

HOUSE BILL No. 5231

August 4, 2009, Introduced by Rep. Meadows 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 17775.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1 SEC. 17775. (1) THIS SECTION MAY BE REFERRED TO AS THE "UNUSED
2 PRESCRIPTION DRUG REPOSITORY PROGRAM".

3 (2) THE BOARD SHALL ESTABLISH, IMPLEMENT, AND ADMINISTER A
4 STATEWIDE UNUSED PRESCRIPTION DRUG REPOSITORY PROGRAM CONSISTENT
5 WITH PUBLIC HEALTH AND SAFETY THROUGH WHICH UNUSED PRESCRIPTION
6 DRUGS, OTHER THAN CONTROLLED SUBSTANCES, MAY BE TRANSFERRED FROM A
7 HEALTH FACILITY OR AGENCY, AN ADULT FOSTER CARE FACILITY, AN
8 ASSISTED LIVING FACILITY, OR A MANUFACTURER TO A PHARMACY OR A
9 CHARITABLE CLINIC THAT ELECTS TO PARTICIPATE IN THE PROGRAM. THE

1 PROGRAM IS CREATED TO DISTRIBUTE UNUSED PRESCRIPTION DRUGS, OTHER
2 THAN CONTROLLED SUBSTANCES, TO THE MEDICALLY INDIGENT.

3 (3) SUBJECT TO SUBSECTION (11), THE BOARD SHALL PROMULGATE
4 RULES AND ESTABLISH PROCEDURES NECESSARY TO ESTABLISH, IMPLEMENT,
5 AND ADMINISTER THE PROGRAM. THE BOARD SHALL PROVIDE TECHNICAL
6 ASSISTANCE TO HEALTH FACILITIES AND AGENCIES, ADULT FOSTER CARE
7 FACILITIES, ASSISTED LIVING FACILITIES, MANUFACTURERS, PHARMACIES,
8 AND CHARITABLE CLINICS THAT ELECT TO PARTICIPATE IN THE PROGRAM.

9 (4) PARTICIPATION IN THE PROGRAM BY A HEALTH FACILITY OR
10 AGENCY, ADULT FOSTER CARE FACILITY, ASSISTED LIVING FACILITY,
11 MANUFACTURER, PHARMACY, OR CHARITABLE CLINIC IS VOLUNTARY. NOTHING
12 IN THIS SECTION REQUIRES ANY HEALTH FACILITY OR AGENCY, ADULT
13 FOSTER CARE FACILITY, ASSISTED LIVING FACILITY, MANUFACTURER,
14 PHARMACY, OR CHARITABLE CLINIC TO PARTICIPATE IN THE PROGRAM.

15 (5) PHARMACIES, HEALTH PROFESSIONALS, AND CHARITABLE CLINICS
16 SHALL USE THE FOLLOWING CRITERIA IN ACCEPTING AND DISPENSING UNUSED
17 PRESCRIPTION DRUGS FOR USE IN THE PROGRAM:

18 (A) ONLY PRESCRIPTION DRUGS IN THEIR ORIGINAL SEALED UNIT DOSE
19 PACKAGING OR UNUSED INJECTABLES SHALL BE ACCEPTED AND DISPENSED
20 UNDER THE PROGRAM.

21 (B) THE PACKAGING SHALL BE UNOPENED.

22 (C) EXPIRED PRESCRIPTION DRUGS SHALL NOT BE ACCEPTED.

23 (D) A PRESCRIPTION DRUG SHALL NOT BE ACCEPTED OR DISPENSED IF
24 THE PERSON ACCEPTING OR DISPENSING THE DRUG HAS REASON TO BELIEVE
25 THAT THE DRUG IS ADULTERATED.

26 (E) CONTROLLED SUBSTANCES SHALL NOT BE ACCEPTED.

