

HOUSE BILL No. 5089

October 18, 2011, Introduced by Reps. Johnson, Ananich, Kurtz, Rendon, Zorn, Huuki, Shirkey, Muxlow, Heise, Hughes, Liss, Hovey-Wright, Lipton, Hooker, Foster and Wayne Schmidt 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 AND SECTION 17776 SHALL BE KNOWN
2 AND MAY BE REFERRED TO AS THE "PROGRAM FOR UTILIZATION OF UNUSED
3 PRESCRIPTION DRUGS".

4 (2) AS USED IN THIS SECTION AND SECTION 17776:

5 (A) "BOARD" MEANS THE MICHIGAN BOARD OF PHARMACY CREATED UNDER
6 SECTION 17721.

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

8 (C) "CHARITABLE CLINIC" MEANS A CHARITABLE NONPROFIT
9 CORPORATION OR FACILITY THAT MEETS ALL OF THE FOLLOWING
10 REQUIREMENTS:

1 (i) IS ORGANIZED AS A NOT-FOR-PROFIT CORPORATION PURSUANT TO
2 THE NONPROFIT CORPORATION ACT, 1982 PA 162, MCL 450.2101 TO
3 450.3192.

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

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

9 (iv) IS ORGANIZED UNDER OR OPERATED AS A PART OF A HEALTH
10 FACILITY OR AGENCY LICENSED UNDER ARTICLE 17.

11 (v) PROVIDES ON AN OUTPATIENT BASIS FOR A PERIOD OF LESS THAN
12 24 CONSECUTIVE HOURS TO PERSONS NOT RESIDING OR CONFINED AT THE
13 FACILITY ADVICE, COUNSELING, DIAGNOSIS, TREATMENT, SURGERY, CARE,
14 OR SERVICES RELATING TO THE PRESERVATION OR MAINTENANCE OF HEALTH.

15 (vi) HAS A LICENSED PHARMACY.

16 (D) "ELIGIBLE FACILITY" MEANS ANY OF THE FOLLOWING:

17 (i) AN ADULT FOSTER CARE FACILITY LICENSED UNDER THE ADULT
18 FOSTER CARE FACILITY LICENSING ACT, 1979 PA 218, MCL 400.701 TO
19 400.737.

20 (ii) AN ASSISTED LIVING FACILITY. AS USED IN THIS SUBPARAGRAPH,
21 "ASSISTED LIVING FACILITY" MEANS ANY HOME OR ESTABLISHMENT
22 OFFERING, COORDINATING, OR PROVIDING SERVICES TO 2 OR MORE
23 INDIVIDUALS WHO MEET THE FOLLOWING:

24 (A) ARE DOMICILED IN THE HOME OR ESTABLISHMENT.

25 (B) ARE NOT RELATED TO THE OPERATOR OF THE HOME OR
26 ESTABLISHMENT.

27 (C) BY CHOICE OR FUNCTIONAL IMPAIRMENTS, NEED ASSISTANCE WITH

1 PERSONAL CARE OR NURSING SUPERVISION.

2 (D) MAY NEED INTERMITTENT OR UNSCHEDULED NURSING CARE.

3 (E) MAY NEED MEDICATION ASSISTANCE.

4 (F) MAY NEED ASSISTANCE WITH TRANSFER OR AMBULATION.

5 (iii) A HEALTH FACILITY OR AGENCY, AS DEFINED IN SECTION 20106.

6 (E) "ELIGIBLE PARTICIPANT" MEANS AN INDIVIDUAL WHO MEETS ALL
7 OF THE FOLLOWING REQUIREMENTS:

8 (i) IS A RESIDENT OF THIS STATE.

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

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

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

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

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

22 (iv) A DENTIST LICENSED UNDER PART 166.

23 (v) AN OPTOMETRIST LICENSED UNDER PART 174.

24 (vi) A PHARMACIST LICENSED UNDER THIS PART.

25 (vii) A PODIATRIST LICENSED UNDER PART 180.

