

Department of Legislative Services
Maryland General Assembly
2017 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

House Bill 602

(Delegate Robinson, *et al.*)

Environment and Transportation

Education, Health, and Environmental Affairs

Keep Antibiotics Effective Act of 2017

This bill 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. Beginning 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. The bill does not apply to cattle, swine, or poultry on farm operations that sell specified limited amounts of cattle, swine, or poultry per year. The Maryland Department of Agriculture (MDA) must annually collect, and report on, specified publicly available data on the use in the State of medically important antimicrobial drugs in cattle, swine, and poultry. The Secretary of Agriculture is authorized to impose an administrative penalty for a violation of the bill's provisions and may adopt regulations to carry out the bill.

Fiscal Summary

State Effect: The bill is expected to be implemented by MDA with existing resources. The bill's penalty provision is not expected to materially affect State finances.

Local Effect: None.

Small Business Effect: Minimal, as discussed below.

Analysis

Bill Summary: Except as otherwise provided in federal law or regulation, the bill does 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) the U.S. Food and Drug Administration (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 the bill's provisions.

Current Law/Background:

Federal Animal Drug Approval

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.

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 antibiotic¹) resistance as one of our most serious health threats, and there is concern about the extent to which the 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 and Resulting Labeling Changes

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

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 the agricultural use of the drugs.

animals. A veterinary feed directive is a written statement issued by a licensed veterinarian, ordering and authorizing the use of a drug in or on an animal feed to treat a client's 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. FDA announced in January 2017 that it had completed the implementation of Guidance for Industry #213 with all products having either aligned with the recommended labeling changes or having had their approvals voluntarily withdrawn.

According to FDA, while its 2012 and 2013 guidance (1) limits medically important antimicrobial drugs to uses in food-producing animals that are considered necessary for assuring animal health (therapeutic uses) and (2) limits such drugs to uses that include veterinary oversight or consultation, they do not address what to do with respect to some currently approved therapeutic drugs that lack defined durations of use (approximately 32% of the therapeutic products affected by Guidance for Industry #213). FDA published a notice in the *Federal Register* in September 2016 seeking comments regarding the establishment of appropriately targeted durations of the use of medically important antimicrobial drugs when they are administered in the feed or water of food-producing animals for therapeutic purposes.

Small Business Effect: The bill may affect small business livestock and poultry producers subject to the bill (and not exempted under the specified exemptions) to the extent the bill requires a change in how those producers use medically important antimicrobial drugs that does not otherwise occur due to changes in federal policy or otherwise. However, it appears that the allowed uses of medically important antimicrobial drugs under the bill largely encompass the practices followed by livestock and poultry producers in the State in the absence of the bill.

Additional Information

Prior Introductions: None.

Cross File: SB 422 (Senator Pinsky, *et al.*) - Education, Health, and Environmental Affairs.

Information Source(s): Maryland Department of Agriculture; Delmarva Poultry Industry, Inc.; Maryland Farm Bureau; Department of Legislative Services

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