

Antimicrobial Use and Stewardship Services Law (SB 27) Frequently Asked Questions



What is the Antimicrobial Use and Stewardship (AUS) program?

The California Department of Food & Agriculture (CDFA) AUS program is working to implement SB 27 (Hill, 2015). It consists of three components: stewardship, surveys and studies, and regulated use. The program is developing antibiotic stewardship guidelines and best management practices to assist producers and veterinarians in making informed decisions regarding the use of medically important antibiotics for the more than 20 livestock species and production types important to California. Surveys and studies will help us better understand the relationship between animal health, antibiotic use, and antibiotic resistance in the state.

2. What is Senate Bill 27 (SB 27)?

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 antibiotics for use in livestock, while minimizing the potential public health impact. The bill resulted in additions to the California Food and Agricultural Code (Division 7, Chapter 4.5, Sections 14400-14408) that address use of medically important antimicrobial drugs (MIADs) in livestock. Through appropriate use of antibiotics, the goal is to optimize livestock health and reduce the selection for antibiotic resistance.

What is a MIAD, and what drugs are affected by SB 27?

MIAD is the abbreviation for <u>medically important</u> antimicrobial <u>drug</u>, which are antimicrobial drugs that are important for treating human disease. All critically important, highly important, and important antimicrobial drugs listed in Appendix A of the federal Food and Drug Administration's Guidance for Industry #152 are considered MIADs and are affected by SB 27.

4. What drugs are not affected by SB 27?

Those types not included are dewormers, hormones, vaccines, non-MIAD antibiotics (such as Monensin, Lasalocid, and Bacitracin), vitamin/mineral/probiotic supplements, and other non-prescription drugs. All federally-labeled prescription only drugs (including water MIADs) will still require a prescription.

5. What does SB 27 change?

Beginning January 1, 2018, all MIADs, other than those intended to be fed to livestock, may only be purchased and administered with a prescription from a California licensed veterinarian within a valid veterinarian-client-patient relationship (VCPR). This means that all MIADs not mixed in feed, including those that are federally labeled for over-the-counter sale, will now require a prescription to be sold or used in California. Under California's pharmacy law,

any drug that requires a prescription is considered a "dangerous drug" and may only be dispensed by a licensed facility or veterinarian.

SB 27 does not change where medicated feed can be purchased. The veterinary feed directive, or VFD, is an existing federal requirement that went into effect January 1, 2017. If you would like more information on VFDs, please visit:

https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM474640.pdf

6. "Regular pattern" preventative use is restricted under SB 27. How do I avoid using a MIAD in a regular pattern while trying to prevent a disease?

We encourage you to speak with your veterinarian and discuss how this change on January 1, 2018 will affect current practices on your farm or ranch.

7. Where can I buy MIADs?

After January 1, 2018, all MIADs that are not mixed in feed will require a prescription from a California licensed veterinarian to be purchased. Prescriptions may only be dispensed by:

- · The prescribing veterinarian
- A veterinary food animal drug retailer (VFADR)
- · A licensed pharmacy

To find a location near you that is licensed to dispense prescriptions drugs, please visit:

www.pharmacy.ca.gov/about/verify_lic

Medically Important Antimicrobial Drugs Prescription or VFD required after January 1, 2018

Aminoglycosides

Gentamicin* (Garacin, Gen-Gard) Neomycin* (Neo-Sol 50, Neovet) Spectinomycin* (L-S50)

Amphenicols

Florfenicol** (Nuflor)

Cephalosporins

Ceftiofur** (Naxcel, Excede) Cephapirin (Today, Tomorrow)

Diaminopyrimidines

Ormetoprim (Rofenaid)

Fluoroguinolones

Danofloxacin**
Enrofloxacin** (Baytril)

Macrolides

Gamithromycin** (Zactran)
Tilmicosin (Pulmotil AC)
Tulathromycin**(Draxxin)
Tylosin* (Tylan, Tylovet, Tyloved)

Lincosamides

Lincomycin* (Lincosol, Lincomix)
Pirlimycin**

Polymyxins

Polymyxin B (Terramycin)

Penicillins

Amoxicillin**
Ampicillin** (Polyflex)
Cloxacillin**
Penicillin* (Procaine Penicillin G)

Streptogramins

Virginiamycin* (V-max, Stafac)

Sulfonamides (Sulfas)

Sulfadimethoxine* (Albon, Sulfamed) Sulfamethazine* (Poultysulfa, Aureo) Sulfaquinoxaline* (Sul-Q-Nox,)

Tetracyclines

Chlortetracycline* (ChlorMax)
Oxytetracycline* (LA-200, Duramycin)
Tetracycline (Tetramed)

* May be used in feed
** Federally labeled as prescription-only

Please note: Example brand names in parentheses, but are not a comprehensive listing. For more details regarding specific products, visit our website.