27 (F) SUBJECT TO THE LIMITATIONS PRESCRIBED IN THIS SUBSECTION,

1 UNUSED PRESCRIPTION DRUGS DISPENSED FOR PURPOSES OF A MEDICAL
2 ASSISTANCE PROGRAM OR DRUG PRODUCT DONATION PROGRAM MAY BE ACCEPTED
3 AND DISPENSED UNDER THE PROGRAM.

4 (G) ANY ADDITIONAL CRITERIA ESTABLISHED IN RULES PROMULGATED
5 UNDER THIS SECTION.

6 (6) A PHARMACY OR CHARITABLE CLINIC THAT MEETS THE ELIGIBILITY
7 REQUIREMENTS ESTABLISHED BY THIS SECTION AND ANY RULES PROMULGATED
8 UNDER THIS SECTION MAY DO ANY OF THE FOLLOWING:

9 (A) DISPENSE PRESCRIPTION DRUGS DONATED UNDER THE PROGRAM TO
10 THE MEDICALLY INDIGENT.

11 (B) CHARGE PERSONS RECEIVING DONATED UNUSED PRESCRIPTION DRUGS
12 A HANDLING FEE ESTABLISHED BY RULE BY THE BOARD.

13 (C) DISTRIBUTE TO AN OUT-OF-STATE CHARITABLE REPOSITORY ANY
14 SURPLUS UNUSED PRESCRIPTION DRUGS DONATED UNDER THIS SECTION.
15 PRESCRIPTION DRUGS DISTRIBUTED UNDER THIS SUBSECTION MAY BE
16 REPACKAGED IN A MANNER APPROPRIATE FOR DISTRIBUTION BY THE PHARMACY
17 OR CHARITABLE CLINIC.

18 (7) A PHARMACY OR CHARITABLE CLINIC THAT MEETS THE ELIGIBILITY
19 REQUIREMENTS ESTABLISHED BY THIS SECTION AND ANY RULES PROMULGATED
20 UNDER THIS SECTION AND THAT ACCEPTS DONATED UNUSED PRESCRIPTION
21 DRUGS FOR THE PROGRAM SHALL DO ALL OF THE FOLLOWING:

22 (A) COMPLY WITH ALL APPLICABLE FEDERAL LAWS AND REGULATIONS
23 AND STATE LAWS AND RULES RELATED TO THE STORAGE AND DISTRIBUTION OF
24 HARMFUL DRUGS.

25 (B) INSPECT ALL DONATED UNUSED PRESCRIPTION DRUGS BEFORE
26 DISPENSING THE PRESCRIPTION DRUGS TO DETERMINE THAT SUCH DRUGS ARE
27 NOT ADULTERATED.

1 (C) DISPENSE PRESCRIPTION DRUGS ONLY PURSUANT TO A
2 PRESCRIPTION ISSUED BY A HEALTH PROFESSIONAL.

3 (8) UNUSED PRESCRIPTION DRUGS DONATED UNDER THE PROGRAM SHALL
4 NOT BE RESOLD. REIMBURSEMENT FROM A GOVERNMENTAL AGENCY TO A
5 CHARITABLE CLINIC DOES NOT CONSTITUTE RESALE OF PRESCRIPTION DRUGS.

6 (9) FOR PURPOSES OF THE LAWFUL DONATION, ACCEPTANCE, OR
7 DISPENSING OF A PRESCRIPTION DRUG UNDER THE PROGRAM, THE FOLLOWING
8 PERSONS THAT ARE IN COMPLIANCE WITH THIS SECTION AND ANY RULES
9 PROMULGATED UNDER THIS SECTION AND IN THE ABSENCE OF BAD FAITH OR
10 GROSS NEGLIGENCE ARE NOT SUBJECT TO CRIMINAL OR CIVIL LIABILITY FOR
11 INJURY OTHER THAN DEATH, OR LOSS TO PERSON OR PROPERTY, OR TO
12 PROFESSIONAL DISCIPLINARY ACTION:

13 (A) THE BOARD.

14 (B) THE DEPARTMENT.

