Chapter 678

(House Bill 652)

AN ACT concerning

Agriculture – Use of Antimicrobial Drugs – Limitations and Reporting Requirements

FOR the purpose of clarifying a certain prohibition on administering a medically important antimicrobial drug in a regular pattern to certain cattle, swine, or poultry; exempting dairy cattle on a farm operation with a certain herd size from certain provisions of law concerning the use of medically important antimicrobial drugs; prohibiting the administration of a medically important antimicrobial drug to certain cattle, swine, or poultry unless ordered by a licensed veterinarian in a certain manner; setting certain limits on the length of time for which a medically important antimicrobial drug may be administered; requiring the Department of Agriculture to adopt certain regulations regarding the routine administration of a medically important antimicrobial drug to dairy cattle entering a dry cycle on or before a certain date; requiring a certain owner veterinarian to submit a copy of a certain prescription record or veterinary feed directive and a certain accounting to the Department of Agriculture on or before a certain date each year; requiring the Department to include certain information in a certain annual report, on or before a certain date; requiring certain reported information to be disaggregated by county except under certain circumstances; requiring the Department to maintain certain records and information in a certain manner and for a certain amount of time; specifying that a certain penalty may be imposed per violation; requiring the Department to provide written notice of the requirements of this Act to each owner that may be affected by this Act on or before a certain date; requiring the notice to be sent in a certain manner; altering certain definitions; defining certain terms; and generally relating to the use of medically important antimicrobial drugs in cattle, swine, and poultry.

BY repealing and reenacting, with amendments,

Article – Agriculture Section 3–1001 through 3–1005 Annotated Code of Maryland (2016 Replacement Volume and 2018 Supplement)

BY repealing and reenacting, without amendments,

Article – Agriculture Section 3–1006 Annotated Code of Maryland (2016 Replacement Volume and 2018 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Agriculture

3-1001.

- (a) In this subtitle the following words have the meanings indicated.
- (b) "ADMINISTERED IN A REGULAR PATTERN" MEANS USED:
- (1) FOR MULTIPLE COURSES OF THERAPY IN THE SAME ANIMAL OR GROUP OF ANIMALS; OR
 - (2) AS STANDARD OPERATING PROCEDURE, INCLUDING:
- (I) IN CORRESPONDENCE WITH A PARTICULAR LIFE STAGE OF AN ANIMAL, SUCH AS IN OVO, AT BIRTH OR HATCH, OR AT WEANING;
- (II) AS AN ONGOING MANAGEMENT STRATEGY OR TOOL, SUCH AS IN CORRESPONDENCE WITH A PARTICULAR:
 - 1. AGE OR WEIGHT OF AN ANIMAL;
 - 2. TIME OF THE WEEK, MONTH, OR YEAR; OR
 - 3. SEASON; OR
- (III) When moving animals from one location to another; or
 - (IV) WHEN DAIRY CATTLE ENTER A DRY CYCLE.
- (C) ["Disease control" means the use of a medically important antimicrobial drug to control the spread] "CONTROL THE SPREAD OF DISEASE OR INFECTION" MEANS TO CONTAIN THE TRANSMISSION of a documented disease or infection present in:
 - (1) A group of animals in contact with each other; or
 - (2) A barn or equivalent animal housing unit.
 - [(c)] (D) "Documented" means acknowledged and recorded.
- (E) (1) "ELEVATED RISK" MEANS A RISK THAT IS SIGNIFICANTLY HIGHER THAN THAT PRESENT UNDER NORMAL OR STANDARD OPERATING CONDITIONS.

(2) "ELEVATED RISK" DOES NOT INCLUDE A RISK TYPICALLY OR FREQUENTLY PRESENT UNDER NORMAL OR STANDARD OPERATING CONDITIONS.

- [(d)] **(F)** "Medically important antimicrobial drug" means any drug from a class of drug or derivative of a class of drug that is:
- (1) (i) Made from a mold or bacterium that kills or slows the growth of other microbes, specifically bacteria; and
- (ii) Used in human beings or intended for use in human beings to treat or prevent disease or infection; or

(2) Listed in:

- (I) Appendix A of the federal Food and Drug Administration's Guidance for Industry #152, including critically important, highly important, or important antimicrobial drugs; **OR**
- (II) A SUBSEQUENT GUIDANCE DOCUMENT CREATED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION THAT RANKS THE MEDICAL IMPORTANCE OF ANTIMICROBIAL DRUGS.
- [(e)] (G) "Medically important antimicrobial drug prescription" means an order issued by a veterinarian licensed in the State in the course of the veterinarian's professional practice:
 - (1) For a medically important antimicrobial drug **!**that is:
 - (i) In a water–soluble powder form; and
- (ii) To be added to the drinking water of cattle, swine, or poultry+; and
- (2) That provides the same or substantially similar information as the information that is required for a veterinary feed directive under Title 21, § 558.6(b)(3) and (4) of the Code of Federal Regulations.

