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AB-1282 Veterinary medicine: blood banks for animals. (2021-2022)

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Date Published: 10/11/2021 02:00 PM

Assembly Bill No. 1282

CHAPTER 752

An act to amend Section 4826 of, to amend, renumber, and add Section 4836.5 of, and to add Article 7 (commencing with Section 4920) to Chapter 11 of Division 2 of, the Business and Professions Code, and to amend Sections 9201, 9210, 9212, 9221, 9231, 9241, 9244, 9269, and 9272 of, to add Sections 9212.5, 9222, 9252, 9253, 9254, and 9255 to, and to repeal Sections 9202, 9203, 9204, 9205, and 9206 of, the Food and Agricultural Code, relating to animal health.

[Approved by Governor October 09, 2021. Filed with Secretary of State October 09, 2021.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1282, Bloom. Veterinary medicine: blood banks for animals.

(1) Existing law, the Veterinary Medicine Practice Act, provides for the licensure and registration of veterinarians and the regulation of the practice of veterinary medicine by the Veterinary Medical Board in the Department of Consumer Affairs. Under the act, prescribed actions constitute the practice of veterinary medicine. The act makes a violation of its provisions a crime.

This bill would include in the actions that constitute the practice of veterinary medicine the collection of blood from an animal for the purpose of transferring or selling that blood and blood component products, as defined, to a licensed veterinarian for use at a registered premises, except in certain circumstances. By expanding the scope of an existing crime, this bill would impose a state-mandated local program.

(2) Existing law permits a registered veterinary technician or a veterinary assistant to administer a drug, including a controlled substance, under the direct or indirect supervision of a licensed veterinarian when done pursuant to the order, control, and full professional responsibility of a licensed veterinarian.

This bill would also permit a registered veterinary technician or 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 premises, under the direct or indirect supervision of a licensed veterinarian, as specified.

(3) Existing law provides for the licensure of commercial blood banks for animals by the Secretary of Food and Agriculture. Existing law also defines a "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.

This bill would establish, within the Veterinary Medicine Practice Act, new procedures governing community blood banks for animals and would impose new requirements on veterinarians engaged in the production of animal blood and blood component products. The bill would define a "community blood bank" as 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. The bill would require each veterinarian who is licensed in California and engages in the production of animal blood or blood component products to meet specified conditions, including following current and best practices on community animal blood banking, using

methods of production that are consistent with current standards of care and practice for the field of veterinary transfusion medicine, and obtaining informed written consent of the owner of the animal blood donor. The bill would prohibit a veterinarian or a community blood bank operating under these provisions from providing payment to a person who provides an animal for the purpose of donating that animal's blood and blood component products for use in their practice and for retail sale and distribution.

The bill would authorize the Veterinary Medical Board to establish a community blood bank registration fee and an annual renewal fee to be paid by community blood banks to cover the costs associated with oversight and inspection of the premises. The bill would prohibit the fees from exceeding the reasonable regulatory costs of administering, implementing, and enforcing these provisions. The bill would require a community blood bank operating under the above-described provisions to comply with specified blood and blood component product registration requirements imposed under existing Food and Agricultural Code provisions. The bill would also require a community blood bank to submit a quarterly report to the Department of Food and Agriculture every 3 months that includes, among other information, the number of donations from community-sourced animals during that quarter, by species of animal. The bill would provide that a violation of these provisions by a community blood bank constitutes cause for corrective action or various other actions by the Veterinary Medical Board. The bill would define related terms, for purposes of carrying out these provisions, including "captive closed colony" and "community sourced."

(4) Existing law prohibits a person from engaging in the production of animal blood and blood component products for retail sale and distribution except in a commercial blood bank for animals licensed by the Secretary of Food and Agriculture that meet certain criteria. A violation of these provisions is a crime.

This bill would instead prohibit a person from engaging in the production of animal blood and blood component products for retail sale and distribution except in a captive closed-colony commercial blood bank for animals licensed by the secretary or in accordance with the above-described provisions governing community blood banks for animals. The bill would require each community blood bank to register blood and blood component products with the secretary in accordance with existing procedures.

