

Date of Hearing: April 29, 2021

ASSEMBLY COMMITTEE ON AGRICULTURE

Robert Rivas, Chair

AB 1282 Bloom – As Amended April 15, 2021

SUBJECT: Veterinary medicine: blood banks for animals

SUMMARY: Allows veterinarians to operate community blood banks for animals, which source blood from animals volunteered by their owners. Establishes conditions for the elimination of captive closed-colony canine blood banks, which source blood from dogs kept, housed, or maintained at a facility for collecting their blood. Allows the importation of animal blood from out-of-state blood banks that comply with California standards. Provides implementation requirements on the Veterinary Medical Board (VMB) and the California Department of Food and Agriculture (CDFA), as specified. Specifically, *this bill*:

- 1) Adds to the practice of veterinary practice the act of collecting blood from an animal for the purpose of transferring or selling that blood and blood component products to a licensed veterinarian at a registered premise.
- 2) Provides for the following definitions:
 - a) Community blood bank means a commercial blood bank for animals that produces animal blood or blood component products solely from community-sourced animals whose owners voluntarily consent to the donation.
 - b) Community sourced means that an animal is:
 - i) Kept, housed, and maintained at the residence of its owner who is a person and not a partnership, association, corporation, or limited liability company;
 - ii) Brought by its owner to a community blood bank for animals to have its blood collected; and,
 - iii) Licensed in accordance with any pet licensing required by the pet owner's state, county, or city of residence.
 - c) Captive closed colony means that an animal is kept, housed, or maintained in any way for collecting its blood.
 - d) Closed-colony blood bank means a commercial blood bank for animals that produces animal blood or blood component products solely from animals held in a captive closed colony.
 - e) Commercial blood bank for animals means an establishment that produces animal blood or blood component products from captive closed-colony or community-sourced animals to market and sell for use in the cure, mitigation, treatment, or prevention of injury or disease in animals.
 - f) Production means the collection of blood or the preparation, testing, processing, storage, or distribution of blood or blood component products for purpose of transfusion.

- g) Adverse event means an event in which an animal is injured, sickened, rendered unconscious, or killed.
 - h) Disposition means adoption, euthanasia, transfer to another blood bank, breeding facility, farm, animal control agency, animal shelter, or rescue organization, or donation or sale for medical research or other purpose.
- 3) Allows a registered veterinary technician or a veterinary assistant to collect blood from an animal for the purpose of transferring or selling the blood and blood component products to a licensed veterinarian at a registered premise, under the direct or indirect supervision of a licensed veterinarian, as specified.
- 4) Allows a California licensed veterinarian to engage in the production of animal blood and blood component products solely for use in their own practice or for a community blood bank under the following conditions:
- a) Operate under conditions, and use methods of production, that are consistent with current standards of care and practice for the field of veterinary transfusion medicine to ensure that the animal blood and blood component products will not be contaminated, dangerous, or harmful.
 - b) Ensure that the production of blood and blood component products is safe and not injurious to the donor animal's health.
 - c) Follow the latest blood banking standards and maintain responsibility over all veterinary and technical policies and procedures that relate to the safety of staff members and donor animals.
 - d) Use bloodborne pathogen testing for all canine and feline blood donors in accordance with the best clinical practices in the veterinary field.
 - e) Ensure that the production of animal blood and blood component products complies with all applicable federal laws and regulations.
 - f) Maintain onsite records available for inspection by VBM including information documenting any history of blood draws or use of anesthesia on the animal, the number and date of donations collected, the volume of blood collected per donation in milliliters, any adverse events, and any complaints from owners regarding animals who donate blood or blood component products.
 - g) Obtain the informed written consent of the owner of the animal blood donor and keep a record of that consent.
- 5) Allows a community blood bank to engage in the production of animal blood and blood component products for retail sale and distribution.
- 6) Prohibits a veterinarian or a community blood bank from providing payment to a person who provides an animal for donating that animal's blood and blood component products for use in their practice or for retail sale and distribution. Clarifies that "payment" does not include fees

for veterinary tests, medications, vaccinations, screenings, or other services that benefit the health of the animal from which the blood or blood component products were taken.