26 (G) "PROGRAM" MEANS THE STATEWIDE UNUSED PRESCRIPTION DRUG
27 REPOSITORY AND DISTRIBUTION PROGRAM KNOWN AS THE PROGRAM FOR

1 UTILIZATION OF UNUSED PRESCRIPTION DRUGS THAT IS ESTABLISHED UNDER
2 THIS SECTION.

3 (3) THE BOARD SHALL ESTABLISH, IMPLEMENT, AND ADMINISTER A
4 STATEWIDE UNUSED PRESCRIPTION DRUG REPOSITORY AND DISTRIBUTION
5 PROGRAM CONSISTENT WITH PUBLIC HEALTH AND SAFETY THROUGH WHICH
6 UNUSED OR DONATED PRESCRIPTION DRUGS, OTHER THAN CONTROLLED
7 SUBSTANCES, MAY BE TRANSFERRED FROM AN ELIGIBLE FACILITY OR
8 MANUFACTURER TO A PHARMACY OR A CHARITABLE CLINIC THAT ELECTS TO
9 PARTICIPATE IN THE PROGRAM. THE PROGRAM IS CREATED TO DISTRIBUTE
10 UNUSED OR DONATED PRESCRIPTION DRUGS, OTHER THAN CONTROLLED
11 SUBSTANCES, TO ELIGIBLE PARTICIPANTS AND TO PROVIDE FOR THE
12 DESTRUCTION AND DISPOSAL OF PRESCRIPTION DRUGS OR OTHER MEDICATIONS
13 THAT ARE INELIGIBLE FOR DISTRIBUTION UNDER THE PROGRAM.

14 (4) PARTICIPATION IN THE PROGRAM BY AN ELIGIBLE FACILITY,
15 MANUFACTURER, PHARMACY, OR CHARITABLE CLINIC IS VOLUNTARY. NOTHING
16 IN THIS SECTION OR SECTION 17776 REQUIRES ANY ELIGIBLE FACILITY,
17 MANUFACTURER, PHARMACY, OR CHARITABLE CLINIC TO PARTICIPATE IN THE
18 PROGRAM.

19 (5) PHARMACIES, HEALTH PROFESSIONALS, AND CHARITABLE CLINICS
20 THAT PARTICIPATE IN THE PROGRAM SHALL USE THE FOLLOWING CRITERIA IN
21 ACCEPTING UNUSED OR DONATED PRESCRIPTION DRUGS FROM ELIGIBLE
22 FACILITIES OR MANUFACTURERS FOR USE IN THE PROGRAM:

23 (A) ONLY PRESCRIPTION DRUGS IN THEIR ORIGINAL SEALED, TAMPER-
24 EVIDENT, AND UNOPENED UNIT DOSE PACKAGING MAY BE ACCEPTED AND
25 DISPENSED. HOWEVER, PRESCRIPTION DRUGS PACKAGED IN SINGLE-UNIT DOSE
26 PACKAGING MAY BE ACCEPTED AND DISPENSED EVEN IF THE OUTSIDE
27 PACKAGING IS OPEN AS LONG AS THE SINGLE-UNIT DOSE PACKAGING IS

1 UNOPENED.

2 (B) THE FOLLOWING SHALL NOT BE ACCEPTED AND DISPENSED:

3 (i) EXPIRED PRESCRIPTION DRUGS.

4 (ii) CONTROLLED SUBSTANCES AS DEFINED IN ARTICLE 7 OR BY
5 FEDERAL LAW.

6 (iii) DRUGS THAT HAVE BEEN HELD OUTSIDE OF A HEALTH
7 PROFESSIONAL'S CONTROL WHERE SANITATION AND SECURITY CANNOT BE
8 ASSURED.

9 (C) A PRESCRIPTION DRUG SHALL NOT BE ACCEPTED AND DISPENSED IF
10 THE PERSON ACCEPTING OR DISPENSING THE DRUG HAS REASON TO BELIEVE
11 THAT THE DRUG IS ADULTERATED.