The bill would require the Department of Food and Agriculture to discontinue its licensing program for commercial blood banks for animals that produce canine blood, as defined, and blood component products sourced from captive closed-colony dogs within 18 months of the secretary making specified findings about the amount of canine blood sold in the state, and satisfying other conditions. The bill would require the calculation of canine blood to be done separately, with whole blood, packed red blood cells, and fresh frozen plasma being measured as separate amounts in estimated milliliters based on weight in grams. The bill would require the department to annually submit specified canine blood collection information to specified members of the Legislature and the Veterinary Medical Board. The bill would require the department, in collaboration with the Veterinary Medical Board, technical experts in animal blood banking, and any other relevant stakeholders, by March 1, 2023, to develop and publish on its internet website a "Community Animal Blood Banking Guidance Resource" or other documents that provide veterinarians, at a minimum, accurate, clear, and concise information regarding best management practices for operating community blood banks. The bill would also prohibit the secretary from accepting new applications to license a commercial blood bank for animals that produce canine blood or blood component products sourced from captive closed-colony dogs. The bill would also require that the secretary, when licensing establishments as captive closed-colony commercial blood banks, to only license establishments that, among other conditions, keep, house, or maintain all animal donors within California state boundaries. The bill would authorize closed-colony blood banks to transition to community-sourced models and continue to operate in accordance with specified provisions.

By expanding the scope of a crime, the bill would impose a state-mandated local program.

(5) Existing law requires an application for a license for an establishment that produces, or proposes to produce, animal blood and blood component products to be made on a form issued by the Secretary of Food and Agriculture and to contain specific information, including a written protocol that addresses the length of time for donation by animals, among other requirements.

This bill would specify that the application for a license applies to any establishment that produces, or proposes to produce, animal blood and blood component products from a closed-colony blood bank. The bill would require the written protocol to be consistent with current standards of care and practice for the field of veterinary transfusion medicine and would require that protocol to include bloodborne pathogen testing for all dog and cat blood donors, as prescribed.

The bill would prohibit a commercial blood bank for animals from discriminating against veterinarians licensed in California in the sale of animal blood or blood component products. The bill would specify that a commercial blood bank for animals that refuses to sell animal blood or blood component products to a veterinarian in circumstances in which that blood bank has an available supply may be deemed by the secretary to be in violation of this provision.

(6) Existing law requires the licensee application fee and license renewal fee for an establishment proposing to produce or producing animal blood and blood component products to be \$250 for each establishment.

This bill would increase the application and annual license fees to \$1,000 for each establishment proposing to produce or producing animal blood and blood component products from a closed-colony blood bank and would allow for these fees to be adjusted annually for inflation. The bill would authorize the Department of Food and Agriculture to set inspection fees, as specified.

(7) Existing law prohibits a person from offering a blood or blood component product for sale unless it is produced in an establishment licensed by the Secretary of Food and Agriculture.

This bill would also permit a person to offer a blood or blood component product that is in accordance with the procedures governing blood banks for animals or imported into the state from an out-of-state blood bank that the secretary would be required to track, administer, and enforce, in compliance with California standards. The bill would require that the importation and sale of canine blood and blood component products from out-of-state sources is only permitted from community blood banks and would additionally require out-of-state community blood banks that sell canine blood and blood component products in the state to submit a quarterly report to the Department of Food and Agriculture every 3 months that includes specified information.

(8) Existing law requires an application for registration of blood or a blood component product to include both a protocol of the methods of production in detail that is followed in the production of the product and a sample of the label to be placed on the blood or blood component product.

This bill would also require that application to include the name and address of the person who owns the property, establishment, institution, or business that sells the blood, and various other information about the products for sale and the facilities. The bill would impose a registration application fee and annual renewal fee in the amount of \$500 for each blood or blood component product for retail sale or use in California. The bill would authorize the Department of Food and Agriculture to increase or decrease the fees in an amount that does not exceed the department's reasonable regulatory costs incurred to administer and enforce product safety standards.

The bill would also require each licensed closed-colony blood bank to maintain an onsite record of the number of donations collected from captive animals, the amount of blood collected per donation in estimated milliliters based on weight in grams, any adverse events, and other specified information. The bill would further require a licensed closed-colony blood bank to submit quarterly reports to the department every 3 months including specified information. The bill would make a violation of this provision and other specified provisions a cause for corrective action, suspension, restriction, or the nonrenewal or revocation of a license by the department. The bill would require proceedings to be conducted in conformity with formal administrative adjudication procedures.