- 7) Allows the VMB to establish a community blood bank registration and renewal fee and appropriate to be paid by community blood banks to cover costs associated with oversight and inspection of the premises, as long as the fee does not exceed the reasonable regulatory costs of administering, implementing, and enforcing the bill's provisions.
- 8) Directs the VMB, upon appropriation by the Legislature, to hire a consultant to assist in developing guidelines and best practices for veterinarians to follow when operating community blood banks.
- 9) Mandates that the VMB adopts and publishes guidelines and best practices for the operation of community blood banks by January 1, 2023. States that such guidelines must be updated as appropriate.
- 10) Requires community blood banks to comply with the following:
 - a) Adhere to all blood product registration requirements established under CDFA.
 - b) Submit a quarterly report to CDFA every three months that includes all of the following information:
 - i) The number of donations from community-sourced animals and total volume in milliliters of whole blood, packed red blood cells, and fresh frozen plasma sold during that quarter, by species of animal;
 - ii) The number and species of animal donors experiencing adverse events, the total number of adverse events, and the nature of adverse events experienced by animals that donate blood;
 - iii) The number and species of animal donors that have donated blood; and,
 - iv) The number and species of animal donors whose blood tested positive for known pathogens, in accordance with the best clinical practices in the veterinary field.
- 11) Requires VMB to take the appropriate disciplinary action against a veterinary licensee who violates community blood banking provisions.
- 12) Adds new requirements on captive closed-colony commercial blood banks for animals. Specifically, requires such blood banks to:
 - a) Operate under conditions and methods of productions that are consistent with current standards of care and practice for the field of veterinary transfusion medicine.
 - b) Requires that all animal donors are kept, housed, and maintained within California state boundaries.
 - c) Add procedures regarding bloodborne pathogen testing for all canine and feline blood donors in accordance with the best clinical practices in the veterinary field.

- 13) Establishes data collection and record-keeping requirements on closed-colony blood banks, including the requirement to maintain onsite record of the number of donations collected from captive animals, the volume of blood collected per donation in milliliters, any adverse events, the disposition of any animals, and other information. Requires a closed-colony blood bank to submit a quarterly report to CDFA, which must be retroactive for 2018, 2019, and 2020, that includes the following information:
 - a) The number of donations from captive animals and total volume in milliliters of whole blood, packed red blood cells, and fresh frozen plasma sold during that quarter, by species of animal.
 - b) The number of captive animals kept, housed, or maintained at the closed-colony blood bank, by species of animal.
 - c) The disposition records of any animals and the total number of animals released for adoption.
 - d) The number and species of animals experiencing adverse events, the total number of adverse events, and the nature of adverse events experienced by captive animals that donate blood.
 - e) The number and species of animal donors whose blood tested positive for known pathogens, in accordance with the best clinical practices in the veterinary field.
- 14) Requires all blood banks, for bloodborne pathogen testing, to use best clinical practices in the veterinary field, including but not limited to any standards and guidelines issued by the American Association of Blood Banks, the Association of Veterinary Hematology and Transfusion Medicine and the most recent Consensus Statement on blood donor infectious disease screening by the American College of Veterinary Internal Medicine.
 - a) Requires veterinarians operating community blood banks to also follow guidelines regarding community blood banks published by the VMB, conditional on their publication.
- 15) Directs CDFA to annually submit and publish a copy of the canine blood collection information to specified legislative committees and VMB.
- 16) Increases the licensing and renewal fees for a closed-colony blood bank under CDFA from \$250 to \$1,000.
- 17) Adds the following information to be included as part of the application for registration of blood or a blood component product under CDFA:
 - a) The name and address of the person who owns the property, establishment, institution, or business that sells the blood.
 - b) The name and address of the person who oversees the production of animal blood and blood component products.
 - c) The type of animal blood and blood component products produced for sale.

- d) A full description of the building, including its address, facilities, equipment, and apparatus, to be used in production of animal blood and blood component products.
- 18) Allows CDFA to establish a registration application fee and annual renewal fee for each establishment proposing to offer blood or blood component products for retail sale or use in California, at an amount yet to be determined.
- 19) Mandates CDFA to discontinue its licensing program for commercial blood banks for animals within 12 months of CDFA determining that community blood banks sold an annual amount of canine blood in California that equals or exceeds the average annual amount closed-colony blood banks sold in the state in 2018, 2019, and 2020, or in four consecutive quarters.
- a) Clarifies that for the purpose of this calculation, canine blood means three categories:
 - i) Whole blood.
 - ii) Packed red blood cells.
 - iii) Fresh frozen plasma.
- 20) Requires CDFA to track, administer, and enforce the importation of animal blood and blood component products from out-of-state blood banks to ensure the products are in compliance with California standards.
- 21) Applies the California Public Records Act (CPRA) to all records held under CDFA, with specified exemptions, related to blood banking, including but not limited to, records relating to applications, fees, or inspections, except for identifying personal information.

