

SENATE BILL No. 373

May 21, 2013, Introduced by Senator HANSEN and referred to the Committee on Health Policy.

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) BEGINNING 90 DAYS AFTER THE EFFECTIVE DATE OF
2 THIS SECTION, THE BOARD, IN CONSULTATION WITH THE DEPARTMENT, SHALL
3 ESTABLISH AND ADMINISTER A PROCESS BY WHICH THE BOARD MAY APPROVE
4 PILOT PROJECTS AS PROVIDED IN THIS SECTION. THE BOARD SHALL NOT
5 APPROVE MORE THAN 25 PILOT PROJECTS UNDER THIS SECTION. THE BOARD
6 SHALL NOT APPROVE MORE THAN 1 PILOT PROJECT TO A PERSON THAT
7 PETITIONS FOR A PILOT PROJECT UNDER THIS SECTION.

8 (2) THE BOARD SHALL ONLY APPROVE A PILOT PROJECT THAT IS
9 DESIGNED TO UTILIZE NEW OR EXPANDED TECHNOLOGY OR PROCESSES AND TO
10 PROVIDE PATIENTS WITH BETTER PHARMACY PRODUCTS OR PROVIDE PHARMACY
11 SERVICES IN A MORE EFFICIENT MANNER. THE BOARD SHALL NOT APPROVE A

1 PILOT PROJECT UNDER THIS SECTION THAT DOES ANY OF THE FOLLOWING:

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

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

5 (C) PROVIDES TO THE PERSON PETITIONING FOR A PILOT PROJECT A
6 COMPETITIVE EDGE OVER ANY OTHER PERSON ENGAGED IN THE PRACTICE OF
7 PHARMACY.

8 (3) THE BOARD MAY GRANT TO A PERSON CONDUCTING AN APPROVED
9 PILOT PROJECT UNDER THIS SECTION AN EXCEPTION TO A RULE PROMULGATED
10 BY THE BOARD UNDER THIS PART. THE BOARD SHALL NOT GRANT AN
11 EXCEPTION UNDER THIS SUBSECTION FROM ANY LAW RELATING TO THE
12 PRACTICE OF PHARMACY. AN EXCEPTION TO A RULE PROMULGATED UNDER THIS
13 PART GRANTED UNDER THIS SUBSECTION MUST BE FOR A SPECIFIED PERIOD
14 OF TIME, WHICH PERIOD MUST NOT EXCEED 18 MONTHS UNLESS EXTENDED
15 UNDER SUBSECTION (9).

16 (4) A PERSON WHO WISHES THE BOARD TO CONSIDER A PILOT PROJECT
17 FOR APPROVAL UNDER THIS SECTION SHALL SUBMIT TO THE DEPARTMENT A
18 PETITION THAT CONTAINS ALL OF THE FOLLOWING INFORMATION:

19 (A) THE NAME, ADDRESS, TELEPHONE NUMBER, ELECTRONIC MAIL
20 ADDRESS, AND PHARMACIST'S LICENSE NUMBER OF THE PHARMACIST
21 RESPONSIBLE FOR OVERSEEING THE PROPOSED PILOT PROJECT.

22 (B) THE SPECIFIC LOCATION AND, IF A PHARMACY, THE PHARMACY
23 LICENSE NUMBER WHERE THE PROPOSED PILOT PROJECT WILL BE CONDUCTED.

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

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

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

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

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

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

12 (vi) IF APPLICABLE, PROCEDURES THE PETITIONER WILL USE DURING
13 THE PROPOSED PILOT PROJECT TO ENSURE THAT THE PUBLIC'S HEALTH AND
14 SAFETY ARE NOT COMPROMISED AS A RESULT OF THE BOARD'S GRANTING AN
15 EXCEPTION TO A RULE AS PROVIDED IN SUBSECTION (3).

16 (5) UPON RECEIPT OF A PETITION FOR APPROVAL OF A PILOT
17 PROJECT, THE DEPARTMENT SHALL INITIALLY REVIEW THE PETITION FOR
18 COMPLETENESS AND APPROPRIATENESS. IF THE PETITION IS INCOMPLETE OR
19 INAPPROPRIATE FOR CONSIDERATION FOR ANY REASON, INCLUDING VIOLATION
20 OF LAW, THE DEPARTMENT SHALL RETURN THE PETITION WITH A LETTER OF
21 EXPLANATION. THE DEPARTMENT SHALL PERFORM THE REVIEW UNDER THIS
22 SUBSECTION WITHIN 30 BUSINESS DAYS AFTER RECEIPT OF THE PETITION.

