HB 652

Department of Legislative Services

Maryland General Assembly
2019 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 652 (Delegate Love, *et al.*)
Environment and Transportation

Agriculture - Use of Antimicrobial Drugs - Limitations and Reporting Requirements

This bill makes various changes to provisions governing the administration of medically important antimicrobial drugs to cattle, swine, or poultry, relating to (1) the allowable administration of the drugs; (2) the definition of "medically important antimicrobial drug"; (3) the applicability of the provisions; (4) the penalty for violating the provisions; and (5) reporting requirements.

Fiscal Summary

State Effect: General fund expenditures increase by $216,400 in FY 2020. Future year expenditures reflect ongoing costs. General fund revenues may increase by an indeterminate amount.

(in dollars)	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
GF Revenue	-	-	-	-	-
GF Expenditure	$216,400	$200,200	$113,100	$116,400	$119,700
Net Effect	($216,400)	($200,200)	($113,100)	($116,400)	($119,700)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate increase; (-) = indeterminate decrease

Local Effect: None.

Small Business Effect: Meaningful.

Analysis

Bill Summary:

Administration of a Medically Important Antimicrobial Drug

Prescription or Veterinary Feed Directive

The bill prohibits the administration of a medically important antimicrobial drug to cattle, swine, or poultry unless ordered by a licensed veterinarian through (1) a medically important antimicrobial drug prescription or (2) a veterinary feed directive.

The bill also amends an existing definition of "medically important antimicrobial drug prescription" to mean an order issued by a veterinarian licensed in the State, in the course of the veterinarian's professional practice, for a medically important antimicrobial drug – eliminating a limitation on its applicability to only a medically important antimicrobial drug that is in a water-soluble powder form, to be added to the drinking water of cattle, swine, or poultry. Pursuant to existing law, a medically important antimicrobial drug prescription must also provide the same or substantially similar information as required for a veterinary feed directive under specified federal regulations. Under existing law, "veterinary feed directive" is defined as a written statement issued by a veterinarian licensed in the State in the course of the veterinarian's professional practice that (1) orders the use of an animal drug in or on animal feed; (2) authorizes an owner or a caretaker of an animal to obtain and use animal feed bearing or containing an animal drug to treat the animal; and meets conditions and requirements under specified federal regulations.

Clarification of "Administered in a Regular Pattern"

Under existing law, a medically important antimicrobial drug may be administered to cattle, swine, or poultry if, in the professional judgment of a licensed veterinarian, the medically important antimicrobial drug is necessary (1) to treat a disease or infection; (2) to control the spread of a disease or infection; or (3) for a surgery or medical procedure. Aside from such administration, under existing law, a medically important antimicrobial drug may not be administered in a regular pattern to cattle, swine, or poultry. The bill defines "administered in a regular pattern" to mean used:

- for multiple courses of therapy in the same animal or group of animals; or
- as standard operating procedure, including (1) in correspondence with a particular life stage of an animal, such as in ovo, at birth or hatch, or at weaning; (2) as an ongoing management strategy or tool, such as in correspondence with a particular age or weight of an animal, time of the week, month, year, or season; (3) when moving animals from one location to another; or (4) when dairy cattle enter a dry cycle.

Duration of Administration

The bill limits the duration for which a medically important antimicrobial drug may be administered to cattle, swine, or poultry to 21 days unless federal label directions mandate a longer period of use. A licensed veterinarian may extend administration of a medically important antimicrobial drug for not more than 21 days if, after conducting an on-site visit, the veterinarian determines that the extension is necessary to treat or control the spread of disease or infection. A licensed veterinarian may grant additional extensions of not more than 21 days, provided that the veterinarian conducts an on-site visit before each extension.

Administration for Prophylaxis

The bill also limits the conditions under which a medically important antimicrobial drug may be administered for prophylaxis (and defines "prophylaxis," a currently undefined term in statute) by defining the term "elevated risk" (also a currently undefined term). Under existing law, a medically important antimicrobial drug may be administered to cattle, swine, or poultry if, in the professional judgment of a licensed veterinarian, the drug is necessary for prophylaxis to address an elevated risk of contraction of a particular disease or infection.

