SENATE BILL No. 825

February 15, 2018, Introduced by Senators BIEDA, HANSEN, HOOD, ANANICH, JONES, ROCCA, HOPGOOD and HERTEL and referred to the Committee on Health Policy.

A bill to amend 1978 PA 368, entitled

"Public health code,"

(MCL 333.1101 to 333.25211) by adding sections 17748e and 17748f.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

SEC. 17748E. (1) SUBJECT TO SUBSECTION (2), BEGINNING JANUARY 1, 2019, A MANUFACTURER OF A PRESCRIPTION DRUG THAT IS MADE AVAILABLE IN THIS STATE AND THAT HAS A WHOLESALE ACQUISITION COST OF $40.00 OR MORE PER COURSE OF THERAPY SHALL FILE AN ANNUAL REPORT WITH THE DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES ON THE COSTS ASSOCIATED WITH THE PRESCRIPTION DRUG FOR THE PRECEDING CALENDAR YEAR. A REPORT FILED UNDER THIS SUBSECTION MUST BE FILED BEFORE MAY 1 OF EACH YEAR IN A FORM AND MANNER PRESCRIBED BY THE DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES.

(2) THE DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES IN

SENATE BILL No. 825

CONSULTATION WITH THE PRESCRIPTION DRUG TRANSPARENCY WORKGROUP CREATED IN SECTION 17748F SHALL CREATE A STANDARDIZED FORM TO BE USED BY MANUFACTURERS OF PRESCRIPTION DRUGS IN REPORTING TO THE DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES UNDER SUBSECTION (1). THE FORM MUST CONTAIN ALL OF THE FOLLOWING INFORMATION:

(A) AN ITEMIZED ACCOUNT OF ALL OF THE FOLLOWING INFORMATION FOR THE CALENDAR YEAR COVERED BY THE REPORT:

(*i*) COSTS PAID BY THE MANUFACTURER FOR RESEARCHING AND DEVELOPING THE PRESCRIPTION DRUG.

(*ii*) COSTS PAID BY THE MANUFACTURER'S PREDECESSOR FOR RESEARCHING AND DEVELOPING THE PRESCRIPTION DRUG.

(*iii*) COSTS PAID BY THE MANUFACTURER AND THE MANUFACTURER'S PREDECESSOR FOR RESEARCHING AND DEVELOPING THE PRESCRIPTION DRUG WITH MONEY MADE AVAILABLE TO THE MANUFACTURER OR THE MANUFACTURER'S PREDECESSOR THROUGH A FEDERAL, STATE, OR OTHER GOVERNMENTAL PROGRAM OR THROUGH A SUBSIDY, GRANT, OR OTHER FORM OF MONETARY SUPPORT.

(*iv*) COSTS PAID BY THE MANUFACTURER FOR CLINICAL TRIALS FOR THE PRESCRIPTION DRUG.

(*v*) COSTS PAID BY THE MANUFACTURER'S PREDECESSOR FOR CLINICAL TRIALS FOR THE PRESCRIPTION DRUG.

(*vi*) COSTS PAID BY THE MANUFACTURER FOR MANUFACTURING AND DISTRIBUTING THE PRESCRIPTION DRUG.

(*vii*) COSTS PAID BY THE MANUFACTURER FOR ACQUIRING THE PRESCRIPTION DRUG, INCLUDING, BUT NOT LIMITED TO, COSTS PAID BY THE MANUFACTURER FOR PURCHASING PATENTS FOR OR LICENSING THE PRESCRIPTION DRUG OR COSTS PAID BY THE MANUFACTURER FOR ACQUIRING PROPERTY RIGHTS TO THE PRESCRIPTION DRUG.

(*viii*) COSTS PAID BY THE MANUFACTURER FOR MARKETING AND ADVERTISING THE PRESCRIPTION DRUG TO CONSUMERS OF THE PRESCRIPTION DRUG, INCLUDING ANY COSTS ASSOCIATED WITH OFFERING AND REDEEMING COUPONS.

(*ix*) COSTS PAID BY THE MANUFACTURER FOR MARKETING AND ADVERTISING THE PRESCRIPTION DRUG TO PRESCRIBERS OF THE PRESCRIPTION DRUG.

