

HOUSE BILL No. 4897

June 12, 2007, Introduced by Reps. Wojno, Accavitti, Miller, Polidori and Bieda 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 SHALL BE KNOWN AND MAY BE CITED
2 AS THE "UTILIZATION OF UNUSED PRESCRIPTION DRUG LAW".

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

1 CHARITABLE CLINIC THAT ELECTS TO PARTICIPATE IN THE DRUG REPOSITORY
2 PROGRAM. THE DRUG REPOSITORY PROGRAM IS CREATED TO DISTRIBUTE
3 UNUSED PRESCRIPTION DRUGS, OTHER THAN CONTROLLED SUBSTANCES, TO
4 RESIDENTS OF THIS STATE WHO ARE MEDICALLY INDIGENT.

5 (3) SUBJECT TO SUBSECTION (11), THE BOARD SHALL PROMULGATE
6 RULES AND ESTABLISH PROCEDURES NECESSARY TO ESTABLISH, IMPLEMENT,
7 AND ADMINISTER THE UNUSED PRESCRIPTION DRUG REPOSITORY PROGRAM
8 CREATED BY THE UTILIZATION OF UNUSED PRESCRIPTION DRUG LAW. THE
9 BOARD SHALL PROVIDE TECHNICAL ASSISTANCE TO HEALTH FACILITIES AND
10 AGENCIES, ADULT FOSTER CARE FACILITIES, ASSISTED LIVING FACILITIES,
11 MANUFACTURERS, PHARMACIES, AND CHARITABLE CLINICS THAT ELECT TO
12 PARTICIPATE IN THE PROGRAM.

13 (4) PARTICIPATION IN THE UTILIZATION OF UNUSED PRESCRIPTION
14 DRUG LAW BY A HEALTH FACILITY OR AGENCY, ADULT FOSTER CARE
15 FACILITY, ASSISTED LIVING FACILITY, MANUFACTURER, PHARMACY, OR
16 CHARITABLE CLINIC IS VOLUNTARY. NOTHING IN THIS SECTION REQUIRES
17 ANY HEALTH FACILITY OR AGENCY, ADULT FOSTER CARE FACILITY, ASSISTED
18 LIVING FACILITY, MANUFACTURER, PHARMACY, OR CHARITABLE CLINIC TO
19 PARTICIPATE IN THE PROGRAM.

20 (5) PHARMACIES, HEALTH PROFESSIONALS, AND CHARITABLE CLINICS
21 SHALL USE THE FOLLOWING CRITERIA IN ACCEPTING AND DISPENSING UNUSED
22 PRESCRIPTION DRUGS FOR USE UNDER THE UTILIZATION OF UNUSED
23 PRESCRIPTION DRUG LAW:

24 (A) ONLY PRESCRIPTION DRUGS IN THEIR ORIGINAL SEALED UNIT DOSE
25 PACKAGING OR UNUSED INJECTABLES SHALL BE ACCEPTED AND DISPENSED
26 PURSUANT TO THE UTILIZATION OF UNUSED PRESCRIPTION DRUG LAW.

27 (B) THE PACKAGING SHALL BE UNOPENED.

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

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

5 (E) CONTROLLED SUBSTANCES SHALL NOT BE ACCEPTED.

6 (F) SUBJECT TO THE LIMITATIONS PRESCRIBED IN THIS SUBSECTION,
7 UNUSED PRESCRIPTION DRUGS DISPENSED FOR PURPOSES OF A MEDICAL
8 ASSISTANCE PROGRAM OR DRUG PRODUCT DONATION PROGRAM MAY BE ACCEPTED
9 AND DISPENSED UNDER THE UTILIZATION OF UNUSED PRESCRIPTION DRUG
10 LAW.

11 (G) ANY ADDITIONAL CRITERIA ESTABLISHED IN RULES PROMULGATED
12 UNDER THIS SECTION.

