CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE

CALIFORNIA CODE OF REGULATIONS
TITLE 3. FOOD AND AGRICULTURE
DIVISION 5. LIVESTOCK DRUGS
CHAPTER 1. SALES OF RESTRICTED LIVESTOCK DRUGS
AND
CHAPTER 2. SALES OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS

INITIAL STATEMENT OF REASONS

California Senate Bill 27 (Hill) was signed by Governor Brown on October 10, 2015 with the intent to preserve the efficacy and ensure current and future availability of medically important antimicrobial drugs for use in livestock to maintain animal health and welfare while minimizing potential public health impacts. The bill resulted in additions to the California Food and Agricultural Code (Division 7, Chapter 4.5, Sections 14400-14408) that address the use of medically important antimicrobial drugs in livestock, development of antimicrobial drug stewardship programs and best management practices, and surveillance of antimicrobial use and practices as well as antimicrobial resistance patterns in bacteria.

To implement the new provisions of Division 7, Chapter 4.5, the California Department of Food and Agriculture (hereafter referred to as "the Department") created the Antimicrobial Use and Stewardship (AUS) program. The AUS program spans two divisions within the Department, the Division of Inspection Services and the Animal Health and Food Safety Services Division. Within the Division of Inspection Services, the Livestock Drug Program is responsible for enforcing the current Livestock Drug Law (Division 7, Chapter 4 of the Food and Agricultural Code) by maintaining the registration of over-the-counter livestock drugs and licenses for the sale of restricted livestock drugs. There are two sections of Division 7, Chapter 4.5 that are subject to the current Livestock Drug Law. For this reason, the Division of Inspection Services has proposed regulations to provide improved clarity on portions of Food and Agricultural Code Division 7, Chapters 4 and 4.5 in an effort to help industry and consumers to better understand the law, while also helping the Department implement the mandates of Senate Bill 27.

SECTIONS AFFECTED

The proposed regulations would create Division 5 Livestock Drugs within Title 3 of the California Code of Regulations. Within Division 5, the proposed regulations would create Chapter 1, Sales of Restricted Livestock Drugs (Sections 5000-5004) and Chapter 2, Sales of Medically Important Antimicrobial Drugs (Sections 5005-5012).

PROBLEM STATEMENT

Food and Agricultural Code (FAC) Section 14401 states that beginning January 1, 2018, a medically important antimicrobial drug shall not be administered to livestock unless ordered by a licensed veterinarian through a prescription or veterinary feed directive, pursuant to a veterinarian-client-patient relationship that meets the requirements of Section 2032.1 of Title 16 of the California Code of Regulations (CCR). However, to ensure that these drugs remain available to livestock producers for their appropriate use in protecting the health of the livestock population of the state, FAC Section 14403 goes on to state that medically important antimicrobial drugs may be sold by retailers licensed pursuant to FAC Division 7, Chapter 4, Article 5. This means that businesses licensed by the Division of Inspection Services to sell

restricted livestock drugs under the current Livestock Drugs Law may continue to sell medically important antimicrobial drugs after FAC Section 14401 goes into effect on January 1, 2018. However, once the law goes into effect, restricted livestock drug licensees may only sell medically important antimicrobial drugs at retail when presented with a valid prescription or veterinary feed directive from a licensed veterinarian.

The existing Livestock Drug Law (FAC Division 7, Chapter 4) would benefit from additional clarity on which types of businesses are required to have a restricted livestock drug license, how to apply for and renew a license, what information is required on the license application, and what records must be kept and for how long. The new law on livestock use of antimicrobial drugs (FAC Division 7, Chapter 4.5) lacks clarity on what restricted livestock drug licensees must do before selling medically important antimicrobial drugs at retail to ensure compliance with the law, what records must be kept and for how long, how medically important antimicrobial drugs must be stored, and how medically important antimicrobial drugs must be labeled prior to retail sale.

The proposed regulations for FAC Division 7, Chapter 4, will clarify the existing statutory requirement that all businesses selling restricted livestock drugs into California are required to have a restricted livestock drug license, will explain how to apply for and renew a license, as well as what records must be kept and how long the records must be kept. The proposed regulations for FAC Division 7, Chapter 4.5, will clarify the additional requirements associated with sales of medically important antimicrobial drugs, including what restricted livestock drug licensees are responsible for verifying prior to selling medically important antimicrobial drugs, additional recordkeeping requirements specific to retail sales of medically important antimicrobial drugs, provisions for the proper storage and inventory of medically important antimicrobial livestock drugs, and instructions for how medically important antimicrobial livestock drugs must be labeled prior to retail sale.

BENEFITS

Clarifying that the existing livestock drug law requires all businesses, regardless of location (in state or out of state) or sales method (online, catalog, etc.), to have a restricted livestock drug license prior to selling restricted livestock drugs in California will help ensure that all restricted livestock drugs, including medically important antimicrobial drugs, are sold appropriately and in accordance with California law.

Specifying how to apply for and renew a restricted livestock drug license will provide improved clarity and uniformity for businesses and will help ensure that businesses become and remain licensed.

Explaining what records must be kept by restricted livestock drug licensees and how long the records must be kept will ensure that records of sale remain available for an adequate period of time for the Department to inspect in order to verify compliance with the requirements of the law.

Clarifying that medically important antimicrobial drugs are considered restricted livestock drugs will help ensure that businesses selling medically important antimicrobial drugs are aware that they must have a restricted livestock drug license and that they are required to comply with the laws and regulations applicable to sales of restricted livestock drugs in addition to medically important antimicrobial drugs.

Explaining what restricted livestock drug licensees are responsible for verifying prior to selling medically important antimicrobial drugs at retail will help ensure that medically important antimicrobial drugs are only sold with a valid prescription or veterinary feed directive from a licensed veterinarian.

Specifying the additional recordkeeping requirements for retail sales of medically important antimicrobial drugs will ensure that Department investigators are able to verify that restricted livestock drug licensees are complying with FAC Division 7, Chapter 4.5, by only selling medically important antimicrobial drugs when presented with a prescription or veterinary feed directive from a licensed veterinarian. The maintenance of adequate sales records will also help the Department monitor the sales and usage of medically important antimicrobial drugs and prepare a report on their use for the Legislature, as required by FAC Division 7, Chapter 4.5.

Clarifying the proper storage and inventory of medically important antimicrobial drugs will minimize the risk of theft, loss, or illegal sale and will help ensure that medically important antimicrobial drugs are only available at retail with a valid prescription or veterinary feed directive from a licensed veterinarian.

Specifying how medically important antimicrobial livestock drugs must be labeled prior to retail sale will help ensure they are administered in accordance with veterinarian guidance and will minimize the risk of improper use that may contribute to antibiotic resistance.

Overall, the broad goal of these regulations is to help ensure that medically important antimicrobial livestock drugs remain available to livestock producers for their appropriate use in protecting the health of the livestock population of the state, and that such use will in turn benefit the general public by maintaining an abundant supply of wholesome food and fiber.

PURPOSE AND NECESSITY

The following paragraphs provide the specific purpose, rationale, and summaries of these proposed additions to the CCR related to sales of restricted livestock drugs and sales of medically important antimicrobial drugs.

DIVISION 5. LIVESTOCK DRUGS

CHAPTER 1. SALES OF RESTRICTED LIVESTOCK DRUGS

ARTICLE 1. DEFINITIONS

Section 5000. Definitions

The Department is adding Section 5000 and Subsections (a) through (d) to ensure language is used consistently throughout the regulations, to provide stakeholders clear understanding of the intent of specific words, and to provide uniform implementation.

