SENATE BILL 201

J1 8lr0873

By: **Senator Brochin**
Introduced and read first time: January 17, 2018
Assigned to: Finance

A BILL ENTITLED

AN ACT concerning

Public Health – Prescription Drug Manufacturers – Sales to Wholesale Distributors

FOR the purpose of requiring a prescription drug or device manufacturer to submit certain average sales prices to the Maryland Department of Health for each calendar quarter within a certain number of days after the end of the quarter; requiring the Department to make the average sales prices submitted by manufacturers available on its website no later than a certain number of days after receipt of the average sales prices; prohibiting a manufacturer from denying a wholesale distributor the right to purchase prescription drugs or devices under certain circumstances; authorizing a circuit court, under certain circumstances, to issue an order requiring certain actions and imposing a certain civil penalty; authorizing a wholesale distributor to bring a certain action to recover damages for certain injury or loss and to seek certain fees under certain circumstances; authorizing the court to award certain fees under certain circumstances and to order a certain party to pay certain fees under certain circumstances; defining certain terms; and generally relating to prescription drug manufacturer sales to wholesale distributors.

BY adding to
Article – Health – General
Section 21–2C–01 through 21–2C–04 to be under the new subtitle "Subtitle 2C. Sale of Prescription Drugs and Devices to Wholesale Distributors"
Annotated Code of Maryland
(2015 Replacement Volume and 2017 Supplement)

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

Article – Health – General

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

SUBTITLE 2C. SALE OF PRESCRIPTION DRUGS AND DEVICES TO WHOLESALE DISTRIBUTORS.

21–2C–01.

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

(B) "AVERAGE SALES PRICE" MEANS THE AVERAGE SALES PRICE:

(1) INCLUDING REBATES AND DISCOUNTS;

(2) AS DEFINED IN 42 U.S.C. § 1395W–3A(C); AND

(3) CALCULATED ACCORDING TO THE METHODS STATED IN 42 C.F.R. § 414.904.

(C) "MANUFACTURER" HAS THE MEANING STATED IN § 12–6C–01 OF THE HEALTH OCCUPATIONS ARTICLE.

(D) "WHOLESALE DISTRIBUTOR" HAS THE MEANING STATED IN § 12–6C–01 OF THE HEALTH OCCUPATIONS ARTICLE.

21–2C–02.

(A) WITHIN 30 DAYS AFTER THE END OF EACH CALENDAR QUARTER, A MANUFACTURER SHALL SUBMIT TO THE DEPARTMENT THE MANUFACTURER'S AVERAGE SALES PRICE FOR THE CALENDAR QUARTER FOR EACH PRESCRIPTION DRUG OR DEVICE MADE AVAILABLE IN THE STATE BY THE MANUFACTURER, LISTED BY NATIONAL DRUG CODE.

(B) THE DEPARTMENT SHALL MAKE AVAILABLE ON ITS WEBSITE THE AVERAGE SALES PRICES SUBMITTED UNDER SUBSECTION (A) OF THIS SECTION NOT LATER THAN 10 DAYS AFTER IT RECEIVES THE AVERAGE SALES PRICES.

21–2C–03.

A MANUFACTURER MAY NOT DENY A WHOLESALE DISTRIBUTOR THE RIGHT TO PURCHASE A PRESCRIPTION DRUG OR DEVICE FROM THE MANUFACTURER IF THE WHOLESALE DISTRIBUTOR AGREES TO PAY THE MANUFACTURER'S AVERAGE SALES PRICE FOR THE PRESCRIPTION DRUG OR DEVICE AS REPORTED FOR THE IMMEDIATELY PRECEDING CALENDAR QUARTER.

21–2C–04.

(A) ON PETITION OF THE DEPARTMENT, A CIRCUIT COURT MAY ISSUE AN ORDER TO:

(1) IMPOSE A CIVIL PENALTY NOT TO EXCEED $10,000 FOR EACH VIOLATION OF THIS SUBTITLE OR ANY REGULATION ADOPTED UNDER THIS SUBTITLE;

(2) REQUIRE A MANUFACTURER THAT VIOLATES § 21–2C–03 OF THIS SUBTITLE TO MAKE THE DRUG AVAILABLE TO THE WHOLESALE DISTRIBUTOR FOR A PERIOD OF UP TO 1 YEAR AT THE MANUFACTURER'S AVERAGE SALES PRICE FOR THE QUARTER IMMEDIATELY PRECEDING THE QUARTER IN WHICH THE VIOLATION OCCURRED; OR

(3) REQUIRE A MANUFACTURER OR A WHOLESALE DISTRIBUTOR TO PRODUCE ANY RECORDS OR OTHER DOCUMENTS THAT MAY BE RELEVANT TO A DETERMINATION OF WHETHER A VIOLATION OF THIS SUBTITLE HAS OCCURRED.

(B) (1) IN ADDITION TO ANY ACTION BY THE DEPARTMENT AUTHORIZED BY THIS SECTION AND ANY OTHER ACTION OTHERWISE AUTHORIZED BY LAW, A WHOLESALE DISTRIBUTOR MAY BRING AN ACTION TO RECOVER DAMAGES FOR INJURY OR LOSS SUSTAINED AS THE RESULT OF A VIOLATION OF § 21–2C–03 OF THIS SUBTITLE.

(2) A WHOLESALE DISTRIBUTOR THAT BRINGS AN ACTION TO RECOVER DAMAGES FOR INJURY OR LOSS UNDER PARAGRAPH (1) OF THIS SUBSECTION AND IS AWARDED DAMAGES MAY ALSO SEEK, AND THE COURT MAY AWARD, REASONABLE ATTORNEY'S FEES.

(3) IF THE COURT DETERMINES, AT ANY TIME, THAT AN ACTION IS BROUGHT IN BAD FAITH OR IS OF A FRIVOLOUS NATURE, THE COURT MAY ORDER THE OFFENDING PARTY TO PAY TO THE OTHER PARTY REASONABLE ATTORNEY'S FEES.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2018.