13 (6) A PHARMACY OR CHARITABLE CLINIC THAT MEETS THE ELIGIBILITY
14 REQUIREMENTS ESTABLISHED BY THE UTILIZATION OF UNUSED PRESCRIPTION
15 DRUG LAW AND ANY RULES PROMULGATED UNDER THIS SECTION MAY DO ANY OF
16 THE FOLLOWING:

17 (A) DISPENSE PRESCRIPTION DRUGS DONATED UNDER THE UTILIZATION
18 OF UNUSED PRESCRIPTION DRUG LAW TO THE MEDICALLY INDIGENT.

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

21 (7) A PHARMACY OR CHARITABLE CLINIC THAT MEETS THE ELIGIBILITY
22 REQUIREMENTS ESTABLISHED BY THE UTILIZATION OF UNUSED PRESCRIPTION
23 DRUG LAW AND ANY RULES PROMULGATED UNDER THIS SECTION AND THAT
24 ACCEPTS DONATED UNUSED PRESCRIPTION DRUGS FOR THE PROGRAM SHALL DO
25 ALL OF THE FOLLOWING:

26 (A) COMPLY WITH ALL APPLICABLE FEDERAL LAWS AND REGULATIONS
27 AND STATE LAWS AND RULES RELATED TO THE STORAGE AND DISTRIBUTION OF

1 HARMFUL DRUGS.

2 (B) INSPECT ALL DONATED UNUSED PRESCRIPTION DRUGS BEFORE
3 DISPENSING THE PRESCRIPTION DRUGS TO DETERMINE THAT SUCH DRUGS ARE
4 NOT ADULTERATED.

5 (C) DISPENSE PRESCRIPTION DRUGS ONLY PURSUANT TO A
6 PRESCRIPTION ISSUED BY A HEALTH PROFESSIONAL.

7 (8) UNUSED PRESCRIPTION DRUGS DONATED UNDER THE UTILIZATION OF
8 UNUSED PRESCRIPTION DRUG LAW SHALL NOT BE RESOLD. FOR PURPOSES OF
9 THE UTILIZATION OF UNUSED PRESCRIPTION DRUG LAW, REIMBURSEMENT FROM
10 GOVERNMENTAL AGENCIES TO CHARITABLE CLINICS SHALL NOT BE CONSIDERED
11 RESALE OF PRESCRIPTION DRUGS.

12 (9) FOR PURPOSES OF THE LAWFUL DONATION, ACCEPTANCE, OR
13 DISPENSING OF PRESCRIPTION DRUGS UNDER THE UTILIZATION OF UNUSED
14 PRESCRIPTION DRUG LAW, THE FOLLOWING PERSONS AND ENTITIES THAT ARE
15 IN COMPLIANCE WITH THE UTILIZATION OF UNUSED PRESCRIPTION DRUG LAW
16 AND ANY RULES PROMULGATED UNDER THIS SECTION AND IN THE ABSENCE OF
17 BAD FAITH OR GROSS NEGLIGENCE SHALL NOT BE SUBJECT TO CRIMINAL OR
18 CIVIL LIABILITY FOR INJURY OTHER THAN DEATH, OR LOSS TO PERSON OR
19 PROPERTY, OR PROFESSIONAL DISCIPLINARY ACTION:

20 (A) THE BOARD.

21 (B) THE DEPARTMENT.

22 (C) A HEALTH FACILITY OR AGENCY, ADULT FOSTER CARE FACILITY,
23 ASSISTED LIVING FACILITY, OR MANUFACTURER THAT DONATES PRESCRIPTION
24 DRUGS TO THE PROGRAM.

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

1 (E) A PHARMACY, CHARITABLE CLINIC, OR HEALTH PROFESSIONAL THAT
2 ACCEPTS OR DISPENSES PRESCRIPTION DRUGS FOR THE PROGRAM.

3 (F) A PHARMACY OR CHARITABLE CLINIC THAT EMPLOYS A HEALTH
4 PROFESSIONAL WHO ACCEPTS UNUSED PRESCRIPTION DRUGS AND WHO CAN
5 LEGALLY DISPENSE PRESCRIPTION DRUGS UNDER PART 177 FOR THE PROGRAM.

