

NEW YORK STATE DEPARTMENT OF HEALTH
WADSWORTH CENTER
ALBANY, NY

COUNCIL ON HUMAN BLOOD AND TRANSFUSION ON SERVICES

Friday, September 6, 2024

MINUTES

Members Present: Joanne Becker, M.D.
Rachel Elder, M.D.
Timothy Hilbert, M.D., Ph.D., J.D., Chair
David Huskie, R.N.
Philip McCarthy, M.D.
Beverly Rauch, Commissioner's Designee
Amy Schmidt, M.D., Ph.D.

DOH Staff Present: Maribeth Dooley
Matthew Kohn, Ph.D., Secretary
Alexa Nagy, J.D (via Webex)
Jason Riegert, J.D. (via Webex)

Members of the Public: Alexandra Budhai, M.D.
(via Webex) Heather Pratt
Eric Senaldi
Mark Ustin
Sarah Vossoughi

Meeting Called to Order

Shortly after 2:00 pm, Dr. Hilbert called the meeting to order and welcomed the participants. Dr. Hilbert welcomed Dr. Joanne Becker, the newest Council member. Council members introduced themselves, 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.

Approval of Minutes of September 13, 2023 meeting

Dr. Hilbert requested discussion of the minutes of the September 13, 2023, 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. Schmidt seconded the motion. The motion was approved unanimously.

Discussion of Ambulance Transfusion Services

Dr. Hilbert invited Ms. Rauch to lead the discussion of ambulance transfusion services. Ms. Rauch described recent and pending statutory changes to the regulation of ambulance transfusion services. Ms. Rauch described Section 3003-b of Article 30 of Public Health Law, which was signed in 2022 and authorized air ambulances to store, distribute and administer blood. Legislation currently awaiting the Governor's approval will expand this Section to include

any (ground and air) ambulance service or life support first response services. Ms. Rauch went on to describe how, once signed into law, the pending changes would supersede regulations in Subpart 58-2 of Title 10 of the New York Codes, Rules and Regulations (NYCRR) pertaining to ambulance transfusion services. Ms. Rauch noted that the pending bill shifted authority from the Blood Resource Program to the Bureau of Emergency Medical Services, and suggested repeal of Subpart 58-2.20 of 10 NYCRR.

The Council discussed the necessity of repealing Subpart 58-2.20, and questioned the ability of the Bureau of Emergency Medical Services to adequately regulate ambulance transfusions services, with members noting, in particular, the historical reasons for specific requirements. Ms. Rauch notes that she and her staff had held several discussions with the Bureau of Emergency Medical Services, and that the Bureau would take a more active role in inspecting the ambulance transfusion services. Dr. Kohn suggested that the Council send a letter to the Bureau describing the Council's long-standing concerns regarding blood transfusions in ambulances.

Ultimately, Ms. Rauch motioned to repeal Subpart 58-2.20, contingent upon the Governor signing the bill. The motion was seconded by Mr. Huskie and was approved with an abstention by Dr. Elder.

Discussion of Blood Services Guidelines

Dr. Hilbert introduced the next topic of discussion, Blood Services Guidelines, and asked Ms. Rauch to describe the Guidelines under discussion. Ms. Rauch informed the Council that proposed changes to the Elective Out-of-Hospital Transfusion Guidelines, as discussed at the September 2023 Council meeting, had been incorporated into the draft and requested further discussion or comments. There were no further comments and Ms. Rauch motioned to adopt the Elective Out-of-Hospital Transfusion Guidelines as presented. Dr. McCarthy seconded, and the motion was approved unanimously.

Discussion of Subpart 58-5 of Title 10

Dr. Hilbert opened the next agenda item, discussion of hematopoietic progenitor cell (HPC) bank director and medical director qualifications and asked Dr. Kohn to lead the discussion. Dr. Kohn described the requirements found in Subpart 58-5 of Title 10, section 58-5.2, for the director and medical director of HPC procurement and processing facilities, noting advances in HPC transplant since the regulations were last amended in 2004. Dr. Kohn indicated that a number of hospitals in New York State were reporting difficulties in finding physicians who met the minimum requirements in regulation, with particular regard to HPCs from bone marrow and umbilical cord. Dr. Kohn noted that any proposed changes to the requirements would require the Council's approval at a future meeting, and invited comments and discussion from the Council on the requirements, and other potential experts with whom to discuss the existing criteria.

Members of the Council discussed the rationale for minimum requirements, as well as the changes in HPC procurement over the past years that have led to a decrease in bone marrow transplant, in particular, as well as the advanced age of medical personnel at various institutions with the required experience. Council members suggested several other sources of information. Dr. Kohn indicated that the Department would reach out, and asked that Council members consult with their peers and provide feedback to the Department, or provide names of experts the Department should contact directly.

Dr. Kohn also noted that proposed revisions to Part 52 of 10 NYCRR, which includes standards for tissue banking, are currently being discussed within the Department, and that Subpart 58-5 makes direct reference to sections within Part 52. The proposed revisions to Part 52 will require conforming changes to Subpart 58-5, but will not substantively change Subpart 58-5.

Following discussion of Subpart 58-5, Dr. Schmidt raised the issue of virtual RNs participating in bedside verification for purposes of initiating a transfusion, which had been discussed at the prior Council meeting. Ms. Rauch indicated that the Department had no knowledge that this practice had been adopted.

Public Comment

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

Adjournment

At approximately 3:20, Dr. Hilbert requested a motion to adjourn. Dr. Elder so motioned, Dr. McCarthy seconded the motion, and following a unanimous vote, the meeting was adjourned.