

HOUSE BILL No. 5223

November 7, 2017, Introduced by Rep. Vaupel 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:

1 SEC. 17748E. (1) BEGINNING JANUARY 1, 2019, IF A PRESCRIPTION
2 DRUG HAS AN ANNUAL WHOLESALE ACQUISITION COST OF \$10,000.00 OR MORE
3 OR A WHOLESALE ACQUISITION COST OF \$10,000.00 OR MORE PER COURSE OF
4 TREATMENT, AND THE MANUFACTURER OF THE PRESCRIPTION DRUG
5 DISTRIBUTES THE PRESCRIPTION DRUG FOR SALE IN THIS STATE, THE
6 MANUFACTURER SHALL FILE AN ANNUAL REPORT WITH THE DEPARTMENT OF
7 HEALTH AND HUMAN SERVICES ON COSTS ASSOCIATED WITH THE PRESCRIPTION
8 DRUG FOR THE PRECEDING CALENDAR YEAR. A REPORT FILED UNDER THIS
9 SUBSECTION MUST BE FILED ON OR BEFORE MAY 1 OF EACH YEAR, BEGINNING
10 MAY 1, 2019, IN A FORM AND MANNER PRESCRIBED BY THE DEPARTMENT OF

1 HEALTH AND HUMAN SERVICES.

2 (2) A REPORT FILED UNDER SUBSECTION (1) MUST CONTAIN AN
3 ITEMIZED ACCOUNT OF ALL OF THE FOLLOWING INFORMATION FOR THE
4 CALENDAR YEAR COVERED BY THE REPORT:

5 (A) TOTAL COSTS PAID BY THE MANUFACTURER AND ANY PREDECESSOR
6 MANUFACTURER FOR MANUFACTURING AND DISTRIBUTING THE PRESCRIPTION
7 DRUG.

8 (B) COSTS PAID BY THE MANUFACTURER OR ANY PREDECESSOR
9 MANUFACTURER FOR RESEARCHING AND DEVELOPING THE PRESCRIPTION DRUG,
10 INCLUDING, BUT NOT LIMITED TO, ALL OF THE FOLLOWING:

11 (i) COSTS FOR RESEARCHING AND DEVELOPING THE PRESCRIPTION DRUG
12 WITH MONEY MADE AVAILABLE TO THE MANUFACTURER OR PREDECESSOR
13 MANUFACTURER THROUGH A FEDERAL, STATE, OR OTHER GOVERNMENTAL
14 PROGRAM OR THROUGH A SUBSIDY, GRANT, OR OTHER FORM OF MONETARY
15 SUPPORT.

16 (ii) AFTER-TAX RESEARCH AND DEVELOPMENT COSTS FOR THE
17 PRESCRIPTION DRUG.

18 (iii) COSTS OF CLINICAL TRIALS FOR THE PRESCRIPTION DRUG.

19 (C) RESEARCH AND DEVELOPMENT COSTS PAID BY A THIRD PARTY FOR
20 THE PRESCRIPTION DRUG.

21 (D) COSTS PAID BY THE MANUFACTURER OR ANY PREDECESSOR
22 MANUFACTURER FOR ACQUIRING THE PRESCRIPTION DRUG, INCLUDING, BUT
23 NOT LIMITED TO, COSTS PAID FOR PURCHASING A PATENT OR LICENSING THE
24 PRESCRIPTION DRUG OR COSTS PAID TO ACQUIRE A PROPERTY RIGHT TO THE
25 PRESCRIPTION DRUG.

26 (E) THE COSTS PAID BY THE MANUFACTURER FOR MARKETING AND
27 ADVERTISING THE PRESCRIPTION DRUG TO CONSUMERS OF THE PRESCRIPTION

1 DRUG, INCLUDING ANY COSTS ASSOCIATED WITH OFFERING AND REDEEMING
2 COUPONS OR OTHER DISCOUNTS.

3 (3) IN ADDITION TO THE ITEMIZED ACCOUNTING OF THE COSTS
4 DESCRIBED IN SUBSECTION (2), A REPORT FILED UNDER SUBSECTION (1)
5 MUST CONTAIN ALL OF THE FOLLOWING INFORMATION FOR THE CALENDAR YEAR
6 COVERED BY THE REPORT:

7 (A) EACH INCREASE IN THE AVERAGE WHOLESALE PRICE OF THE
8 PRESCRIPTION DRUG FOR THAT YEAR, EXPRESSED AS A PERCENTAGE OF THE
9 AVERAGE WHOLESALE PRICE, AND THE DATE ON WHICH EACH INCREASE
10 OCCURRED.

11 (B) EACH INCREASE IN THE WHOLESALE ACQUISITION COST FOR THE
12 PRESCRIPTION DRUG FOR THAT YEAR, EXPRESSED AS A PERCENTAGE OF THE
13 WHOLESALE ACQUISITION COST, AND THE DATE ON WHICH EACH INCREASE
14 OCCURRED.

15 (C) THE TOTAL PROFIT EXPECTED FROM THE SALES OF THE
16 PRESCRIPTION DRUG.

