

SUBSTITUTE FOR
HOUSE BILL NO. 5089

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:

11 (i) IS ORGANIZED AS A NOT-FOR-PROFIT CORPORATION PURSUANT TO

1 THE NONPROFIT CORPORATION ACT, 1982 PA 162, MCL 450.2101 TO
2 450.3192.

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

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

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

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

14 (vi) HAS A LICENSED PHARMACY.

15 (D) "ELIGIBLE FACILITY" MEANS A MEDICAL INSTITUTION AS THAT
16 TERM IS DEFINED IN R 338.486 OF THE MICHIGAN ADMINISTRATIVE CODE.

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

19 (i) IS A RESIDENT OF THIS STATE.

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

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

1 LICENSE:

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

4 (ii) A PHYSICIAN'S ASSISTANT LICENSED UNDER PART 170, 175, OR
5 180.

6 (iii) A DENTIST LICENSED UNDER PART 166.

7 (iv) AN OPTOMETRIST LICENSED UNDER PART 174.

8 (v) A PHARMACIST LICENSED UNDER THIS PART.

9 (vi) A PODIATRIST LICENSED UNDER PART 180.

10 (G) "PROGRAM" MEANS THE STATEWIDE UNUSED PRESCRIPTION DRUG
11 REPOSITORY AND DISTRIBUTION PROGRAM KNOWN AS THE PROGRAM FOR
12 UTILIZATION OF UNUSED PRESCRIPTION DRUGS THAT IS ESTABLISHED UNDER
13 THIS SECTION.

14 (3) THE BOARD SHALL ESTABLISH, IMPLEMENT, AND ADMINISTER A
15 STATEWIDE UNUSED PRESCRIPTION DRUG REPOSITORY AND DISTRIBUTION
16 PROGRAM CONSISTENT WITH PUBLIC HEALTH AND SAFETY THROUGH WHICH
17 UNUSED OR DONATED PRESCRIPTION DRUGS, OTHER THAN CONTROLLED
18 SUBSTANCES, MAY BE TRANSFERRED FROM AN ELIGIBLE FACILITY OR
19 MANUFACTURER TO A PHARMACY OR A CHARITABLE CLINIC THAT ELECTS TO
20 PARTICIPATE IN THE PROGRAM. THE PROGRAM IS CREATED TO DISPENSE
21 UNUSED OR DONATED PRESCRIPTION DRUGS, OTHER THAN CONTROLLED
22 SUBSTANCES, TO ELIGIBLE PARTICIPANTS AND TO PROVIDE FOR THE
23 DESTRUCTION AND DISPOSAL OF PRESCRIPTION DRUGS OR OTHER MEDICATIONS
24 THAT ARE INELIGIBLE FOR DISPENSING UNDER THE PROGRAM.

25 (4) PARTICIPATION IN THE PROGRAM BY AN ELIGIBLE FACILITY,
26 MANUFACTURER, PHARMACY, OR CHARITABLE CLINIC IS VOLUNTARY. NOTHING
27 IN THIS SECTION OR SECTION 17776 REQUIRES ANY ELIGIBLE FACILITY,

1 MANUFACTURER, PHARMACY, OR CHARITABLE CLINIC TO PARTICIPATE IN THE
2 PROGRAM.

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

7 (A) ONLY PRESCRIPTION DRUGS IN THEIR ORIGINAL SEALED, TAMPER-
8 EVIDENT, AND UNOPENED UNIT DOSE PACKAGING MAY BE ACCEPTED FOR
9 DISPENSING. HOWEVER, PRESCRIPTION DRUGS PACKAGED IN SINGLE-UNIT
10 DOSE PACKAGING MAY BE ACCEPTED FOR DISPENSING EVEN IF THE OUTSIDE
11 PACKAGING IS OPEN AS LONG AS THE SINGLE-UNIT DOSE PACKAGING IS
12 UNOPENED.

13 (B) THE FOLLOWING SHALL NOT BE ACCEPTED FOR DISPENSING:

14 (i) EXPIRED PRESCRIPTION DRUGS.

15 (ii) CONTROLLED SUBSTANCES AS DEFINED IN ARTICLE 7 OR BY
16 FEDERAL LAW.

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

20 (iv) DRUGS THAT CAN ONLY BE DISPENSED TO A PATIENT REGISTERED
21 WITH THE DRUG'S MANUFACTURER UNDER FEDERAL FOOD AND DRUG
22 ADMINISTRATION REQUIREMENTS.

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

26 (D) SUBJECT TO THE LIMITATIONS PRESCRIBED IN THIS SUBSECTION,
27 UNUSED OR DONATED PRESCRIPTION DRUGS DISPENSED FOR PURPOSES OF A

1 MEDICAL ASSISTANCE PROGRAM OR DRUG PRODUCT DONATION PROGRAM MAY BE
2 ACCEPTED FOR DISPENSING UNDER THE PROGRAM.

3 (E) ANY ADDITIONAL CRITERIA ESTABLISHED IN RULES PROMULGATED
4 UNDER THIS SECTION.