15 (C) A HEALTH FACILITY OR AGENCY, ADULT FOSTER CARE FACILITY,
16 ASSISTED LIVING FACILITY, OR MANUFACTURER THAT DONATES PRESCRIPTION
17 DRUGS TO THE PROGRAM.

18 (D) A MANUFACTURER OR ITS REPRESENTATIVE THAT DIRECTLY DONATES
19 PRESCRIPTION DRUGS IN PROFESSIONAL SAMPLES TO A PHARMACY OR
20 CHARITABLE CLINIC FOR THE PROGRAM.

21 (E) A PHARMACY, CHARITABLE CLINIC, OR HEALTH PROFESSIONAL THAT
22 ACCEPTS, DISPENSES, OR DISTRIBUTES PRESCRIPTION DRUGS FOR THE
23 PROGRAM.

24 (F) A PHARMACY OR CHARITABLE CLINIC THAT EMPLOYS A HEALTH
25 PROFESSIONAL WHO ACCEPTS UNUSED PRESCRIPTION DRUGS FOR THE PROGRAM
26 AND WHO MAY LEGALLY DISPENSE PRESCRIPTION DRUGS UNDER THIS PART.

27 (10) FOR PURPOSES OF THE LAWFUL DONATION, ACCEPTANCE, OR

1 DISPENSING OF A PRESCRIPTION DRUG MANUFACTURED BY THE MANUFACTURER
2 THAT IS DONATED BY ANY ENTITY UNDER THE PROGRAM, A MANUFACTURER IS
3 NOT, IN THE ABSENCE OF BAD FAITH OR GROSS NEGLIGENCE, SUBJECT TO
4 CRIMINAL OR CIVIL LIABILITY FOR INJURY OTHER THAN FOR DEATH, OR
5 LOSS TO PERSON OR PROPERTY, INCLUDING, BUT NOT LIMITED TO,
6 LIABILITY FOR FAILURE TO TRANSFER OR COMMUNICATE PRODUCT OR
7 CONSUMER INFORMATION OR FOR FAILURE TO TRANSFER OR COMMUNICATE THE
8 EXPIRATION DATE OF THE DONATED PRESCRIPTION DRUG.

9 (11) THE BOARD SHALL PROMULGATE EMERGENCY RULES UNDER THE
10 ADMINISTRATIVE PROCEDURES ACT OF 1969 BY OCTOBER 1, 2009 TO
11 ESTABLISH, IMPLEMENT, AND ADMINISTER THE PROGRAM. PERMANENT RULES
12 SHALL BE PROMULGATED PURSUANT TO THE ADMINISTRATIVE PROCEDURES ACT
13 OF 1969 AS SOON AS PRACTICAL AFTER EMERGENCY RULES HAVE BEEN
14 PROMULGATED. THE DEPARTMENT SHALL INCLUDE ALL OF THE FOLLOWING IN
15 RULES PROMULGATED UNDER THIS SECTION:

16 (A) ELIGIBILITY CRITERIA FOR PHARMACIES AND CHARITABLE CLINICS
17 AUTHORIZED TO RECEIVE AND DISPENSE DONATED PRESCRIPTION DRUGS FOR
18 THE PROGRAM.

19 (B) ELIGIBILITY CRITERIA FOR THE MEDICALLY INDIGENT.

20 (C) ESTABLISHMENT OF A FORMULARY THAT INCLUDES ALL
21 PRESCRIPTION DRUGS APPROVED BY THE FEDERAL FOOD AND DRUG
22 ADMINISTRATION.

23 (D) STANDARDS AND PROCEDURES FOR TRANSFER, ACCEPTANCE, SAFE
24 STORAGE, SECURITY, AND DISPENSING OF DONATED PRESCRIPTION DRUGS.

25 (E) A PROCESS FOR SEEKING INPUT FROM THE DEPARTMENT IN
26 ESTABLISHING PROVISIONS THAT AFFECT HEALTH FACILITIES AND AGENCIES,
27 ADULT FOSTER CARE FACILITIES, AND ASSISTED LIVING FACILITIES.