Subsection (a) defines “designated individual” as a person that is responsible for maintaining a restricted livestock drug licensee’s compliance with California livestock drug laws and regulations. This language is based on Business and Professions Code (BPC) Section 4196(d)

which requires veterinary food-animal drug retailers to have a designated representative responsible for compliance with the law. The use of the term designated individual is consistent with the terminology used by restricted livestock drug licensees. This term has been differentiated from the terminology used by veterinary food-animal drug retailers to prevent confusion because a designated representative as defined in BPC Section 4051 refers to an individual licensed by the Board of Pharmacy. The identification of a designated individual is necessary in order to protect public health and safety in the handling, storage, and sale of restricted livestock drugs, and the inclusion of this definition is necessary to clarify what the designated individual is responsible for.

Subsection (b) defines “livestock.” This definition is consistent with FAC Section 14205. The proposed regulations have been added to clarify that the term livestock refers to all animals in a species that are typically raised, kept, or used for profit and defines the meaning of “raised, kept, or used for profit.” This is necessary to clarify that all animals belonging to a species that are typically used for financial gain, commercial use, breeding, competition, or show, or whose owners are engaged in business using animals for financial gain, commercial use, breeding, competition, or show are subject to these regulations.

Subsection (c) defines “restricted livestock drug.” This definition is consistent with FAC Section 14203. The proposed regulations have been added to clarify that “antibiotic preparations” includes medically important antimicrobial drugs as defined in FAC Section 14400(a). This is necessary to clarify that medically important antimicrobial drugs are considered a subset of the broader classification of restricted livestock drugs and are subject to the same laws and regulations. In addition, the regulation has been written using the term “Secretary” instead of “director.” This is necessary to maintain consistency with the terminology used in the Department’s other regulations, as the Department is in the process of changing all statutory and regulatory references from “director” to “Secretary.”

Subsection (d) defines “restricted livestock drug licensee” as a business that is licensed pursuant to FAC Division 7, Chapter 4, Article 5. This definition is necessary to clarify that any business selling restricted livestock drugs in California must have a license issued by the Department.

ARTICLE 2. GENERAL PROVISIONS

Section 5001. Sales of Restricted Livestock Drugs

Subsection (a) is added to clarify that a person shall not sell any restricted livestock drug in California unless he or she holds a license to do so issued pursuant to FAC Division 7, Chapter 4, Article 5. This language is consistent with FAC Section 14321, although the regulation has been written using the term “he or she” instead of “he.” This is necessary to maintain consistency with the terminology used in the Department’s other regulations and to clarify that the law applies to all people.

Subsection (a)(1) is added to specify what the broad term “sell” means and clarifies that this includes alternative methods of sales, such as online and catalog sales, in addition to traditional in-person sales made at physical stores and mobile units in California. Subsection (a)(2) is added to clarify that a business who makes any sale of a restricted livestock drug into California must obtain a restricted livestock drug license prior to any such sale. Subsection (a)(3) is

consistent with FAC Section 14326 and is included in the proposed regulations for ease of reference and to clarify that all locations and mobile units that conduct sales of restricted livestock drugs must obtain a separate restricted livestock drug license.

The Department maintains that the intent of FAC Division 7, Chapter 4, is to require a license for all sales of restricted livestock drugs. However, the law was enacted in 1967 and has not been amended since 1976. Since that time, alternate methods of sale have emerged. The proposed regulations are necessary to clarify that the law applies to all methods of sale in order to ensure the law remains effective. This is particularly important with the recent adoption of FAC Division 7, Chapter 4.5, which requires medically important antimicrobial drugs to be sold only with a veterinary prescription or veterinary feed directive and requires the Department to monitor sales and use. Specifying that every method of sale (Subsection (a)(1)), every business selling into California (Subsection (a)(2)), and every business location (Subsection (a)(3)) must have a separate restricted livestock drug license will ensure that all restricted livestock drugs, including medically important antimicrobial drugs, are sold in accordance with the law and are subject to its recordkeeping requirements, thereby reducing unregulated sales and ensuring that the Department is able to gather an accurate representation of medically important antimicrobial drug sales data to fulfill the mandates set forth in FAC Section 14405(b)(1).

Subsection (b) is added to clarify that upon issuance of a restricted livestock drug license, the Department shall provide the licensee with the most current version of the livestock drug laws and regulations. The provision also informs licensees that the failure to receive a copy of the laws and regulations is not a defense for violation. The proposed regulations are necessary to provide accountability for the Department to inform industry of the law, as well as for industry to comply with the law. Providing licensees with the most current version of the laws and regulations will help them more quickly gain compliance, including the new requirements on sales of medically important antimicrobial drugs. This provision demonstrates the Department's commitment to working with businesses to achieve compliance, while at the same time enforcing the law.

Subsection (c) is added to clarify that each business selling restricted livestock drugs must have one individual named on the license application that is responsible for maintaining compliance with state laws and regulations. The proposed regulations are necessary to add a measure of accountability that will encourage licensees to achieve and remain in compliance with the law. By naming a designated individual, the licensee is certifying that this person is responsible for ensuring that all employees who handle sales transactions of restricted livestock drugs know the required procedures for documenting sales and, in the case of medically important antimicrobial livestock drugs, know the additional requirements for storage, verification, labeling, and recordkeeping.

Subsection (d) is added to clarify that all livestock drugs sold by restricted livestock drug licensees must be registered pursuant to FAC Division 7, Chapter 4, Article 4. This is consistent with FAC Section 14281 and is necessary to ensure that restricted livestock drug licensees are aware of the statutory requirement that they may only sell those livestock drugs that are registered in California.

ARTICLE 3. LICENSING

Section 5002. License Application

Subsection (a) is added to clarify the information applicants must provide on the restricted livestock drug license application form. This language is consistent with FAC Section 14322; however, the regulation has been written using the term “Secretary” instead of “director” and “he or she” instead of “he” to maintain consistency with the terminology used in the Department’s other regulations and to clarify that the law applies to all people. The law currently states that the application shall be on a form which is supplied by the director and shall contain such information as he may require; the proposed regulations are necessary to clarify the specific information that is required on the form.

Subsection (a)(1) requires the applicant to specify the legal business name, Federal Tax ID number, and telephone number of the firm. Subsection (a)(2) requires the applicant to provide the full name of the owner or owners of the firm. Subsection (a)(3) requires the applicant to provide the firm’s mailing address, including street number, city, county, state, and ZIP code. Subsections (a)(1) through (a)(3) are necessary to establish the firm’s legal business identity as well as the person(s) liable for the license and subject to enforcement actions. Contact information is necessary to ensure the Department can communicate with the firm in the event of a violation at the location of business to be licensed.

Subsection (a)(4) requires the applicant to provide the location of the business to be licensed. If the business is a physical premises, the applicant must provide the street number, city, county, state, and ZIP code. This is necessary to ensure the Department can locate the licensed premises for inspection and enforcement purposes. If the business is conducting online sales, the applicant must provide the website where sales are made. This is necessary so the Department can verify the website has the capacity to comply with California law, including limiting sales to livestock drugs that are registered in California as well as requiring the submission of a veterinary prescription or veterinary feed directive for medically important antimicrobial drugs.

