. Hilbert inquired about the need for regulations pertaining to manual pheresis, as this is not commonly done. Dr. Chiofolo agreed. Dr. Symula indicated the language is there to allow flexibility if needed. Dr. Hilbert questioned the language on serological tests for syphilis, and Dr. Symula informed him the offending language had been deleted.

Dr. Chiofolo asked for a motion to approve the Emergency Regulation Package. Dr. McCarthy motioned for approval and Dr. Hilbert seconded. The motion was approved unanimously.

Public Comment

No public comments were made by observers.

Subsequent Meeting

Dr. Chiofolo reiterated the need for another meeting in late March or early April.

Adjournment

Dr. McCarthy made a motion to adjourn the meeting, which was seconded by Dr. Hilbert, and following a unanimous vote, the meeting was adjourned.