SB 607

Department of Legislative Services

Maryland General Assembly
2016 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 607 (Senator Pinsky, *et al.*)
Education, Health, and Environmental Affairs

Agriculture - Cattle, Swine, and Poultry - Use of Antimicrobial Drugs

This bill prohibits, beginning February 1, 2017, and subject to certain exceptions, an owner of cattle, swine, or poultry from administering or authorizing an agent to administer a medically important antimicrobial drug to the cattle, swine, or poultry without a prescription or veterinary feed directive issued by a licensed veterinarian under specified conditions. A medically important antimicrobial drug may not be administered to cattle, swine, or poultry for growth promotion, feed efficiency or weight gain purposes, or routine disease prevention and may be administered only for a use authorized by a prescription or veterinary feed directive. The bill specifies related requirements, including a reporting requirement applicable to a veterinarian who issues a veterinary feed directive, and authorizes the Secretary of Agriculture to impose an administrative penalty for a violation of the bill's provisions.

Fiscal Summary

State Effect: General fund expenditures increase by at least $61,400 in FY 2017 due to Maryland Department of Agriculture (MDA) personnel costs. Future years reflect annualization and inflation. General fund revenues may increase due to collection of administrative penalties.

(in dollars)	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
GF Revenue	-	-	-	-	-
GF Expenditure	$61,400	$76,600	$79,600	$82,800	$86,100
Net Effect	($61,400)	($76,600)	($79,600)	($82,800)	($86,100)

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

Local Effect: None.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary: Except as otherwise provided in federal law or regulation, the bill does not apply to antimicrobial use in (1) dairy cattle; (2) cattle on a farm operation that sells fewer than 200 cattle per year; (3) swine on a farm operation that sells fewer than 200 swine per year; or (4) poultry on a farm operation that sells fewer than 60,000 birds per year.

Beginning February 1, 2017, a medically important antimicrobial drug may only be administered with a prescription or a veterinary feed directive issued by a licensed veterinarian in the context of a veterinarian-client-patient relationship that meets specified federal criteria. In addition, the veterinarian must have, within the previous six months, visited the farm operation in which the cattle, swine, or poultry is located, and have determined that the medically important antimicrobial drug is necessary (1) to treat a documented disease or infection; (2) for disease control; (3) for a surgery or a medical procedure; or (4) to prevent a disease that results from a veterinarian-documented specific event that significantly increases disease risk relative to normal facility operating conditions.

A "veterinary feed directive" is 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 (3) meets specified federal conditions and requirements.

A medically important antimicrobial drug must be administered in a manner that treats the fewest number of cattle, swine, or poultry for the shortest duration necessary for the use authorized by the prescription or the veterinary feed directive.

By February 1, 2018, and each February 1 thereafter, a veterinarian who issues a veterinary feed directive must submit to MDA specified information from each veterinary feed directive issued during the previous calendar year. MDA must maintain and make available for public review the information submitted, in a manner that provides the greatest public disclosure of records and information while protecting the identity of the farm operation or owner of the farm operation to which the veterinary feed directive relates. MDA must also report to the General Assembly on the information submitted, by December 1, 2018, and each December 1 thereafter.

The Secretary of Agriculture may impose an administrative penalty of up to $2,000 on a person who violates the bill's provisions. MDA may adopt regulations to carry out the bill.

Current Law:

Federal Regulation

Animal drugs, including those included in animal feed, go through a U.S. Food and Drug Administration (FDA) approval process called the New Animal Drug Application (NADA) process. The drug sponsor, often a pharmaceutical company, is responsible for collecting information on the safety (both with respect to the target animals and humans) and effectiveness of a new animal drug, which FDA reviews. There is also a process for withdrawal of approval based on various grounds, such as later experience or scientific data showing that the drug is unsafe under the approved conditions of use. Certain modified approval procedures apply to drugs for minor species or for minor uses in major species.

Antimicrobial resistance is considered during the NADA process, and FDA has had guidance in place since 2003 (Guidance for Industry #152) establishing a risk analysis methodology "for evaluating human food safety with respect to the potential microbiological effects of antimicrobial new animal drugs on food-borne bacteria of human health concern."

State Regulation

MDA's State Chemist Section (SCS) administers the Maryland Commercial Feed Law. Under the Maryland Commercial Feed Law, SCS must sample, inspect, test, and make analyses of commercial feed distributed in the State to the extent considered necessary to ensure compliance with the law. A distributor generally must register each brand name or product name of commercial feed before distributing it in the State, unless it has been registered by another person and the product label has not been altered or changed.