12 (D) SUBJECT TO THE LIMITATIONS PRESCRIBED IN THIS SUBSECTION,
13 UNUSED OR DONATED PRESCRIPTION DRUGS DISPENSED FOR PURPOSES OF A
14 MEDICAL ASSISTANCE PROGRAM OR DRUG PRODUCT DONATION PROGRAM MAY BE
15 ACCEPTED AND DISPENSED UNDER THE PROGRAM.

16 (E) ANY ADDITIONAL CRITERIA ESTABLISHED IN RULES PROMULGATED
17 UNDER THIS SECTION.

18 (6) A PHARMACY OR CHARITABLE CLINIC THAT MEETS THE ELIGIBILITY
19 REQUIREMENTS FOR PARTICIPATION IN THE PROGRAM AND ANY RULES
20 PROMULGATED UNDER THIS SECTION MAY DO ANY OF THE FOLLOWING:

21 (A) DISPENSE PRESCRIPTION DRUGS ACCEPTED UNDER THE PROGRAM TO
22 ELIGIBLE PARTICIPANTS.

23 (B) IF ESTABLISHED BY RULE UNDER THIS SECTION, CHARGE ELIGIBLE
24 PARTICIPANTS WHO RECEIVE PRESCRIPTION DRUGS UNDER THE PROGRAM A
25 HANDLING FEE FOR THE SERVICE.

26 (7) A PHARMACY OR CHARITABLE CLINIC THAT PARTICIPATES IN THE
27 PROGRAM AND ACCEPTS PRESCRIPTION DRUGS FOR THE PROGRAM SHALL DO ALL

1 OF THE FOLLOWING:

2 (A) COMPLY WITH ALL APPLICABLE FEDERAL LAWS AND REGULATIONS
3 AND STATE LAWS AND RULES RELATED TO THE STORAGE AND DISTRIBUTION OF
4 HARMFUL DRUGS.

5 (B) INSPECT ALL ACCEPTED PRESCRIPTION DRUGS BEFORE DISPENSING
6 THE PRESCRIPTION DRUGS TO DETERMINE THAT THE DRUGS ARE NOT
7 ADULTERATED.

8 (C) DISPENSE PRESCRIPTION DRUGS ONLY PURSUANT TO A
9 PRESCRIPTION ISSUED BY A HEALTH PROFESSIONAL.

10 (8) A PHARMACY, HEALTH PROFESSIONAL, OR CHARITABLE CLINIC THAT
11 ACCEPTS PRESCRIPTION DRUGS UNDER THE PROGRAM SHALL NOT RESELL THE
12 PRESCRIPTION DRUGS. RECEIPT OF A FEE FROM AN ELIGIBLE PARTICIPANT,
13 IF ESTABLISHED IN RULES PROMULGATED UNDER THIS SECTION, OR
14 REIMBURSEMENT FROM A GOVERNMENTAL AGENCY TO A CHARITABLE CLINIC
15 DOES NOT CONSTITUTE RESALE OF PRESCRIPTION DRUGS UNDER THIS
16 SUBSECTION.

17 (9) FOR PURPOSES OF THE LAWFUL DONATION, ACCEPTANCE, OR
18 DISPENSING OF PRESCRIPTION DRUGS UNDER THE PROGRAM, THE FOLLOWING
19 PERSONS THAT ARE IN COMPLIANCE WITH THE PROGRAM, THIS SECTION AND
20 SECTION 17776, AND ANY RULES PROMULGATED UNDER THIS SECTION AND IN
21 THE ABSENCE OF BAD FAITH OR GROSS NEGLIGENCE ARE NOT SUBJECT TO
22 CRIMINAL OR CIVIL LIABILITY FOR INJURY OTHER THAN DEATH, OR LOSS TO
23 PERSON OR PROPERTY, OR PROFESSIONAL DISCIPLINARY ACTION:

24 (A) THE BOARD.

25 (B) THE DEPARTMENT.

26 (C) AN ELIGIBLE FACILITY OR MANUFACTURER THAT DONATES
27 PRESCRIPTION DRUGS TO THE PROGRAM.

