

HOUSE SUBSTITUTE FOR
SENATE BILL NO. 373

A bill to amend 1978 PA 368, entitled
"Public health code,"
(MCL 333.1101 to 333.25211) by adding section 17723.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1 SEC. 17723. (1) SUBJECT TO THIS SECTION, THE BOARD MAY APPROVE
2 A PILOT PROJECT THAT IS DESIGNED TO UTILIZE NEW OR EXPANDED
3 TECHNOLOGY OR PROCESSES AND TO PROVIDE PATIENTS WITH BETTER
4 PHARMACY PRODUCTS OR PROVIDE PHARMACY SERVICES IN A MORE EFFICIENT
5 MANNER. THE BOARD SHALL ENSURE THAT A PILOT PROJECT IT APPROVES
6 UNDER THIS SECTION IS FOCUSED ON MAINTAINING OR IMPROVING PATIENT
7 CARE IN THE DELIVERY OF PHARMACY SERVICES AND IMPROVING PATIENT
8 OUTCOMES. THE DEPARTMENT MAY CHARGE PETITIONERS A FILING FEE
9 SUFFICIENT TO COVER THE DEPARTMENT'S COSTS INCURRED WHILE

1 ADMINISTERING AND MONITORING THE PILOT PROJECT UNDER THIS SECTION.

2 (2) THE DEPARTMENT SHALL DO ALL OF THE FOLLOWING:

3 (A) ESTABLISH AND ADMINISTER A PROCESS TO RECEIVE, REVIEW, AND
4 ACCEPT OR DENY PETITIONS FOR PROPOSED PILOT PROJECTS.

5 (B) ESTABLISH TIME FRAMES FOR THE RECEIPT, REVIEW, AND
6 APPROVAL OR DENIAL OF PETITIONS FOR PROPOSED PILOT PROJECTS.

7 (C) DESIGNATE THE INDIVIDUALS WHO WILL REVIEW AND EVALUATE
8 PETITIONS FOR PROPOSED PILOT PROJECTS.

9 (3) THE BOARD SHALL NOT APPROVE MORE THAN 10 PILOT PROJECTS
10 UNDER THIS SECTION. IF IT DETERMINES NECESSARY, THE BOARD OR
11 DEPARTMENT MAY FURTHER LIMIT THE NUMBER OF APPROVED PILOT PROJECTS
12 BASED ON THE SCOPE AND TYPE OF PETITIONS FOR PROPOSED PILOT
13 PROJECTS RECEIVED.

14 (4) THE BOARD SHALL NOT APPROVE A PILOT PROJECT THAT DOES ANY
15 OF THE FOLLOWING:

16 (A) EXPANDS THE DEFINITION OF THE PRACTICE OF PHARMACY.

17 (B) PROVIDES FOR THE THERAPEUTIC SUBSTITUTION OR SUBSTITUTION
18 OF MEDICAL DEVICES USED IN PATIENT CARE.

19 (C) ALLOWS A PHARMACY OR PHARMACIST TO BE INVOLVED WITH A
20 PILOT PROJECT IF THE PHARMACY'S OR PHARMACIST'S LICENSE IS NOT
21 CURRENT OR IS UNDER INVESTIGATION FOR OR SUBJECT TO A SANCTION FOR
22 A VIOLATION OF THIS ACT.

23 (5) THE DEPARTMENT, IN CONSULTATION WITH THE BOARD, MAY GRANT
24 TO A PETITIONER CONDUCTING AN APPROVED PILOT PROJECT UNDER THIS
25 SECTION AN EXCEPTION TO A RULE PROMULGATED UNDER THIS PART. THE
26 DEPARTMENT SHALL NOT GRANT AN EXCEPTION UNDER THIS SUBSECTION FROM
27 ANY LAW RELATING TO THE PRACTICE OF PHARMACY. THE DEPARTMENT SHALL

1 GRANT AN EXCEPTION UNDER THIS SUBSECTION FOR A SPECIFIED PERIOD OF
2 TIME, WHICH PERIOD MUST NOT EXCEED 18 MONTHS UNLESS EXTENDED UNDER
3 SUBSECTION (12).

4 (6) A PETITIONER WHO WISHES THE BOARD TO CONSIDER A PILOT
5 PROJECT FOR APPROVAL UNDER THIS SECTION SHALL SUBMIT TO THE
6 DEPARTMENT A PETITION THAT CONTAINS ALL OF THE FOLLOWING
7 INFORMATION:

8 (A) THE NAME, ADDRESS, TELEPHONE NUMBER, ELECTRONIC MAIL
9 ADDRESS, AND MICHIGAN LICENSE NUMBER OF THE PHARMACIST RESPONSIBLE
10 FOR OVERSEEING THE PROPOSED PILOT PROJECT.