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

8 (A) DISPENSE PRESCRIPTION DRUGS ACCEPTED UNDER THE PROGRAM TO
9 ELIGIBLE PARTICIPANTS.

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

13 (7) A PHARMACY OR CHARITABLE CLINIC THAT PARTICIPATES IN THE
14 PROGRAM AND ACCEPTS PRESCRIPTION DRUGS FOR THE PROGRAM SHALL DO ALL
15 OF THE FOLLOWING:

16 (A) COMPLY WITH ALL APPLICABLE FEDERAL LAWS AND REGULATIONS
17 AND STATE LAWS AND RULES RELATED TO THE STORAGE AND DISTRIBUTION OF
18 HARMFUL DRUGS.

19 (B) INSPECT ALL ACCEPTED PRESCRIPTION DRUGS BEFORE DISPENSING
20 THE PRESCRIPTION DRUGS TO DETERMINE THAT THE DRUGS ARE NOT
21 ADULTERATED.

22 (C) DISPENSE PRESCRIPTION DRUGS ONLY PURSUANT TO A
23 PRESCRIPTION ISSUED BY A HEALTH PROFESSIONAL.

24 (8) A PHARMACY, HEALTH PROFESSIONAL, OR CHARITABLE CLINIC THAT
25 ACCEPTS PRESCRIPTION DRUGS UNDER THE PROGRAM SHALL NOT RESELL THE
26 PRESCRIPTION DRUGS. RECEIPT OF A FEE FROM AN ELIGIBLE PARTICIPANT,
27 IF ESTABLISHED IN RULES PROMULGATED UNDER THIS SECTION, OR

1 REIMBURSEMENT FROM A GOVERNMENTAL AGENCY TO A CHARITABLE CLINIC
2 DOES NOT CONSTITUTE RESALE OF PRESCRIPTION DRUGS UNDER THIS
3 SUBSECTION.

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

11 (A) THE BOARD.

12 (B) THE DEPARTMENT.

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

15 (D) A MANUFACTURER OR ITS REPRESENTATIVE THAT DIRECTLY DONATES
16 PRESCRIPTION DRUGS IN PROFESSIONAL SAMPLES TO A CHARITABLE CLINIC
17 UNDER THE PROGRAM.

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

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

23 (10) A MANUFACTURER IS NOT, IN THE ABSENCE OF BAD FAITH,
24 SUBJECT TO CRIMINAL PROSECUTION OR LIABILITY IN TORT OR OTHER CIVIL
25 ACTION FOR INJURY, DEATH, OR LOSS TO PERSON OR PROPERTY FOR MATTERS
26 RELATED TO THE DONATION, ACCEPTANCE, OR DISPENSING OF A
27 PRESCRIPTION DRUG MANUFACTURED BY THE MANUFACTURER THAT IS DONATED

1 BY ANY PERSON UNDER THE PROGRAM, INCLUDING, BUT NOT LIMITED TO,
2 LIABILITY FOR FAILURE TO TRANSFER OR COMMUNICATE PRODUCT OR
3 CONSUMER INFORMATION OR THE EXPIRATION DATE OF THE DONATED
4 PRESCRIPTION DRUG.

5 (11) SUBJECT TO SUBSECTION (12), THE DEPARTMENT, IN
6 CONSULTATION WITH THE BOARD, SHALL PROMULGATE RULES UNDER THE
7 ADMINISTRATIVE PROCEDURES ACT OF 1969 AND ESTABLISH PROCEDURES
8 NECESSARY TO ESTABLISH, IMPLEMENT, AND ADMINISTER THE PROGRAM. THE
9 BOARD SHALL PROVIDE TECHNICAL ASSISTANCE TO ELIGIBLE FACILITIES,
10 MANUFACTURERS, PHARMACIES, AND CHARITABLE CLINICS THAT PARTICIPATE
11 IN THE PROGRAM.

12 (12) THE DEPARTMENT, IN CONSULTATION WITH THE BOARD, SHALL
13 PROMULGATE EMERGENCY RULES UNDER THE ADMINISTRATIVE PROCEDURES ACT
14 OF 1969 ON OR BEFORE THE EXPIRATION OF 6 MONTHS AFTER THE EFFECTIVE
15 DATE OF THIS SECTION TO ESTABLISH, IMPLEMENT, AND ADMINISTER THE
16 PROGRAM. THE DEPARTMENT, IN CONSULTATION WITH THE BOARD, SHALL
17 PROMULGATE PERMANENT RULES PURSUANT TO THE ADMINISTRATIVE
18 PROCEDURES ACT OF 1969 AS SOON AS PRACTICAL AFTER EMERGENCY RULES
19 HAVE BEEN PROMULGATED UNDER THIS SUBSECTION. THE DEPARTMENT AND THE
20 BOARD SHALL INCLUDE ALL OF THE FOLLOWING IN RULES PROMULGATED UNDER
21 THIS SECTION:

22 (A) ELIGIBILITY CRITERIA FOR PHARMACIES AND CHARITABLE CLINICS
23 AUTHORIZED TO ACCEPT AND DISPENSE PRESCRIPTION DRUGS FOR THE
24 PROGRAM.