Subsection (a)(5) requires the applicant to identify a designated individual for the business to be licensed who is responsible for compliance with livestock drug law and who will also serve as the primary emergency contact. This is necessary to ensure that all licensed businesses have one person responsible for ensuring all employees who handle sales transactions of restricted livestock drugs know the required procedures for documenting sales and, in the case of medically important antimicrobial livestock drugs, know the additional requirements for storage, verification, labeling, and recordkeeping. Applicants must provide the designated individual’s name, title, email address, and telephone number. This is necessary to ensure the Department can communicate with the designated individual in the event of a violation or emergency at the licensed location. As a precautionary measure, Subsection (a)(6) requires the applicant to identify a secondary emergency contact for the business to be licensed, in the event the designated individual is unavailable during an emergency.

Subsection (a)(7) requires the applicant to disclose whether the business to be licensed is a mobile unit and, if so, to provide the license plate number. This is necessary to ensure the Department can locate the mobile unit for inspection and enforcement purposes.

Subsection (a)(8) requires the applicant to disclose the company type from a list of options including corporation, partnership, individual, limited liability company, co-partnership, or other.

If other is selected, the applicant must specify the type. This is necessary to ensure the Department maintains an accurate record of which types of businesses are licensed.

Subsection (a)(9) requires the applicant to disclose the type of sales conducted by the business to be licensed - sales made directly to the end user for the purpose of administration to livestock and/or sales made to other businesses for the purpose of resale. This is necessary to help the Department conduct targeted outreach and education efforts as well as inspection and enforcement efforts. FAC Division 7, Chapter 4.5, requires the Department to collect data on retail sales of medically important antimicrobial drugs. In order to ensure that sales are not counted multiple times, the Department will utilize the information provided on the license application form to help identify where to collect data on sales of medically important antimicrobial drugs made directly to the end user for administration to livestock, rather than sales made to other businesses for the purpose of resale.

Subsection (a)(10) requires the applicant to disclose whether the business to be licensed will sell medically important antimicrobial drugs. This is necessary to help the Department identify where to conduct targeted outreach and education on the proper storage, sale, labeling, and recordkeeping of medically important antimicrobial drugs. This is also necessary to help the Department identify which locations to inspect for compliance and to collect sales data to fulfill the mandates set forth in FAC Section 14405(b)(1).

Subsection (a)(11) requires that the owner of the firm or designated individual for the business to be licensed provide a certification that the information provided on the application is complete, true, and accurate. The form must include their name, title, signature and the date signed. This is necessary to ensure that the information provided on the form is correct and to maintain a record of who certified the information’s accuracy, in the event a discrepancy is discovered.

Subsection (b) is added to clarify that a restricted livestock drug license application form must be accompanied by a license application fee of fifty dollars ($50). Subsection (b)(1) clarifies that the license application fee is not refundable if the license is refused. Subsection (b)(2) clarifies that a restricted livestock drug license fee covers the remainder of the current calendar year in which it is issued. Subsections (b) and (b)(1) are consistent with FAC Section 14323, Subsection (b)(2) is consistent with FAC Section 14324, and all three sections have been included in the proposed regulations for ease of reference. Subsection (b)(3) clarifies that the license fee shall not be reduced to cover a fraction of a year. FAC Section 14323 makes no provision for a reduced fee. This is necessary because the full fee is needed to cover program administrative costs to process applications, as these costs are not impacted by the date license applications are submitted.

Subsection (c) is added to clarify how restricted livestock drug license applications and fees must be submitted. Subsection (c)(1) states that applications and fees may be submitted electronically using the Feed, Fertilizer, and Livestock Drugs Regulatory Services online registration database and Subsection (c)(2) states that applications and fees may be submitted by mail using a paper form. This is necessary to ensure that the applications received are consistent and provide all required information.

Subsection (d) is added to clarify that a restricted livestock drug licensee must notify the Department within thirty (30) calendar days if any of the information provided on the license

application changes after the license is issued. This is necessary to ensure the Department has the most current information available and can communicate with the licensee in the event of an emergency or violation. Thirty days was determined to be an appropriate notification period based on observations of what is currently done in the industry. In addition, requiring information to be updated within thirty days is consistent with the timeframe provided in the Department's other regulations, such as 3 CCR Section 2300(k)(2) which requires manufacturers of registered fertilizing materials to notify the Secretary within thirty days of any change to a product's composition.

Section 5003. License Renewal

Subsection (a) is added to clarify that restricted livestock drug licenses must be renewed annually using the provided renewal form. This is necessary to provide guidance and consistency on how to renew a license.

Subsection (b) is added to clarify that the fee for license renewal is fifty dollars ($50) payable on or before January 31 of each year. If the fee is not paid by that date, a penalty of fifty dollars ($50) shall be added to the fee. This is consistent with FAC Section 14325 and has been included in the proposed regulations for ease of reference.

Subsection (c) is added to clarify that restricted livestock drug license renewal applications and accompanying fees must be submitted in the same manner as applications. This is necessary to provide guidance and consistency on how license renewals and fees must be submitted.

Subsection (d) is added to clarify that a restricted livestock drug licensee must notify the Department in a timely manner if any of the information provided on the license renewal changes after the license is renewed. This is necessary to ensure the Department has the most current information available and can communicate with the licensee in the event of an emergency or violation.

ARTICLE 4. RECORDKEEPING

Section 5004. Sales Records

Subsection (a) is added to clarify that restricted livestock drug licensees must maintain a record of each sale of a restricted livestock drug. This is consistent with FAC Section 14328; however, language has been added to clarify that the record shall be maintained in California, or with the Secretary's permission, at another location. This is necessary to ensure that the Department has access to sales records for inspection and enforcement purposes in order to verify that all restricted livestock drugs, including medically important antimicrobial drugs, are sold in accordance with the law. In addition, this will ensure the Department is able to gather an accurate representation of medically important antimicrobial drug sales to fulfill the mandates set forth in FAC Section 14405(b)(1).

Subsection (b) is added to clarify what information is required to be part of the record of each sale of a restricted livestock drug. This is consistent with FAC Section 14329. However, FAC Section 14329(e) states the record shall include, "Any other information as the director may determine is reasonably necessary to carry out the provisions of this chapter." For this reason, regulations are needed to clarify the additional information that will be required.

Subsection (b)(1) requires the record to include the established drug name or trade name, route of administration, quantity, and lot number of each restricted livestock drug sold. FAC Section 14329(a) requires the record to include the "kind" of drug sold; the proposed regulations clarify that the term "kind" specifically refers to the established drug name or trade name and the route of administration. This was determined in consultation with Department veterinarians in order to ensure the Department will be able to collect adequate information on the drugs and routes of administration used, which will help fulfill the mandates set forth in FAC Section 14405(b)(1). This is necessary to provide clarity for restricted livestock drug licensees regarding what specifically must be recorded and will ensure that an adequate and consistent record is maintained of what types of restricted livestock drugs are sold. In addition, recording the drug name and route of administration will allow the Department to collect data to fulfill the mandates set forth in FAC Section 14405(b)(1). Requiring the quantity sold is consistent with FAC Section 14329(a) and has been included in the proposed regulations for ease of reference. Requiring the lot number(s) is consistent with FAC Section 14329(e) and is necessary in order to trace any restricted livestock drugs that are recalled.

Subsection (b)(2) requires the record to include the date of sale of each restricted livestock drug sold. This is consistent with FAC Section 14329(b) and has been included in the proposed regulations for ease of reference.