11 (B) THE SPECIFIC LOCATION WHERE THE PROPOSED PILOT PROJECT
12 WILL BE CONDUCTED. THE PETITIONER SHALL INCLUDE THE MICHIGAN
13 LICENSE NUMBER OF THE PHARMACY AND A STATEMENT THAT THE MICHIGAN
14 LICENSE OF THE PHARMACY AND ANY PHARMACIST INVOLVED WITH THE PILOT
15 PROJECT IS CURRENT, IS NOT UNDER INVESTIGATION FOR OR SUBJECT TO A
16 SANCTION FOR A VIOLATION OF THIS ACT, AND WILL REMAIN IN GOOD
17 STANDING FOR THE DURATION OF THE PILOT PROJECT.

18 (C) A DETAILED SUMMARY OF THE PROPOSED PILOT PROJECT THAT
19 INCLUDES ALL OF THE FOLLOWING:

20 (i) THE GOALS, HYPOTHESIS, AND OBJECTIVES, AS APPLICABLE, OF
21 THE PROPOSED PILOT PROJECT.

22 (ii) A FULL EXPLANATION OF THE PROPOSED PILOT PROJECT AND HOW
23 THE PROJECT WILL BE CONDUCTED.

24 (iii) THE INITIAL TIME FRAME FOR THE PILOT PROJECT, INCLUDING
25 THE PROPOSED START DATE AND LENGTH OF THE PROJECT, WHICH INITIAL
26 TIME FRAME MUST NOT EXCEED 18 MONTHS.

27 (iv) ALL BACKGROUND INFORMATION AND LITERATURE REVIEW, AS

1 APPLICABLE, TO SUPPORT THE PROPOSED PILOT PROJECT.

2 (v) IF APPLICABLE, IDENTIFICATION OF THE RULES PROMULGATED
3 UNDER THIS PART FROM WHICH THE PETITIONER IS REQUESTING AN
4 EXCEPTION AS PROVIDED IN SUBSECTION (5) IN ORDER TO COMPLETE THE
5 PROPOSED PILOT PROJECT AND A REQUEST FOR THAT EXCEPTION.

6 (vi) IF APPLICABLE, PROCEDURES THE PETITIONER WILL USE DURING
7 THE PROPOSED PILOT PROJECT TO ENSURE THAT THE PUBLIC'S HEALTH AND
8 SAFETY ARE NOT COMPROMISED AS A RESULT OF AN EXCEPTION TO A RULE
9 BEING GRANTED UNDER SUBSECTION (5).

10 (vii) THE PROCEDURES THE PETITIONER WILL USE TO PROTECT THE
11 IDENTITY AND PRIVACY OF PATIENTS IN ACCORDANCE WITH EXISTING
12 FEDERAL AND STATE LAW AND CONSISTENT WITH REGULATIONS PROMULGATED
13 UNDER THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF
14 1996, PUBLIC LAW 104-191.

15 (7) UPON APPROVAL OF A PETITION FOR A PILOT PROJECT, THE
16 DEPARTMENT SHALL SPECIFY A TIME PERIOD FOR THE OPERATION OF THAT
17 PILOT PROJECT, WHICH PERIOD MUST NOT EXCEED 18 MONTHS UNLESS
18 EXTENDED UNDER SUBSECTION (11). THE DEPARTMENT, IN CONSULTATION
19 WITH THE BOARD, MAY INCLUDE APPROPRIATE CONDITIONS OR
20 QUALIFICATIONS ON THE APPROVAL OF A PILOT PROJECT. THE DEPARTMENT
21 OR BOARD MAY SUSPEND THE OPERATION OF A PILOT PROJECT IF IT
22 DETERMINES THAT THE PETITIONER OR ANY PERSON INVOLVED WITH THE
23 PILOT PROJECT HAS DEVIATED THE OPERATION OF THE PILOT PROJECT FROM
24 THE PLAN OF OPERATION THAT WAS APPROVED.

