HOUSE BILL 1085

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By: **Delegate K. Young**
Introduced and read first time: February 8, 2019
Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

Drug Manufacturers – Drug Take–Back Programs

FOR the purpose of requiring manufacturers of certain drugs to operate a certain drug take–back program or enter into a certain agreement with a drug take–back organization or the Maryland Department of Health; requiring, on or before a certain date, manufacturers of certain drugs and certain drug take–back organizations to submit a certain proposal to the Department; requiring manufacturers of certain drugs to pay certain costs and fees associated with the drug take–back program; providing that the State may recover only certain costs and requiring that certain recovered costs be allocated in a certain manner; prohibiting manufacturers from charging certain fees to recoup certain costs; requiring the Department to determine whether a certain program complies with certain requirements and to provide certain notification within a certain time period; requiring a manufacturer to update its drug take–back program and submit a certain proposal to the Department on a certain basis; requiring a certain manufacturer to show evidence of joining a certain program or to submit a certain proposal within a certain time period; establishing a certain penalty; requiring certain programs to report to the Department at a date and manner established by the Department; requiring the Department to submit a certain report to the Governor, Secretary of Health, and General Assembly on or before a certain date each year; defining certain terms; and generally relating to drug manufacturers and drug take–back programs.

BY adding to
Article – Health – General
Section 21–228
Annotated Code of Maryland
(2015 Replacement Volume and 2018 Supplement)

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

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.

Article – Health – General

21–228.

(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(2) "AUTHORIZED COLLECTOR" MEANS:

(I) A PERSON THAT IS REGISTERED WITH THE UNITED STATES DRUG ENFORCEMENT ADMINISTRATION TO COLLECT CONTROLLED SUBSTANCES FOR THE PURPOSES OF SAFE DISPOSAL AND DESTRUCTION;

(II) A STATE OR LOCAL LAW ENFORCEMENT AGENCY; OR

(III) A PERSON AUTHORIZED BY THE DEPARTMENT TO PROVIDE ALTERNATIVE COLLECTION METHODS FOR COVERED DRUGS THAT ARE NOT CONTROLLED SUBSTANCES.

(3) "COVERED DRUG" MEANS ANY SUBSTANCE RECOGNIZED AS A DRUG UNDER 21 U.S.C. § 321(G)(1) THAT IS SOLD, OFFERED FOR SALE, OR DISPENSED IN THE STATE, WHETHER DIRECTLY OR THROUGH A WHOLESALER, IN ANY FORM, INCLUDING PRESCRIPTION AND NONPRESCRIPTION DRUGS, DRUGS IN MEDICAL DEVICES AND COMBINATION PRODUCTS, BRAND AND GENERIC DRUGS, AND DRUGS FOR VETERINARY USE.

(4) "DRUG TAKE–BACK ORGANIZATION" MEANS AN ORGANIZATION DESIGNATED BY A MANUFACTURER OR A GROUP OF MANUFACTURERS TO ACT AS AN AGENT ON BEHALF OF THE MANUFACTURER OR GROUP OF MANUFACTURERS TO OPERATE AND IMPLEMENT A DRUG TAKE–BACK PROGRAM AS AUTHORIZED BY THIS SECTION.

(5) "MANUFACTURER" MEANS A PERSON, COMPANY, CORPORATION, OR OTHER ENTITY ENGAGED IN THE MANUFACTURE OF COVERED DRUGS SOLD IN THE STATE.

(B) (1) EACH MANUFACTURER OF A COVERED DRUG THAT IS SOLD OR DISTRIBUTED IN THE STATE SHALL:

(I) OPERATE A DRUG TAKE–BACK PROGRAM APPROVED BY THE DEPARTMENT;

(II) ENTER INTO AN AGREEMENT WITH A DRUG TAKE–BACK ORGANIZATION TO OPERATE A DRUG TAKE–BACK PROGRAM APPROVED BY THE

DEPARTMENT; OR

(III) ENTER INTO AN AGREEMENT WITH THE DEPARTMENT TO OPERATE A DRUG TAKE–BACK PROGRAM ON BEHALF OF THE MANUFACTURER.

(2) A MANUFACTURER MAY OPERATE A DRUG TAKE–BACK PROGRAM UNDER PARAGRAPH (1) OF THIS SUBSECTION JOINTLY WITH OTHER MANUFACTURERS.