(9) Existing law provides that all records held by the Department of Food and Agriculture relating to the provisions on commercial blood banks for animals and biologics are confidential and not subject to disclosure under the California Public Records Act, except that those records are accessible to law enforcement officers with jurisdiction over a matter covered by these provisions.

This bill would provide that "identifying personal information," as defined, would be kept confidential and not subject to disclosure under the act. The bill, however, would allow for the disclosure of certain information so long as the data does not contain individually identifiable information and would require disclosure of information that is already in the public domain. The bill would define "identifying personal information" to mean certain information pertaining to the owner of an animal donor, as specified, including social security number, date of birth, and related information.

(10) Existing law exempts from the provisions governing commercial blood banks for animals and biologics certain entities and also licensed private veterinarians who collect blood or blood products solely for their own practice.

This bill would also exempt from those provisions licensed veterinarians engaged in the production of animal blood and blood component products for community blood banks for animals, except as specified.

(11) Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

(12) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 4826 of the Business and Professions Code is amended to read:

4826. A person practices veterinary medicine, surgery, and dentistry, and the various branches thereof, when the person does any one of the following:

(a) Represents oneself as engaged in the practice of veterinary medicine, veterinary surgery, or veterinary dentistry in any of its branches.

(b) Diagnoses or prescribes a drug, medicine, appliance, application, or treatment of whatever nature for the prevention, cure, or relief of a wound, fracture, bodily injury, or disease of animals.

(c) Administers a drug, medicine, appliance, application, or treatment of whatever nature for the prevention, cure, or relief of a wound, fracture, bodily injury, or disease of animals, except where the medicine, appliance, application, or treatment is administered by a registered veterinary technician or a veterinary assistant at the direction of and under the direct supervision of a licensed veterinarian subject to Article 2.5 (commencing with Section 4836) or where the drug, including, but not limited to, a drug that is a controlled substance, is administered by a registered veterinary technician or a veterinary assistant pursuant to Section 4836.1. However, no person, other than a licensed veterinarian, may induce anesthesia unless authorized by regulation of the board.

(d) Performs a surgical or dental operation upon an animal.

(e) Performs any manual procedure for the diagnosis of pregnancy, sterility, or infertility upon livestock or Equidae.

(f) Collects blood from an animal for the purpose of transferring or selling that blood and blood component products to a licensed veterinarian at a registered premises, except where the blood is collected by a registered veterinary technician or veterinary assistant at the direction of, and under the direct supervision of, a licensed veterinarian subject to Article 2.5 (commencing with Section 4836) or where the blood is collected by a registered veterinary technician or a veterinary assistant pursuant to Section 4836.5. For purposes of this section, "blood and blood component products" has the same meaning as defined in Section 4920.

(g) Uses any words, letters, or titles in such connection or under such circumstances as to induce the belief that the person using them is engaged in the practice of veterinary medicine, veterinary surgery, or veterinary dentistry. This use shall be prima facie evidence of the intention to represent oneself as engaged in the practice of veterinary medicine, veterinary surgery, or veterinary dentistry.

SEC. 2. Section 4836.5 is added to the Business and Professions Code, to read:

4836.5. (a) Notwithstanding any other law, a registered veterinary technician or a veterinary assistant may 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 premises, under the direct or indirect supervision of a licensed veterinarian when done pursuant to the order, control, and full professional responsibility of a licensed veterinarian.

(b) For purposes of this section, the following definitions apply:

(1) "Blood and blood component products" has the same meaning as that term is defined in Section 4920.

(2) "Direct supervision" has the same meaning as that term is defined in subdivision (e) of Section 2034 of Title 16 of the California Code of Regulations.

(3) "Indirect supervision" has the same meaning as that term is defined in subdivision (f) of Section 2034 of Title 16 of the California Code of Regulations.

SEC. 3. Section 4836.5 of the Business and Professions Code is amended and renumbered to read:

4836.6. The board shall take action pursuant to Article 4 (commencing with Section 4875) of this chapter against any veterinarian licensed or authorized to practice in this state who permits any registered veterinary technician or veterinary assistant to perform any animal health care services other than those allowed by this article.