25 (8) IF DETERMINED APPROPRIATE FOR THE PILOT PROJECT APPROVED
26 UNDER THIS SECTION, THE BOARD OR DEPARTMENT MAY REQUIRE THE
27 PETITIONER TO NOTIFY PATIENTS THAT PHARMACY SERVICES ARE BEING

1 PROVIDED AS PART OF A PILOT PROJECT. IF REQUIRED UNDER THIS
2 SUBSECTION, THE PETITIONER SHALL NOTIFY PATIENTS IN THE MANNER
3 REQUIRED BY THE BOARD OR DEPARTMENT.

4 (9) THE PETITIONER SHALL ALLOW THE DEPARTMENT TO INSPECT AND
5 REVIEW PILOT PROJECT DOCUMENTATION AND THE PILOT PROJECT SITE AT
6 ANY TIME DURING THE REVIEW PROCESS AND AFTER THE PILOT PROJECT IS
7 APPROVED. THE PHARMACIST RESPONSIBLE FOR OVERSEEING AN APPROVED
8 PILOT PROJECT SHALL FORWARD ALL OF THE FOLLOWING TO THE DEPARTMENT:

9 (A) PROGRESS REPORTS AT INTERVALS SPECIFIED BY THE DEPARTMENT.

10 (B) A SUMMARY OF THE RESULTS OF THE PROJECT AND CONCLUSIONS
11 DRAWN FROM THE RESULTS OF THE PROJECT WITHIN 3 MONTHS AFTER
12 COMPLETION OF THE PILOT PROJECT.

13 (10) THE INDIVIDUALS DESIGNATED TO REVIEW AND EVALUATE
14 PETITIONS UNDER SUBSECTION (2) (C) SHALL REVIEW THE PROGRESS REPORTS
15 AND THE SUMMARY OF THE RESULTS OF THE PILOT PROJECT SUBMITTED UNDER
16 SUBSECTION (9). WITHIN 90 DAYS AFTER RECEIPT OF THE SUMMARY OF THE
17 RESULTS OF THE PILOT PROJECT UNDER SUBSECTION (9), THE INDIVIDUALS
18 DESIGNATED TO REVIEW AND EVALUATE PETITIONS UNDER SUBSECTION (2) (C)
19 SHALL SUBMIT A WRITTEN REPORT TO THE DEPARTMENT REGARDING THE
20 RESULTS OF THE PILOT PROJECT. THE DEPARTMENT SHALL PROVIDE A COPY
21 OF THE WRITTEN REPORT SUBMITTED UNDER THIS SUBSECTION TO THE BOARD.
22 THE INDIVIDUALS DESIGNATED TO REVIEW AND EVALUATE PETITIONS UNDER
23 SUBSECTION (2) (C) SHALL SUBMIT A COPY OF THE WRITTEN REPORT TO THE
24 PETITIONER AT LEAST 2 WEEKS BEFORE THE BOARD MEETING AT WHICH THE
25 REPORT WILL BE CONSIDERED BY THE BOARD. UPON THE REQUEST OF THE
26 PETITIONER, THE BOARD SHALL ALLOW THE PETITIONER TO MAKE A
27 PRESENTATION TO THE BOARD.

1 (11) IF DETERMINED APPROPRIATE BY THE BOARD AT THE MEETING AT
2 WHICH THE WRITTEN REPORT IS CONSIDERED UNDER SUBSECTION (10), AND
3 IF APPROVED BY THE DEPARTMENT, THE SPECIFIED PERIOD OF TIME FOR
4 CONDUCTING A PILOT PROJECT UNDER SUBSECTION (7) MAY BE EXTENDED FOR
5 AN ADDITIONAL PERIOD OF UP TO 18 MONTHS. THE BOARD OR DEPARTMENT
6 SHALL NOT GRANT AN EXTENSION THAT WOULD RESULT IN A SPECIFIED
7 PERIOD OF TIME FOR CONDUCTING A PILOT PROJECT UNDER THIS SECTION TO
8 EXCEED 36 MONTHS.

9 (12) IF THE DEPARTMENT, IN CONSULTATION WITH THE BOARD,
10 DETERMINES THAT A PILOT PROJECT FOR WHICH AN EXCEPTION TO A RULE
11 HAS BEEN GRANTED UNDER SUBSECTION (5) SHOULD BE EXTENDED SO THAT
12 RULES MAY BE PROMULGATED IN ORDER TO ALLOW THE PILOT PROJECT TO BE
13 CONDUCTED ON A PERMANENT BASIS, THE DEPARTMENT MAY EXTEND THE
14 EXCEPTION TO THE RULE FOR AN ADDITIONAL PERIOD OF UP TO 18 MONTHS.

15 Enacting section 1. This amendatory act takes effect 90 days
16 after the date it is enacted into law.