

NEW YORK STATE DEPARTMENT OF HEALTH
WADSWORTH CENTER
ALBANY, NY

COUNCIL ON HUMAN BLOOD AND TRANSFUSION SERVICES

Wednesday, December 2, 2020
(by Webex Video Call)

MINUTES

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

Members Absent: Phillip McCarthy, M.D.

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
Bridges, James
Brinser, Roger
Cherny, Nelli
Clifford, Celia
Clifford, Karen
Dalheim, Amy
Driscoll, Christine
Espinoza, Ruth
Farallo, Marianne
Fialkow, Lawrence
Frei, Cristin
Handy, Madison
Jacobson, Jessica
Jett, Betsy
Kramer, Kristin
Locher, Maria
O'Rourke, Mark
Rosenfeld, Rose
Sachais, Bruce
Schmidt, Amy
Schwartz, Jordana
Sexton, Jamie
Silver, Alicia
Spier, Bill

Stoker, Brian
Sullivan, Gracemarie
Ustin, Mark
Vandervort, Margaret
Webber, Scott
White, Karla

Meeting Called to Order

Dr. Chiofalo called the meeting to order at 11:00 a.m. and welcomed the participants. Council members introduced themselves, followed by DOH staff. Dr. Kohn identified the additional observers.

Approval of Minutes of September 4, 2020 meeting

Dr. Chiofalo requested discussion of the minutes of the September 4, 2020, Council meeting, and as there was none, requested a motion to approve the minutes as presented. Dr. Elder motioned to approve them as presented, Mr. Huskie seconded the motion. The motion was approved unanimously.

Proposed Changes to Regulations

Dr. Symula provided a brief recap of the changes to sections 58-2.14 and 58-2.15, and the addition of 52-2.28, that were adopted by the Department following the Council's meeting in September, and advised the Council about the rulemaking process. Notably, the emergency regulation adopted by the Department is temporary, it expires initially after 90 days, and any subsequent re-adoptions expire after 60 days. He also stated that the Department intends to make permanent revisions through the standard rulemaking process.

Dr. Symula informed the Council that, in response to public comments, the Department intends to revise both the emergency regulation and the proposed permanent rule. Additionally, he noted that certain new requirements in the emergency regulation will not be enforced as written until appropriate revisions can be made.

Dr. Symula went on to inform the Council that they will most likely need to meet again in mid-January to amend and approve changes to both the emergency regulation and the proposed permanent rule, and then again in March to once again re-approve the expiring emergency regulation. Finally, following a second public comment period after approval of the proposed permanent regulation in January, the Council is expected to meet in April or May to vote on the permanent rule.

Finally, Dr. Symula summarized the public comments that were received. Comments questioned the necessity of the responsible physician holding a NYS Certificate of Qualification in Blood Banking Collection – Comprehensive or board certification in clinical pathology or clinical pathology/laboratory medicine. The Department is not currently enforcing this requirement as written. Comments also questioned the need for a physician, physician assistant, nurse practitioner or registered nurse to be present on-site during collections. The Department is not currently enforcing this requirement as written. Comments addressed the requirement for who could obtain consent, and Dr. Symula clarified the Department's stance on this indicating that obtaining consent may be delegated to an appropriately trained individual but

that the information must be approved by licensed healthcare personnel. There were additional, technical comments about the regulation, and the Department is considering whether clarification is needed.

Dr. Chiofolo invited questions and discussion from the members. Dr. Elder asked for clarification on formatting of the regulatory package and the timing of the process regarding the permanent rule changes, and questioned one of the technical requirements in 58-2.15. Dr. Chiofolo responded that the requirement was in agreement with the guidelines of AABB. Dr. Hilbert asked about enforcement discretion and dissemination of that information. Dr. Symula responded that Department staff would discuss the best approach.

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

Public Comment

Ms. Rauch invited public comments, Dr. Kohn announced that several members of the public had expressed a desire to make comments.

First to speak was Roger Brinser from Takeda, who mentioned Takeda had submitted comments and thanked the Council for considering them.

Dr. Bruce Sachais from the New York Blood Center spoke next, registering the New York Blood Center's concerns with some of the changes in the proposed emergency regulation and permanent regulation, specifically with regard to qualifications of personnel obtaining consent and supervising care of donors that do not reflect the current industry standards. Dr. Sachais commented that rather than aligning New York's requirements with federal standards, the emergency and proposed regulations are more stringent posing significant regulatory burdens to regulated entities.

Bill Spier from PPTA thanked the Department and Council for updating the regulations on source plasma.

Betsy Jett at the New York Blood Center asked about how regulated entities will be informed of the changes to the rules.

Subsequent Meeting

Dr. Chiofolo noted that another meeting would be scheduled for some time in January.

Adjournment

Mr. Huskie made a motion to adjourn the meeting. It was seconded by Dr. Hilbert, and following a unanimous vote, the meeting was adjourned.