SEC. 4. Article 7 (commencing with Section 4920) is added to Chapter 11 of Division 2 of the Business and Professions Code, to read:

Article 7. Community Blood Banks for Animals

4920. For the purposes of this article, the following definitions apply:

- (a) "Adverse event" means an event in which an animal is injured, sickened, rendered unconscious, or killed.
- (b) "Blood and blood component products" has the same meaning as in Section 9201 of the Food and Agricultural Code and means whole blood collected directly from a donor animal for transfusion or the blood components for transfusion, including packed red blood cells, platelet-rich plasma, platelet concentrates, fresh plasma, fresh frozen plasma, frozen plasma, cryoprecipitate, and cryosupernatant. Antibody products like hyperimmune serums are considered "biologics" and are excluded from this definition of blood and blood component products.
- (c) "Captive closed colony" means that an animal is kept, housed, or maintained in any way for the purpose of 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) "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.
- (g) "Community sourced" means that an animal is all of the following:
 - (1) Kept, housed, and maintained at the residence of its owner who is a person and not a partnership, association, corporation, or limited liability company.
 - (2) Brought by its owner to a community blood bank for animals to have its blood collected.
 - (3) Licensed in accordance with any pet licensing required by the pet owner's state, county, or city of residence.
- (h) "Production" means the collection of blood or the preparation, testing, processing, storage, or distribution of blood or blood component products for purpose of transfusion.

4920.1. For purposes of liability pursuant to this article, the production and use of whole blood, plasma, blood products, and blood derivatives for purposes of injecting or transfusing the same, or any of them, into an animal shall be construed to be, and is declared to be, the rendition of a service by each and every person, firm, or corporation participating therein, and shall not be construed to be, and is declared not to be, a sale of that whole blood, plasma, blood products, or blood derivatives.

4920.2. Each veterinarian who is licensed in California and engages in the production of animal blood and blood component products solely for use in their own practice or for a community blood bank operating under this article shall meet all of the following conditions:

- (a) Follow current and best practices on community animal blood banking, which may include those developed pursuant to Section 9255 of the Food and Agricultural Code.
- (b) 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.
- (c) Ensure that the production of blood and blood component products is safe and not injurious to the donor animal's health.
- (d) Follow, to the extent possible, the latest blood banking standards, which may include the latest published edition of the American Association of Blood Banks' standards, and maintain responsibility over all veterinary and technical policies and procedures that relate to the safety of staff members and donor animals.
- (e) Utilize bloodborne pathogen testing for all canine and feline blood donors in accordance with the best clinical practices in the veterinary field, which may include the most recent Consensus Statement on blood donor infectious disease screening by the American College of Veterinary Internal Medicine.
- (f) Ensure that the production of animal blood and blood component products complies with all applicable federal laws and regulations, including, but not limited to, Chapter 5 (commencing with Section 151) of Title 21 of the United States Code.
- (g) Maintain onsite records available for inspection by the Veterinary Medical Board including information documenting any history of blood draws or use of anesthesia on the animal, the number and date of donations collected, the estimated milliliters of blood

collected per donation based on weight in grams, any adverse events, and any complaints from owners regarding animals who donate blood or blood component products.

(h) Obtain the informed written consent of the owner of the animal blood donor and keep a record of that consent.

4920.3. (a) A veterinarian or a community blood bank operating under this article shall not provide payment to a person who provides an animal for the purpose of donating that animal's blood and blood component products for use in their practice or for retail sale and distribution.

(b) For purposes of this section, "payment" means the transfer to any person of money or other valuable consideration that can be converted to money by the recipient. For purposes of this section, "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.

4920.4. The Veterinary Medical Board may establish a community blood bank registration fee and annual renewal fee to be paid by community blood banks to cover costs associated with oversight and inspection of the premises. The fee shall not exceed the reasonable regulatory costs of administering, implementing, and enforcing the provisions of this article.

4920.5. A community blood bank operating under this article shall 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.

4920.6. A community blood bank operating under this article shall submit a quarterly report to the Department of Food and Agriculture every three months that includes all of the following information:

(a) The number of donations from community-sourced animals and separate total amounts of whole blood, packed red blood cells, and fresh frozen plasma sold in California during that quarter, by species of animal in estimated milliliters based on weight in grams.

(b) 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.

(c) The number and species of animal donors that have donated blood.

(d) 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, which may include the most recent Consensus Statement for blood donor infectious disease screening by the American College of Veterinary Internal Medicine.