Subsection (b)(3) requires the record to include the name, address, telephone number, and email address (optional) of the purchaser of each restricted livestock drug sold. Requiring the name and address of the purchaser is consistent with FAC Section 14329(c) and has been included in the proposed regulations for ease of reference. Requiring the purchaser's telephone number is consistent with FAC Section 14329(e) and is necessary in order to contact the purchaser in the event that a restricted livestock drug is recalled. Providing the option for the purchaser to provide their email address is consistent with FAC Section 14329(e) and is necessary to provide an alternate means of contacting the purchaser in the event that a restricted livestock drug is recalled. In addition, allowing purchasers to provide their email address will allow the Department to conduct targeted outreach and surveys on the use of medically important antimicrobial drugs to fulfill the mandates set forth in FAC Section 14405(b)(1).

Subsection (b)(4) requires the record to include the signature of the purchaser of each restricted livestock drug sold. This is consistent with FAC Section 14329(d) and has been included in the proposed regulations for ease of reference.

Subsection (b)(5) clarifies that in addition to the requirements outlined in this chapter, any restricted livestock drug licensee selling medically important antimicrobial drugs at retail is responsible for complying with the additional recordkeeping requirements listed in 3 CCR Section 5008. This is necessary to ensure that all restricted livestock drug licensees are aware that there are additional requirements they must comply with for retail sales of medically important antimicrobial drugs.

Subsection (c) is added to clarify that restricted livestock drug licensees must keep a record of each restricted livestock drug sold for at least three years following the transaction. FAC Section 14330 states that if a licensee fails to keep adequate records, their license can be revoked; the proposed regulation is necessary to clarify the required retention period. Three years was

determined to be an appropriate retention period because this is the length of time that veterinary food-animal drug retailers are required to maintain records as well as the amount of time that records of veterinary feed directives must be maintained. In addition, maintaining records for three years will allow the Department sufficient time to visit all licensees for inspection.

Subsection (d) is added to clarify that the record of each sale of a restricted livestock drug is subject to audit by the Secretary and shall be made available to the Secretary upon request. Depending on the location of the restricted livestock drug licensee, sales records may be audited by onsite inspection (in California) or by the provision of records by mail (out of state). FAC Section 14295 gives the Department authority to conduct investigations necessary to carry out FAC Division 7, Chapter 4, and the regulations adopted pursuant to it. This is necessary to ensure the Department can inspect records to verify compliance with the law.

CHAPTER 2. SALES OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS

ARTICLE 1. DEFINITIONS

Section 5005. Definitions

The Department is adding Section 5005 and Subsections (a) through (i) to ensure language is used consistently throughout the regulations, to provide stakeholders clear understanding of the intent of specific words, and to provide uniform implementation.

Subsection (a) defines “dispense” as selling a medically important antimicrobial drug to a purchaser under a lawful veterinary prescription or veterinary feed directive. This definition is based on FAC Section 14401 which mandates a veterinary prescription or veterinary feed directive for the administration of medically important antimicrobial drugs. This definition is in accordance with the definition of dispense given in BPC Section 4024, however, it has been simplified for the purposes of this chapter to only refer to veterinary prescriptions or veterinary feed directives given by veterinarians for the use of medically important antimicrobial drugs. This definition is necessary to ensure that restricted livestock drug licensees may only sell medically important antimicrobial drugs to purchasers that provide a veterinary prescription or veterinary feed directive.

Subsection (b) defines “extra label use.” This definition is consistent with Section 530.3(a) of Title 21 of the Code of Federal Regulations (CFR) and has been included in the proposed regulations for ease of reference.

Subsection (c) defines “inventory” as a record of accountability for all medically important antimicrobial drugs. The use of the term inventory is in accordance with commonly used terminology in the industry. This definition is necessary to clarify that restricted livestock drug licensees must maintain a record of accountability for the purchase, storage, and sale of all medically important antimicrobial drugs.

Subsection (d) defines “livestock.” This definition is consistent with FAC Section 14400(b). The proposed regulations have been added to clarify that the term livestock refers to all animals in a species that are typically raised, kept, or used for profit and defines the meaning of “raised, kept, or used for profit.” This is necessary to clarify that all animals belonging to a species that

are typically used for financial gain, commercial use, breeding, competition, or show, or whose owners are engaged in business using animals for financial gain, commercial use, breeding, competition, or show are subject to these regulations. In addition, this definition is necessary to clarify that for the purposes of this chapter, livestock does not include bees.

Subsection (e) defines "medically important antimicrobial drug." This definition is consistent with FAC Section 14400(a). The proposed regulations have been added to clarify that medically important antimicrobial drugs are considered a subset of the broader classification of restricted livestock drugs because they fall under FAC Section 14203(d) "antibiotic preparations" and are subject to the same laws and regulations.

Subsection (f) defines "restricted livestock drug." This definition is consistent with FAC Section 14203. The proposed regulations have been added to clarify that "antibiotic preparations" includes medically important antimicrobial drugs as defined in FAC Section 14400(a). This is necessary to clarify that medically important antimicrobial drugs are considered a subset of the broader classification of restricted livestock drugs and are subject to the same laws and regulations. In addition, the regulation has been written using the term "Secretary" instead of "director." This is necessary to maintain consistency with the terminology used in the Department's other regulations, as the Department is in the process of changing all statutory and regulatory references from "director" to "Secretary."

Subsection (g) defines "restricted livestock drug licensee" as a business that is licensed pursuant to FAC Division 7, Chapter 4, Article 5. This definition is necessary to clarify that any business selling restricted livestock drugs in California must have a license issued by the Department.

Subsection (h) defines "veterinary feed directive." This definition is consistent with Section 558.3 of Title 21 of the CFR and has been included in the proposed regulations for ease of reference.

Subsection (i) defines "veterinary prescription." This is necessary to clarify that a restricted livestock drug licensee may only sell a medically important antimicrobial drug to a purchaser that presents a lawful non-verbal order given by a licensed veterinarian. Use of the term lawful conveys that the prescription must comply with veterinary practice requirements of 16 CCR Section 2032.2. However, the term "non-verbal" was used for the purposes of this chapter instead of the term "written" to ensure that retailers with the appropriate capacity may accept electronic and faxed prescriptions. In addition, the definition clarifies that only veterinary prescriptions for the use of medically important antimicrobial drugs are subject to this chapter. The definition also clarifies that a restricted livestock drug licensee cannot sell a medically important antimicrobial drug if the prescription is provided orally by a veterinarian (e.g., over the phone). This is necessary to ensure that (1) the restricted livestock drug licensee can verify that the prescribing veterinarian is licensed prior to dispensing the medically important antimicrobial drug to the purchaser, (2) the restricted livestock drug licensee can keep a copy of the veterinary prescription on file so the Department can inspect sales records to verify compliance with the law, and (3) the purchaser can retain a copy of the prescription that contains the instructions for administering the medication.

ARTICLE 2. GENERAL PROVISIONS

Section 5006. Sales of Medically Important Antimicrobial Drugs

Subsection (a) is added to clarify that medically important antimicrobial drugs may be sold by retailers licensed pursuant to FAC Division 7, Chapter 4, Article 5 with a prescription or veterinary feed directive from a licensed veterinarian. This is consistent with FAC Section 14403(a) and has been included in the proposed regulations for ease of reference.

Subsection (b) is added to clarify that medically important antimicrobial drugs are a subset of the broader classification of restricted livestock drugs. This is necessary in order to clarify that medically important antimicrobial drugs are not only subject to FAC Division 7, Chapter 4.5, but that they are also subject to the broader livestock drug law in FAC Division 7, Chapter 4, and 3 CCR Division 5, Chapter 1.

Subsection (c) is added to clarify that a restricted livestock drug licensee shall not sell any drug that is required by federal law to be sold on prescription only unless they also hold a valid license under BPC Division 2, Chapter 9 allowing them to do so. This is necessary in order to ensure compliance with federal law and to clarify that FAC Division 7, Chapter 4.5 does not grant restricted livestock drug licensees the authority to sell livestock drugs that are federally labeled as prescription only.