EXISTING LAW:

- 1) Provides for the licensure and regulation of veterinary medicine by VBM in the Department of Consumer Affairs.
- 2) Authorizes VBM to deny, revoke, or suspend a license or registration or assess a fine for a violation of specified acts, including the employment of anyone but a veterinarian licensed in this state to demonstrate the use of biologics in the treatment of animals.
- 3) Prohibits any person from collecting blood from animals or preparing, testing, processing, storing, or distributing blood or blood component products, as defined, from animals, for retail sale and distribution except in a commercial blood bank for animals that is licensed by the Secretary of CDFA (Secretary), except as provided.
- 4) Defines commercial blood bank for animals to mean an establishment that produces animal blood or blood component products to market and sell for use in the cure, mitigation, treatment, or prevention of injury or disease in animals.
- 5) Requires the Secretary to license establishments as commercial blood banks for animals that meet all of the following:

- a) Operate under conditions, and use methods of production, to ensure that the animal blood and blood component products will not be contaminated, dangerous, or harmful;
 - b) Produce animal blood and blood component products under the direct supervision of a person qualified in the field; and,
 - c) Maintain onsite records containing information documenting how the animal was acquired and any history of blood draws or use of anesthesia on the animal, except as provided.
- 6) Requires an application for a license to contain specified information, including a written protocol that addresses all of the following:
- a) Maximum length of time for donation by animal donors, or minimum health parameters for animal donors;
 - b) Frequency and volume of blood collected from animal blood donors;
 - c) Socialization and exercise programs for animal blood donors;
 - d) Method of identification of each animal, including microchip or tattoo;
 - e) Ongoing veterinary care, including an annual physical exam and vaccination schedule for animals held in blood donor facilities;
 - f) Husbandry standards for feeding, watering, sanitation, housing, handling, and care in transit, with minimums based on the standards set forth pursuant to the federal Animal Welfare Act; and,
 - g) Implementation of a permissive adoption program.
- 7) Governs the disclosure of information collected and maintained by public agencies pursuant to CPRA.
- 8) Provides that public records are open to inspection at all times during the office hours of the state or local agency and every person has a right to inspect any public record, except as provided.
- 9) Generally, all public records are accessible to the public upon request, unless the record requested is exempt from public disclosure.
- 10) Provides that all records held by CDFA relating to commercial blood banks for animals including, but not limited to, records relating to applications, fees, or inspections, are confidential and are not subject to disclosure under CPRA, except those records are accessible to law enforcement officers with jurisdiction, as provided.

FISCAL EFFECT: Unknown

COMMENTS: In California, two commercial blood banks for animals produce blood products under California licenses. Commercial blood banks for animals are establishments that produce animal blood products to market or sell for the use in the cure, mitigation, treatment or prevention of injury or disease in animals. California law prohibits the offering for sale or use of any animal blood product unless it is produced in an establishment licensed by CDFA. California requires a license for each commercial blood bank for animal establishments and requires the registration of each blood product being produced and sold. Application and licensing requirements must be met to qualify for licensure.

California requires all dog blood sold for veterinary purposes to come from a closed colony facility. A closed colony facility is a facility in which dogs live for a set amount of time solely for the purpose of donating blood. California veterinarians also may obtain blood for transfusions from other, healthy dogs being treated in their veterinary offices or from the dogs of their employees. Legislation in 2018 clarified that licensed private veterinarians who collect blood products solely for use in their own practice is exempt from having to obtain an animal blood bank license.

Under current law, California veterinarians must purchase blood from a closed colony commercial blood bank in the state, or they can collect dog blood for use in their own practice. CDFA is responsible for all oversight of the closed colony commercial facilities in California, which is the only state with this type of regulated commercial blood banks. Other states handle canine blood for transfusions at local hospitals and clinics, which operate under federal regulations and veterinary medicine guidelines. Most out of state animal blood banks are Community Blood Donor Programs (CBDP). The community blood bank system in other states allows for the sale of blood products.

Critics of closed-colony blood banks point to more humane models of supplying animal blood and blood products, including the use of the community-sourced blood banks. Similar to traditional human blood donations, this model relies on volunteer pet owners, who bring in their animals to be donors for the blood bank. There are several advantages to this model: first, the ethical assurance that the animals are not routinely exploited for their blood, as community-sourced blood banks rely entirely on volunteers pet owners.