4920.7. Each veterinarian who is licensed in California and operates a closed-colony blood bank shall comply with Chapter 1.5 (commencing with Section 9201) of Part 1 of Division 5 of the Food and Agricultural Code.

4920.8. A violation of this article by a community blood bank shall constitute a cause for corrective action, suspension, restriction, or the nonrenewal or revocation of a license or registration by the Veterinary Medical Board pursuant to Article 4 (commencing with Section 4875).

SEC. 5. Section 9201 of the Food and Agricultural Code is amended to read:

9201. Unless the context otherwise requires, the following definitions govern the construction of this chapter:

(a) "Adverse event" means an event in which an animal is injured, sickened, rendered unconscious, or killed.

(b) "Animal" includes, but is not limited to, any domesticated fowl or nonhuman mammal or any wild fowl, bird, or mammal that is reduced to captivity.

(c) "Biologics" means all viruses, serums, antibody products, toxins (excluding substances that are selectively toxic to microorganisms, such as antibiotics), or analogous products at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and that act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response.

(d) "Blood and blood component products" means whole blood collected directly from a donor animal for transfusion or the blood components for transfusion, including packed red blood cells, platelet-rich plasma, platelet concentrates, fresh plasma, fresh frozen plasma, frozen plasma, cryoprecipitate, and cryosupernatant. Antibody products like hyperimmune serums are considered "biologics" and are excluded from this definition of blood and blood component products.

(e) "Captive closed colony" has the same meaning as in Section 4920 of the Business and Professions Code and means that an animal is kept, housed, or maintained in any way for the purpose of collecting its blood.

(f) "Closed-colony blood bank" has the same meaning as in Section 4920 of the Business and Professions Code and means a commercial blood bank for animals that produces animal blood or blood component products solely from animals held in a captive closed colony.

(g) "Commercial blood bank for animals" has the same meaning as in Section 4920 of the Business and Professions Code and 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.

(h) "Community blood bank" has the same meaning as in Section 4920 of the Business and Professions Code and 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.

(i) "Community sourced" has the same meaning as in Section 4920 of the Business and Professions Code and means that an animal is all of the following:

- (1) Kept, housed, and maintained at the residence of its owner who is a person and not a partnership, association, corporation, or limited liability company.
- (2) Brought by its owner to a community blood bank to have its blood collected.
- (3) Licensed in accordance with any pet licensing required by the pet owner's state, county, or city of residence.

(j) "Production" has the same meaning as in Section 4920 of the Business and Professions Code and means collection of blood or the preparation, testing, processing, storage, or distribution of blood or blood component products for the purpose of transfusion.

SEC. 6. Section 9202 of the Food and Agricultural Code is repealed.

SEC. 7. Section 9203 of the Food and Agricultural Code is repealed.

SEC. 8. Section 9204 of the Food and Agricultural Code is repealed.

SEC. 9. Section 9205 of the Food and Agricultural Code is repealed.

SEC. 10. Section 9206 of the Food and Agricultural Code is repealed.

SEC. 11. Section 9210 of the Food and Agricultural Code is amended to read:

9210. (a) A person shall not engage in the production of animal blood and blood component products for retail sale and distribution except in a captive closed-colony commercial blood bank for animals licensed by the secretary or in accordance with Article 7 (commencing with Section 4920) of Chapter 11 of Division 2 of the Business and Professions Code.

(b) Notwithstanding subdivision (a), a community blood bank for animals operating pursuant to Article 7 (commencing with Section 4920) of Chapter 11 of Division 2 of the Business and Professions Code shall register blood and blood component products with the secretary in accordance with Article 5 (commencing with Section 9241).

SEC. 12. Section 9212 of the Food and Agricultural Code is amended to read:

9212. The secretary shall license establishments as captive closed-colony commercial blood banks for animals that meet all of the following:

- (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) Produce animal blood and blood component products under the direct supervision of a person qualified in the field.
- (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.
- (d) Keep, house, or maintain all animal donors within California state boundaries.

SEC. 13. Section 9212.5 is added to the Food and Agricultural Code, to read:

9212.5. (a) (1) The department shall discontinue its licensing program for commercial blood banks for animals that produce canine blood and blood component products sourced from captive closed-colony dogs within 18 months of making a finding and provision of notice as follows:

(A) Based on the quarterly reports required under Section 4920.6 of the Business and Professions Code, subdivision (c) of Section 9252, and subdivision (b) of Section 9253, every three months, the secretary shall calculate the total estimated amount of canine blood sold in California that quarter by community blood banks and, separately, the total estimated amount of canine blood that closed-colony blood banks sold in the state during the same period. This information shall be publicly posted on the department's internet website along with annual totals compiled each year.