[(f)] **(H)** "Owner" means a person that:

- (1) Has an ownership interest in cattle, swine, or poultry, including a right or an option to purchase the cattle, swine, or poultry; or
- (2) Is otherwise engaged in the business of obtaining live cattle, swine, or poultry under a growing agreement for the purpose of either slaughtering the cattle, swine, or poultry or selling the cattle, swine, or poultry for slaughter.

- (I) "PROPHYLAXIS" MEANS THE PREVENTION OF DISEASE OR INFECTION IN THE ABSENCE OF DOCUMENTED CLINICAL SIGNS OF DISEASE OR INFECTION.
- (J) "TREAT A DISEASE OR INFECTION" MEANS TO RESOLVE CLINICAL SIGNS OF INFECTION OR DISEASE IN AN INFECTED ANIMAL.
- [(g)] (K) "Veterinary feed directive" means 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 the conditions and requirements specified under Title 21, § 558.6 of the Code of Federal Regulations.

3-1002.

Except as otherwise provided in federal law or regulation, this subtitle does not apply to antimicrobial use in:

- (1) Cattle on a farm operation that sells fewer than 200 cattle per year;
- (2) Dairy cattle on a farm operation with a herd size of fewer than ${\color{red} \mathbf{10}}$ 300 dairy cattle;
 - (3) Swine on a farm operation that sells fewer than 200 swine per year; or
- [(3)] **(4)** Poultry on a farm operation that sells fewer than 60,000 birds per year.

3-1003.

- (a) A MEDICALLY IMPORTANT ANTIMICROBIAL DRUG MAY NOT BE ADMINISTERED <u>IN FEED OR WATER</u> 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.

- **(B)** (1) On or after January 1, 2018, and subject to subsection **[(b)] (C)** of this section, 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:
 - (i) To treat a disease or infection;
 - (ii) To control the spread of a disease or infection; or
 - (iii) For a surgery or medical procedure.
- (2) (I) On or after 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 medically important antimicrobial drug is necessary for prophylaxis to address an elevated risk of contraction of a particular disease or infection.
- (II) NOTWITHSTANDING SUBSECTION (E) OF THIS SECTION, ADMINISTRATION OF A MEDICALLY IMPORTANT ANTIMICROBIAL DRUG FOR THE PURPOSE OF PROPHYLAXIS MAY NOT EXCEED 21 DAYS UNLESS FEDERAL LABEL DIRECTIONS MANDATE REQUIRE A LONGER PERIOD OF USE.
- [(b)] (C) Unless administration of a medically important antimicrobial drug is consistent with subsection [(a)(1)] (B)(1) of this section, a medically important antimicrobial drug may not be administered in a regular pattern to cattle, swine, or poultry.
- [(c)] **(D)** A medically important antimicrobial drug may not be administered to cattle, swine, or poultry solely for the purpose of:
 - (1) Promoting weight gain; or
 - (2) Improving feed efficiency.
- (E) (1) EXCEPT AS PROVIDED IN PARAGRAPHS (2) AND (3) OF THIS SUBSECTION, A MEDICALLY IMPORTANT ANTIMICROBIAL DRUG MAY NOT BE ADMINISTERED TO CATTLE, SWINE, OR POULTRY FOR A PERIOD LONGER THAN 21 DAYS.
- (2) A MEDICALLY IMPORTANT ANTIMICROBIAL DRUG MAY BE ADMINISTERED TO CATTLE, SWINE, OR POULTRY FOR A PERIOD LONGER THAN 21 DAYS IF THE FEDERAL LABEL DIRECTIONS FOR THE DRUG MANDATE REQUIRE A LONGER PERIOD OF USE.
- (3) (I) 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.

- (II) 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.
- (F) ON OR BEFORE JANUARY 1, 2021, THE DEPARTMENT SHALL ADOPT REGULATIONS PROHIBITING THE ROUTINE ADMINISTRATION OF A MEDICALLY IMPORTANT ANTIMICROBIAL DRUG TO DAIRY CATTLE ENTERING A DRY CYCLE EXCEPT WHEN NECESSARY BASED ON AN ASSESSMENT OF THE PRESENCE OF AN INTRAMAMMARY INFECTION.

