

**ECONOMIC AND FISCAL IMPACT STATEMENT****(REGULATIONS AND ORDERS)**

STD. 399 (Rev. 10/2019)

**ECONOMIC IMPACT STATEMENT**

DEPARTMENT NAME <b>Food and Agriculture</b>	CONTACT PERSON <b>Sean Brady, DVM</b>	EMAIL ADDRESS <b>sean.brady@cdfa.ca.gov</b>	TELEPHONE NUMBER <b>916-208-0500</b>
DESCRIPTIVE TITLE FROM NOTICE REGISTER OR FORM 400 <b>Animal Blood Banks</b>			NOTICE FILE NUMBER <b>Z -2024-0123-02</b>

**A. ESTIMATED PRIVATE SECTOR COST IMPACTS** *Include calculations and assumptions in the rulemaking record.*

1. Check the appropriate box(es) below to indicate whether this regulation:

- |  |  |
|--|--|
| <input checked="" type="checkbox"/> a. Impacts business and/or employees | <input checked="" type="checkbox"/> e. Imposes reporting requirements              |
| <input checked="" type="checkbox"/> b. Impacts small businesses          | <input checked="" type="checkbox"/> f. Imposes prescriptive instead of performance |
| <input type="checkbox"/> c. Impacts jobs or occupations                  | <input type="checkbox"/> g. Impacts individuals                                    |
| <input type="checkbox"/> d. Impacts California competitiveness           | <input type="checkbox"/> h. None of the above (Explain below):                     |

*If any box in Items 1 a through g is checked, complete this Economic Impact Statement.**If box in Item 1.h. is checked, complete the Fiscal Impact Statement as appropriate.*2. The CDFA estimates that the economic impact of this regulation (which includes the fiscal impact) is:  
(Agency/Department)

- Below \$10 million
- Between \$10 and \$25 million
- Between \$25 and \$50 million
- Over \$50 million *[If the economic impact is over \$50 million, agencies are required to submit a [Standardized Regulatory Impact Assessment](#) as specified in Government Code Section 11346.3(c)]*

3. Enter the total number of businesses impacted: 4Describe the types of businesses (Include nonprofits): Animal Blood BanksEnter the number or percentage of total businesses impacted that are small businesses: 100%4. Enter the number of businesses that will be created: Unknown eliminated: 0Explain: CDFA anticipates an unknown number of community blood banks will be created. AB 1282 (Stats. 2021, Ch5. Indicate the geographic extent of impacts:  Statewide  
 Local or regional (List areas): \_\_\_\_\_6. Enter the number of jobs created: Unknown and eliminated: 0Describe the types of jobs or occupations impacted: No immediate impact on jobs at existing commercial blood banks.By providing clarity in the marketplace the regulation will accelerate the creation of new community blood7. Will the regulation affect the ability of California businesses to compete with other states by making it more costly to produce goods or services here?  YES  NO

If YES, explain briefly: \_\_\_\_\_

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**ECONOMIC IMPACT STATEMENT (CONTINUED)****B. ESTIMATED COSTS** *Include calculations and assumptions in the rulemaking record.*

1. What are the total statewide dollar costs that businesses and individuals may incur to comply with this regulation over its lifetime? \$ 3,016,000
- a. Initial costs for a small business: \$ 4,000 Annual ongoing costs: \$ 25,000 Years: ~30
- b. Initial costs for a typical business: \$ 4,000 Annual ongoing costs: \$ 25,000 Years: ~30
- c. Initial costs for an individual: \$ 4,000 Annual ongoing costs: \$ 25,000 Years: ~30
- d. Describe other economic costs that may occur: Small increase in cost of blood and blood component products (\$3 - \$25) purchased. Small increase in amount paid by pet owners for veterinary procedures requiring a blood transfusion (\$3 - \$25).
2. If multiple industries are impacted, enter the share of total costs for each industry: CDFA anticipates blood bank fees will be passed on to emergency hospitals. In turn, emergency hospitals will pass the cost on to owners of pets undergoing transfusion.
3. If the regulation imposes reporting requirements, enter the annual costs a typical business may incur to comply with these requirements. Include the dollar costs to do programming, record keeping, reporting, and other paperwork, whether or not the paperwork must be submitted. \$ 0
4. Will this regulation directly impact housing costs?  YES  NO  
If YES, enter the annual dollar cost per housing unit: \$ \_\_\_\_\_  
Number of units: \_\_\_\_\_
5. Are there comparable Federal regulations?  YES  NO
- Explain the need for State regulation given the existence or absence of Federal regulations: AB 1282 (Ch 752, Statutes of 2021) altered the regulatory framework for blood banks in California. A robust regulatory framework is necessary to implement, interpret, and make specific rules for blood banks in California.
- Enter any additional costs to businesses and/or individuals that may be due to State - Federal differences: \$ 0