(B) If the secretary finds that community blood banks sold an annual amount of canine blood in California that equals or exceeds the annual amount closed-colony blood banks sold in four consecutive quarters, then the secretary shall provide notice on the department's internet website that discontinues its licensing program for closed-colony blood banks for dogs within 18 months from the date of that notice.

(2) The calculation of canine blood pursuant to this subdivision shall be done separately, with whole blood, packed red blood cells, and fresh frozen plasma being measured as separate amounts in estimated milliliters based on weight in grams.

(3) For purposes of this section, "canine blood" means whole blood, packed red blood cells, and fresh frozen plasma.

(b) Upon enactment of this section, the secretary shall not accept any new applications to license a commercial blood bank for animals that produces canine blood or blood component products sourced from captive closed-colony dogs.

(c) Closed-colony blood banks may transition to community-sourced models and continue to operate in accordance with Article 7 (commencing with Section 4920) of Chapter 11 of Division 2 of the Business and Professions Code.

SEC. 14. Section 9221 of the Food and Agricultural Code is amended to read:

9221. An application for a license for any establishment that produces, or proposes to produce, animal blood and blood component products from a closed-colony blood bank shall be made on forms issued by the secretary. The application shall contain all of the following:

(a) The name and address of the person who owns the property, establishment, or institution in which it is proposed to produce animal blood and blood component products.

(b) The name and address of the person who shall oversee the production of animal blood and blood component products.

(c) The type of animal blood and blood component products that shall be produced.

(d) A full description of the building, including its address, facilities, equipment, and apparatus, to be used in the production of animal blood and blood component products.

(e) A written protocol, consistent with current standards of care and practice for the field of veterinary transfusion medicine, that addresses all of the following:

(1) Maximum length of time for donation by animal donors, or minimum health parameters for animal donors.

(2) Frequency and amount of blood collected from animal blood donors in estimated milliliters based on weight in grams.

(3) Socialization and exercise programs for animal blood donors.

(4) Method of identification of each animal, including microchip or tattoo.

(5) Ongoing veterinary care, including an annual physical exam and vaccination schedule for animals held in blood donor facilities.

(6) 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 (7 U.S.C. Sec. 2131 et seq.) in Part 3 (commencing with Section 3.1) of Subchapter A of Chapter 1 of Title 9 of the Code of Federal Regulations.

(7) Implementation of a permissive adoption program.

(8) Bloodborne pathogen testing for all canine and feline blood donors in accordance with the best clinical practices in the veterinary field, which may include the most recent Consensus Statement on blood donor infectious disease screening by the American College of Veterinary Internal Medicine.

(f) An oversight letter identifying the oversight veterinarian who will be responsible for oversight of the facility. The letter shall be from the oversight veterinarian, and shall be maintained on file by the secretary. Oversight veterinarians shall be licensed to practice veterinary medicine in California. In the event of a change of the oversight veterinarian, it is the oversight veterinarian's responsibility to give notice to the secretary of the termination of the oversight veterinarian within 30 days of the termination date of the oversight veterinarian. An oversight letter from the incoming oversight veterinarian shall be submitted to the secretary within 30 days of the termination date of the prior oversight veterinarian.

(g) Additional information that the secretary finds is necessary for the proper administration and enforcement of this chapter.

SEC. 15. Section 9222 is added to the Food and Agricultural Code, to read:

9222. (a) A commercial blood bank for animals shall not discriminate against veterinarians licensed in California in the sale of animal blood or blood component products.

(b) A commercial blood bank for animals, as described in subdivision (a), that refuses to sell animal blood or blood component products to a veterinarian in circumstances in which that blood bank has an available supply may be deemed by the secretary to be in violation of this provision against discriminatory business practices.

SEC. 16. Section 9231 of the Food and Agricultural Code is amended to read:

9231. The license application fee and license renewal fee under this chapter for an establishment proposing to produce or producing animal blood and blood component products from a closed-colony blood bank shall be as follows:

(a) The application and annual license fee shall be one thousand dollars (\$1,000) for each establishment, which shall be the fee for the fiscal year, or portion thereof, ending June 30 of each year. When an applicant is a city, county, state, or district, or an official thereof, no fee shall be required under this section.