Subsection (d) is added to clarify that the provisions of this chapter only apply to medically important antimicrobial drugs sold by restricted livestock drug licensees to the end user for the purpose of administration to livestock, rather than sales made to other businesses for the purpose of resale. This is necessary because FAC Division 7, Chapter 4.5 requires the Department to collect data on sales of medically important antimicrobial drugs to prepare a report on their use for the Legislature. Restricted livestock drug licensees should only maintain the information required by this chapter for the retail sale of medically important antimicrobial drugs to ensure that sales are only counted once (from the retailer to the end user) rather than multiple times (from manufacturer to distributor to retailer to the end user). Collecting sales data from multiple points in the supply chain will lead to inflated sales numbers that do not accurately describe the amount of medically important antimicrobial drugs actually administered to livestock.

ARTICLE 3. ADDITIONAL REQUIREMENTS FOR RETAIL SALES OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS

Section 5007. Verification

Subsection (a) is added to clarify that a restricted livestock drug licensee shall not sell a medically important antimicrobial drug at retail without the purchaser first providing a valid veterinary prescription or veterinary feed directive. This is consistent with FAC Section 14403 and the proposed regulations clarify that the veterinary prescription or veterinary feed directive must be valid and must be provided prior to sale. Requiring the veterinary prescription or veterinary feed directive before sale is necessary to ensure that the restricted livestock drug licensee can verify that the prescription or veterinary feed directive is valid prior to dispensing a medically important antimicrobial drug. The term valid means that the veterinary prescription or veterinary feed directive is (1) not expired and (2) has been issued by a veterinarian licensed by the California Veterinary Medical Board (VMB). The prohibition on dispensing an expired prescription is necessary to ensure that medically important antimicrobial drugs are dispensed

in accordance with a veterinarian's instructions, are used for the shortest duration necessary (per FAC Section 14404(c)(3)), and are not used in a regular pattern (per FAC Section 14402(d)). The requirement for prescribing veterinarians to be licensed by the VMB is consistent with the requirements of the California Veterinary Medicine Practice Act. BPC Section 4830 prohibits veterinarians that are not licensed in California from establishing a veterinarian-client-patient relationship with a patient located in California. FAC Section 14401 requires a veterinarian to establish a veterinarian-client-patient relationship prior to prescribing medically important antimicrobial drugs. Therefore, veterinarians that are not licensed in California are prohibited from prescribing medically important antimicrobial drugs for patients located in California because they legally cannot establish the required veterinarian-client-patient relationship.

Subsection (b) is added to clarify that a restricted livestock drug licensee is required to verify that the veterinarian listed on a veterinary prescription or veterinary feed directive is currently licensed by the VMB prior to completing the retail sale of any medically important antimicrobial drug. Subsection (b)(1) specifies that restricted livestock drug licensees must use the Department of Consumer Affairs' licensing and enforcement website for verification. This is necessary to ensure that only valid orders from licensed veterinarians are filled and will help mitigate the unlawful sale of medically important antimicrobial drugs as a result of fraudulent prescriptions.

Subsection (c) is added to clarify the expiration dates for veterinary prescriptions and veterinary feed directives. This clarifies that a restricted livestock drug licensee may not sell a medically important antimicrobial drug at retail if the veterinary prescription or veterinary feed directive provided by the purchaser is expired or was issued more than six months prior to the date of sale. This six month limit is consistent with 21 CFR 558.6(b)(3)(v) and 16 CCR Section 1780.1(g)(2). This limit is necessary to ensure that medically important antimicrobial drugs are used for the shortest duration necessary (per FAC Section 14404(c)(3)) and are not used in a regular pattern (per FAC Section 14402(d)).

Section 5008. Sales Records

Subsection (a) is added to clarify that in addition to the broader recordkeeping requirements for sales of restricted livestock drugs listed in 3 CCR Section 5004, restricted livestock drug licensees are required to keep records of additional information on retail sales of medically important antimicrobial drugs. This is necessary to ensure that medically important antimicrobial drugs are sold in accordance with the law and that the Department is able to gather an accurate representation of retail sales to fulfill the mandates set forth in FAC Section 14405(b)(1). FAC Section 14329(e) states the record shall include, "Any other information as the director may determine is reasonably necessary to carry out the provisions of this chapter." For this reason, regulations are needed to clarify the additional information that will be required.

Subsection (a)(1) requires the record to include the name and VMB license number of the prescribing veterinarian. This is necessary to ensure that there is adequate information available in the sales record to allow the Department to verify that prescribing veterinarians are licensed. In addition, this will allow both the restricted livestock drug licensee and the Department to contact the veterinarian for verification if a fraudulent prescription is suspected.

Subsection (a)(2) requires the record to include a unique transaction identification number for each retail sale of a medically important antimicrobial drug. This number must be listed on the record of sale as well as on the corresponding copy of the veterinary prescription or veterinary feed directive maintained on file. This is necessary to ensure investigators are able to find the appropriate corresponding prescription for each entry in the sales record and will aid in the investigation of fraudulent prescriptions.

Subsection (a)(3) requires the record to include a copy of the veterinary prescription or veterinary feed directive labeled with the corresponding unique transaction identification number. Requiring restricted livestock drug licensees to maintain copies of veterinary prescriptions and veterinary feed directives will enable the Department to verify that medically important antimicrobial drugs are being sold in accordance with the law and will allow the Department to monitor usage of medically important antimicrobial drugs to fulfill the mandates set forth in FAC Section 14405(b)(1). Requiring the veterinary prescription or veterinary feed directive to be labeled with a unique transaction identification number is necessary to ensure investigators are able to find the appropriate corresponding prescription for each entry in the sales record and will aid in the investigation of fraudulent prescriptions.

Subsection (b) is added to clarify that restricted livestock drug licensees must keep a record of each medically important antimicrobial drug sold at retail, including the accompanying copy of the veterinary prescription or veterinary feed directive, for at least three years following the retail transaction. FAC Section 14330 states that if a restricted livestock drug licensee fails to keep adequate records, their license can be revoked; the proposed regulation is necessary to clarify the required retention period. Three years was determined to be an appropriate retention period because this is the length of time that veterinary food-animal drug retailers are required to maintain records as well as the amount of time that records of veterinary feed directives must be maintained. In addition, maintaining records for three years will allow the Department sufficient time to visit all licensees for inspection.

Subsection (c) is added to clarify that the record of each retail sale of a medically important antimicrobial drug, including the accompanying copy of the veterinary prescription or veterinary feed directive, is subject to audit by the Secretary and shall be made available to the Secretary upon request. Depending on the location of the restricted livestock drug licensee, sales records may be audited by onsite inspection (in California) or by the provision of records by mail (out of state). FAC Section 14295 gives the Department authority to conduct investigations necessary to carry out FAC Division 7, Chapter 4, and the regulations adopted pursuant to it. This is necessary to ensure the Department can inspect records to verify compliance with the law.

Section 5009. Storage and Inventory

Subsection (a) is added to clarify that restricted livestock drug licensees must store medically important antimicrobial drugs in a secure, lockable area. This language is taken from BPC Section 4197(a)(1) which states that veterinary food-animal drug retailers shall store drugs in a secure, lockable area. FAC Section 14330 states that if a licensee fails to properly handle or store such drugs, their license can be revoked; the proposed regulation is necessary to clarify what constitutes proper storage and handling to ensure that all medically important antimicrobial drugs are sold in accordance with the law and to minimize the risk for losses or thefts.

