

DEPARTMENT OF FOOD AND AGRICULTURE
TITLE 3. CALIFORNIA CODE OF REGULATIONS
NOTICE OF PROPOSED ACTION
ANIMAL BLOOD BANKS

NOTICE IS HEREBY GIVEN that the Department of Food and Agriculture (herein after referred to as "Department") proposes to adopt the regulations described below in the Informative Digest/Policy Statement Overview after considering all comments, objections, and recommendations regarding this proposal. Publication of this notice commences a 45-day public comment period.

PUBLIC HEARING

The Department has not scheduled a public hearing for this proposal. However, a public hearing will be held if the Department receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days before the close of the written comment period.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action to the Department. Comments can be submitted via e-mail to sean.brady@cdfa.ca.gov, or mailed to the address listed below. The written comment period begins on **February 2, 2024 and closes on March 18, 2024**. The Department is not required to respond to comments that are outside the scope of this Notice or comments that are not received or postmarked during the written comment period.

WRITTEN COMMENTS AND REQUEST FOR PUBLIC HEARING

All written comments and any requests for a public hearing should be directed to the following person:

Sean Brady, DVM
Department of Food and Agriculture
Animal Health and Food Safety Services
Animal Blood Banks
1220 N Street, Sacramento, CA 95814
Telephone (916) 208-0500
E-mail: sean.brady@cdfa.ca.gov

AUTHORITY AND REFERENCE

Food and Agricultural Code (FAC) section 14 authorizes the Department to adopt rules and regulations in accordance with the Administrative Procedure Act. Additional authority vested in FAC grants the Department Secretary the authority to amend or repeal rules and regulations.

FAC section 407 authorizes the Secretary of the Department to adopt such regulations as are reasonably necessary to carry out the provisions of the FAC which the Secretary is directed or authorized to administer or enforce.

FAC section 9221(g) authorizes the Secretary of the Department to collect necessary and proper information on the application for a license for an establishment that produces, or proposes to produce, animal blood or blood component products from a closed-colony blood bank.

FAC section 9231(d) authorizes the Department to set inspection fees in an amount not to exceed the Department's reasonable regulatory costs incurred with the oversight of commercial blood banks for animals.

FAC section 9244(b) authorizes the Department to set fees in an amount that will cover the Department's reasonable regulatory costs incurred to administer and enforce product safety standards for animal blood and blood component products.

FAC section 9245 authorizes the Secretary of the Department to impose conditions on the production or use of blood and blood component products as necessary to ensure product safety standards and compliance with facility requirements.

FAC section 9251 authorizes the Secretary of the Department to adopt reasonably necessary rules and regulations for the administration and enforcement of requirements relating to commercial blood banks for animals.

Business and Professions Code (BPC) section 4920.5 requires community blood banks operating pursuant to Article 7 of Chapter 11 of Division 2 of the BPC to comply with blood or blood component product registration requirements under Article 5 (commencing with section 9241) of Chapter 1.5 of Part 1 of Division 5 of the Food and Agricultural Code.

BPC section 4920.6 authorizes the Department to collect quarterly reports from community blood banks operating pursuant to Article 7 of Chapter 11 of Division 2 of the BPC.

The proposed regulation implements, interprets, and makes specific sections 9201, 9210, 9212, 9221, 9231, 9241, 9242, 9243, 9244, 9245, 9252, 9253 and 9266 of the FAC and sections 4920.4 and 4920.6 of the BPC.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

To implement AB 1282, the Department proposes to amend Title 3, California Code of Regulations, Division 2, Chapter 8, and adopt new Articles 1 – 4 (commencing with section 1303) to implement, interpret, and make specific laws relating to animal blood banking.

Summary of Existing Laws and Effect of the Proposed Action

In 2021, Governor Gavin Newsom signed AB 1282 (Stats. 2021, Ch. 725), the California Pet Blood Bank Modernization Act (Act) into law. The goal of the Act is to address the shortage of animal blood available for veterinary transfusion medicine in California and transition the state from closed colony blood banks to community blood banks. The Act directs the Department to adopt reasonably necessary rules and regulations for administration and enforcement of these changes.

The proposed regulations would establish the application requirements for a closed-colony facility license and the circumstances under which the Department would discontinue the closed-colony licensing program. The proposed regulations would require that a commercial blood bank that is not a closed-colony blood bank or otherwise registered as a community blood bank be licensed by the Department and establish the licensing requirement for those establishments. The proposed regulation would establish quarterly reporting requirements for closed-colony blood banks licensed with the Department. The proposed regulations would require that those with blood or blood competent products registered with the Department be inspected at least once a year. The proposed regulations would also require that commercial blood banks licensed by the Department be inspected at least once a year. The proposed regulations would also establish the fees that commercial blood banks for animals with products registered with the Department pay to the Department.

Anticipated Benefits of the Proposal

This proposal will ensure stakeholders have a clear understanding of when the Department will discontinue its licensing program for closed-colony blood banks. It will increase the supply of lifesaving blood and blood component products offered for sale to California veterinarians and ultimately improve the quality of veterinary transfusion medicine in the state. The proposal clarifies facility inspections and quarterly reporting requirements, allowing the Department to monitor animal health and welfare. By setting clear requirements and fee structures for those persons wanting to sell animal blood and blood component products, the Department anticipates more community blood banks will begin entering the market.

