APPROVED

NEW YORK STATE DEPARTMENT OF HEALTH
WADSWORTH CENTER
ALBANY, NY

COUNCIL ON HUMAN BLOOD AND TRANSFUSION SERVICES

Friday, September 4, 2020
(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 Derek Symula, Ph.D.
Members of the Public:	Roger Brinser Nelli Cherny Karen Clifford Amy Dalheim Ruth Espinoza Marianne Farallo Dannielle Melendez Mark O'Rourke Bill Spier Brian Stoker Mark Ustin Margaret Vandervort Karla White

Meeting Called to Order

Dr. Chiofolo called the meeting to order at 9:00 a.m. and welcomed the participants. With the exception of Dr. Elder, who joined the meeting later, Council members introduced themselves. DOH staff introduced themselves, including Ms. Rauch who joined the committee as the Commissioner's Designee, and Dr. Kohn identified the additional observers.

Appointment of Secretary

Ms. Rauch proposed to appoint Dr. Kohn as the Council Secretary. Dr. McCarthy motioned to appoint Dr. Kohn as Secretary, Mr. Huskie seconded the motion, and the Council voted unanimously to approve the motion, excluding Dr. Elder who was not yet present.

Proposed Changes to Regulations

Dr. Symula provided a brief overview to the proposed changes to sections 58-2.14 and 58-2.15 and addition of a new section 58-2.28, noting that the proposed changes are intended to harmonize New York's requirements with national standards. He described the rulemaking process, noting the emergency regulation that was being discussed in response to the COVID-19 pandemic would expire in 90 days of adoption and would need re-adoption for another 60 days. Proposed amendments to the regulation would be published for public comment, and the Council would need to meet again to vote on a final proposed amendment to take the place of the emergency regulation.

Dr. Symula detailed the proposed changes, indicating the new regulation would incorporate by reference federal requirements for the collection of plasma and other blood components by apheresis, and the new section, 58-2.28, formally adds those requirements. He added the federal requirements, found in 21 CFR 630 and 640, cover the same areas as current NYS requirements in 58-2.14 and 58-2.15, and would replace many of the existing NYS requirements. The proposed amendments:

- will allow a blood bank director to delegate many duties to a responsible physician who does not need to qualify as a blood bank director;
- remove personnel titles that are not used in the federal requirements or elsewhere;
- allow healthcare personnel in addition to a physician to obtain informed consent;
- remove requirements for donor infectious disease testing and default to federal requirements;
- remove most other donor qualification requirements;
- adopt nationally recognized criteria for the volume and frequency of donation to determine the suitability of a potential donor for a specific procedure;
- allow non-physician healthcare personnel to fulfill onsite requirements, and restrict the requirement to only when collection occurs;
- remove specific requirements for personnel qualifications and instead reference simplified training requirements;
- remove technical requirements for apheresis, plasmapheresis, and record keeping, and default to federal requirements.

Dr. Chiofolo questioned the use of the terms "source plasma" and "serial plasmapheresis," noting they are not interchangeable. Dr. Symula indicated we would strive to make the language more consistent in the permanent regulation. Mr. Huskie questioned the meaning of the term "technical staff" in the proposed 58-2.14(f). Dr. Symula affirmed that this meant staff who were trained in the donation process, as described in 58-2.14(e). Dr. Chiofolo questioned the use of "leukocytes, and granulocytes" in 58-2.15(e)(2)(i) as redundant. He also questioned the restriction in 58-2.15(e)(2)(iii) on donors not donating more than 24 times in a twelve month period. However, the proposed language is consistent with the American Association of Blood Banks. Dr. Hilbert questioned whether informed consent needed to be obtained by a physician, physician's assistant, nurse practitioner, or a registered nurse, at each visit, especially for source plasma or serial plasmapheresis donors who donate repeatedly. Dr. Symula noted that these are NYS-specific requirements and that the proposed amendments did not require informed consent at the time of each donation.

Dr. McCarthy motioned to approve the changes as presented, Dr. Hilbert seconded with clarifications as discussed. The motion was approved unanimously.

Public Comment

No public comments were made.

Subsequent Meeting

At Dr. Chiofolo's suggestion, there was a brief discussion of the need to meet around the end of November or early December to vote on re-adopting the emergency regulation and approve the permanent regulation changes.

Adjournment

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