



Advancing Transfusion and
Cellular Therapies Worldwide

October 20, 2017

Keith Van Wagner
Assistant Chief Counsel
California Health & Human Services Agency
California Department of Public Health
Office of Legal Services
1415 L Street, Suite 500
Sacramento, CA 95814

RE: Blood Centers of California Petition Hearing Re: Title 17, California Code of Regulations, Section 1002(a)(2)

Dear Mr. Van Wagner:

AABB is an international, not-for-profit association representing individuals and institutions involved in the field of transfusion medicine and cellular therapies. The association is committed to improving health through the development and delivery of standards, accreditation, and educational programs that focus on optimizing patient and donor care and safety. AABB individual membership includes physicians, nurses, scientists, researchers, administrators, medical technologists, and other health care providers.

AABB supports the Blood Centers of California's request for reconsideration of the request to amend Title 17, Section 1002 (a)(2) of the California Code of Regulations. The amendment would change the current language to the following:

(2) The employee placed in charge, in the absence of a qualified physician must be a registered nurse. The registered nurse shall be available for consultation via telephone, audio/video – real time chat (synchronous) or other electronic means.

Blood centers in California supply lifesaving blood and blood components, and are highly regulated by the Food and Drug Administration, AABB and the state. California is the only state that mandates that a registered nurse (RN) be physically present at all sites whenever blood is donated. AABB *Standards for Blood Banks and Transfusion Services* (AABB Standards), which are recognized by California state law and are used throughout the world, include standards related to personnel qualifications, training and competencies. Importantly, neither AABB Standards nor FDA require the physical presence of an RN at all sites when blood is donated.

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Similar to other health care providers, blood centers are affected by the shortage of licensed health care personnel in California – Registered Nurses and Clinical Laboratory Scientists. In addition, blood centers are facing significant economic pressures. Salaries of licensed personnel are key drivers of the cost of blood. Regulatory agencies require stringent safety requirements which promote the safety of blood and blood products but typically funding is not provided to implement new measures. These factors, in addition to the high cost of other benefits in California, strongly influence the cost of providing blood and blood products in California.

AABB is committed to the health and safety of donors and patients. AABB supports the use of telehealth in the blood center environment. While donors are generally healthy young people and adults, some donors may have reactions as a result of the donation process, such as bruising or pain at the site of needle insertion or mild systemic reactions (i.e., dizziness or fainting). Blood centers work to prevent these reactions through education prior to, during and after donation, and their efforts help reduce the numbers of reactions that occur. AABB believes that the use of telehealth is a viable option for responding to adverse events that may occur during the donation process.

Telehealth is being used more frequently in a variety of settings, and has been shown to be effective and efficient. To that end, we are fully supportive of the move to permit an RN to be available via telehealth to provide necessary nursing skills and expertise during the donation process.

If you have any questions, please contact Leah Stone, Director of Public Policy & Advocacy at 301-215-6554 or lmstone@aabb.org.

Sincerely,

A handwritten signature in black ink that reads "Mary Beth Bassett". The signature is written in a cursive, flowing style.

Mary Beth Bassett
AABB President