State Regulation Consistency Evaluation

The Department has evaluated this proposal and has concluded that it is not inconsistent or incompatible with existing regulations of closed-colony animal blood banks and community animal blood banks in California.

DISCLOSURES REGARDING THE PROPOSED ACTION

The Department has made the following initial determinations:

Mandate on Local Agencies and School Districts: None.

Costs or Savings to Any State Agency: The new fees as proposed, will cover the Department's costs incurred to administer and enforce animal blood and blood component product safety standards.

Costs to Any Local Agency or School District for Which Government Code section 17500 et seq., Require Reimbursement: None.

Nondiscretionary Costs/Savings to Local Agencies: None

Cost or Savings in Federal Funding to the State: None.

The Department has made an initial determination that the proposed regulatory action will not have any significant statewide adverse economic impact directly affecting California businesses including the ability of California businesses to compete with businesses in other states.

Cost Impacts on Representative Private Persons or Businesses: According to the Department's projections, the implementation of the proposed action is anticipated to incur an annual expense of approximately \$100,000 for the commercial blood bank industry in California. This financial burden is expected to be transferred downstream to emergency veterinary hospitals, subsequently slightly increasing the cost of animal blood transfusions at these facilities.

Anticipated Compliance Requirements as a Result of this Proposal: This proposal affects persons or businesses applying for a license to operate an animal blood bank and to register blood product components with the Department. It requires applicants and licensees to submit to the Department licensure and registration forms, quarterly reports, and it contains record keeping requirements.

Effect on Housing Costs: None.

RESULTS OF THE ECONOMIC IMPACT ASSESSMENT/ANALYSIS

The Department concludes that it is: (1) likely that the proposal will have no immediate impact on jobs at existing commercial blood banks and will facilitate the creation of an unknown number of jobs at newly formed community blood banks; (2) likely that this proposal will accelerate the creation of new businesses operating as community blood banks and clarify when businesses operating as closed-colony blood banks will be eliminated; (3) likely this proposal will facilitate the expansion of the unknown number of veterinary hospitals into the blood banking marketplace; (4) likely the enhanced enforcement and reporting responsibilities will protect consumers and the industry. Finally, this proposed rulemaking will have no impact on the general public and the protection of public health and safety.

SMALL BUSINESS DETERMINATION

The Department has initially determined that the proposed adoption of this regulatory action would affect small businesses.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5(a)(13), the Department must determine that no reasonable alternative it considered or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Department invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations at the scheduled hearing if one is requested by the public or during the written comment period.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND INFORMATION AND TEXT OF THE PROPOSAL

Copies of the exact language of the proposed regulations and the Initial Statement of Reasons, and all the information upon which the proposal is based, may be obtained by contacting the persons named below or by accessing the Department's website as indicated below in this Notice.

The Department will have the rulemaking file available for inspection and copying throughout the rulemaking process at its office located at 1220 N Street, Sacramento, CA 95814. As of the date this notice is published in the California Regulatory Notice Register, the rulemaking file consists of this Notice, Proposed Text, the Initial Statement of Reasons and the Material Relied Upon which at this time consists of (1) Consensus Statement on blood donor infectious disease screening by the American College of Veterinary Internal Medicine, (2) California Consumer Price Index 2022/2023, and (3) Animal Blood Bank Program Expenditure/Revenue report. Copies may be obtained by contacting Dr. Sean Brady at the address or phone number listed below.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS

Upon its completion, copies of the Final Statement of Reasons may be obtained by contacting the persons named below.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments received, the Department may amend the proposed regulations substantially as described in this Notice. If the Department makes modifications, which are sufficiently related to the originally proposed text, it will make the modified text (with changes clearly indicated) available to the public for at least 15 days before the Department adopts the regulations as modified. Please send requests for copies of any modified regulations to the attention of Dr. Sean Brady at the address listed below. The Department will accept written comments on the modified regulations for 15 days after the date on which they are made available.

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons and the text of the proposed regulations shown in strikeout and underline format, can be accessed through the Department's website at: <http://www.cdfa.ca.gov/ahfss/regulations.html>, or by contacting the contact person named below in this Notice.

CONTACT PERSONS

Inquiries, written comments, copies of the proposed text of the regulations, the Initial Statement of Reasons, modified text of the regulation, if any, or other information upon which the rulemaking proposal is based, are to be addressed to the following person:

Sean Brady, DVM
Department of Food and Agriculture
Animal Health and Food Safety Services
Animal Blood Banks
1220 N Street, Sacramento, CA 95814
Telephone (916) 208-0500
E-mail: sean.brady@cdfa.ca.gov

The back-up person is:

Nancy Grillo
Department of Food and Agriculture
Animal Health and Food Safety Services

Division Administration
1220 N Street, Sacramento, CA 95814
Telephone (916) 900-5000
E-mail: nancy.grillo@cdfa.ca.gov