Subsection (b) is added to clarify that entry into areas where medically important antimicrobial drugs are held shall be limited to authorized personnel. This provision is modeled after BPC Section 4196(c) which describes requirements for veterinary food-animal drug retailers. FAC Section 14330 states that if a licensee fails to properly handle or store such drugs, their license can be revoked; the proposed regulation is necessary to clarify what constitutes proper storage and handling to ensure that all medically important antimicrobial drugs are sold in accordance with the law and to minimize the risk for losses or thefts.

Subsection (c) is added to clarify that restricted livestock drug licensees must develop policies and train employees on the proper handling and sale of medically important antimicrobial drugs. Subsection (c)(1) requires policies for the receipt, security, storage, inventory, labeling, and dispensing of medically important antimicrobial drugs. Subsection (c)(2) requires policies for identifying, recording, and internally reporting losses or thefts of medically important antimicrobial drugs. Subsection (c)(3) requires policies for maintaining a correct inventory of medically important antimicrobial drugs and verifying that inventory records are free from errors and inaccuracies. Subsection (c)(4) requires policies for maintaining records to document proper storage proper storage conditions for medically important antimicrobial drugs as recommended by the manufacturer and required by regulation. These provisions are modeled after BPC Section 4198 which describes requirements for veterinary food-animal drug retailers. This is necessary to ensure that all medically important antimicrobial drugs are sold in accordance with the law and to minimize the risk for losses or thefts.

Subsection (d) is added to clarify that restricted livestock drug licensees must keep a record of all invoices and records of shipment for medically important antimicrobial drugs for at least three years from the date of shipment. FAC Section 14330 states that if a licensee fails to keep adequate records or is not properly handling or storing such drugs, their license can be revoked; the proposed regulation is necessary to clarify the required retention period. Three years was determined to be an appropriate retention period because this is the length of time that veterinary food-animal drug retailers are required to maintain records as well as the amount of time that records of veterinary feed directives must be maintained. In addition, maintaining records for three years will allow the Department sufficient time to visit all licensees for inspection.

Subsection (e) is added to clarify that the invoices and records of shipment for medically important antimicrobial drugs are subject to audit by the Secretary and shall be made available to the Secretary upon request. Depending on the location of the restricted livestock drug licensee, records of shipment may be audited by onsite inspection (in California) or by the provision of records by mail (out of state). FAC Section 14295 gives the Department authority to conduct investigations necessary to carry out FAC Division 7, Chapter 4, and the regulations adopted pursuant to it. This is necessary to ensure the Department can inspect records to verify compliance with the law. In addition, ensuring access to records of invoices and shipments will allow the Department to determine the amount of drugs purchased compared to the amount sold to determine if medically important antimicrobial drugs are being sold unlawfully.

Section 5010. Labeling

Subsection (a) is added to clarify that a restricted livestock drug licensee must dispense a medically important antimicrobial drug in accordance with its federally approved label. However, if the medically important antimicrobial drug is prescribed by a veterinarian for an extra label

use, the restricted livestock drug licensee must dispense the drug with an added label including all of the elements listed in Subsections (a)(1) through (a)(8). This is necessary to allow for extra label use when directed by a veterinarian.

Subsection (a)(1) requires the label to include the date dispensed. Subsection (a)(2) requires the label to include the name and address of the prescribing veterinarian. Subsection (a)(3) requires the label to include the name of the client who was issued the veterinary prescription or veterinary feed directive. Subsection (a)(4) requires the label to include the established name of the medically important antimicrobial drug or, if formulated from more than one active ingredient, the established name of each ingredient. Subsection (a)(5) requires the label to include the class/species or identification of the animal or the herd, flock, pen, lot, or other group of animals being treated. Subsection (a)(6) requires the label to include the condition for which the medically important antimicrobial drug was prescribed. Subsection (a)(7) requires the label to include the directions for use, including dosage, frequency, route of administration, duration of treatment, and withdrawal time. Subsection (a)(8) requires the label to include the date of expiration. This list of required elements is modeled after 21 CFR Section 530.12; these elements are necessary to include on the label to ensure medically important antimicrobial drugs are administered to livestock according to the prescribing veterinarian's instructions.

Subsection (b) is added to clarify that if a veterinary prescription or veterinary feed directive describing extra label use does not include sufficient information, the restricted livestock drug licensee must contact the prescribing veterinarian to obtain the required information prior to dispensing the medically important antimicrobial drug and shall document any such request for clarification. This is necessary to ensure medically important antimicrobial drugs are administered to livestock according to the prescribing veterinarian's instructions.

ARTICLE 4. VIOLATIONS AND PENALTIES

Section 5011. Violations

The Department is adding Section 5011 and Subsections (a) through (h) to provide restricted livestock drug licensees with a clear understanding of the statutory and regulatory requirements for the sale of medically important antimicrobial drugs and to provide a framework for uniform implementation and enforcement. Subsections (a) through (h) describe the violations that will be cited in the event of a failure to comply with any of the provisions described in Sections 5006 through 5010 of this chapter. The specific purpose and necessity for each violation is provided within the description for Sections 5006 through 5010 of this chapter. Subsections (a) through (h) are necessary to ensure the Department is consistent and transparent in its enforcement actions.

Subsection (a) is added to clarify that it is unlawful for any restricted livestock drug licensee to sell any medically important antimicrobial drug that is required by federal law to be sold on prescription only unless they also hold a valid license under BPC Division 2, Chapter 9 allowing them to do so. Reference Section 5006(c) for a description of the specific purpose and necessity of this provision.

Subsection (b) is added to clarify that it is unlawful for any restricted livestock drug licensee to sell any medically important antimicrobial drug at retail unless the purchaser provides a valid

veterinary prescription or veterinary feed directive. Reference Section 5007(a) for a description of the specific purpose and necessity of this provision.

Subsection (c) is added to clarify that it is unlawful for any restricted livestock drug licensee to sell any medically important antimicrobial drug at retail if the veterinary prescription or veterinary feed directive provided by the purchaser is not issued by a veterinarian licensed by the VMB. Reference Sections 5007(a) and (b) for a description of the specific purpose and necessity of this provision.

Subsection (d) is added to clarify that it is unlawful for any restricted livestock drug licensee to sell any medically important antimicrobial drug at retail beyond the expiration date listed on the veterinary prescription or veterinary feed directive or if the date of issuance of the veterinary prescription or veterinary feed directive is more than six months prior to the date of purchase. Reference Section 5007(c) for a description of the specific purpose and necessity of this provision.

Subsection (e) is added to clarify that it is unlawful for any restricted livestock drug licensee to prevent entry into and inspection of any premises where medically important antimicrobial drugs are stored or sold. Reference Section 5008(c) for a description of the specific purpose and necessity of this provision.

Subsection (f) is added to clarify that it is unlawful for any restricted livestock drug licensee to fail to keep adequate retail sales records of medically important antimicrobial drugs or to fail to make the required records available to the Secretary upon request as required by Section 5008 of this chapter. Reference Section 5008 for a description of the specific purpose and necessity of this provision.

Subsection (g) is added to clarify that it is unlawful for any restricted livestock drug licensee to fail to comply with the minimum standards for storage and inventory of medically important antimicrobial drugs as required by Section 5009 of this chapter. Reference Section 5009 for a description of the specific purpose and necessity of this provision.