1 (F) A PROCESS FOR SEEKING INPUT FROM THE DEPARTMENT IN
2 ESTABLISHING PROVISIONS THAT AFFECT MENTAL HEALTH AND SUBSTANCE
3 ABUSE CLIENTS.

4 (G) STANDARDS AND PROCEDURES FOR INSPECTING DONATED
5 PRESCRIPTION DRUGS TO ENSURE THAT THE PRESCRIPTION DRUGS MEET THE
6 REQUIREMENTS OF THE PROGRAM AND TO ENSURE THAT, IN THE PROFESSIONAL
7 JUDGMENT OF THE PHARMACIST, THE PRESCRIPTION DRUGS MEET ALL FEDERAL
8 AND STATE STANDARDS FOR PRODUCT INTEGRITY.

9 (H) PROCEDURES FOR THE DESTRUCTION OR DISPOSAL OF PRESCRIPTION
10 DRUGS OR OTHER MEDICATIONS THAT ARE DONATED AND THAT ARE CONTROLLED
11 SUBSTANCES OR OTHERWISE INELIGIBLE FOR DISTRIBUTION UNDER THE
12 PROGRAM.

13 (I) PROCEDURES FOR VERIFYING WHETHER THE CHARITABLE CLINIC,
14 PHARMACY, RESPONSIBLE PHARMACIST, OR OTHER HEALTH PROFESSIONALS
15 PARTICIPATING IN THE PROGRAM ARE LICENSED AND IN GOOD STANDING WITH
16 THE APPLICABLE LICENSING BOARD.

17 (J) ESTABLISHMENT OF STANDARDS FOR ACCEPTANCE OF UNUSED
18 PRESCRIPTION DRUGS FROM HEALTH FACILITIES AND AGENCIES, ADULT
19 FOSTER CARE FACILITIES, AND ASSISTED LIVING FACILITIES.

20 (K) ANY OTHER STANDARDS AND PROCEDURES THE BOARD CONSIDERS
21 APPROPRIATE OR NECESSARY TO ESTABLISH, IMPLEMENT, AND ADMINISTER
22 THE PROGRAM.

23 (12) PURSUANT TO THE RULES PROMULGATED AND PROCEDURES
24 ESTABLISHED FOR THE PROGRAM UNDER THIS SECTION, A RESIDENT OF A
25 HEALTH FACILITY OR AGENCY, ADULT FOSTER CARE FACILITY, OR ASSISTED
26 LIVING FACILITY, OR THE REPRESENTATIVE OR GUARDIAN OF A RESIDENT,
27 MAY DONATE UNUSED PRESCRIPTION DRUGS, OTHER THAN CONTROLLED

1 SUBSTANCES, FOR DISPENSATION TO THE MEDICALLY INDIGENT UNDER THE
2 PROGRAM.

3 (13) THIS SECTION DOES NOT IMPAIR OR SUPERSEDE THE PROVISIONS
4 REGARDING THE CANCER DRUG REPOSITORY PROGRAM CREATED IN SECTION
5 17780. IF ANY PROVISION OF THIS SECTION CONFLICTS WITH A PROVISION
6 OF THAT SECTION WITH REGARD TO CANCER DRUGS, THAT SECTION CONTROLS.

7 (14) AS USED IN THIS SECTION:

8 (A) "ADULT FOSTER CARE FACILITY" MEANS AN ADULT FOSTER CARE
9 FACILITY LICENSED UNDER THE ADULT FOSTER CARE FACILITY LICENSING
10 ACT, 1979 PA 218, MCL 400.701 TO 400.737.

11 (B) "CANCER DRUG" MEANS THAT TERM AS DEFINED IN SECTION 17780.

