## 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 (1) 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.