

Antimicrobial Use and Stewardship

FAC 14400-14408: Frequently Asked Questions



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

The California Department of Food & Agriculture (CDFA) AUS program implements the Food and Agriculture Code (FAC) 14400-14408, previously referred to as SB 27 (Hill, 2015). The AUS team consists of three components: Stewardship, Surveys & Studies, and Regulated Use. The program has developed antibiotic stewardship guidelines and best management practices to assist producers and veterinarians to make informed decisions regarding the use of medically important antibiotics. AUS research also helps to further understanding of the relationship between animal health, antibiotic use, and antibiotic resistance in the state.

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

California Senate Bill 27 (Hill) was signed by Governor Brown on October 10, 2015, with the intent to ensure current and future availability and efficacy of antibiotics for use in livestock and minimize the potential public health impacts of antibiotic resistance. The bill added to the California Food and Agriculture Code (Division 7, Chapter 4.5, Sections 14400-14408) to address the use of medically important antimicrobial drugs (MIADs) in livestock and created CDFA's AUS program. Through appropriate use of antibiotics, the goal is to optimize livestock health and mitigate the selection for antibiotic resistance.

3. 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 that can be accelerated by the use of antibiotics. Even appropriate antibiotic use poses the risk of promoting antibiotic resistance. Since antibiotic-resistant infections in humans and animals have the potential to cause severe illness, it is essential that producers and veterinarians continue to work together to amend practices contributing to the expansion of antibiotic resistance.

4. What is a MIAD, and what drugs are affected by the amendment to the Food and Agriculture Code?

MIAD is the abbreviation for <u>medically</u> important <u>antimicrobial</u> drug, an antimicrobial drug 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 (FDA)'s Guidance for Industry (GFI) #152 are considered MIADs and were affected. For this FAQ, the terms antimicrobials and antibiotics are interchangeable.

5. What drugs were not affected?

Drug types not included are dewormers, hormones, vaccines, non-MIAD antibiotics (such as monensin, lasalocid, and bacitracin), coccidiostats, vitamin/mineral/probiotic supplements, and other non-prescription drugs. All federally labeled, prescription-only drugs (including MIADs in water) still require a prescription.

6. What changed with the implementation of FAC 14400-14408?

Effective 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). (See 8 for more on VCPR.) Where a producer can purchase medicated feed was not affected. The veterinary feed directive (VFD) is a federal requirement that went into effect January 1, 2017. Federal law, through Guidance for Industry #263, similarly brought the rest of the nation's medically important antibiotic drugs under veterinary control in June 2023.

If you would like more information on VFDs, please visit: https://www.fda.gov/downloads/Animal Veterinary/GuidanceComplianceEnforcement/ GuidanceforIndustry/UCM474640.pdf.

If you would like more information on GFI#263, please visit: https://www.fda.gov/animal-veterinary/antimicrobial-resistance/gfi-263-frequently-asked-questions-farmers-and-ranchers.

7. Where can I buy MIADs?

All MIADs that are not mixed in feed require a prescription from a California licensed veterinarian to be purchased and administered. These drugs may be available at the following:

- A licensed veterinarian
- A veterinary food animal drug retailer (VFADR)
- A licensed pharmacy
- A licensed online pharmacy

For more information about availability, please visit: https://www.cdfa.ca.gov/AHFSS/aus/docs/Antimicrobial_Availability_Producer.pdf.

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

The veterinarian-client-patient relationship (VCPR) describes the basic requirements for a healthy interaction among veterinarians, their clients, and the patients.

In California, a VCPR can be established when all of the following occur:

- The client has authorized the licensed veterinarian to assume responsibility to make medical judgment regarding the health of the animal, including the need for medical treatment.
- The veterinarian has agreed to assume responsibility and has communicated with the client about an appropriate course of treatment.
- The veterinarian is personally acquainted with the care of the animal(s), by way of an examination of the animal, either in person or by use of synchronous audio-video communication (telehealth**), 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.

9. Why is veterinary oversight important?

Veterinarians have the medical training and expertise to partner with producers to accurately identify and evaluate a health issue, as well as to prescribe appropriate treatment. Veterinarians are familiar with up-to-date diagnostic methods and utilize those tools to ensure any medication used is the best one for the job. This minimizes both wasted time and money for a drug that may not give the expected results. Together, veterinarians and producers can identify the best practices for the farm or ranch to optimize animal health through disease prevention.

^{**}Throughout this document, the term telehealth or telemedicine used as it may be more familiar to readers. In order to be compliant with California code, synchronous audio-video communication is required for establishing a telehealth VCPR.



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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 producer groups, it's often helpful to contact your local or state organizations for directions 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. If finding veterinarians to provide timely access to treatment is challenging in your area, please email us at CDFA_AUS@CDFA.CA.GOV to address potential solutions in these areas.

11. Does antibiotic resistance in animals cause antibiotic resistant infections in humans?

To date, there is no scientific consensus regarding direct links between antibiotic resistance caused by the use of antibiotics in animals. Regardless, the spread of antibiotic-resistant infections, in both humans and animals, is an important health concern. Stewardship surrounding the usage of antibiotics in livestock not only reduces 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.

12. How will we know if changes implemented are making an impact on reducing antibiotic resistance?

Through our surveys, regional listening sessions, and contracted studies, AUS collects 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. For more information on current trends, published both in journal articles and on our webpage, check out our website:

https://www.cdfa.ca.gov/AHFSS/aus/.

13. Are there limits for how long a veterinarian can write a prescription or a Veterinary Feed Directive (VFD)?

A VFD can be written for a maximum of six months with the maximum duration of use following the approved directions in the Code of Federal Regulations. It cannot be written through a VCPR established by telehealth**, pursuant to federal law. A prescription issued from an in-person VCPR can be written for up to a year and six months using telehealth**. Antimicrobial drugs can be written only for 14 days if VCPR is established through telehealth**, before needing to examine the animal to extend treatment.

CONTACT AUS

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Medically Important Antimicrobial Drugs

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)

Fluoroquinolones

Danofloxacin
Enrofloxacin (Baytril)

Lincosamides

Lincomycin* (Lincosol, Lincomix)
Pirlimycin

Macrolides

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

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

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