12 (C) "CHARITABLE CLINIC" MEANS A CHARITABLE NONPROFIT
13 CORPORATION OR FACILITY THAT MEETS ALL OF THE FOLLOWING
14 REQUIREMENTS:

15 (i) IS ORGANIZED AS A NOT-FOR-PROFIT CORPORATION PURSUANT TO
16 THE NONPROFIT CORPORATION ACT, 1982 PA 162, MCL 450.2101 TO
17 450.3192.

18 (ii) HOLDS A VALID EXEMPTION FROM FEDERAL INCOME TAXATION
19 ISSUED PURSUANT TO SECTION 501(A) OF THE INTERNAL REVENUE CODE, 26
20 USC 501.

21 (iii) IS LISTED AS AN EXEMPT ORGANIZATION UNDER SECTION 501(C)
22 OF THE INTERNAL REVENUE CODE, 26 USC 501.

23 (iv) PROVIDES ON AN OUTPATIENT BASIS FOR A PERIOD OF LESS THAN
24 24 CONSECUTIVE HOURS TO PERSONS NOT RESIDING OR CONFINED AT THE
25 FACILITY ADVICE, COUNSELING, DIAGNOSIS, TREATMENT, SURGERY, CARE,
26 OR SERVICES RELATING TO THE PRESERVATION OR MAINTENANCE OF HEALTH.

27 (v) HAS A LICENSED OUTPATIENT PHARMACY.

(D) "HEALTH FACILITY OR AGENCY" MEANS THAT TERM AS DEFINED IN SECTION 20106.

(E) "HEALTH PROFESSIONAL" MEANS ANY OF THE FOLLOWING INDIVIDUALS LICENSED AND AUTHORIZED TO PRESCRIBE AND DISPENSE DRUGS OR TO PROVIDE MEDICAL, DENTAL, OR OTHER HEALTH-RELATED DIAGNOSES, CARE, OR TREATMENT WITHIN THE SCOPE OF HIS OR HER PROFESSIONAL LICENSE:

(i) A PHYSICIAN LICENSED TO PRACTICE MEDICINE OR OSTEOPATHIC MEDICINE AND SURGERY UNDER PART 170 OR 175.

(ii) A REGISTERED PROFESSIONAL NURSE LICENSED UNDER PART 172.

(iii) A PHYSICIAN'S ASSISTANT LICENSED UNDER PART 170.

(iv) A DENTIST LICENSED UNDER PART 166.

(v) AN OPTOMETRIST LICENSED UNDER PART 174.

(vi) A PHARMACIST LICENSED UNDER THIS PART.

(vii) A PODIATRIST LICENSED UNDER PART 180.

(F) "MEDICALLY INDIGENT" MEANS AN INDIVIDUAL WHO MEETS ALL OF THE FOLLOWING REQUIREMENTS:

(i) IS A RESIDENT OF THIS STATE.

(ii) IS ELIGIBLE TO RECEIVE MEDICAID OR MEDICARE OR HAS NO HEALTH INSURANCE AND OTHERWISE LACKS REASONABLE MEANS TO PURCHASE PRESCRIPTION DRUGS, AS PRESCRIBED IN RULES PROMULGATED UNDER THIS SECTION.

(G) "OUT-OF-STATE CHARITABLE REPOSITORY" MEANS EITHER OF THE FOLLOWING:

(i) A WHOLESALE DISTRIBUTOR THAT IS A BONA FIDE CHARITABLE, RELIGIOUS, OR NONPROFIT ORGANIZATION LOCATED OUTSIDE OF THIS STATE THAT IS AN EXEMPT ORGANIZATION UNDER SECTION 501(C)(3) OF THE

1 INTERNAL REVENUE CODE, 26 USC 501.

2 (ii) A FOREIGN MEDICAL AID MISSION GROUP THAT DISTRIBUTES
3 PHARMACEUTICALS AND HEALTH CARE SUPPLIES TO NEEDY PEOPLE IN FOREIGN
4 COUNTRIES.

5 (H) "PROGRAM" MEANS THE UNUSED PRESCRIPTION DRUG REPOSITORY
6 PROGRAM ESTABLISHED UNDER THIS SECTION.