25 (B) ELIGIBILITY CRITERIA FOR ELIGIBLE PARTICIPANTS.

26 (C) ESTABLISHMENT OF A LIST OF PRESCRIPTION DRUGS THAT ARE NOT
27 ELIGIBLE FOR ACCEPTANCE AND DISPENSING UNDER THE PROGRAM.

1 (D) STANDARDS AND PROCEDURES FOR TRANSFER, TRANSPORTATION,
2 ACCEPTANCE, SAFE STORAGE, SECURITY, AND DISPENSING OF PRESCRIPTION
3 DRUGS.

4 (E) A PROCESS FOR SEEKING INPUT FROM THE DEPARTMENT OF HUMAN
5 SERVICES AND THE DEPARTMENT OF COMMUNITY HEALTH IN ESTABLISHING
6 PROVISIONS THAT AFFECT ELIGIBLE FACILITIES.

7 (F) A PROCESS FOR SEEKING INPUT FROM THE DEPARTMENT OF HUMAN
8 SERVICES AND THE DEPARTMENT OF COMMUNITY HEALTH IN ESTABLISHING
9 PROVISIONS THAT AFFECT MENTAL HEALTH AND SUBSTANCE ABUSE CLIENTS.

10 (G) STANDARDS AND PROCEDURES FOR INSPECTING ACCEPTED
11 PRESCRIPTION DRUGS TO ENSURE THAT THE PRESCRIPTION DRUGS MEET THE
12 REQUIREMENTS OF THE PROGRAM AND TO ENSURE THAT, IN THE PROFESSIONAL
13 JUDGMENT OF THE PHARMACIST, THE PRESCRIPTION DRUGS MEET ALL FEDERAL
14 AND STATE STANDARDS FOR PRODUCT INTEGRITY.

15 (H) PROCEDURES FOR THE DESTRUCTION AND ENVIRONMENTALLY SOUND
16 DISPOSAL OF PRESCRIPTION DRUGS OR OTHER MEDICATIONS THAT ARE
17 ACCEPTED AND THAT ARE INELIGIBLE FOR DISPENSING UNDER THE PROGRAM.

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

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

24 (K) ESTABLISHMENT OF STANDARDS FOR THE ACCEPTANCE BY A
25 PHARMACY, HEALTH PROFESSIONAL, OR CHARITABLE CLINIC THAT
26 PARTICIPATES IN THE PROGRAM FROM ANY PERSON OF A PRESCRIPTION DRUG
27 OR ANY OTHER MEDICATION THAT IS INELIGIBLE FOR DISPENSING UNDER THE

1 PROGRAM FOR DESTRUCTION AND DISPOSAL.

2 (I) ANY OTHER STANDARDS AND PROCEDURES THE DEPARTMENT, IN
3 CONSULTATION WITH THE BOARD, CONSIDERS APPROPRIATE OR NECESSARY TO
4 ESTABLISH, IMPLEMENT, AND ADMINISTER THE PROGRAM.

5 (13) PURSUANT TO THE RULES PROMULGATED AND STANDARDS AND
6 PROCEDURES ESTABLISHED FOR THE PROGRAM UNDER THIS SECTION, A
7 RESIDENT OF AN ELIGIBLE FACILITY OR THE REPRESENTATIVE OR GUARDIAN
8 OF A RESIDENT OF AN ELIGIBLE FACILITY MAY DONATE UNUSED
9 PRESCRIPTION DRUGS FOR DISPENSING TO ELIGIBLE PARTICIPANTS UNDER
10 THE PROGRAM.

11 (14) PURSUANT TO RULES PROMULGATED AND STANDARDS AND
12 PROCEDURES ESTABLISHED FOR THE PROGRAM UNDER THIS SECTION, A PERSON
13 MAY DELIVER TO A PHARMACY, HEALTH PROFESSIONAL, OR CHARITABLE
14 CLINIC THAT PARTICIPATES IN THE PROGRAM A PRESCRIPTION DRUG OR ANY
15 OTHER MEDICATION THAT IS INELIGIBLE FOR DISPENSING UNDER THE
16 PROGRAM FOR DESTRUCTION AND DISPOSAL.

17 (15) THIS SECTION AND SECTION 17776 DO NOT IMPAIR OR SUPERSEDE
18 THE PROVISIONS REGARDING THE CANCER DRUG REPOSITORY PROGRAM
19 ESTABLISHED IN SECTION 17780. IF ANY PROVISION OF THIS SECTION OR
20 SECTION 17776 CONFLICTS WITH A PROVISION OF SECTION 17780 WITH
21 REGARD TO A CANCER DRUG, SECTION 17780 CONTROLS.

22 Enacting section 1. This amendatory act does not take effect
23 unless House Bill No. 5090 of the 96th Legislature is enacted into
24 law.