

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 DEPARTMENT MAY
2 APPROVE 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 DEPARTMENT MAY CHARGE PETITIONERS A FILING FEE
6 SUFFICIENT TO COVER THE DEPARTMENT'S COSTS INCURRED WHILE
7 ADMINISTERING AND MONITORING THE PILOT PROJECT UNDER THIS SECTION.
8 (2) THE DEPARTMENT, IN CONSULTATION WITH THE BOARD, SHALL DO
9 ALL OF THE FOLLOWING:

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

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

5 (C) DESIGNATE THE INDIVIDUALS WHO WILL REVIEW PETITIONS FOR
6 PROPOSED PILOT PROJECTS.

7 (3) THE DEPARTMENT SHALL NOT APPROVE MORE THAN 25 PILOT
8 PROJECTS UNDER THIS SECTION. IF IT DETERMINES NECESSARY, THE
9 DEPARTMENT MAY FURTHER LIMIT THE NUMBER OF APPROVED PILOT PROJECTS
10 BASED ON THE SCOPE AND TYPE OF PETITIONS FOR PROPOSED PILOT
11 PROJECTS RECEIVED.

12 (4) THE DEPARTMENT SHALL NOT APPROVE A PILOT PROJECT THAT DOES
13 ANY OF THE FOLLOWING:

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

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

17 (5) THE DEPARTMENT, IN CONSULTATION WITH THE BOARD, MAY GRANT
18 TO A PETITIONER CONDUCTING AN APPROVED PILOT PROJECT UNDER THIS
19 SECTION AN EXCEPTION TO A RULE PROMULGATED UNDER THIS PART. THE
20 DEPARTMENT SHALL NOT GRANT AN EXCEPTION UNDER THIS SUBSECTION FROM
21 ANY LAW RELATING TO THE PRACTICE OF PHARMACY. THE DEPARTMENT SHALL
22 GRANT AN EXCEPTION UNDER THIS SUBSECTION FOR A SPECIFIED PERIOD OF
23 TIME, WHICH PERIOD MUST NOT EXCEED 18 MONTHS UNLESS EXTENDED UNDER
24 SUBSECTION (11).

25 (6) A PETITIONER WHO WISHES THE DEPARTMENT TO CONSIDER A PILOT
26 PROJECT FOR APPROVAL UNDER THIS SECTION SHALL SUBMIT TO THE
27 DEPARTMENT A PETITION THAT CONTAINS ALL OF THE FOLLOWING

1 INFORMATION:

2 (A) THE NAME, ADDRESS, TELEPHONE NUMBER, ELECTRONIC MAIL
3 ADDRESS, AND MICHIGAN LICENSE NUMBER OF THE PHARMACIST RESPONSIBLE
4 FOR OVERSEEING THE PROPOSED PILOT PROJECT.

5 (B) THE SPECIFIC LOCATION WHERE THE PROPOSED PILOT PROJECT
6 WILL BE CONDUCTED. THE PETITIONER SHALL INCLUDE THE MICHIGAN
7 LICENSE NUMBER OF THE PHARMACY AND A STATEMENT THAT THE MICHIGAN
8 LICENSE OF THE PHARMACY AND ANY PHARMACIST INVOLVED WITH THE PILOT
9 PROJECT IS CURRENT AND WILL REMAIN IN GOOD STANDING FOR THE
10 DURATION OF THE PILOT PROJECT.

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

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

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

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

20 (iv) ALL BACKGROUND INFORMATION AND LITERATURE REVIEW, AS
21 APPLICABLE, TO SUPPORT THE PROPOSED PILOT PROJECT.

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

26 (vi) IF APPLICABLE, PROCEDURES THE PETITIONER WILL USE DURING
27 THE PROPOSED PILOT PROJECT TO ENSURE THAT THE PUBLIC'S HEALTH AND

1 SAFETY ARE NOT COMPROMISED AS A RESULT OF AN EXCEPTION TO A RULE
2 BEING GRANTED UNDER SUBSECTION (5) .

3 (vii) THE PROCEDURES THE PETITIONER WILL USE TO PROTECT THE
4 IDENTITY AND PRIVACY OF PATIENTS IN ACCORDANCE WITH EXISTING
5 FEDERAL AND STATE LAW AND CONSISTENT WITH REGULATIONS PROMULGATED
6 UNDER THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF
7 1996, PUBLIC LAW 104-191.