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

20 (E) THE PRICE FOR THE PRESCRIPTION DRUG THAT IS CHARGED TO
21 CONSUMERS OF THE PRESCRIPTION DRUG WHO ARE LOCATED IN A COUNTRY
22 OTHER THAN THE UNITED STATES, AS REQUIRED BY THE DEPARTMENT OF
23 HEALTH AND HUMAN SERVICES.

24 (4) A MANUFACTURER MUST OBTAIN AN AUDIT BY AN INDEPENDENT
25 THIRD PARTY OF A REPORT PREPARED UNDER THIS SECTION BEFORE THE
26 REPORT IS FILED UNDER SUBSECTION (1). THE MANUFACTURER SHALL SELECT
27 THE THIRD PARTY FROM AMONG A LIST OF POTENTIAL AUDITORS MADE

1 AVAILABLE BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.

2 (5) AFTER COMPLETING AN AUDIT UNDER SUBSECTION (4), THE THIRD
3 PARTY THAT CONDUCTED THE AUDIT SHALL FILE A SUMMARY OF THE AUDIT
4 WITH THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON OR BEFORE MAY 1
5 OF THE FOLLOWING YEAR, IN A FORM AND MANNER PRESCRIBED BY THE
6 DEPARTMENT OF HEALTH AND HUMAN SERVICES. THE MANUFACTURER SHALL PAY
7 ALL COSTS ASSOCIATED WITH AUDITING AND FILING A SUMMARY UNDER THIS
8 SUBSECTION.

9 (6) SUBJECT TO SECTION 17748F(14), THE DEPARTMENT OF HEALTH
10 AND HUMAN SERVICES SHALL POST ON ITS INTERNET WEBSITE A SEARCHABLE
11 DATABASE WITH DATA FROM THE REPORTS FILED UNDER SUBSECTION (1) AND
12 ANY INFORMATION THAT THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
13 DETERMINES IS NECESSARY TO ASSIST THE GENERAL PUBLIC IN
14 UNDERSTANDING THE DATA.

15 (7) A MANUFACTURER WHO FAILS TO FILE THE REPORT REQUIRED UNDER
16 SUBSECTION (1) IS SUBJECT TO AN ADMINISTRATIVE FINE OF \$100,000.00.

17 (8) THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, IN
18 CONSULTATION WITH THE DEPARTMENT AND THE BOARD, MAY PROMULGATE
19 RULES TO IMPLEMENT THIS SECTION.

20 SEC. 17748F. (1) THE PRESCRIPTION DRUG COST ADVISORY
21 COMMISSION IS CREATED WITHIN THE DEPARTMENT OF HEALTH AND HUMAN
22 SERVICES.

23 (2) THE COMMISSION CONSISTS OF THE FOLLOWING MEMBERS APPOINTED
24 BY THE DIRECTOR OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES:

25 (A) AN INDIVIDUAL WHO REPRESENTS THE PHARMACEUTICAL INDUSTRY.

26 (B) AN INDIVIDUAL WHO REPRESENTS THE LARGEST INSURER IN THIS
27 STATE. AS USED IN THIS SUBDIVISION, "INSURER" MEANS THAT TERM AS

1 DEFINED IN SECTION 106 OF THE INSURANCE CODE OF 1956, 1956 PA 218,
2 MCL 500.106.

3 (C) AN INDIVIDUAL WHO REPRESENTS A HEALTH MAINTENANCE
4 ORGANIZATION AS THAT TERM IS DEFINED IN SECTION 3501 OF THE
5 INSURANCE CODE OF 1956, 1956 PA 218, MCL 500.3501.

6 (D) AN INDIVIDUAL WHO REPRESENTS PHARMACY BENEFIT MANAGERS.

7 (E) ONE OR MORE INDIVIDUALS WHO REPRESENT CONSUMERS OF
8 PRESCRIPTION DRUGS.

9 (F) ONE OR MORE INDIVIDUALS WHO REPRESENT PRESCRIBERS.

10 (3) THE MEMBERS FIRST APPOINTED TO THE COMMISSION MUST BE
11 APPOINTED WITHIN 15 DAYS AFTER THE EFFECTIVE DATE OF THIS SECTION.

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

16 (5) IF A VACANCY OCCURS ON THE COMMISSION, THE DIRECTOR OF THE
17 DEPARTMENT OF HEALTH AND HUMAN SERVICES SHALL MAKE AN APPOINTMENT
18 FOR THE UNEXPIRED TERM IN THE SAME MANNER AS THE ORIGINAL
19 APPOINTMENT.

20 (6) THE DIRECTOR OF THE DEPARTMENT OF HEALTH AND HUMAN
21 SERVICES MAY REMOVE A MEMBER OF THE COMMISSION FOR INCOMPETENCE,
22 DERELICTION OF DUTY, MALFEASANCE, MISFEASANCE, OR NONFEASANCE IN
23 OFFICE, OR ANY OTHER GOOD CAUSE.