(B) ALL OF THE FOLLOWING INFORMATION FOR THE CALENDAR YEAR COVERED BY THE REPORT:

(*i*) EACH INCREASE IN THE WHOLESALE ACQUISITION PRICE OF THE PRESCRIPTION DRUG FOR THAT YEAR, EXPRESSED AS A PERCENTAGE OF THE WHOLESALE ACQUISITION PRICE, AND THE DATE ON WHICH EACH INCREASE OCCURRED.

(*ii*) THE TOTAL PROFIT DERIVED FROM SALES OF THE PRESCRIPTION DRUG, EXPRESSED IN TOTAL DOLLARS AND AS A PERCENTAGE OF THE MANUFACTURER'S TOTAL PROFIT FOR THAT YEAR.

(*iii*) THE TOTAL AMOUNT OF FINANCIAL ASSISTANCE THAT THE MANUFACTURER HAS PROVIDED THROUGH PATIENT PRESCRIPTION ASSISTANCE PROGRAMS FOR THE PRESCRIPTION DRUG.

(*iv*) ANY TAX BENEFIT RECEIVED DURING THAT YEAR FROM A GOVERNMENTAL ENTITY, THE DATE THE TAX BENEFIT WAS RECEIVED, AND THE GOVERNMENTAL ENTITY PROVIDING THE TAX BENEFIT. AS USED IN THIS SUBPARAGRAPH, "TAX BENEFIT" MEANS ANY TAX CREDIT, DEDUCTION, OR EXEMPTION OR ANY GRANT, LOAN, OR OTHER ECONOMIC INCENTIVE.

(C) THE PRICE FOR THE PRESCRIPTION DRUG THAT IS CHARGED TO CONSUMERS OF THE PRESCRIPTION DRUG WHO ARE LOCATED IN A COUNTRY OTHER THAN THE UNITED STATES, AS REQUIRED BY THE DEPARTMENT OF

INSURANCE AND FINANCIAL SERVICES.

(3) A MANUFACTURER MUST OBTAIN AN AUDIT BY AN INDEPENDENT THIRD PARTY OF A REPORT PREPARED UNDER THIS SECTION BEFORE THE REPORT IS FILED UNDER SUBSECTION (1). THE MANUFACTURER MUST SELECT THE THIRD PARTY FROM AMONG A LIST OF POTENTIAL AUDITORS MADE AVAILABLE BY THE DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES.

(4) AFTER COMPLETING AN AUDIT UNDER SUBSECTION (3) OF A REPORT FOR A CALENDAR YEAR, THE THIRD PARTY THAT CONDUCTED THE AUDIT SHALL FILE A SUMMARY OF THE AUDIT WITH THE DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES ON OR BEFORE MAY 1 OF THE FOLLOWING YEAR, IN A FORM AND MANNER PRESCRIBED BY THE DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES. THE MANUFACTURER SHALL PAY ALL COSTS ASSOCIATED WITH AUDITING AND FILING A SUMMARY UNDER THIS SUBSECTION.

(5) THE DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES SHALL PUBLISH ON ITS INTERNET WEBSITE EACH REPORT FILED UNDER SUBSECTION (1) AND SHALL SUBMIT A COPY OF EACH REPORT FILED UNDER SUBSECTION (1) TO THE LEGISLATURE.

(6) A MANUFACTURER THAT FAILS TO FILE THE REPORT REQUIRED UNDER SUBSECTION (1) IS SUBJECT TO AN ADMINISTRATIVE FINE OF $1,000.00 FOR EACH DAY THAT THE REPORT IS NOT FILED WITH THE DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES.

SEC. 17748F. (1) THE PRESCRIPTION DRUG TRANSPARENCY WORKGROUP IS CREATED WITHIN THE DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES.

(2) THE WORKGROUP CONSISTS OF THE FOLLOWING 9 MEMBERS APPOINTED BY THE DIRECTOR OF THE DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES:

(A) ONE INDIVIDUAL WHO REPRESENTS THE PHARMACEUTICAL INDUSTRY.

(B) ONE INDIVIDUAL WHO REPRESENTS HEALTH INSURERS.

(C) TWO INDIVIDUALS WHO REPRESENT THE DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES OR THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.

(D) ONE INDIVIDUAL WHO REPRESENTS PHARMACY BENEFIT MANAGERS.

