HB 701

Department of Legislative Services

Maryland General Assembly
2015 Session

FISCAL AND POLICY NOTE

House Bill 701 (Delegate S. Robinson, *et al.*)
Environment and Transportation

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

This bill prohibits, with specified exceptions, a person from engaging in the "nontherapeutic use" of a "medically important antimicrobial drug" in cattle, swine, or poultry produced in the State for human consumption, beginning October 1, 2016. Beginning October 1, 2017, and each October 1 thereafter, a farm operation in which a medically important antimicrobial drug is used in cattle, swine, or poultry must submit specified information regarding the use of the drug(s) to the Maryland Department of Agriculture (MDA). MDA must then report on the information received to the General Assembly by December 1 of each year. The Secretary of Agriculture may impose an administrative penalty of up to $2,000 for a violation of the bill's provisions.

Fiscal Summary

State Effect: General fund expenditures increase by $159,800 in FY 2017 for MDA to hire a veterinarian and an agricultural inspector to implement and enforce the bill. Future years reflect annualization and inflation. Revenues are not materially affected.

(in dollars)	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
Revenues	$0	$0	$0	$0	$0
GF Expenditure	0	159,800	145,200	152,000	159,100
Net Effect	$0	($159,800)	($145,200)	($152,000)	($159,100)

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

Local Effect: The bill does not directly affect local government finances.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary: The bill does not apply to antimicrobial use in (1) dairy cattle; (2) cattle on a farm operation that sells less than 200 cattle per year; (3) swine on a farm operation that sells less than 200 swine per year; or (4) poultry on a farm operation that sells less than 60,000 birds per year.

A "medically important antimicrobial drug" is a drug or derivative of a drug that is (1) made from a mold or bacterium that kills or slows the growth of other microbes, specifically bacteria, and is used in human beings or intended for use in human beings to treat or prevent disease or infection or (2) listed in specified U.S. Food and Drug Administration (FDA) industry guidance (Guidance for Industry #152).

"Nontherapeutic use" means the use of a medically important antimicrobial drug in agricultural animal production in the absence of a documented disease or infection. It includes growth promotion, feed efficiency, weight gain, routine disease prevention, or any other routine purpose. However, it does not include the use of a medically important antimicrobial drug to control the spread of disease or infection in a barn or equivalent animal housing unit if the use is for (1) a limited and medically appropriate duration and (2) animals that have been deemed high risk for disease or infection.

Current Law:

Federal Regulation

Animal drugs, including those included in animal feed, go through an 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. Although Maryland law, for the most part, does not specifically address drugs in animal feed and SCS does not have a formal agreement with FDA to regulate drugs, SCS ensures the safety of feeds containing drugs by requiring conformance with FDA law.

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 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."

[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.

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 or consulting with a producer to establish customized disease management protocols.

FDA subsequently issued guidance in December 2013, 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. The guidance establishes a three-year timeframe for implementation, at which point FDA will evaluate the rate of adoption of the proposed changes and consider any further action. FDA notes in the guidance that use of medicated feed other than in accordance with its label is not permitted by law.

State Fiscal Effect: General fund expenditures increase by $159,812 in fiscal 2017, which accounts for the October 1, 2016 effective date of the nontherapeutic use prohibition. This estimate reflects the cost of hiring a veterinarian and an agricultural inspector to implement and enforce the bill. It includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses. The estimate assumes that the new employees are hired on July 1, 2016.

MDA indicates that implementing and enforcing the bill's provisions cannot be handled by existing staff without limiting their ability to fulfill existing responsibilities. The additional veterinarian and agricultural inspector are expected to review, analyze, and track information submitted by affected farm operations, visit 10% of affected farms each year to monitor compliance, and take other actions necessary to implement and enforce the bill.

Positions	2
Salaries and Fringe Benefits	$134,930
Other Operating Expenses	24,882
Total FY 2017 State Expenditures	**$159,812**

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

The collection of any administrative or other penalties is not expected to materially affect State revenues.

Small Business Effect: The bill may have a meaningful impact on at least some small business livestock producers subject to the bill (and not exempted under the specified exemptions). MDA has indicated in the past that in a given year, producers, with the exception of organic producers, generally use some antibiotics in their animals, whether for therapeutic or nontherapeutic purposes. 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, it appears that the bill's prohibition is 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. Producers are also affected by the bill's reporting requirements.

Additional Information

Prior Introductions: None.

Cross File: SB 463 (Senator Pinsky, *et al.*) - Education, Health, and Environmental Affairs.

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

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min/lgc

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