6 (10) FOR PURPOSES OF THE LAWFUL DONATION, ACCEPTANCE, OR
7 DISPENSING OF A PRESCRIPTION DRUG MANUFACTURED BY THE MANUFACTURER
8 THAT IS DONATED BY ANY ENTITY UNDER THE UTILIZATION OF UNUSED
9 PRESCRIPTION DRUG LAW, A MANUFACTURER SHALL NOT, IN THE ABSENCE OF
10 BAD FAITH OR GROSS NEGLIGENCE, BE SUBJECT TO CRIMINAL OR CIVIL
11 LIABILITY FOR INJURY OTHER THAN FOR DEATH, OR LOSS TO PERSON OR
12 PROPERTY, INCLUDING, BUT NOT LIMITED TO, LIABILITY FOR FAILURE TO
13 TRANSFER OR COMMUNICATE PRODUCT OR CONSUMER INFORMATION OR FOR
14 FAILURE TO TRANSFER OR COMMUNICATE THE EXPIRATION DATE OF THE
15 DONATED PRESCRIPTION DRUG.

16 (11) THE BOARD SHALL PROMULGATE EMERGENCY RULES UNDER THE
17 ADMINISTRATIVE PROCEDURES ACT OF 1969 BY DECEMBER 1, 2007 TO
18 ESTABLISH, IMPLEMENT, AND ADMINISTER THE UTILIZATION OF UNUSED
19 PRESCRIPTION DRUG LAW. PERMANENT RULES SHALL BE PROMULGATED
20 PURSUANT TO THE ADMINISTRATIVE PROCEDURES ACT OF 1969 AS SOON AS
21 PRACTICAL AFTER EMERGENCY RULES HAVE BEEN PROMULGATED. THE BOARD
22 SHALL INCLUDE ALL OF THE FOLLOWING IN RULES PROMULGATED UNDER THIS
23 SECTION:

24 (A) ELIGIBILITY CRITERIA FOR PHARMACIES AND CHARITABLE CLINICS
25 AUTHORIZED TO RECEIVE AND DISPENSE DONATED PRESCRIPTION DRUGS FOR
26 THE PROGRAM.

27 (B) ELIGIBILITY CRITERIA FOR THE MEDICALLY INDIGENT.

1 (C) ESTABLISHMENT OF A FORMULARY THAT INCLUDES ALL
2 PRESCRIPTION DRUGS APPROVED BY THE FEDERAL FOOD AND DRUG
3 ADMINISTRATION.

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

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

9 (F) A PROCESS FOR SEEKING INPUT FROM THE DEPARTMENT IN
10 ESTABLISHING PROVISIONS THAT AFFECT MENTAL HEALTH AND SUBSTANCE
11 ABUSE CLIENTS.

12 (G) STANDARDS AND PROCEDURES FOR INSPECTING DONATED
13 PRESCRIPTION DRUGS TO ENSURE THAT THE DRUGS ARE IN COMPLIANCE WITH
14 THE UTILIZATION OF UNUSED PRESCRIPTION DRUG LAW AND TO ENSURE THAT,
15 IN THE PROFESSIONAL JUDGMENT OF THE PHARMACIST, THE MEDICATIONS
16 MEET ALL FEDERAL AND STATE STANDARDS FOR PRODUCT INTEGRITY.

17 (H) PROCEDURES FOR DESTRUCTION OF MEDICATIONS THAT ARE DONATED
18 AND THAT ARE CONTROLLED SUBSTANCES OR OTHERWISE INELIGIBLE FOR
19 DISTRIBUTION UNDER THE PROGRAM.

20 (I) PROCEDURES FOR VERIFYING WHETHER THE CHARITABLE CLINIC,
21 PHARMACY, RESPONSIBLE PHARMACIST, OR OTHER HEALTH PROFESSIONALS
22 PARTICIPATING IN THE PROGRAM ARE LICENSED AND IN GOOD STANDING WITH
23 THE APPLICABLE LICENSING BOARD.