The University of California at Davis (UCD) does operate a Canine CDBP. The UCD Veterinary Blood Bank began screening donor dogs in February 2008 for enrollment into a community-based donation program. The hospital's blood bank collects, processes and stores canine blood needed for transfusions to treat a variety of conditions in dogs. UCD is not allowed to sell any canine blood products to other entities.

Currently, CDFA provides oversight of California Licensed Blood Banks for Animals. At a minimum of once per year, CDFA inspects every facility maintained by a Commercial Blood Bank for Animals that is licensed by the state. The expectations are laid out in statute, which also incorporate Federal Code of Regulations related to the Federal Animal Welfare Act. CDFA sends two people on these inspections, and one is always a veterinarian. Any issues are noted and re-checked for compliance.

According to the author, "This vital legislation would modernize California law to provide a safe, ethically-sourced animal blood supply for use in veterinary practice, addressing both blood supply shortage as well as animal welfare concerns. Currently, there are only two commercial

blood banks for animals in California, both of which confine donor animals in closed-colonies to accord with the state's existing regulatory framework. Not only do they keep hundreds of dogs in cages for years while their blood is routinely harvested, but the demand for animal blood to perform transfusions and respond to medical emergencies outstrips their supply. This bill would authorize community blood banks for animals similar to human models, allowing blood collection from pets whose owners voluntarily consent to the donation. It would phase out captive, closed-colony canine blood banks over time and permit the safe importation of animal blood from out-of-state community banks in compliance with California standards to further ensure an adequate blood supply for veterinary needs.”

Supporters state, “Animal blood banks provide veterinarians with blood products needed for transfusions to save the lives of pets that have been injured or have various health issues. Current law limits the supply of these lifesaving products by preventing blood collection from community-based banks, which operate very similar to human blood banks by bringing in dogs from the community to donate blood and then return home with their human families. A study published in the *Journal of Applied Animal Welfare Science* concluded, 'community-based canine volunteer donor programs for animal blood banks can be successful while maintaining high safety standards and ethical treatment of volunteers.' Additional safety measures are required in the bill with new requirements for blood-borne pathogen testing for all animal donors. Simultaneously, AB 1282 will initiate a phase out of the 'closed-colony' commercial blood bank model, which operate by keeping dogs in cages for most or all of their life to be bled. These dogs, usually greyhounds, are deprived of a normal life with their human companions and deserve better. Once the phase out is complete, AB 1282 will require all blood banks to be maintained by a licensed veterinarian, ensuring a completely safe and regulated environment for all community animal donors. AB 1282 also ends the public record exemption for commercial blood banks by making them subject to the California Public Records Act for more transparency into the business of how animal blood products are produced.”

Opponents state, “The ongoing pandemic has exacerbated the logistics of the veterinary care and treatment process. It is unlikely that community donors will voluntarily provide their pets for donations; nor will veterinarians be in a position to handle or want to handle the issues associated with being an approved community donor facility. This will likely continue for a longtime, irrespective of any opening up of the economy. Until there is better clarity as to how veterinary services are going to be adequately provided in our state, it is premature to mandate a new regime (and closure of an ongoing regime).”

The California Veterinary Medical Association (CVMA) expressed concerns related to shifting California to a new animal blood collection model. The concerns focus on maintaining a sufficient supply of animal blood and ensuring the quality of animal blood product remains safe for veterinary use. CVMA focused on two issues:

- 1) Under this bill, CDFA will make the determination of the “trigger” threshold to wind-down closed colony blood banks. To ensure the assessment is properly carried out, CVMA believes CDFA is in need of experts, potentially contracted positions, to collect and review the data. This would require an appropriation of some sort.
- 2) To ensure the animal blood supply is safe, there is a need to develop protocols and guidance for veterinarians to follow when engaging in donor blood banking. Recent

amendments would grant the Veterinary Medical Board a position to develop the needed protocols, but there is still a funding issue to be resolved.

POLICY CONSIDERATIONS:

Suggested Technical Amendment: This bill, when discussing units of blood measurements, uses volume and milliliter. In discussion with several organization who draw blood, it was stated the standard measurement is milliliter and weight. In order to ensure there are not discrepancies in the language, the author may wish to adjust this wording, as this bill moves forward.

