

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.

6 (2) THE DEPARTMENT, IN CONSULTATION WITH THE BOARD, SHALL DO
7 ALL OF THE FOLLOWING:

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

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

3 (C) DESIGNATE THE INDIVIDUALS WHO WILL REVIEW PETITIONS FOR
4 PROPOSED PILOT PROJECTS.

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

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

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

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

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

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

27 (A) THE NAME, ADDRESS, TELEPHONE NUMBER, ELECTRONIC MAIL

1 ADDRESS, AND MICHIGAN LICENSE NUMBER OF THE PHARMACIST RESPONSIBLE
2 FOR OVERSEEING THE PROPOSED PILOT PROJECT.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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