(b) Licenses shall be renewed every year. The annual renewal fee shall be paid on or before the first day of July of each year.

(c) The license application fee and licensee renewal fee under this chapter shall be adjusted annually for inflation. The adjustments shall be rounded off to the nearest whole dollar.

(d) The department may set inspection fees in an amount that shall not exceed the department's reasonable regulatory costs incurred in connection with implementing this chapter. The fees shall include amounts sufficient to repay any amount loaned from the General Fund to establish the program.

SEC. 17. Section 9241 of the Food and Agricultural Code is amended to read:

9241. No person shall offer for sale or use any of the following:

(a) Any biologic unless it is manufactured pursuant to the terms of a valid license or permit issued by the United States Department of Agriculture.

(b) Any blood or blood component product unless it is produced in an establishment licensed by the secretary or in accordance with Article 7 (commencing with Section 4920) of Chapter 11 of Division 2 of the Business and Professions Code, or imported into the state pursuant to Section 9252 and registered with the department in accordance with Section 9244.

SEC. 18. Section 9244 of the Food and Agricultural Code is amended to read:

9244. (a) An application for registration of blood or a blood component product shall include all of the following:

(1) The name and address of the person who owns the property, establishment, institution, or business that sells the blood.

(2) The name and address of the person who oversees the production of animal blood and blood component products.

(3) The type of animal blood and blood component products produced for sale.

(4) 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.

(5) A protocol of the methods of production in detail that is followed in the production of the product.

(6) A sample of the label to be placed on the blood or blood component product.

(b) The registration application fee and annual renewal fee for an establishment proposing to offer blood or blood component products for retail sale or use in California shall be as follows:

(1) The registration application fee and annual renewal fee shall be five hundred dollars (\$500) for each product, which shall be the fee for the fiscal year, or portion thereof, ending June 30 of each year.

(2) Registration shall be renewed every year. The annual renewal fee shall be paid on or before July 1 of each year.

(3) The application and renewal fees under this chapter shall be adjusted annually for inflation. The adjustments shall be rounded off to the nearest whole dollar.

(4) Fees may be increased or decreased by the department but shall not exceed the department's reasonable regulatory costs incurred to administer and enforce product safety standards set forth in this chapter.

SEC. 19. Section 9252 is added to the Food and Agricultural Code, to read:

9252. (a) The secretary shall track, administer, and enforce the safe importation and sale of animal blood and blood component products from out-of-state blood banks for animals that produce those blood and blood component products in compliance with California standards.

(b) Importation and sale of canine blood and blood component products from out-of-state sources shall only be permitted from community blood banks.

(c) Out-of-state community blood banks that sell canine blood and blood component products in California under this section shall submit a quarterly report to the department every three months that includes the separate total amounts of canine whole blood, packed red blood cells, and fresh frozen plasma sold in the state during that quarter, in estimated milliliters based on weight in grams.

SEC. 20. Section 9253 is added to the Food and Agricultural Code, to read:

9253. (a) A closed-colony blood bank licensed under this chapter shall maintain an onsite record of the number of donations collected from captive animals, the amount of blood collected per donation in estimated milliliters based on weight in grams, any adverse events, the disposition of any animals, and any other information necessary to comply with this section.

(b) A closed-colony blood bank licensed under this chapter shall submit a quarterly report to the department every three months including all of the following:

(1) The number of donations from captive animals and separate total amount in milliliters of whole blood, packed red blood cells, and fresh frozen plasma sold in California during that quarter, by species of animal in estimated milliliters based on weight in grams.

(2) The number of captive animals kept, housed, or maintained at the closed-colony blood bank, by species of animal.

(3) The disposition records of any animals and the total number of animals released for adoption.

(4) 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.

(5) 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, which may include the most recent Consensus Statement for blood donor infectious disease screening by the American College of Veterinary Internal Medicine.

(c) A violation of this section, Section 9210, or Section 9212 shall constitute a cause for corrective action, suspension, restriction, or the nonrenewal or revocation of a license by the department. The proceedings for the suspension or revocation of a license shall be conducted pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code. The secretary shall have all the powers granted in that chapter.