3-1004.

- (a) Each year the Department shall 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; and
- (4) Appropriate national **AND STATE** trade associations, organizations, and councils.
- (b) ON OR BEFORE FEBRUARY 1, 2021, AND EACH FEBRUARY 1 THEREAFTER, AN OWNER A LICENSED VETERINARIAN SHALL SUBMIT TO THE DEPARTMENT, IN A MANNER DETERMINED BY THE DEPARTMENT:
- (1) A COPY OF <u>THE RECORD PRESCRIBING</u> THE MEDICALLY IMPORTANT ANTIMICROBIAL DRUG PRESCRIPTION OR <u>A COPY OF THE</u> VETERINARY FEED DIRECTIVE FOR EACH MEDICALLY IMPORTANT ANTIMICROBIAL DRUG, <u>AS LISTED IN APPENDIX A OF THE FEDERAL FOOD AND DRUG ADMINISTRATION'S GUIDANCE FOR INDUSTRY #152, ADMINISTERED <u>IN FEED OR WATER</u> TO CATTLE, SWINE, OR POULTRY DURING THE PREVIOUS CALENDAR YEAR; AND</u>
- (2) AN ACCOUNTING, AS PROVIDED BY THE OWNER, OF THE TOTAL NUMBER OF ANIMALS RAISED DURING THE PREVIOUS CALENDAR YEAR, CATEGORIZED BY SPECIES AND PRODUCTION CLASS.
- (C) (1) On or before December 1, 2019, and each December 1 <u>FEBRUARY 1, 2020, AND EACH FEBRUARY 1</u> thereafter, the Department shall report to the General

Assembly, in accordance with § 2–1246 of the State Government Article, on the data collected under [subsection] SUBSECTIONS (a) AND (B) of this section.

- (2) On or before December <u>February</u> 1, 2021, the report shall include the following information for the previous calendar year:
- (I) THE TOTAL NUMBER OF ANIMALS RAISED ON FARM OPERATIONS COVERED BY THIS SUBTITLE, CATEGORIZED BY SPECIES AND PRODUCTION CLASS;
- (II) THE SPECIFIC ANTIMICROBIAL ACTIVE INGREDIENTS AND CLASSES OF ANTIMICROBIAL ACTIVE INGREDIENTS USED;
- (III) THE TOTAL WEIGHT OF ANTIMICROBIAL ACTIVE INGREDIENTS USED;
- (IV) INDICATIONS FOR WHICH VETERINARIANS PRESCRIBED MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS; AND
- (V) PATTERNS OF USE FOR MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS, INCLUDING DURATION AND SEASONAL VARIATION.
- (3) (I) SUBJECT TO SUBPARAGRAPH (II) OF THIS PARAGRAPH, THE INFORMATION REQUIRED UNDER PARAGRAPH (2) OF THIS SUBSECTION SHALL BE DISAGGREGATED BY COUNTY.
- (II) IF THERE ARE TWO OR FEWER REPORTING FARM OPERATIONS IN A PARTICULAR COUNTY FOR ANY OF THE CATEGORIES DESCRIBED IN PARAGRAPH (2) OF THIS SUBSECTION, THE DEPARTMENT MAY REPORT THE INFORMATION FOR THAT CATEGORY ON A REGIONAL OR STATEWIDE BASIS.
- (D) THE DEPARTMENT SHALL MAINTAIN ALL RECORDS AND INFORMATION RELATING TO THE ADMINISTRATION OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS SUBMITTED TO THE DEPARTMENT UNDER THIS SECTION:
- (1) IN A MANNER THAT PROTECTS THE IDENTITY OF THE FARM OPERATION THAT SUBMITTED THE INFORMATION OWNER, OPERATOR, AND VETERINARIAN FOR WHOM THE INFORMATION WAS SUBMITTED; AND
 - (2) FOR AT LEAST 5 YEARS.

3-1005.

The Secretary may impose an administrative penalty, not exceeding \$2,000 PER VIOLATION, on a person that violates this subtitle.

3-1006.

The Department may adopt regulations to carry out this subtitle.

SECTION 2. AND BE IT FURTHER ENACTED, That:

- (a) On or before November 1, 2019, the Department of Agriculture shall provide written notice of the requirements of this Act to each owner that may be affected by this Act.
 - (b) The notice shall be sent by first-class mail to the owner's last known address.

SECTION $\frac{3}{2}$. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2019.

Enacted under Article II, § 17(c) of the Maryland Constitution, May 25, 2019.