The bill defines "elevated risk" as a risk that is significantly higher than that present under normal or standard operating conditions and does not include a risk typically or frequently present under normal or standard operating conditions. "Prophylaxis" is defined as the prevention of disease or infection in the absence of documented clinical signs of disease or infection.

The bill also limits the duration for which a medically important antimicrobial drug may be administered to cattle, swine, or poultry for the purpose of prophylaxis to 21 days, without extension, unless federal label directions mandate a longer period of use.

Definition of "Medically Important Antimicrobial Drug"

The definition of "medically important antimicrobial drug" is modified to include any drug from a class of drug or derivative of a class of drug that is listed in a guidance document that ranks the medical importance of antimicrobial drugs, created by the federal Food and Drug Administration (FDA) subsequent to FDA's Guidance for Industry #152.

Applicability of Medically Important Antimicrobial Drug Provisions

The bill appears to expand the applicability of the medically important antimicrobial drug provisions to dairy cattle on a farm operation with a herd size of 10 or more dairy cattle. Under existing law, the provisions do not apply to antimicrobial use in cattle on a farm

operation that sells fewer than 200 cattle per year, but by adding another exception for dairy cattle on a farm operation with a herd size of fewer than 10 dairy cattle, the bill appears to affirm the applicability of the provisions to dairy cattle on a farm operation with a herd size of 10 or more dairy cattle.

Penalty Provision

The bill modifies an existing penalty provision to establish that the Secretary of Agriculture may impose an administrative penalty of up to $2,000 *per violation* on a person that violates the medically important antimicrobial drug provisions.

Reporting

Owners

By February 1, 2021, and each February 1 thereafter, an owner of cattle, swine, or poultry must submit to the Maryland Department of Agriculture (MDA), in a manner determined by the department, (1) a copy of the medically important antimicrobial drug prescription or veterinary feed directive for each medically important antimicrobial drug administered to cattle, swine, or poultry during the previous calendar year and (2) an accounting of the total number of animals raised during the previous calendar year, categorized by species and production class.

Maryland Department of Agriculture

By December 1, 2021, an existing annual report required to be submitted by MDA to the General Assembly by December 1 of each year must include, for the previous calendar year, (1) the total number of animals raised on farm operations covered by the provisions governing medically important antimicrobial drugs, categorized by species and production class; (2) the specific antimicrobial active ingredients and classes of antimicrobial active ingredients used; (3) the total weight of antimicrobial active ingredients used; (4) indications for which veterinarians prescribed medically important antimicrobial drugs; and (5) patterns of use for medically important antimicrobial drugs, including duration and seasonal variation. The information must be disaggregated by county, unless there are two or fewer reporting farm operations in a particular county for any of the categories of information, in which case MDA may report the information for that category on a regional or statewide basis.

MDA must maintain all records and information relating to the administration of medically important antimicrobial drugs submitted to the department (1) in a manner that protects the identity of the farm operation that submitted the information and (2) for at least five years.

The bill also requires that the annual report, which, under existing law, must include specified publicly available data on the use in the State of medically important antimicrobial drugs in cattle, swine, and poultry, must include data from appropriate *State* trade associations, organizations, and councils in addition to data from appropriate national trade associations, organizations, and councils.

Notice to Owners

By November 1, 2019, MDA must provide written notice of the bill's requirements to each owner that may be affected by them. The notice must be sent by first-class mail to the owner's last known address.

Current Law: Pursuant to Chapters 787 and 788 of 2017, State law prohibits the administration of a medically important antimicrobial drug to cattle, swine, or poultry solely for the purpose of promoting weight gain or improving feed efficiency. As of January 1, 2018, a medically important antimicrobial drug may be administered to cattle, swine, or poultry if, in the professional judgment of a licensed veterinarian, the drug is necessary (1) to treat, or control the spread of, a disease or infection; (2) for a surgery or medical procedure; or (3) provided the drug is not administered in a regular pattern, for prophylaxis to address an elevated risk of contraction of a particular disease or infection.

Recently adopted MDA regulations define "regular pattern" as repeating the dosage of a medically important antimicrobial drug, known as pulse dosing, to the same animal or group of animals, that is inconsistent with its approved duration and indication of use. The regulations also define "prophylaxis" as the administration for preventative use of a medically important antimicrobial drug to an animal or multiple animals to address an elevated risk of contraction of a particular disease or infection.