(d) For purposes of this section, "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. Disposition records shall include all of the following:

(1) The species and breed of animal.

(2) The animal's registered name, license number, microchip, and tattoo, if present.

(3) The name and address of the individual or entity that received the animal and the purpose for which the animal was received.

SEC. 21. Section 9254 is added to the Food and Agricultural Code, to read:

9254. The department shall annually submit a copy of the canine blood collection information that it publicly posts on its internet website pursuant to subparagraph (A) of paragraph (1) of subdivision (a) of Section 9212.5 to the Chair and Vice Chair of the Assembly Business and Professions Committee, the Chair and Vice Chair of the Senate Business, Professions and Economic Development Committee, the Chairs and Vice Chairs of the Assembly and Senate Agriculture Committees, and the Veterinary Medical Board.

SEC. 22. Section 9255 is added to the Food and Agricultural Code, to read:

9255. (a) The department, in collaboration with the Veterinary Medical Board, technical experts in animal blood banking, and any other relevant stakeholders, shall develop and make available a "Community Animal Blood Banking Guidance Resource" or other documents that provide veterinarians, at a minimum, accurate, clear, and concise information regarding best management practices for operating community blood banks.

(b) On or before March 1, 2023, the department shall publish the guidance resource or other documents described in subdivision (a) on its internet website. The guidance resource or other documents shall include primary information and best practices in all of the following areas:

- (1) Animal donor qualification, selection, and screening.
- (2) Bloodborne pathogen testing.
- (3) Safe blood products handling, processing, labeling, and storage.

SEC. 23. Section 9269 of the Food and Agricultural Code is amended to read:

9269. (a) Except as provided in subdivision (b), the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code) shall apply to all records held by the department relating to this chapter, including, but not limited to, records relating to applications, fees, or inspections required by this chapter.

(b) (1) Except as provided in subdivisions (c) and (d), identifying personal information that is contained in records described in subdivision (a) shall be confidential and not subject to disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

(2) This subdivision does not prevent the disclosure by the department of data regarding age, race, ethnicity, national origin, or gender of individuals whose personal information is protected pursuant to this section, so long as the data does not contain individually identifiable information.

(c) Records held by the department relating to this chapter shall be accessible to law enforcement officers and state and local agencies with jurisdiction over any matter covered by this chapter.

(d) The department shall, upon request, disclose information in records relating to this chapter that is already in the public domain.

(e) (1) For purposes of this section, "identifying personal information" means the following information pertaining to the owner of an animal donor that is collected for purposes of coordinating, conducting, or documenting a donation from the animal owned by that person and is maintained by the department in relation to this chapter:

- (A) Social security number.
- (B) Date of birth.
- (C) Physical description.
- (D) Home address.
- (E) Statements of personal worth or personal financial data.
- (F) Personal medical history.
- (G) Employment history.

(H) Email address.

(I) Information that reveals any electronic network location or identity.

(2) For purposes of this subdivision, a person who owns, operates, maintains, or oversees a commercial blood bank for animals shall not be considered the owner of an animal donor.

SEC. 24. Section 9272 of the Food and Agricultural Code is amended to read:

9272. This chapter shall not apply to any of the following:

(a) Licensed facilities primarily engaged in the collection, preparation, testing, processing, storage, or distribution of human blood or blood products, and any biologic as defined in Section 9201 produced by that facility is sold or distributed only to an establishment licensed by this chapter.

(b) Clinical laboratories licensed pursuant to Chapter 3 (commencing with Section 1200) of Division 2 of the Business and Professions Code whose only biologics are autogenous bacterins prepared at the request of licensed veterinarians.

(c) Licensed private veterinarians who collect blood or blood products solely for use in their own practice or pursuant to Article 7 (commencing with Section 4920) of Chapter 11 of Division 2 of the Business and Professions Code, except with respect to Article 5 (commencing with Section 9241) and Section 9255.

SEC. 25. The Legislature finds and declares that Section 23 of this act, which amends Section 9269 of the Food and Agricultural Code, imposes a limitation on the public's right of access to the meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following finding to demonstrate the interest protected by this limitation and the need for protecting that interest:

In order to protect the privacy of owners of community-sourced animal donors and encourage their participation in animal blood donation programs, it is necessary to limit the public's right of access to their personal information.

SEC. 26. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.