

State of California--Health and Human Services Agency California Department of Public Health



February 26, 2024

Notice of New Reporting Requirement for California Biologics Licensed Facilities Donor Adverse Events (DAE)

Dear Facility Owner / Director:

Amendment of California Health and Safety Code (HSC) 1607 took effect on January 1, 2023. A blood bank shall annually report to the department any adverse donor event requiring emergency medical intervention.

HSC § 1607

(3)(A) A blood bank shall annually report to the department any adverse donor events requiring emergency medical intervention that occur pursuant to this subdivision, including the date, location, type of adverse event, onsite response, and whether a registered nurse was physically present on the premises.

The first annual blood donor adverse event (DAE) reporting is <u>due on May 1, 2024</u> for events that occurred on January 1, 2023 thru December 31, 2023.

The Excel file reporting tool can be downloaded from our website:

https://www.cdph.ca.gov/BloodBanksandBiologics

Send finalized reports with Subject: "DAE Report" by email to: CDPH.LFSResearchDataUnit@cdph.ca.gov

Sincerely,

Section Chief, Laboratory Licensing and Registration Blood Banks and Biologics