Subsection (h) is added to clarify that it is unlawful for any restricted livestock drug licensee to fail to comply with the minimum standards for labeling medically important antimicrobial drugs sold at retail as required by Section 5010 of this chapter. Reference Section 5010 for a description of the specific purpose and necessity of this provision.

Section 5012. Penalties

The Department is adding Section 5012 and Subsections (a) through (d) to provide restricted livestock drug licensees with a clear understanding of the penalties associated with violating the statutory and regulatory requirements for the sale of medically important antimicrobial drugs. This section is necessary to ensure the Department is consistent and transparent in its application of administrative remedies associated with violations of the statute and regulations.

Subsection (a) is added to clarify that upon a finding a violation, the Secretary shall issue a notice of warning.

Subsection (b) is added to clarify that a person who violates this chapter shall be liable for a civil penalty of two hundred and fifty dollars ($250) for each day a violation occurs if at least one notice of warning has been issued by the Secretary for a prior violation within the preceding 12-month period. FAC Section 14408 states that a person who violates the chapter shall be liable for a civil penalty of not more than $250. The proposed regulation clarifies that the Department has set the penalty at the maximum amount of $250. This is due to the implementation of a notice of warning for a first violation; the Department believes that setting the penalty at the maximum amount will serve as a deterrent for subsequent violations.

Subsection (c) is added to clarify that for a second or subsequent violation, a person who violates this chapter shall be punishable by an administrative fine, levied by the Secretary, in the amount of five hundred dollars ($500) for each day a violation occurs. This is consistent with FAC Section 14408 and has been included in the proposed regulations for ease of reference.

Subsection (d) is added to clarify that a person may contest a penalty or fine for any violation specified in Section 5011 by requesting a hearing before the Secretary and explains how to request a hearing. This is necessary to ensure restricted livestock drug licensees are aware they have the right to appeal a violation by requesting a hearing pursuant to the procedural requirements outlined in FAC Section 14382 and Government Code Title 2, Division 3, Part 1, Chapter 5.

Subsection (e) is added to clarify that the Secretary may, after a hearing, refuse to issue or renew, or may suspend or revoke a restricted livestock drug license for any violation of this chapter, pursuant to the procedural requirements outlined in FAC Section 14382 and Government Code Title 2, Division 3, Part 1, Chapter 5. This is necessary to ensure restricted livestock drug licensees are aware of the existing administrative hearing process for appealing violations.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS

STD 399 Attachment.

ECONOMIC IMPACT ASSESSMENT/ANALYSIS

The requirement for businesses selling restricted livestock drugs to obtain a license from the Department, renew the license annually, and maintain a record of restricted livestock drugs sold are all provisions of the existing livestock drug law (FAC Division 7, Chapter 4). Chapter 1 of the proposed regulation is only making specific the procedures for applying for and renewing a license, updating the information licensees are required to maintain in the sales record, and clarifying how long the sales record must be maintained. Clarifying these existing requirements is not expected to lead to the creation or elimination of jobs or businesses within California, or to impact the number of businesses licensed by the Department.

Chapter 1 of the proposed regulation clarifies that the existing livestock drug law (FAC Division 7, Chapter 4) applies to alternative methods of sale, such as online and catalog sales, in addition to traditional in-person sales made at physical stores and mobile units in California. The Department maintains that this is already a provision of the existing statute, which is supported by the fact that there are currently three out of state businesses licensed by the Department. The proposed regulation is only seeking to clarify this existing statutory requirement and is

necessary to ensure that all restricted livestock drugs, including medically important antimicrobial drugs, are sold in accordance with the law and are subject to its recordkeeping requirements. This is particularly important with the recent adoption of FAC Division 7, Chapter 4.5, which requires medically important antimicrobial drugs to be sold only with a veterinary prescription or veterinary feed directive and requires the Department to monitor sales and use.

The Department acknowledges that clarification of this existing statutory requirement could cause some unlicensed businesses to stop selling restricted livestock drugs rather than becoming licensed. However, the Department believes this risk is limited because the benefit to businesses of becoming licensed (sales revenue) would far outweigh the associated costs ($50 license fee per location, plus minimal administrative costs to comply with recordkeeping requirements). In addition, the Department maintains that any change in the number of restricted livestock drug licensees would be a result of enforcement of the existing law, rather than an impact of the regulations. For this reason, the Department believes it is unlikely that this provision of the proposed regulations will lead to the creation or elimination of jobs or businesses within California.

The requirement for medically important antimicrobial drugs to be sold only on the order of a licensed veterinarian is a provision of the existing livestock use of medically important antimicrobial drugs law (FAC Division 7, Chapter 4.5). This law also provides that medically important antimicrobial drugs prescribed by a licensed veterinarian may be sold at retail by restricted livestock drug licensees. Chapter 2 of the proposed regulation is only making specific the additional procedures restricted livestock drug licensees must follow to ensure they are in compliance with FAC Division 7, Chapter 4.5, by clarifying the verification, recordkeeping, storage, and labeling requirements for retail sales of medically important antimicrobial drugs. This is necessary to mitigate the risk of theft or unlawful sale of medically important antimicrobial drugs, which will minimize the risk of improper use that may contribute to antibiotic resistance.

The Department acknowledges this provision could potentially lead to some restricted livestock drug licensees choosing to no longer sell medically important antimicrobial drugs rather than comply with the verification, recordkeeping, storage, and labeling requirements. However, the Department believes the risk of this is limited because the benefit to restricted livestock drug licensees of selling medically important antimicrobial drugs (sales revenue) would outweigh the associated administrative costs. If a restricted livestock drug licensee chooses to no longer sell medically important antimicrobial drugs due to the increased administrative requirements, it is unlikely the business would cancel their restricted livestock drug license altogether, as they would likely continue selling other types of restricted livestock drugs. For this reason, the Department does not anticipate that this provision of the proposed regulations will impact the number of restricted livestock drug licensees or result in the elimination of jobs or businesses within California.

Overall, the Department believes that the proposed regulations will benefit the health and welfare of California residents. The proposed regulations will bring clarity to the existing law and will reduce the likelihood of unlawful sales. The lawful sale of restricted livestock drugs, including medically important antimicrobial drugs, will help ensure that a safe supply of livestock drugs remain available to producers for their appropriate use in protecting the health of the livestock population of the state, thereby maintaining an abundant supply of wholesome food

and fiber. This will also help to preserve the efficacy and ensure current and future availability of medically important antimicrobial drugs while minimizing potential public health impacts.

Ultimately, the Department has concluded that it is:

(1) unlikely that the proposed regulations will create or eliminate jobs within the State of California;

(2) unlikely that the proposed regulations will create new businesses or eliminate existing businesses within the State of California;

(3) unlikely that the proposed regulations will affect the expansion of businesses currently doing business within the State of California; and

(4) likely that the proposed regulations will benefit the health and welfare of California residents by maintaining an abundant supply of wholesome food and fiber while at the same time preserving the efficacy of medically important antimicrobial drugs and minimizing potential public health impacts.

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS

As of March 2017, there were 307 businesses licensed by the Department to sell restricted livestock drugs. Three of these businesses are located outside of California and have therefore not been included in the total number of businesses. Of the total 304 California businesses impacted, approximately 176 were determined to be small businesses and 128 were determined to be typical businesses. This estimate was based on an assessment of firm size. Firms with only one licensed location were determined to be “small” businesses, while firms with more than one licensed location were determined to be “typical” businesses. Although the proposed regulations will directly affect businesses statewide, including small businesses, the Department concludes that the economic impact, including the ability of California businesses to compete with businesses in other states, will not be significant.