23 (6) UPON DETERMINATION UNDER SUBSECTION (5) THAT A PETITION IS
24 COMPLETE AND APPROPRIATE, THE DEPARTMENT SHALL CREATE A REVIEW
25 COMMITTEE THAT CONSISTS OF APPROPRIATE DEPARTMENT STAFF, 1 OR MORE
26 MEMBERS OF THE BOARD, AND, IF CONSIDERED NECESSARY BY THE
27 DEPARTMENT OR THE BOARD, OTHER RESOURCE PERSONNEL. THE REVIEW

1 COMMITTEE SHALL REVIEW THE PETITION AND SUBMIT A WRITTEN
2 RECOMMENDATION TO THE BOARD REGARDING APPROVAL OR DENIAL OF THE
3 PROPOSED PILOT PROJECT. THE REVIEW COMMITTEE SHALL SUBMIT A COPY OF
4 ITS WRITTEN RECOMMENDATION TO THE PETITIONER AT LEAST 2 WEEKS
5 BEFORE THE BOARD MEETING AT WHICH THE RECOMMENDATION WILL BE
6 CONSIDERED BY THE BOARD. THE BOARD SHALL ALLOW THE PETITIONER AND A
7 REPRESENTATIVE OF THE REVIEW COMMITTEE EQUAL TIME FOR PRESENTATIONS
8 TO THE BOARD IF REQUESTED BY THE REVIEW COMMITTEE OR BOARD. UPON
9 HEARING THE PRESENTATIONS, IF APPLICABLE, THE BOARD SHALL APPROVE
10 OR DENY THE PETITION. IF THE BOARD APPROVES THE PETITION, THE
11 APPROVAL SHALL BE SPECIFIC FOR THAT PILOT PROJECT AND FOR A
12 SPECIFIED PERIOD OF TIME, WHICH PERIOD MUST NOT EXCEED 18 MONTHS
13 UNLESS EXTENDED UNDER SUBSECTION (9). THE BOARD MAY INCLUDE
14 CONDITIONS OR QUALIFICATIONS ON ITS APPROVAL OF A PILOT PROJECT IF
15 CONSIDERED APPROPRIATE BY THE BOARD.

16 (7) THE PETITIONER SHALL ALLOW THE DEPARTMENT OR THE BOARD TO
17 INSPECT AND REVIEW PILOT PROJECT DOCUMENTATION AND THE PILOT
18 PROJECT SITE AT ANY TIME DURING THE REVIEW PROCESS AND AFTER THE
19 PILOT PROJECT IS APPROVED. THE PHARMACIST RESPONSIBLE FOR
20 OVERSEEING AN APPROVED PILOT PROJECT SHALL FORWARD TO THE BOARD
21 PROGRESS REPORTS AT INTERVALS SPECIFIED BY THE BOARD IN ADDITION TO
22 A SUMMARY OF THE RESULTS OF THE PROJECT AND CONCLUSIONS DRAWN FROM
23 THE RESULTS OF THE PROJECT WITHIN 3 MONTHS AFTER COMPLETION OF THE
24 PILOT PROJECT.

25 (8) THE REVIEW COMMITTEE FOR THE PILOT PROJECT UNDER
26 SUBSECTION (6) OR SIMILAR REVIEW COMMITTEE CREATED BY THE BOARD
27 SHALL REVIEW THE SUMMARY OF THE RESULTS OF THE PILOT PROJECT

1 SUBMITTED UNDER SUBSECTION (7) AND SHALL SUBMIT A WRITTEN REPORT TO
2 THE BOARD REGARDING THE RESULTS OF THE PILOT PROJECT. THE REVIEW
3 COMMITTEE SHALL SUBMIT A COPY OF ITS WRITTEN REPORT TO THE
4 PETITIONER AT LEAST 2 WEEKS BEFORE THE BOARD MEETING AT WHICH THE
5 REPORT WILL BE CONSIDERED BY THE BOARD. THE BOARD SHALL ALLOW THE
6 PETITIONER AND A REPRESENTATIVE OF THE REVIEW COMMITTEE EQUAL TIME
7 FOR PRESENTATIONS TO THE BOARD IF REQUESTED BY THE REVIEW COMMITTEE
8 OR BOARD.

9 (9) IF DETERMINED APPROPRIATE, THE BOARD MAY EXTEND THE
10 SPECIFIED PERIOD OF TIME FOR THE CONDUCT OF A PILOT PROJECT UNDER
11 SUBSECTION (6) FOR AN ADDITIONAL PERIOD OF 18 MONTHS. THE BOARD
12 SHALL NOT GRANT AN EXTENSION THAT WOULD RESULT IN A SPECIFIED
13 PERIOD OF TIME FOR THE CONDUCT OF A PILOT PROJECT UNDER THIS
14 SECTION THAT EXCEEDS 36 MONTHS. IF THE BOARD DETERMINES THAT A
15 PILOT PROJECT FOR WHICH AN EXCEPTION TO A RULE HAS BEEN GRANTED
16 UNDER SUBSECTION (3) SHOULD BE EXTENDED SO THAT RULES MAY BE
17 PROMULGATED IN ORDER TO ALLOW THE PILOT PROJECT TO BE CONDUCTED ON
18 A PERMANENT BASIS, THE BOARD MAY EXTEND THE EXCEPTION TO THE RULE
19 FOR AN ADDITIONAL PERIOD OF 18 MONTHS. THE BOARD AND THE DEPARTMENT
20 MAY UTILIZE THE REVIEW COMMITTEE PROCESS UNDER SUBSECTION (6) FOR
21 THE PURPOSE OF AUTHORIZING EXTENSIONS UNDER THIS SUBSECTION.