Wind-Down of the Closed Colony System: This bill requires the eventual elimination of closed colony canine blood banks, once CDFA makes a determination that community blood banks are producing enough canine blood to replace the current supply. This bill currently sets this definition and sets the “trigger” for phasing out closed colony blood banks. The threshold is when community blood banks annual sales of canine blood in California equals or exceeds the average annual amount of canine blood that closed-colony blood banks sold in the state in 2018, 2019, and 2020, or in four consecutive quarters. Once CDFA determines either of these conditions are met, the closed colony blood banks will have a year to wind down.

With concern about how this will affect California’s animal blood supply or the ramp up time for community animal blood banks, the committee may want to discuss if the current definition is adequate to ensure a steady supply of canine blood.

Safe Animal Blood Products Protocols: This bill requires, in relation to bloodborne pathogens testing, states that protocols “Utilize bloodborne pathogen testing for all canine and feline blood donors in accordance with the best clinical practices in the veterinary field, including, but not limited to, any standards and guidelines issued by the Association of Veterinary Hematology and Transfusion Medicine (AVHTM) and the most recent Consensus Statement on blood donor infectious disease screening by the American College of Veterinary Internal Medicine (ACVIM).” While ACVIM periodically published a consensus statement, the most recent in 2016, AVHTM does not have any published protocols or guidelines.

AVHTM, in its newsletter, shares a fair number of peer-reviewed articles on the issues related to animal blood banks. In an undated statement on AVHTM website it does state “*The AVHTM fully supports and promotes the American Veterinary Medical Association (AVMA) Animal Welfare Principles and the American College of Veterinary Internal Medicine (ACVIM) consensus statement for blood donor screening for blood-borne pathogens. While we are not a regulatory agency, and while no current guidelines exist specifically related to the housing and treatment of animal blood donors, the AVTHM, in collaboration with the veterinary professional community, is invested in the long-term goal of developing veterinary blood banking standards and guidelines.*”

The committee may wish to consider if AVHTM should be listed as one of the required sources for California Animal Blood Bank Protocols or if including AVHTM’s future guidelines should be made permissive when developing California protocols.

RELATED LEGISLATION:

SB 202 (Wilk) of 2019: Would have modified the definition of a commercial blood bank for animals to include establishments that collect blood not only from captive closed-colony animals

but also community-sourced animals. Vetoed by the Governor. In his veto message, Governor Newsom writes:

“This bill permits commercial blood banks for animals to collect blood from community-sourced animal blood and imposes rules around the collection of community-sourced animal blood. I am supportive of changing California's law governing animal blood donation. However, this bill does not go far enough. I ask that the Legislature send me legislation that effectively leads to the phasing-out of "closed colonies," where dogs are kept in cages for months and years to harvest their blood for sale. The legislation should provide for the safe and humane treatment of donor animals, the welfare of the recipients and adequate oversight and enforcement of this program.”

AB 366 (Bloom) of 2019: Would have prohibited a person from engaging in the production of canine blood and blood component products or biologics for retail sale and distribution unless that person is licensed as a canine blood bank by CDFA, among other specified requirements, Held in the Assembly Committee on Agriculture at the request of author.

SB 1115 (Wilk) of 2020 would have modified the definition of a commercial blood bank for animals to limit the definition to establishments that collect blood from community-sourced animals. Would have excluded from the definition of a commercial blood bank for animals establishments that collect blood from captive closed-colony animals. The bill would have implemented a wind-down of closed colony blood banks. Held in the Assembly.

AB 1953 (Bloom) of 2020 would have allowed veterinarians to establish community blood banks and set up a mechanism to wind-down closed colony blood banks in California. Held in the Assembly.

REGISTERED SUPPORT / OPPOSITION:

Support

American Society for the Prevention of
Cruelty to Animals
Animal Legal Defense Fund
Beagle Freedom Project
Best Friends Animal Society
California Animal Welfare Association
Cruelty Free International
Direct Action Everywhere
Gayle Paul
Grey2kusa
In Defense of Animals
JaneunChained
Los Angeles Democrats for The Protection
of Animals
Lovebug's Rescue
Michelson Center for Public Policy

People for The Ethical Treatment of
Animals (PETA)
Poison Free Malibu
Project CounterGlow
Project Minnie
Riverside Animal Rights Voters
San Diego Humane Society and SPCA
San Francisco SPCA
Seeds to Inspire Foundation
Social Compassion in Legislation
St. John Creative
Start Rescue
Valley Humane Society
Vegan of La
Women United for Animal Welfare
(WUFAW)

394 Individuals

Oppose Unless Amended

Hemopet

Other

California Veterinary Medical Association

Opposition

None on file

Other

California Veterinary Medical Association

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