HOUSE BILL No. 6158

May 22, 2008, Introduced by Reps. Valentine, Kathleen Law, Ebli, Simpson, Cushingberry, Brown, Donigan, Bieda, Miller, Tobocman, Byrum, Corriveau, Leland, Meadows, Vagnozzi, Gonzales, Hammon, Hammel, Clack, Condino, Jackson, Bennett, Gillard, Mayes, Young, Dean, Espinoza, Lemmons, Alma Smith, Johnson, Melton and Constan 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 section 17790.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

SEC. 17790. (1) ON OR BEFORE MARCH 1, 2009 AND SUBJECT TO SUBSECTION (2), EACH MANUFACTURER AND WHOLESALE DISTRIBUTOR SHALL ADOPT A COMPREHENSIVE COMPLIANCE PROGRAM THAT COMPLIES WITH THE PUBLICATION ENTITLED "COMPLIANCE PROGRAM GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS" PUBLISHED BY THE OIG. A MANUFACTURER OR WHOLESALE DISTRIBUTOR SHALL INCLUDE IN ITS COMPREHENSIVE COMPLIANCE PROGRAM POLICIES FOR COMPLIANCE WITH THE PUBLICATION ENTITLED "CODE ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS" PUBLISHED BY PHRMA.

HOUSE BILL No. 6158

(2) IF THE "COMPLIANCE PROGRAM GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS" PUBLICATION IS REVISED BY THE OIG AFTER THE EFFECTIVE DATE OF THIS SECTION, THE DEPARTMENT MAY BY ORDER ADOPT THE REVISIONS IF THE NEW PUBLICATION PROVIDES AT LEAST THE SAME OR ADDITIONAL GUIDANCE TO MANUFACTURERS AND WHOLESALE DISTRIBUTORS REGARDING INTERNAL CONTROLS AND PROCEDURES THAT PROMOTE ADHERENCE TO APPLICABLE STATUTES, REGULATIONS, AND REQUIREMENTS OF THE FEDERAL HEALTH CARE PROGRAMS AND IN EVALUATING AND, AS NECESSARY, REFINING EXISTING COMPLIANCE PROGRAMS. IF THE "CODE ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS" PUBLICATION IS REVISED BY PHRMA AFTER THE EFFECTIVE DATE OF THIS SECTION, THE DEPARTMENT MAY BY ORDER ADOPT THE REVISIONS IF THE NEW PUBLICATION PROVIDES AT LEAST THE SAME OR ADDITIONAL GUIDANCE TO MANUFACTURERS AND WHOLESALE DISTRIBUTORS REGARDING ETHICAL INTERACTIONS WITH PRESCRIBERS THAT RELATE TO THE MARKETING OF PRESCRIPTION DRUG PRODUCTS. IF NEW GUIDANCE IS ADOPTED BY THE DEPARTMENT UNDER THIS SUBSECTION, THE DEPARTMENT SHALL PUBLISH THE NEW GUIDANCE AND NOTIFY MANUFACTURERS AND WHOLESALE DISTRIBUTORS LICENSED UNDER THIS ARTICLE OF THE NEW GUIDANCE. A MANUFACTURER OR WHOLESALE DISTRIBUTOR SHALL MAKE CONFORMING CHANGES TO ITS COMPREHENSIVE COMPLIANCE PROGRAM ON OR BEFORE THE EXPIRATION OF 6 MONTHS AFTER NOTICE BY THE DEPARTMENT IS GIVEN UNDER THIS SUBSECTION.

(3) EACH MANUFACTURER AND WHOLESALE DISTRIBUTOR SHALL INCLUDE IN ITS COMPREHENSIVE COMPLIANCE PROGRAM ALL OF THE FOLLOWING:

(A) LIMITS ON GIFTS OR INCENTIVES PROVIDED TO PRESCRIBERS, IN ACCORDANCE WITH THIS SECTION.

(B) A SPECIFIC ANNUAL DOLLAR LIMIT ON GIFTS, PROMOTIONAL

MATERIALS, OR ITEMS OR ACTIVITIES THAT THE MANUFACTURER OR WHOLESALE DISTRIBUTOR MAY GIVE OR OTHERWISE PROVIDE TO AN INDIVIDUAL PRESCRIBER IN ACCORDANCE WITH THE "COMPLIANCE PROGRAM GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS", WITH THE "CODE ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS", AND WITH ANY REVISIONS TO THOSE PUBLICATIONS ADOPTED UNDER SUBSECTION (2).

(4) NOTWITHSTANDING SUBSECTION (3), DRUG SAMPLES GIVEN TO PRESCRIBERS INTENDED FOR FREE DISTRIBUTION TO PATIENTS, FINANCIAL SUPPORT FOR CONTINUING MEDICAL EDUCATION FORUMS, AND FINANCIAL SUPPORT FOR HEALTH EDUCATIONAL SCHOLARSHIPS ARE EXEMPT FROM ANY LIMITS IF THAT SUPPORT IS PROVIDED IN A MANNER THAT CONFORMS TO THE "COMPLIANCE PROGRAM GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS", WITH THE "CODE ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS", AND WITH ANY REVISIONS TO THOSE PUBLICATIONS ADOPTED UNDER SUBSECTION (2).

(5) PAYMENTS MADE FOR LEGITIMATE PROFESSIONAL SERVICES PROVIDED BY A PRESCRIBER, INCLUDING, BUT NOT LIMITED TO, CONSULTING, ARE EXEMPT FROM ANY LIMITS AS LONG AS THE PAYMENT DOES NOT EXCEED THE FAIR MARKET VALUE OF THE SERVICES PROVIDED AND PAYMENTS ARE MADE IN A MANNER THAT CONFORMS TO THE "COMPLIANCE PROGRAM GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS", WITH THE "CODE ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS", AND WITH ANY REVISIONS TO THOSE PUBLICATIONS ADOPTED UNDER SUBSECTION (2).

(6) A MANUFACTURER OR WHOLESALE DISTRIBUTOR SHALL ANNUALLY REPORT TO THE DEPARTMENT THAT IT IS IN COMPLIANCE WITH ITS COMPREHENSIVE COMPLIANCE PROGRAM AND THIS SECTION. THE MANUFACTURER OR WHOLESALE DISTRIBUTOR SHALL REPORT ON A FORM AND IN THE MANNER

PRESCRIBED BY THE DEPARTMENT. THE MANUFACTURER OR WHOLESALE DISTRIBUTOR SHALL MAKE ITS COMPREHENSIVE COMPLIANCE PROGRAM AND ITS ANNUAL REPORT OF COMPLIANCE WITH THE PROGRAM AVAILABLE TO THE PUBLIC ON THE MANUFACTURER'S OR WHOLESALE DISTRIBUTOR'S WEBSITE AND SHALL ALSO PROVIDE A TOLL-FREE TELEPHONE NUMBER WHERE A COPY OR COPIES OF THE COMPREHENSIVE COMPLIANCE PROGRAM AND ITS ANNUAL REPORT OF COMPLIANCE WITH THE PROGRAM MAY BE OBTAINED.

(7) AS USED IN THIS SECTION:

(A) "OIG" MEANS THE OFFICE OF INSPECTOR GENERAL OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES.

(B) "PHRMA" MEANS THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA.

(8) THIS SECTION TAKES EFFECT JANUARY 1, 2009.

Enacting section 1. This amendatory act does not take effect unless Senate Bill No.____ or House Bill No. 6159(request no. 07255'08) of the 94th Legislature is enacted into law.