"Medically important antimicrobial drug" means any drug from a class of drug or derivative of a class of drug that is:

- (1) made from a mold or bacterium that kills or slows the growth of other microbes, specifically bacteria and (2) used in human beings or intended for use in human beings to treat or prevent disease or infection; or
- listed in Appendix A of FDA's Guidance for Industry #152, including critically important, highly important, or important antimicrobial drugs.

Except as otherwise provided in federal law or regulation, the State law provisions governing administration of medically important antimicrobial drugs to cattle, swine, or poultry do not apply to antimicrobial use in (1) cattle on a farm operation that sells fewer than 200 cattle per year; (2) swine on a farm operation that sells fewer than 200 swine per year; or (3) poultry on a farm operation that sells fewer than 60,000 birds per year.

Each year, MDA must collect publicly available data on the use in the State of medically important antimicrobial drugs in cattle, swine, and poultry from (1) the U.S. Department of Agriculture; (2) the Centers for Disease Control and Prevention; (3) FDA; and (4) appropriate national trade associations, organizations, and councils. By December 1, 2019, and each December 1 thereafter, MDA must report to the General Assembly on the data collected.

The Secretary of Agriculture may impose an administrative penalty of up to $2,000 on a person who violates State law provisions governing administration of medically important antimicrobial drugs to cattle, swine, or poultry.

Background: FDA indicates that antimicrobial resistance is a national and worldwide public health challenge. Judicious use of antimicrobial drugs can effectively fight bacterial infections, but use and misuse can also promote the development of antimicrobial-resistant bacteria. In 2017, FDA completed a process begun in 2013 to transition medically important antimicrobial drugs (important in human medicine) used in feed or drinking water of food-producing animals to veterinary oversight and to eliminate use of the drugs for production purposes such as growth promotion.

A five-year plan for supporting antimicrobial stewardship in veterinary settings, issued in September 2018 by FDA's Center for Veterinary Medicine (CVM), indicates that CVM plans to (1) develop and implement a strategy to ensure that all medically important antimicrobial drugs used in food-producing animals are labeled with an appropriately targeted duration of use and (2) issue a strategy to bring products in dosage forms other than feed and drinking water use (*e.g.*, injectable products) that remain on the market as over-the-counter products, under veterinary oversight.

State Fiscal Effect: General fund expenditures increase by $216,433 in fiscal 2020, which accounts for the bill's October 1, 2019 effective date. This estimate reflects the costs of (1) hiring a part-time administrative officer and an office secretary within MDA to manage outreach and assistance to owners and the collection and reporting of data required under the bill and (2) software development costs to establish and maintain an online software application to collect and manage the data reported by owners. It includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses. Additional personnel expenditures may be incurred to the extent existing personnel cannot absorb additional responsibilities necessary to ensure compliance with the bill. MDA expects that a portion of the time of an existing assistant Attorney General and a field veterinarian will be devoted to implementing and enforcing the bill.

Positions	1.5
Salaries and Fringe Benefits	$66,589
Software Development	140,000
Operating Expenses	9,844
Total FY 2020 State Expenditures	**$216,433**

Future year expenditures reflect full salaries with annual increases and employee turnover and ongoing operating expenses.

State Revenues: General fund revenues may increase to the extent additional administrative penalties are collected due to the bill's changes. The extent of any increase in penalty revenues cannot be reliably estimated.

Small Business Effect: The bill is expected to have a meaningful impact on small business livestock, dairy, and poultry producers subject to the bill (and not exempted under the specified exemptions). The bill limits the allowable administration of medically important antimicrobial drugs to cattle, swine, and poultry and increases the extent of veterinary oversight needed for the administration of the drugs. The bill may put Maryland producers at a disadvantage to producers in other states to the extent it decreases producers' level of production and/or increases input costs for alternative disease prevention measures. Small business owners of cattle, swine, or poultry (unless exempted from the bill) are also affected, at least operationally, by the bill's reporting requirement.

Additional Information

Prior Introductions: None.

Cross File: SB 471 (Senator Pinsky, *et al.*) - Education, Health, and Environmental Affairs.

Information Source(s): Maryland Department of Agriculture; Maryland Farm Bureau; Delmarva Poultry Industry, Inc.; U.S. Food and Drug Administration; Department of Legislative Services

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