24 (7) THE DIRECTOR OF THE DEPARTMENT OF HEALTH AND HUMAN
25 SERVICES SHALL CALL THE FIRST MEETING OF THE COMMISSION. AT THE
26 FIRST MEETING, THE COMMISSION SHALL ELECT FROM AMONG ITS MEMBERS A
27 CHAIRPERSON AND OTHER OFFICERS AS IT CONSIDERS NECESSARY OR

1 APPROPRIATE. AFTER THE FIRST MEETING, THE COMMISSION SHALL MEET AT
2 LEAST QUARTERLY, OR MORE FREQUENTLY AT THE CALL OF THE CHAIRPERSON
3 OR IF REQUESTED BY 4 OR MORE MEMBERS.

4 (8) A MAJORITY OF THE MEMBERS OF THE COMMISSION CONSTITUTE A
5 QUORUM FOR THE TRANSACTION OF BUSINESS AT THE MEETING OF THE
6 COMMISSION. A MAJORITY OF THE MEMBERS PRESENT AND SERVING ARE
7 REQUIRED FOR OFFICIAL ACTION OF THE COMMISSION.

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

11 (10) SUBJECT TO SUBSECTION (14), A WRITING PREPARED, OWNED,
12 USED, IN THE POSSESSION OF, OR RETAINED BY THE COMMISSION IS
13 SUBJECT TO THE FREEDOM OF INFORMATION ACT, 1976 PA 442, MCL 15.231
14 TO 15.246.

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

19 (12) THE COMMISSION SHALL DO ALL OF THE FOLLOWING:

20 (A) SUBJECT TO SUBSECTION (14), ASSIST THE DEPARTMENT OF
21 HEALTH AND HUMAN SERVICES IN CREATING A REPORT THAT INCLUDES ALL OF
22 THE FOLLOWING BASED ON DATA OBTAINED FROM THE REPORTS FILED UNDER
23 SECTION 17748E:

24 (i) DETAILS ON PRESCRIPTION DRUG PRICES, COSTS, AND COST
25 TRENDS.

26 (ii) POLICY RECOMMENDATIONS ON WAYS TO MITIGATE INCREASES IN
27 THE PRICES OF PRESCRIPTION DRUGS AS A MEANS TO REDUCE THE COSTS OF

1 HEALTH CARE IN THIS STATE WHILE MAINTAINING ACCESS TO QUALITY
2 HEALTH CARE.

3 (iii) ANY ADDITIONAL INFORMATION CONSIDERED NECESSARY BY THE
4 DEPARTMENT OF HEALTH AND HUMAN SERVICES.

5 (B) MAKE RECOMMENDATIONS TO THE DEPARTMENT OF HEALTH AND HUMAN
6 SERVICES REGARDING THE COUNTRIES TO BE INCLUDED IN THE REPORT FOR
7 PURPOSES OF SECTION 17748E(3) (E) .

8 (C) MAKE RECOMMENDATIONS TO THE DEPARTMENT OF HEALTH AND HUMAN
9 SERVICES REGARDING INFORMATION TO POST ON THE INTERNET WEBSITE OF
10 THE DEPARTMENT OF HEALTH AND HUMAN SERVICES TO ASSIST THE GENERAL
11 PUBLIC IN UNDERSTANDING THE DATA OBTAINED UNDER SECTION 17748E.

12 (13) THE DEPARTMENT OF HEALTH AND HUMAN SERVICES SHALL POST
13 THE REPORT CREATED IN SUBSECTION (12) ON THE WEBSITE OF THE
14 DEPARTMENT OF HEALTH AND HUMAN SERVICES AND SUBMIT A COPY OF THE
15 REPORT TO THE HOUSE OF REPRESENTATIVES AND SENATE STANDING
16 COMMITTEES ON HEALTH POLICY, INSURANCE, AND APPROPRIATIONS.

17 (14) IF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OR THE
18 COMMISSION DETERMINES FROM THE DATA OBTAINED FROM A REPORT FILED
19 UNDER SECTION 17748E OR ANY OTHER INFORMATION THAT A MANUFACTURER
20 HAS POTENTIALLY VIOLATED THE MICHIGAN ANTITRUST REFORM ACT, 1984 PA
21 274, MCL 445.771 TO 445.788, THE MICHIGAN CONSUMER PROTECTION ACT,
22 1976 PA 331, MCL 445.901 TO 445.922, OR ANY OTHER LAW OF THIS
23 STATE, THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OR THE
24 COMMISSION SHALL NOTIFY THE OFFICE OF THE ATTORNEY GENERAL.
25 INFORMATION OBTAINED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
26 OR THE COMMISSION UNDER SECTION 17745E IS EXEMPT FROM DISCLOSURE
27 UNDER THE FREEDOM OF INFORMATION ACT, 1976 PA 442, MCL 15.231 TO

1 15.246, OR FROM PUBLICATION UNDER THIS SECTION AND SECTION 17745E,
2 IF THE ATTORNEY GENERAL DETERMINES THAT PUBLICATION OF THE
3 INFORMATION WOULD BE INAPPROPRIATE OR WOULD UNDERMINE AN
4 INVESTIGATION OR LITIGATION.

5 (15) AS USED IN THIS SECTION, "COMMISSION" MEANS THE
6 PRESCRIPTION DRUG ADVISORY COMMISSION CREATED IN SUBSECTION (1).

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