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California Department of Public Health



EDMUND G. BROWN JR.
Governor

March 13, 2018

VIA ELECTRONIC MAIL AND FIRST CLASS MAIL

Susan Noone
President
Blood Centers of California
PO Box 2569
Sacramento, CA 95812

RESPONSE TO REQUEST FOR RECONSIDERATION OF PETITION TO AMEND
CALIFORNIA CODE OF REGULATIONS, TITLE 17, SECTION 1002(a)(2)

Dear Ms. Noone,

Thank you for contacting the California Department of Public Health (Department) on behalf of the Blood Centers of California (BCC).

Under Government Code section 11340.7(c), any interested person may request that a state agency reconsider a decision regarding a regulation amendment petition. On May 30, 2017, CDPH received from the BCC a request for reconsideration of a denial to amend California Code of Regulations, title 17, section 1002(a)(2). On November 7, 2017, a public hearing was granted regarding this reconsideration. Based upon hearing testimony, additional supporting documents, and pursuant to the requirements of Government Code section 11340.7, the Department issues this response to the BCC's petition.

The BCC requests an amendment to California Code of Regulations, title 17, section 1002(a)(2). Specifically, the BCC requests the following change:

(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 the telephone, audio/video – real time chat (synchronous) or other electronic means.

BCC members and interested parties attended a public hearing with Department representatives on November 7, 2017, and presented evidence to support these changes. The BCC submitted additional information on November 20, 2017, regarding adverse donor reactions, additional complementary documents, and responses from

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registered nurses (RN) throughout the country, in support of its request for reconsideration. Positions of support for this amendment from BCC were unanimous and each party submitted statements asserting that donor safety in the form of donor reactions during collections is not negatively affected in other areas of the country, where RNs are not required to be physically present during blood collection activities.

The Department appreciates the additional information provided by the BCC and the opportunity to have heard from BCC members and interested parties at the November 7, 2017, public hearing regarding the petition. The Department has carefully reviewed and considered the data and information submitted regarding the petition. The Department has also re-reviewed current blood center and regulatory practices in California and other areas of the United States.

Health and Safety Code section 1610 requires the Department to make rules and regulations governing the production of all biologics produced in establishments under Health and Safety Code section 1609, subdivision (c). The Department recognizes the importance and complexity of the issues raised by this petition. Thus, the Department has decided to exercise its authority and grant BCC's petition to initiate the rulemaking process to amend California Code of Regulations, title 17, section 1002(a)(2). During the rulemaking process set forth under the Administrative Procedure Act (Gov. Code, § 1340 et. seq.), the Department may, additionally, focus on the acuity of donor adverse events, mobile blood drives, whole blood vs apheresis procedures, and the actual mechanisms of telehealth processes where no data was provided during the petition consideration process. The Department intends to conclude the rulemaking action within a reasonable period.

If you have any questions, you may contact me at Keith.VanWagner@cdph.ca.gov or (916) 445-2012.

Sincerely,



Keith Van Wagner
Assistant Chief Counsel
Regulations, Privacy & Special Projects