**C. ESTIMATED BENEFITS** *Estimation of the dollar value of benefits is not specifically required by rulemaking law, but encouraged.*

1. Briefly summarize the benefits of the regulation, which may include among others, the health and welfare of California residents, worker safety and the State's environment: This proposal does not directly affect the health and welfare of California residents, worker safety and the State's environment. It is likely the proposal will result in the increased supply of safe blood products for transfusion, which is vital to animal health.
2. Are the benefits the result of:  specific statutory requirements, or  goals developed by the agency based on broad statutory authority?  
Explain: The stated goals of AB1282 (Ch 752, 2021) are to increase blood supply and transition to community blood banks.
3. What are the total statewide benefits from this regulation over its lifetime? \$ 100,000 - \$300,000/ annu
4. Briefly describe any expansion of businesses currently doing business within the State of California that would result from this regulation: By providing clarity on the requirements for operating commercial blood banks in California, the proposal will result in an unknown number of veterinary hospitals entering the animal blood banking marketplace.

**D. ALTERNATIVES TO THE REGULATION** *Include calculations and assumptions in the rulemaking record. Estimation of the dollar value of benefits is not specifically required by rulemaking law, but encouraged.*

1. List alternatives considered and describe them below. If no alternatives were considered, explain why not: 1) Sum of product sales as trigger for discontinuation of closed colony blood banks - may result in inadequate supply of certain products. 2) Increasing product registration fees - would create barrier to entry for new businesses.

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**ECONOMIC IMPACT STATEMENT (CONTINUED)**

2. Summarize the total statewide costs and benefits from this regulation and each alternative considered:

Regulation: Benefit: \$ \_\_\_\_\_ Cost: \$ \_\_\_\_\_

Alternative 1: Benefit: \$ \_\_\_\_\_ Cost: \$ \_\_\_\_\_

Alternative 2: Benefit: \$ \_\_\_\_\_ Cost: \$ \_\_\_\_\_

3. Briefly discuss any quantification issues that are relevant to a comparison of estimated costs and benefits for this regulation or alternatives: \_\_\_\_\_

4. Rulemaking law requires agencies to consider performance standards as an alternative, if a regulation mandates the use of specific technologies or equipment, or prescribes specific actions or procedures. Were performance standards considered to lower compliance costs?  YES  NO

Explain: \_\_\_\_\_

**E. MAJOR REGULATIONS** *Include calculations and assumptions in the rulemaking record.*

***California Environmental Protection Agency (Cal/EPA) boards, offices and departments are required to submit the following (per Health and Safety Code section 57005). Otherwise, skip to E4.***

1. Will the estimated costs of this regulation to California business enterprises **exceed \$10 million**?  YES  NO

***If YES, complete E2. and E3  
If NO, skip to E4***

2. Briefly describe each alternative, or combination of alternatives, for which a cost-effectiveness analysis was performed:

Alternative 1: \_\_\_\_\_

Alternative 2: \_\_\_\_\_

*(Attach additional pages for other alternatives)*

3. For the regulation, and each alternative just described, enter the estimated total cost and overall cost-effectiveness ratio:

Regulation: Total Cost \$ \_\_\_\_\_ Cost-effectiveness ratio: \$ \_\_\_\_\_

Alternative 1: Total Cost \$ \_\_\_\_\_ Cost-effectiveness ratio: \$ \_\_\_\_\_

Alternative 2: Total Cost \$ \_\_\_\_\_ Cost-effectiveness ratio: \$ \_\_\_\_\_

4. Will the regulation subject to OAL review have an estimated economic impact to business enterprises and individuals located in or doing business in California exceeding \$50 million in any 12-month period between the date the major regulation is estimated to be filed with the Secretary of State through 12 months after the major regulation is estimated to be fully implemented?

YES  NO

*If YES, agencies are required to submit a [Standardized Regulatory Impact Assessment \(SRIA\)](#) as specified in Government Code Section 11346.3(c) and to include the SRIA in the Initial Statement of Reasons.*

5. Briefly describe the following:

The increase or decrease of investment in the State: \_\_\_\_\_

The incentive for innovation in products, materials or processes: \_\_\_\_\_

The benefits of the regulations, including, but not limited to, benefits to the health, safety, and welfare of California residents, worker safety, and the state's environment and quality of life, among any other benefits identified by the agency: \_\_\_\_\_

**ECONOMIC AND FISCAL IMPACT STATEMENT  
(REGULATIONS AND ORDERS)**

**FISCAL IMPACT STATEMENT**

**A. FISCAL EFFECT ON LOCAL GOVERNMENT** *Indicate appropriate boxes 1 through 6 and attach calculations and assumptions of fiscal impact for the current year and two subsequent Fiscal Years.*

1. Additional expenditures in the current State Fiscal Year which are reimbursable by the State. (Approximate)  
(Pursuant to Section 6 of Article XIII B of the California Constitution and Sections 17500 et seq. of the Government Code).