Based on investigator observations in the field, the Department anticipates that compliance with the proposed regulations will only require use of existing facilities and basic office equipment for the majority of restricted livestock drug licensees. It is reasonable to assume that the majority of businesses have a stockroom, office, or other employee-only location where medically important antimicrobial drugs can be stored and a computer, printer/copier, and internet connection in order to facilitate basic business activities. However, the exact number of restricted livestock drug licensees that will incur additional costs as a result of the proposed regulations is unknown. For this reason, the Department has prepared an estimate of total statewide dollar costs under the assumption that all businesses will incur additional costs to comply with the proposed regulations. This is in order to overestimate rather than underestimate the potential impact on businesses; the Department believes that the total actual cost to businesses will likely be significantly less. Based on investigator observations, the Department’s cost estimate assumes that small businesses utilize paper recordkeeping systems, while typical businesses utilize computerized recordkeeping systems.

The initial costs for a small business to comply with the proposed regulation is estimated to be $1,941.73 in the first year and $1,128.96 for each subsequent year. The first year cost estimate includes a separate refrigerator for the secure employee-only storage area to be used for medically important antimicrobial drugs that require refrigeration, a computer for creating labels and verifying veterinarian licenses, a printer/copier for copying prescriptions and printing labels, an internet connection for verifying veterinarian licenses, toner for copying prescriptions and printing labels, paper for copying prescriptions, file storage for storing copies of prescriptions, labels for labeling prescriptions, labor cost for training staff to comply with new requirements, and labor cost to conduct veterinarian license verification. The annual ongoing cost estimate includes an internet connection for verifying veterinarian licenses, toner for copying prescriptions and printing labels, paper for copying prescriptions, file storage for storing copies of prescriptions, labels for labeling prescriptions, and labor cost to conduct veterinarian license verification.

The initial costs for a typical business to comply with the proposed regulation is estimated to be $1,564.77 in the first year and $711.38 for each subsequent year. The first year cost estimate includes a separate refrigerator for the secure employee-only storage area to be used for medically important antimicrobial drugs that require refrigeration, system upgrades to accommodate tracking of additional data, data storage for storing prescriptions electronically, labels for labeling prescriptions, labor cost for training staff to comply with new requirements, and labor cost to conduct veterinarian license verification. The annual ongoing cost estimate includes data storage for storing prescriptions electronically, labels for labeling prescriptions, and labor cost to conduct veterinarian license verification.

Based on the assumption that all businesses will incur the additional costs described above, total statewide dollar costs are estimated to be $542,035.04 in the first year and $289,753.60 for each subsequent year for businesses to maintain compliance with the proposed regulations. This total includes costs for small and typical businesses multiplied by 176 small and 128 typical businesses. Please reference the STD 399 Attachment for additional information and calculations.

Therefore, for the reasons discussed above, the Department has concluded the proposed regulations will not have a significant statewide adverse economic impact.

REASONABLE ALTERNATIVES TO THE REGULATIONS AND THE DEPARTMENT'S REASONS FOR REJECTING THOSE ALTERNATIVES

The Department considered omitting clarification of the existing statutory requirement for alternative and out of state businesses to obtain a restricted livestock drug license prior to selling restricted livestock drugs into California. However, it was determined that this is needed to bring clarity to the existing law and to ensure that restricted livestock drugs, including medically important antimicrobial drugs, are sold in accordance with California livestock drug laws and regulations. Although this is an existing requirement and there are already three out of state businesses licensed, preliminary research by Department investigators has shown there are unlicensed retailers selling restricted livestock drugs, including medically important antimicrobial drugs, into California. For this reason, the Department determined that a regulation clarifying this statute is necessary. The proposed regulation will provide enhanced clarity of the existing requirement, thereby reducing the potential for violations and unlawful sales.

The Department considered omitting the requirement for restricted livestock drug licensees to verify that the prescribing veterinarian is licensed by the California Veterinary Medical Board prior to selling a medically important antimicrobial drug. However, it was determined this could lead to restricted livestock drug licensees inadvertently dispensing fraudulent prescriptions for medically important antimicrobial drugs given by unlicensed practitioners.

The Department considered omitting the requirement for restricted livestock drug licensees to keep a copy of the prescription or veterinary feed directive on file for each medically important antimicrobial drug sold. However, it was determined this would not allow the Department to verify that medically important antimicrobial drugs are being sold in accordance with the law. If there is no copy of the prescription on file, the Department cannot verify that the restricted livestock drug licensee required the purchaser to present a veterinary prescription or veterinary feed directive prior to selling a medically important antimicrobial drug. In addition, this would not allow the Department to investigate possible fraudulent prescriptions.

The Department considered omitting the requirement for restricted livestock drug licensees to develop and implement procedures for inventory and storage of medically important antimicrobial drugs. However, it was determined that improper storage could lead to the theft or illegal sale of medically important antimicrobial drugs, which would increase the risk of improper use and antibiotic resistance. In addition, requiring the maintenance of inventory records will allow the Department to compare the record of drugs purchased to the record of drugs sold to determine if any medically important antimicrobial drugs are being sold unlawfully.

The Department considered including the requirement for restricted livestock drug licensees to add a label to each medically important antimicrobial drug sold; however, it was determined that it would be too burdensome and ultimately unnecessary. Restricted livestock drug licensees do not have the same capacity or oversight as pharmacies or veterinary food-animal drug retailers; this is why restricted livestock drug licensees may only sell drugs that are federally labeled as over the counter. Although FAC Division 7, Chapter 4.5 states that all medically important antimicrobial drugs may only be sold in California on the order of a veterinarian, most of these drugs are still federally labeled as over the counter and are therefore not subject to federal requirements governing the labeling of prescription drugs at the point of sale. Furthermore, FAC Section 14403 expressly exempts restricted livestock drug licensees from the requirements applicable to veterinary food-animal drug retailers found in BPC Section 4196. All medically important antimicrobial drugs are already labeled with federally approved instructions for use. For this reason, it was determined that licensees should only be required to add a label to any medically important antimicrobial drug prescribed for extra label use. This is to ensure that any directions that differ from the federal label remain easily accessible to ensure medically important antimicrobial drugs are administered in accordance with a veterinarian’s guidance.

The Department considered including the requirement for restricted livestock drug licensees to submit quarterly sales reports of all medically important antimicrobial drugs sold at retail. However, it was determined that this would be too burdensome, both for licensees as well as Department staff. At this time, there is no existing infrastructure or reporting mechanism in place for licensees to utilize to report sales to the Department. In addition, the Department cannot support the staffing level that would be required to transcribe and analyze quarterly sales data from all licensees. The Department plans to take a proactive approach by working directly with licensees to promote awareness and achieve compliance with the new requirements for sales of medically important antimicrobial drugs. For this reason, the Department has determined that

conducting individual licensee inspections, either by onsite inspection of locations in California or by the provision of records by mail for locations out of state, would be the most effective solution because it will allow the Department to educate licensees, verify compliance with the law, and collect retail sales data simultaneously. If the Department develops the necessary reporting infrastructure and secures adequate funding for the required personnel, additional regulations governing retail sales reporting may be proposed in the future.

Pursuant to Government Code Section 11346.9(a)(4), the Department has determined that no alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulations, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Pursuant to Government Code Section 11346.9(a)(5), if anyone proposes an alternative that would lessen the adverse economic impact on small businesses, the final statement of reasons must include an explanation setting forth the Department's reasons for rejecting any proposed alternatives.

DUPLICATION OR CONFLICT WITH FEDERAL REGULATIONS

The proposed regulations do not duplicate or conflict with federal regulations.