(E) ONE INDIVIDUAL WHO REPRESENTS CONSUMERS OF PRESCRIPTION DRUGS.

(F) TWO INDIVIDUALS WHO REPRESENT PRESCRIBERS.

(G) ONE INDIVIDUAL WHO REPRESENTS PHARMACISTS.

(3) THE MEMBERS FIRST APPOINTED TO THE WORKGROUP MUST BE APPOINTED WITHIN 30 DAYS AFTER THE EFFECTIVE DATE OF THE AMENDATORY ACT THAT ADDED THIS SECTION.

(4) MEMBERS OF THE WORKGROUP SHALL SERVE FOR TERMS OF 4 YEARS OR UNTIL A SUCCESSOR IS APPOINTED, WHICHEVER IS LATER, EXCEPT THAT OF THE MEMBERS FIRST APPOINTED 3 SHALL SERVE FOR 1 YEAR, 3 SHALL SERVE FOR 2 YEARS, AND 3 SHALL SERVE FOR 3 YEARS.

(5) IF A VACANCY OCCURS ON THE WORKGROUP, THE DIRECTOR OF THE DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES SHALL MAKE AN APPOINTMENT FOR THE UNEXPIRED TERM IN THE SAME MANNER AS THE ORIGINAL APPOINTMENT.

(6) THE DIRECTOR OF THE DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES MAY REMOVE A MEMBER OF THE WORKGROUP FOR INCOMPETENCE, DERELICTION OF DUTY, MALFEASANCE, MISFEASANCE, OR NONFEASANCE IN OFFICE, OR ANY OTHER GOOD CAUSE.

(7) THE DIRECTOR OF THE DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES SHALL CALL THE FIRST MEETING OF THE WORKGROUP. AT THE

FIRST MEETING, THE WORKGROUP SHALL ELECT FROM AMONG ITS MEMBERS A CHAIRPERSON AND OTHER OFFICERS AS IT CONSIDERS NECESSARY OR APPROPRIATE. AFTER THE FIRST MEETING, THE WORKGROUP SHALL MEET AT LEAST QUARTERLY, OR MORE FREQUENTLY AT THE CALL OF THE CHAIRPERSON OR IF REQUESTED BY 4 OR MORE MEMBERS.

(8) A MAJORITY OF THE MEMBERS OF THE WORKGROUP CONSTITUTE A QUORUM FOR THE TRANSACTION OF BUSINESS AT THE MEETING OF THE WORKGROUP. A MAJORITY OF THE MEMBERS PRESENT AND SERVING ARE REQUIRED FOR OFFICIAL ACTION OF THE WORKGROUP.

(9) THE BUSINESS THAT THE WORKGROUP MAY PERFORM MUST BE CONDUCTED AT A PUBLIC MEETING OF THE WORKGROUP HELD IN COMPLIANCE WITH THE OPEN MEETINGS ACT, 1976 PA 267, MCL 15.261 TO 15.275.

(10) A WRITING PREPARED, OWNED, USED, IN THE POSSESSION OF, OR RETAINED BY THE WORKGROUP IS SUBJECT TO THE FREEDOM OF INFORMATION ACT, 1976 PA 442, MCL 15.231 TO 15.246.

(11) MEMBERS OF THE WORKGROUP SHALL SERVE WITHOUT COMPENSATION. HOWEVER, MEMBERS OF THE WORKGROUP MAY BE REIMBURSED FOR THEIR ACTUAL AND NECESSARY EXPENSES INCURRED IN THE PERFORMANCE OF THEIR OFFICIAL DUTIES AS MEMBERS OF THE WORKGROUP.

(12) SUBJECT TO SECTION 17748E, WITHIN 30 DAYS AFTER THE WORKGROUP IS APPOINTED UNDER THIS SECTION, THE WORKGROUP SHALL MAKE RECOMMENDATIONS TO THE DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES ON THE CREATION OF A STANDARD REPORT FORM TO BE USED BY MANUFACTURERS OF PRESCRIPTION DRUGS IN REPORTING UNDER SECTION 17748E.

(13) AS USED IN THIS SECTION, "WORKGROUP" MEANS THE PRESCRIPTION DRUG TRANSPARENCY WORKGROUP CREATED UNDER SUBSECTION

(1).

Enacting section 1. This amendatory act takes effect 90 days after the date it is enacted into law.