24 (J) ESTABLISHMENT OF STANDARDS FOR ACCEPTANCE OF UNUSED
25 PRESCRIPTION DRUGS FROM HEALTH FACILITIES AND AGENCIES, ADULT
26 FOSTER CARE FACILITIES, AND ASSISTED LIVING FACILITIES.

27 (K) ANY OTHER STANDARDS AND PROCEDURES THE BOARD CONSIDERS

1 APPROPRIATE OR NECESSARY TO ESTABLISH, IMPLEMENT, AND ADMINISTER
2 THE PROVISIONS OF THE UTILIZATION OF UNUSED PRESCRIPTION DRUG LAW.

3 (12) PURSUANT TO THE RULES PROMULGATED AND PROCEDURES
4 ESTABLISHED FOR THE PROGRAM UNDER THIS SECTION, A RESIDENT OF A
5 HEALTH FACILITY OR AGENCY, ADULT FOSTER CARE FACILITY, OR ASSISTED
6 LIVING FACILITY, OR THE REPRESENTATIVE OR GUARDIAN OF A RESIDENT,
7 MAY DONATE UNUSED PRESCRIPTION DRUGS, OTHER THAN CONTROLLED
8 SUBSTANCES, FOR DISPENSATION TO MEDICALLY INDIGENT PERSONS UNDER
9 THE PROGRAM.

10 (13) THIS SECTION DOES NOT IMPAIR OR SUPERSEDE THE PROVISIONS
11 REGARDING THE CANCER DRUG REPOSITORY PROGRAM CREATED IN SECTION
12 17780. IF ANY PROVISION OF THIS SECTION CONFLICTS WITH A PROVISION
13 OF THAT SECTION WITH REGARD TO CANCER DRUGS, THAT SECTION CONTROLS.

14 (14) AS USED IN THIS SECTION:

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

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

19 (C) "CHARITABLE CLINIC" MEANS A CHARITABLE NONPROFIT
20 CORPORATION OR FACILITY, WHICH CORPORATION OR FACILITY MEETS ALL OF
21 THE FOLLOWING REQUIREMENTS:

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

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

27 (iii) IS LISTED AS AN EXEMPT ORGANIZATION UNDER SECTION 501(C)

1 OF THE INTERNAL REVENUE CODE, 26 USC 501.

2 (iv) PROVIDES ON AN OUTPATIENT BASIS FOR A PERIOD OF LESS THAN
3 24 CONSECUTIVE HOURS TO PERSONS NOT RESIDING OR CONFINED AT THE
4 FACILITY ADVICE, COUNSELING, DIAGNOSIS, TREATMENT, SURGERY, CARE,
5 OR SERVICES RELATING TO THE PRESERVATION OR MAINTENANCE OF HEALTH.

6 (v) HAS A LICENSED OUTPATIENT PHARMACY.

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

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

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

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

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

18 (iv) A DENTIST LICENSED UNDER PART 166.

19 (v) AN OPTOMETRIST LICENSED UNDER PART 174.

20 (vi) A PHARMACIST LICENSED UNDER THIS PART.

21 (vii) A PODIATRIST LICENSED UNDER PART 180.

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

24 (i) IS A RESIDENT OF THIS STATE.

25 (ii) IS ELIGIBLE TO RECEIVE MEDICAID OR MEDICARE OR HAS NO
26 HEALTH INSURANCE AND OTHERWISE LACKS REASONABLE MEANS TO PURCHASE
27 PRESCRIBED MEDICATIONS, AS PRESCRIBED IN RULES PROMULGATED UNDER

1 THIS SECTION.

2 (G) "PROGRAM" MEANS THE UTILIZATION OF UNUSED PRESCRIPTION

3 DRUG REPOSITORY PROGRAM ESTABLISHED UNDER THIS SECTION.