(C) ON OR BEFORE JANUARY 1, 2020, EACH MANUFACTURER AND DRUG TAKE–BACK ORGANIZATION THAT HAS A CONTRACT WITH A MANUFACTURER SHALL SUBMIT TO THE DEPARTMENT, IN A MANNER AND FORM DETERMINED BY THE DEPARTMENT, A PROPOSAL FOR A DRUG TAKE–BACK PROGRAM THAT, AT A MINIMUM:

(1) CERTIFIES THAT THE DRUG TAKE–BACK PROGRAM WILL ACCEPT ALL COVERED DRUGS REGARDLESS OF THE PRODUCER OF THE DRUG;

(2) PROVIDES CONTACT INFORMATION FOR THE PERSON SUBMITTING THE PLANNED DRUG TAKE–BACK PROGRAM;

(3) DETAILS A COLLECTION SYSTEM THAT IS GEOGRAPHICALLY DISTRIBUTED IN A WAY TO ENSURE ACCESS IN RURAL AND UNDERSERVED AREAS TO PROVIDE CONVENIENT, ONGOING COLLECTION SERVICES TO ALL PERSONS SEEKING TO DISPOSE OF COVERED DRUGS UNDER THIS SECTION;

(4) DESCRIBES OTHER COLLECTION METHODS THROUGH WHICH COVERED DRUGS WILL BE COLLECTED BY AN AUTHORIZED COLLECTOR;

(5) EXPLAINS HOW COVERED DRUGS WILL BE SAFELY AND SECURELY TRACKED AND HANDLED FROM COLLECTION THROUGH FINAL DISPOSAL AND DESTRUCTION AND THE POLICIES THAT WILL BE IMPLEMENTED TO ENSURE SECURITY AND COMPLIANCE WITH ALL APPLICABLE LAWS AND REGULATIONS, INCLUDING DISPOSAL AND DESTRUCTION AT AN AUTHORIZED WASTE DISPOSAL FACILITY THAT MEETS FEDERAL REQUIREMENTS;

(6) DESCRIBES THE PUBLIC EDUCATION AND OUTREACH ACTIVITIES THAT WILL BE PERFORMED, INCLUDING THE ADVERTISING OF COLLECTION LOCATIONS ON A WEBSITE AND THE USE OF SIGNAGE AND OTHER WRITTEN MATERIALS, AND HOW THE EFFECTIVENESS OF PUBLIC EDUCATION AND OUTREACH ACTIVITIES WILL BE EVALUATED;

(7) (I) DETAILS HOW THE COSTS OF AN AUTHORIZED COLLECTOR

WILL BE REIMBURSED, INCLUDING COSTS RETROACTIVE TO OCTOBER 1, 2019; AND

(II) IF MORE THAN ONE MANUFACTURER WILL BE INVOLVED IN THE PLANNED DRUG TAKE–BACK PROGRAM, DETAILS A PLAN FOR THE FAIR AND REASONABLE MANNER OF ALLOCATING COSTS AMONG THE PARTICIPANTS IN THE PROGRAM SO THAT THE COSTS PAID BY EACH MANUFACTURER ARE REASONABLY RELATED TO THE VOLUME OR VALUE OF COVERED DRUGS SOLD IN THE STATE; AND

(8) PROVIDES ANY FURTHER INFORMATION CONSIDERED APPROPRIATE BY THE DEPARTMENT.

(D) (1) EACH MANUFACTURER SHALL PAY ALL ADMINISTRATIVE AND OPERATIONAL FEES ASSOCIATED WITH THE MANUFACTURER'S DRUG TAKE–BACK PROGRAM, INCLUDING THE COST OF COLLECTING, TRANSPORTING, AND DISPOSING OF COVERED DRUGS FROM AN AUTHORIZED COLLECTOR AND THE RECYCLING OR DISPOSAL OF PACKAGING COLLECTED WITH THE COVERED DRUG.

(2) EACH MANUFACTURER SHALL PAY COSTS INCURRED BY THE STATE IN THE ADMINISTRATION AND ENFORCEMENT OF THE MANUFACTURER'S DRUG TAKE–BACK PROGRAM.

(3) THE STATE MAY RECOVER FROM THE MANUFACTURER ONLY THE STATE'S ACTUAL COSTS RELATED TO ADMINISTRATION AND ENFORCEMENT OF THE MANUFACTURER'S DRUG TAKE–BACK PROGRAM.

(4) IF MANUFACTURERS JOINTLY CONDUCT A DRUG TAKE–BACK PROGRAM, THE COSTS OF ADMINISTRATION AND ENFORCEMENT SHALL BE FAIRLY AND REASONABLY ALLOCATED AMONG THE MANUFACTURERS IN A MANNER THAT IS REASONABLY RELATED TO THE VOLUME OR VALUE OF COVERED DRUGS SOLD BY THE MANUFACTURERS IN THE STATE.

(5) A MANUFACTURER MAY NOT CHARGE A POINT–OF–SALE OR OTHER FEE TO A CONSUMER, OR A FEE THAT COULD BE PASSED ON TO A CONSUMER, TO RECOUP THE COST OF THE MANUFACTURER'S DRUG TAKE–BACK PROGRAM.

