HB 1075

Department of Legislative Services

Maryland General Assembly
2015 Session

FISCAL AND POLICY NOTE

House Bill 1075 (Delegate Morhaim)
Environment and Transportation

Agriculture - Antibiotic Drug Usage - Food-Producing Animals

This bill prohibits a person from administering, or providing any commercial feed or water that contains, an antibiotic drug to a "food-producing animal" (1) in the absence of any clinical sign of disease; (2) for the purpose of growth promotion, feed efficiency, weight gain, routine disease prevention, or any other routine purpose; and (3) without a prescription from a licensed veterinarian. The Maryland Department of Agriculture (MDA) must establish by regulation a specified program to track antibiotic drug usage in food-producing animals, ensure food-producing animals are raised in a manner that ensures their health, track antibiotic-resistant bacteria and patterns of emerging resistances (in consultation with the Department of Health and Mental Hygiene (DHMH)), and conduct specified monitoring for antibiotic-resistant bacteria. Specified labeling and reporting requirements must also be established by regulation.

Fiscal Summary

State Effect: General fund expenditures increase by $524,900 in FY 2016 for MDA to enforce the bill's prohibition and implement the regulatory program. 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	524,900	595,200	622,200	650,500	680,300
Net Effect	($524,900)	($595,200)	($622,200)	($650,500)	($680,300)

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: "Food-producing animal" means an animal raised in the State for human consumption.

The monitoring for antibiotic-resistant bacteria that MDA must conduct under the regulatory program must be of (1) meat and poultry from food-producing animals sold in stores and (2) air, soil, and water in close proximity to specified large animal feeding operations.

Regulations adopted by MDA under the bill's provisions must establish labeling requirements for meat and poultry from food-producing animals, including requirements for identifying the farm operation and farm location. The regulations must also require a farm operation that raises food-producing animals to submit a specified report each year to MDA on antibiotic drug usage for the previous calendar year, if applicable.

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. 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."

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

[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.

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.

DHMH Tracking of Antibiotic Resistance

State law requires reporting of information on diseases and conditions designated by the Secretary of Health and Mental Hygiene to DHMH. The department currently tracks antibiotic resistant bacteria and patterns of emerging resistance and communicates with MDA about antibiotic resistance.

State Fiscal Effect: General fund expenditures increase by $524,850 in fiscal 2016, which accounts for the bill's October 1, 2015 effective date. This estimate reflects the cost of hiring nine personnel to implement and enforce the bill's prohibition and administer the regulatory program that must be established. It includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses.

MDA indicates that a significant increase in staffing and related expenses is needed to implement the bill at a reasonable level of effectiveness. The nine new positions include:

- one veterinarian – to oversee and supervise the various aspects of the program;
- four agricultural inspectors – to collect samples for analysis and monitor antibiotic drug use and the health of food-producing animals;
- three agricultural lab scientists – to perform analysis for antibiotic-resistant bacteria on product and environmental samples; and
- one administrative officer – to conduct investigations and assist with compilation and summation of inspection and lab results.

It is assumed that MDA uses DHMH information, along with information gathered under the new regulatory program, to fulfill the bill's requirement to track antibiotic-resistant bacteria and patterns of emerging resistances.

Positions	9
Salaries and Fringe Benefits	$406,086
Other Operating Expenses	118,764
Total FY 2016 State Expenditures	**$524,850**

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

Small Business Effect: The bill may have a meaningful impact on at least some small business livestock producers. 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 producers may also be subject to new requirements established under the regulatory program to ensure that food-producing animals are raised in a manner that ensures their health.

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. Smaller animal agriculture operations that use over-the-counter, antibiotic-containing feed without the services of a veterinarian may have to bear additional costs of the services of a veterinarian. However, that impact on small producers may occur in the near future as a result of implementation of the FDA 2012 and 2013 guidance, even in the absence of the bill. Producers are also affected by the bill's reporting requirements. Costs may also be incurred to comply with labeling requirements established by MDA by regulation. Licensed veterinarians may benefit.

Additional Information

Prior Introductions: None.

Cross File: SB 470 (Senator Nathan-Pulliam) - Education, Health, and Environmental Affairs.

Information Source(s): Maryland Department of Agriculture; Maryland Department of the Environment; Department of Health and Mental Hygiene; Maryland Association of

County Health Officers; U.S. Food and Drug Administration; Delmarva Poultry Industry, Inc.; Department of Legislative Services

Fiscal Note History: First Reader - February 27, 2015
min/lgc

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