Background:

Antimicrobial/Antibiotic Resistance

A 2013 report by the U.S. Centers for Disease Control and Prevention (*Antibiotic Resistance Threats in the United States*) refers to antimicrobial (or antibiotic[1]) resistance as one of our most serious health threats, and there is concern about the extent to which use of antimicrobial drugs in animal agriculture contributes to antimicrobial resistance in humans and animals. A 2012 FDA guidance document (Guidance for

[1]"Antimicrobial" drugs are used to kill or slow the growth of microorganisms (bacteria, viruses, fungi, parasites). "Antibiotic" drugs are a subset of antimicrobial drugs used to kill or slow the growth of bacteria. The terms "antimicrobial" and "antibiotic" are sometimes used interchangeably, yet drug-resistant bacteria appear to be the primary concern related to agricultural use of the drugs.

Industry #209), which establishes principles for judicious use of antimicrobial drugs in the feed and drinking water of food-producing animals, states that "[t]he scientific community generally agrees that antimicrobial drug use is a key driver for the emergence of antimicrobial-resistant bacteria." In the document, FDA summarizes past reports and studies on the use of antimicrobial drugs in animal agriculture and determines that judicious use of medically important antimicrobial drugs is important to minimize resistance development and preserve their effectiveness as therapies for humans and animals.

FDA Guidance

FDA's 2012 guidance appears to be aimed at those "medically important antimicrobial drugs" approved prior to the implementation of the 2003 guidance mentioned above. The 2012 guidance distinguishes between drugs approved before and after the implementation of the 2003 guidance and states that "FDA believes the approach outlined in [the 2003 guidance] for evaluating microbiological safety as part of the drug approval process has been very effective … and is protective of public health."

The 2012 FDA guidance considers the use of medically important antimicrobial drugs in animal feed or water for treatment, control (administration to a group of animals where a certain amount of the group have a disease), and prevention of specific diseases as uses that are necessary for assuring animal health and, therefore, appropriate uses. The guidance recommends veterinary oversight or consultation but notes that the oversight or consultation could include direct diagnosis and administration of therapies by a veterinarian or simply a veterinarian periodically visiting and consulting with a producer to establish customized disease management protocols. FDA recently also revised its veterinary feed directive regulations as part of the implementation of its policy framework for the judicious use of medically important antimicrobial drugs in food-producing animals.

FDA issued guidance in December 2013 (Guidance for Industry #213), for the sponsors of the drugs, to facilitate voluntary changes to conditions of use labeling on the drugs consistent with the 2012 guidance on their judicious use. FDA notes in the guidance that use of medicated feed other than in accordance with its label is not permitted by law. According to FDA, all of the affected drug sponsors have committed to implementing the changes described in the 2013 guidance by a December 2016 target date. FDA indicates that its guidance does not phase out long-term or open-ended disease prevention uses and that it is continuing to analyze that issue.

State Expenditures: General fund expenditures increase by at least $61,448 in fiscal 2017, which accounts for the bill's October 1, 2016 effective date. This estimate reflects the cost of hiring an administrative officer to manage the collection, listing, and reporting of veterinary feed directive information provided by veterinarians (including

outreach and assistance prior to initial submission of information) and documentation of any noncompliance under the bill in general. It includes a salary, 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 program veterinarian, inspector, assistant Attorney General, and administrative officer will be devoted to implementing and enforcing the bill. The bill may, therefore, contribute to the need for additional personnel beyond the one administrative officer.

Position	1
Salary and Fringe Benefits	$56,633
Operating Expenses	4,815
Total FY 2017 State Expenditures	**$61,448**

Future year expenditures reflect a full salary with annual increases and employee turnover as well as annual increases in ongoing operating expenses.

State Revenues: General fund revenues may increase to the extent administrative penalties are collected under the bill. The extent of any increase cannot be reliably estimated.

Small Business Effect: The bill may have a meaningful impact on at least some small business livestock and poultry producers subject to the bill (and not exempted under the specified exemptions). Despite potential changes in permitted uses of antibiotics in animal agriculture by the end of 2016, under FDA's 2012 and 2013 voluntary industry guidance, the bill's prohibition appears to be more restrictive than permitted, labeled uses of antibiotics that conform to the FDA guidance, at least with respect to disease prevention (where a disease has not yet been detected in an animal or flock or herd). 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. Veterinarians are affected, at least operationally, by the bill's reporting requirement.

Additional Information

Prior Introductions: None.

Cross File: HB 829 (Delegate S. Robinson, *et al.*) - Environment and Transportation.

Information Source(s): Maryland Department of Agriculture, U.S. Food and Drug Administration, U.S. Centers for Disease Control and Prevention, Department of Legislative Services

Fiscal Note History: First Reader - February 28, 2016
md/lgc

Analysis by: Scott D. Kennedy

Direct Inquiries to:
(410) 946-5510
(301) 970-5510