1 (D) A MANUFACTURER OR ITS REPRESENTATIVE THAT DIRECTLY DONATES
2 PRESCRIPTION DRUGS IN PROFESSIONAL SAMPLES TO A PHARMACY OR
3 CHARITABLE CLINIC UNDER THE PROGRAM.

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

6 (F) A PHARMACY OR CHARITABLE CLINIC THAT EMPLOYS A HEALTH
7 PROFESSIONAL WHO ACCEPTS PRESCRIPTION DRUGS FOR THE PROGRAM AND WHO
8 MAY LEGALLY DISPENSE PRESCRIPTION DRUGS UNDER THIS PART.

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

18 (11) SUBJECT TO SUBSECTION (12), THE DEPARTMENT, IN
19 CONSULTATION WITH THE BOARD, SHALL PROMULGATE RULES UNDER THE
20 ADMINISTRATIVE PROCEDURES ACT OF 1969 AND ESTABLISH PROCEDURES
21 NECESSARY TO ESTABLISH, IMPLEMENT, AND ADMINISTER THE PROGRAM. THE
22 BOARD SHALL PROVIDE TECHNICAL ASSISTANCE TO ELIGIBLE FACILITIES,
23 MANUFACTURERS, PHARMACIES, AND CHARITABLE CLINICS THAT PARTICIPATE
24 IN THE PROGRAM.

25 (12) THE DEPARTMENT, IN CONSULTATION WITH THE BOARD, SHALL
26 PROMULGATE EMERGENCY RULES UNDER THE ADMINISTRATIVE PROCEDURES ACT
27 OF 1969 ON OR BEFORE THE EXPIRATION OF 6 MONTHS AFTER THE EFFECTIVE

1 DATE OF THIS SECTION TO ESTABLISH, IMPLEMENT, AND ADMINISTER THE
2 PROGRAM. THE DEPARTMENT, IN CONSULTATION WITH THE BOARD, SHALL
3 PROMULGATE PERMANENT RULES PURSUANT TO THE ADMINISTRATIVE
4 PROCEDURES ACT OF 1969 AS SOON AS PRACTICAL AFTER EMERGENCY RULES
5 HAVE BEEN PROMULGATED UNDER THIS SUBSECTION. THE DEPARTMENT AND THE
6 BOARD SHALL INCLUDE ALL OF THE FOLLOWING IN RULES PROMULGATED UNDER
7 THIS SECTION:

8 (A) ELIGIBILITY CRITERIA FOR PHARMACIES AND CHARITABLE CLINICS
9 AUTHORIZED TO ACCEPT AND DISPENSE PRESCRIPTION DRUGS FOR THE
10 PROGRAM.

11 (B) ELIGIBILITY CRITERIA FOR ELIGIBLE PARTICIPANTS.

12 (C) ESTABLISHMENT OF A FORMULARY THAT INCLUDES ALL
13 PRESCRIPTION DRUGS APPROVED BY THE FEDERAL FOOD AND DRUG
14 ADMINISTRATION.

15 (D) STANDARDS AND PROCEDURES FOR TRANSFER, TRANSPORTATION,
16 ACCEPTANCE, SAFE STORAGE, SECURITY, AND DISPENSING OF PRESCRIPTION
17 DRUGS.

18 (E) A PROCESS FOR SEEKING INPUT FROM THE DEPARTMENT OF HUMAN
19 SERVICES AND THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS IN
20 ESTABLISHING PROVISIONS THAT AFFECT ELIGIBLE FACILITIES.

21 (F) A PROCESS FOR SEEKING INPUT FROM THE DEPARTMENT OF HUMAN
22 SERVICES IN ESTABLISHING PROVISIONS THAT AFFECT MENTAL HEALTH AND
23 SUBSTANCE ABUSE CLIENTS.