8 (7) UPON APPROVAL OF A PETITION FOR A PILOT PROJECT, THE
9 DEPARTMENT SHALL SPECIFY A TIME PERIOD FOR THE OPERATION OF THAT
10 PILOT PROJECT, WHICH PERIOD MUST NOT EXCEED 18 MONTHS UNLESS
11 EXTENDED UNDER SUBSECTION (10) . THE DEPARTMENT, IN CONSULTATION
12 WITH THE BOARD, MAY INCLUDE APPROPRIATE CONDITIONS OR
13 QUALIFICATIONS ON ITS APPROVAL OF A PILOT PROJECT.

14 (8) THE PETITIONER SHALL ALLOW THE DEPARTMENT TO INSPECT AND
15 REVIEW PILOT PROJECT DOCUMENTATION AND THE PILOT PROJECT SITE AT
16 ANY TIME DURING THE REVIEW PROCESS AND AFTER THE PILOT PROJECT IS
17 APPROVED. THE PHARMACIST RESPONSIBLE FOR OVERSEEING AN APPROVED
18 PILOT PROJECT SHALL FORWARD ALL OF THE FOLLOWING TO THE DEPARTMENT:

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

20 (B) A SUMMARY OF THE RESULTS OF THE PROJECT AND CONCLUSIONS
21 DRAWN FROM THE RESULTS OF THE PROJECT WITHIN 3 MONTHS AFTER
22 COMPLETION OF THE PILOT PROJECT.

23 (9) THE INDIVIDUALS DESIGNATED TO REVIEW PETITIONS UNDER
24 SUBSECTION (2) (C) SHALL REVIEW THE PROGRESS REPORTS AND THE SUMMARY
25 OF THE RESULTS OF THE PILOT PROJECT SUBMITTED UNDER SUBSECTION (8) .
26 WITHIN 90 DAYS AFTER RECEIPT OF THE SUMMARY OF THE RESULTS OF THE
27 PILOT PROJECT UNDER SUBSECTION (8) , THE INDIVIDUALS DESIGNATED TO

1 REVIEW PETITIONS UNDER SUBSECTION (2) (C) SHALL SUBMIT A WRITTEN
2 REPORT TO THE DEPARTMENT REGARDING THE RESULTS OF THE PILOT
3 PROJECT. THE DEPARTMENT SHALL PROVIDE A COPY OF THE WRITTEN REPORT
4 SUBMITTED UNDER THIS SUBSECTION TO THE BOARD. THE INDIVIDUALS
5 DESIGNATED TO REVIEW PETITIONS UNDER SUBSECTION (2) (C) SHALL SUBMIT
6 A COPY OF THE WRITTEN REPORT TO THE PETITIONER AT LEAST 2 WEEKS
7 BEFORE THE BOARD MEETING AT WHICH THE REPORT WILL BE CONSIDERED BY
8 THE BOARD. THE BOARD SHALL ALLOW THE PETITIONER TO MAKE A
9 PRESENTATION TO THE BOARD UPON REQUEST OF THE BOARD.

10 (10) IF DETERMINED APPROPRIATE BY THE BOARD AT THE MEETING AT
11 WHICH THE WRITTEN REPORT IS CONSIDERED UNDER SUBSECTION (9), AND IF
12 APPROVED BY THE DEPARTMENT, THE SPECIFIED PERIOD OF TIME FOR
13 CONDUCTING A PILOT PROJECT UNDER SUBSECTION (7) MAY BE EXTENDED FOR
14 AN ADDITIONAL PERIOD OF UP TO 18 MONTHS. THE DEPARTMENT, IN
15 CONSULTATION WITH THE BOARD, SHALL NOT GRANT AN EXTENSION THAT
16 WOULD RESULT IN A SPECIFIED PERIOD OF TIME FOR CONDUCTING A PILOT
17 PROJECT UNDER THIS SECTION THAT EXCEEDS 36 MONTHS.

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

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