(E) (1) WITHIN 60 DAYS AFTER RECEIPT OF A PROPOSAL FOR A DRUG TAKE–BACK PROGRAM, THE DEPARTMENT SHALL DETERMINE WHETHER THE PROPOSED DRUG TAKE–BACK PROGRAM COMPLIES WITH THE REQUIREMENTS OF THIS SECTION AND SHALL NOTIFY THE APPLICANT OF THE DEPARTMENT'S DECISION.

(2) THE DEPARTMENT MAY CONDUCT A PUBLIC HEARING BEFORE APPROVING A PROPOSED DRUG TAKE–BACK PROGRAM.

(3) IF THE DRUG TAKE–BACK PROGRAM IS APPROVED, THE DEPARTMENT SHALL NOTIFY THE APPLICANT IN WRITING OF THE APPROVAL.

(4) IF THE DRUG TAKE–BACK PROGRAM IS NOT APPROVED, THE DEPARTMENT SHALL NOTIFY THE APPLICANT IN WRITING AND THE APPLICANT SHALL SUBMIT A REVISED DRUG TAKE–BACK PROGRAM PROPOSAL WITHIN 30 DAYS AFTER RECEIVING NOTIFICATION THAT THE PROGRAM WAS NOT APPROVED.

(5) IF THE DEPARTMENT REJECTS THE REVISED PROPOSAL SUBMITTED UNDER PARAGRAPH (4) OF THIS SUBSECTION, THE MANUFACTURER SUBMITTING THE PROPOSAL SHALL BE CONSIDERED OUT OF COMPLIANCE WITH THIS SECTION AND SHALL BE SUBJECT TO THE PENALTY ESTABLISHED UNDER SUBSECTION (G) OF THIS SECTION.

(6) THE DEPARTMENT SHALL PROVIDE, AND UPDATE ANNUALLY ON THE DEPARTMENT'S WEBSITE, A LIST OF ALL MANUFACTURERS PARTICIPATING IN A DRUG TAKE–BACK PROGRAM APPROVED BY THE DEPARTMENT.

(F) (1) AT LEAST EVERY 3 YEARS, EACH MANUFACTURER AND DRUG TAKE–BACK ORGANIZATION SHALL UPDATE THE DRUG TAKE–BACK PROGRAM OPERATED BY THE MANUFACTURER OR DRUG TAKE–BACK ORGANIZATION AND SUBMIT AN UPDATED PROPOSAL TO THE DEPARTMENT.

(2) A MANUFACTURER WHO BEGINS TO OFFER A COVERED DRUG IN THE STATE AFTER OCTOBER 1, 2019, SHALL PROVIDE EVIDENCE OF JOINING AN APPROVED DRUG TAKE–BACK PROGRAM OR SUBMIT A PROPOSAL FOR A DRUG TAKE–BACK PROGRAM WITHIN 90 DAYS FOLLOWING THE INITIAL OFFER FOR SALE OF A COVERED DRUG IN THE STATE.

(3) ANY PROPOSED CHANGE TO A DRUG TAKE–BACK PROGRAM SHALL BE SUBMITTED IN WRITING AND APPROVED BY THE DEPARTMENT.

(G) (1) A PERSON IN VIOLATION OF THIS SECTION IS SUBJECT TO A CIVIL PENALTY NOT EXCEEDING $1,000.

(2) EACH DAY ON WHICH A VIOLATION OF THIS SECTION OCCURS IS A SEPARATE VIOLATION.

(H) EACH APPROVED DRUG TAKE–BACK PROGRAM SHALL REPORT TO THE DEPARTMENT AT A DATE AND MANNER ESTABLISHED BY THE DEPARTMENT.

(I) ON OR BEFORE OCTOBER 1 EACH YEAR, THE DEPARTMENT SHALL

SUBMIT TO THE GOVERNOR, THE SECRETARY, AND, IN ACCORDANCE WITH § 2–1246 OF THE STATE GOVERNMENT ARTICLE, THE GENERAL ASSEMBLY A REPORT ON:

(1) ALL DRUG TAKE–BACK PROGRAM ACTIVITIES;

(2) THE WEIGHT OF COVERED DRUGS COLLECTED BY EACH PROGRAM;

(3) A DESCRIPTION OF COLLECTION ACTIVITIES;

(4) THE NAME AND LOCATION OF ALL COLLECTION SITES;

(5) PUBLIC EDUCATION AND OUTREACH ACTIVITIES;

(6) AN EVALUATION OF THE EFFICACY OF THE PROGRAM AND OF EACH COLLECTION METHOD; AND

(7) ANY MANUFACTURER OUT OF COMPLIANCE OR SUBJECT TO A PENALTY UNDER SUBSECTION (G) OF THIS SECTION.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2019.