\$ \_\_\_\_\_

a. Funding provided in \_\_\_\_\_

Budget Act of \_\_\_\_\_ or Chapter \_\_\_\_\_, Statutes of \_\_\_\_\_

b. Funding will be requested in the Governor's Budget Act of \_\_\_\_\_

Fiscal Year: \_\_\_\_\_

2. Additional expenditures in the current State Fiscal Year which are NOT reimbursable by the State. (Approximate)  
(Pursuant to Section 6 of Article XIII B of the California Constitution and Sections 17500 et seq. of the Government Code).

\$ \_\_\_\_\_

*Check reason(s) this regulation is not reimbursable and provide the appropriate information:*

a. Implements the Federal mandate contained in \_\_\_\_\_

b. Implements the court mandate set forth by the \_\_\_\_\_ Court.

Case of: \_\_\_\_\_ vs. \_\_\_\_\_

c. Implements a mandate of the people of this State expressed in their approval of Proposition No. \_\_\_\_\_

Date of Election: \_\_\_\_\_

d. Issued only in response to a specific request from affected local entity(s).

Local entity(s) affected: \_\_\_\_\_  
\_\_\_\_\_

e. Will be fully financed from the fees, revenue, etc. from: \_\_\_\_\_

Authorized by Section: \_\_\_\_\_ of the \_\_\_\_\_ Code;

f. Provides for savings to each affected unit of local government which will, at a minimum, offset any additional costs to each;

g. Creates, eliminates, or changes the penalty for a new crime or infraction contained in \_\_\_\_\_

3. Annual Savings. (approximate)

\$ \_\_\_\_\_

4. No additional costs or savings. This regulation makes only technical, non-substantive or clarifying changes to current law regulations.

5. No fiscal impact exists. This regulation does not affect any local entity or program.

6. Other. Explain This proposal is industry funded by licensing fees, product registration fees, and per milliliter fees for blood and blood component products to cover State administrative and enforcement cost

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**FISCAL IMPACT STATEMENT (CONTINUED)**

**B. FISCAL EFFECT ON STATE GOVERNMENT** *Indicate appropriate boxes 1 through 4 and attach calculations and assumptions of fiscal impact for the current year and two subsequent Fiscal Years.*

1. Additional expenditures in the current State Fiscal Year. (Approximate)

\$ \_\_\_\_\_

*It is anticipated that State agencies will:*

a. Absorb these additional costs within their existing budgets and resources.

b. Increase the currently authorized budget level for the \_\_\_\_\_ Fiscal Year

2. Savings in the current State Fiscal Year. (Approximate)

\$ \_\_\_\_\_

3. No fiscal impact exists. This regulation does not affect any State agency or program.

4. Other. Explain This proposal is industry funded by licensing fees, product registration fees, and per milliliter fees for blood and blood component products to cover State administrative and enforcement cost

**C. FISCAL EFFECT ON FEDERAL FUNDING OF STATE PROGRAMS** *Indicate appropriate boxes 1 through 4 and attach calculations and assumptions of fiscal impact for the current year and two subsequent Fiscal Years.*

1. Additional expenditures in the current State Fiscal Year. (Approximate)

\$ \_\_\_\_\_

2. Savings in the current State Fiscal Year. (Approximate)

\$ \_\_\_\_\_

3. No fiscal impact exists. This regulation does not affect any federally funded State agency or program.

4. Other. Explain \_\_\_\_\_

FISCAL OFFICER SIGNATURE

 **Nathan Johnson**

 Digitally signed by Nathan Johnson  
Date: 2024.05.03 17:02:54 -07'00'

DATE

*The signature attests that the agency has completed the STD. 399 according to the instructions in SAM sections 6601-6616, and understands the impacts of the proposed rulemaking. State boards, offices, or departments not under an Agency Secretary must have the form signed by the highest ranking official in the organization.*

AGENCY SECRETARY

 **Annette Jones**

 Digitally signed by Annette Jones  
Date: 2024.05.06 13:00:22 -07'00'

DATE

*Finance approval and signature is required when SAM sections 6601-6616 require completion of Fiscal Impact Statement in the STD. 399.*

DEPARTMENT OF FINANCE PROGRAM BUDGET MANAGER



DATE