24 (G) STANDARDS AND PROCEDURES FOR INSPECTING ACCEPTED
25 PRESCRIPTION DRUGS TO ENSURE THAT THE PRESCRIPTION DRUGS MEET THE
26 REQUIREMENTS OF THE PROGRAM AND TO ENSURE THAT, IN THE PROFESSIONAL
27 JUDGMENT OF THE PHARMACIST, THE PRESCRIPTION DRUGS MEET ALL FEDERAL

1 AND STATE STANDARDS FOR PRODUCT INTEGRITY.

2 (H) PROCEDURES FOR THE DESTRUCTION AND ENVIRONMENTALLY SOUND
3 DISPOSAL OF PRESCRIPTION DRUGS OR OTHER MEDICATIONS THAT ARE
4 ACCEPTED AND THAT ARE CONTROLLED SUBSTANCES OR OTHERWISE INELIGIBLE
5 FOR DISTRIBUTION UNDER THE PROGRAM.

6 (I) PROCEDURES FOR VERIFYING WHETHER THE CHARITABLE CLINIC,
7 PHARMACY, PHARMACIST, OR OTHER HEALTH PROFESSIONALS PARTICIPATING
8 IN THE PROGRAM ARE LICENSED AND IN GOOD STANDING WITH THE
9 APPLICABLE LICENSING BOARD.

10 (J) ESTABLISHMENT OF STANDARDS FOR ACCEPTANCE OF UNUSED OR
11 DONATED PRESCRIPTION DRUGS FROM ELIGIBLE FACILITIES.

12 (K) ESTABLISHMENT OF STANDARDS FOR THE ACCEPTANCE BY A
13 PHARMACY, HEALTH PROFESSIONAL, OR CHARITABLE CLINIC THAT
14 PARTICIPATES IN THE PROGRAM FROM ANY PERSON OF A PRESCRIPTION DRUG
15 OR ANY OTHER MEDICATION THAT IS INELIGIBLE FOR DISTRIBUTION UNDER
16 THE PROGRAM FOR DESTRUCTION AND DISPOSAL.

17 (L) ANY OTHER STANDARDS AND PROCEDURES THE DEPARTMENT, IN
18 CONSULTATION WITH THE BOARD, CONSIDERS APPROPRIATE OR NECESSARY TO
19 ESTABLISH, IMPLEMENT, AND ADMINISTER THE PROGRAM.

20 (13) PURSUANT TO THE RULES PROMULGATED AND STANDARDS AND
21 PROCEDURES ESTABLISHED FOR THE PROGRAM UNDER THIS SECTION, A
22 RESIDENT OF AN ELIGIBLE FACILITY OR THE REPRESENTATIVE OR GUARDIAN
23 OF A RESIDENT OF AN ELIGIBLE FACILITY MAY DONATE UNUSED
24 PRESCRIPTION DRUGS FOR DISPENSING TO ELIGIBLE PARTICIPANTS UNDER
25 THE PROGRAM.

26 (14) PURSUANT TO RULES PROMULGATED AND STANDARDS AND
27 PROCEDURES ESTABLISHED FOR THE PROGRAM UNDER THIS SECTION, A PERSON

1 MAY DELIVER TO A PHARMACY, HEALTH PROFESSIONAL, OR CHARITABLE
2 CLINIC THAT PARTICIPATES IN THE PROGRAM A PRESCRIPTION DRUG OR ANY
3 OTHER MEDICATION THAT IS INELIGIBLE FOR DISTRIBUTION UNDER THE
4 PROGRAM FOR DESTRUCTION AND DISPOSAL.

5 (15) THIS SECTION AND SECTION 17776 DO NOT IMPAIR OR SUPERSEDE
6 THE PROVISIONS REGARDING THE CANCER DRUG REPOSITORY PROGRAM
7 ESTABLISHED IN SECTION 17780. IF ANY PROVISION OF THIS SECTION OR
8 SECTION 17776 CONFLICTS WITH A PROVISION OF SECTION 17780 WITH
9 REGARD TO A CANCER DRUG, SECTION 17780 CONTROLS.

10 Enacting section 1. This amendatory act does not take effect
11 unless Senate Bill No.____ or House Bill No. 5090(request no.
12 00714'11 **) of the 96th Legislature is enacted into law.