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8. What does a retailer need to do in order to sell MIADs that are not mixed in feed?

After January 1, 2018, a retailer wishing to fill prescriptions for MIADs must apply for a license with the California Board of Pharmacy. The facility must become licensed as a pharmacy or Veterinary Food Animal Drug Retailer (VFADR). Additional restrictions for sale may apply. For more information on applying for a pharmacy license, please visit: www.pharmacy.ca.gov/applicants/apply_facility

9. Why is veterinary oversight important?

Veterinarians have the medical training and expertise to partner with their producers to accurately identify and evaluate a health crisis, and prescribe appropriate treatment. Veterinarians are familiar with up-to-date diagnostic methods, and can perform them to ensure the medication used is the best one for the job, minimizing both wasted time and money for a drug that may not give the expected result. Together, veterinarians and producers can identify the best practices for the farm or ranch to optimize animal health in order to prevent disease.

10. I don't have a veterinarian for my livestock. Where do I find one?

There are several online resources for you to seek out veterinary care for your livestock. The California Veterinary Medical Association (CVMA) has an online resource to find California-based vets. If you belong to any associations or groups, often it's helpful to contact the local or state organizations for direction to a veterinarian. It is critical not to wait for an emergency to establish a working relationship, as prompt veterinary care can impact health outcomes.

11. What is a VCPR? How do I know if I have one?

The veterinarian-client-patient relationship, or VCPR, describes the basic requirements for a healthy interaction among veterinarians, their clients, and the patients. In California, a VCPR is established when the client has authorized the licensed veterinarian to assume responsibility for making medical judgements and the need for medical treatment of the patient (including the prescription of antibiotics) AND the veterinarian has agreed to assuming that responsibility and has communicated with the client an appropriate course of treatment.

In order to establish a valid VCPR, the veterinarian must be personally acquainted with the care of the animal(s) by way of an examination of the animal or by medically appropriate and timely visits to the premises where the animals are kept AND have enough knowledge of the animal(s) to give at least a general or preliminary diagnosis of the medical condition.

12. What is antibiotic resistance?

Antibiotic resistance is the ability of bacteria to resist the effects of an antibiotic – that is, the bacteria are not killed, and their growth is not stopped. Resistant bacteria survive exposure to the antibiotic and continue to multiply in the body, potentially causing more harm and spreading to other animals or people. Antibiotic resistance is a natural phenomenon, which can be accelerated by the use of antibiotics. Even appropriate antibiotic use poses the risk of promoting antibiotic resistance. Since antibiotic resistant infection in humans and animals has the potential to cause severe illness, it is essential that we work together to mitigate practices contributing to the expansion of antibiotic resistance.

13. Does antibiotic resistance in animals cause antibiotic resistant infection in humans?

To date, there is no scientific consensus regarding direct links between antibiotic resistance, caused by the use of antibiotics, in animals and resistant foodborne infection in humans. Regardless, the spread of antibiotic resistance and antibiotic resistant infections, in both humans and animals, is an important health concern. Stewardship surrounding the usage of antibiotics in livestock not only supports the reduction of potentially harmful impacts from their use, but also preserves the effectiveness of antibiotic drugs. By working together to support these efforts, we can promote animal health and a clean and wholesome food supply in California.

14. How will we know if changes implemented following SB 27 make an impact on reducing antibiotic resistance?

Through our surveys, regional listening sessions, and contracted studies, we will be able to accrue data and anecdotal support for various programs and changes. No recommendations should reduce animal health, or cause animal suffering. Our methodical information gathering and sampling will help provide baselines and track usage and resistance trends moving forward.

Contact Antimicrobial Use and Stewardship



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https://www.cdfa.ca.gov/ahfss/AUS/



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