

HOUSE BILL 283

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2lr1556
CF SB 274

By: **Chair, Health and Government Operations Committee and Delegate Elliott**

Introduced and read first time: January 27, 2012

Assigned to: Health and Government Operations

Committee Report: Favorable with amendments

House action: Adopted

Read second time: February 23, 2012

CHAPTER _____

1 AN ACT concerning

2 **State Board of Pharmacy – Sunset Extension and Revisions**

3 FOR the purpose of continuing the State Board of Pharmacy in accordance with the
4 provisions of the Maryland Program Evaluation Act (sunset law) by extending
5 to a certain date the termination provisions relating to the statutory and
6 regulatory authority of the Board; providing that staff of the Board hired after a
7 certain date are in the executive service or management service or are a special
8 appointment in the State Personnel Management System; requiring the Board,
9 in consultation with the Secretary of Health and Mental Hygiene, to determine
10 appropriate job classifications and grades for the staff of the Board; altering the
11 dates on which a pharmacy permit and a wholesale distributor permit expires;
12 altering the date by which the Board must send certain renewal information to
13 certain permit holders; repealing certain provisions requiring certain
14 physician–pharmacist agreements to be approved by the State Board of
15 Physicians and the State Board of Pharmacy; repealing certain provisions that
16 prohibit the State Board of Physicians and the State Board of Pharmacy from
17 approving certain physician–pharmacist agreements under certain
18 circumstances; repealing certain provisions relating to the time period during
19 which a physician–pharmacist agreement is valid; requiring a certain physician
20 and a certain pharmacist to submit a copy of a certain agreement to a certain
21 board; requiring a therapy management contract to apply only to conditions for
22 which protocols have been agreed to by certain parties; repealing a certain
23 provision requiring ~~the establishment of~~ certain fees related to therapy
24 management to be established in regulations; authorizing the State Board of

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 (2) The Board may designate 1 of its staff as an executive director.

2 (3) STAFF HIRED AFTER SEPTEMBER 30, 2012, ARE IN THE
3 EXECUTIVE SERVICE OR MANAGEMENT SERVICE OR ARE SPECIAL
4 APPOINTMENTS IN THE STATE PERSONNEL MANAGEMENT SYSTEM.

5 (4) THE BOARD, IN CONSULTATION WITH THE SECRETARY,
6 SHALL DETERMINE THE APPROPRIATE JOB CLASSIFICATIONS AND GRADES FOR
7 ALL STAFF.

8 12-407.

9 (a) A pharmacy permit expires on the [December 31] **MAY 31** after its
10 effective date, unless the pharmacy permit is renewed for a 2-year term as provided in
11 this section.

12 (b) (1) Except as provided in paragraph (2) of this subsection, on or before
13 [October 1] **MARCH 1** of the year the permit expires, the Board shall send to each
14 pharmacy permit holder a renewal notice for each pharmacy permit by first-class mail
15 to the last known address of the pharmacy permit holder.

16 12-6A-01.

17 (a) In this subtitle the following words have the meanings indicated.

18 (f) “Physician-pharmacist agreement” means an [approved] agreement
19 between a licensed physician and a licensed pharmacist that is disease-state specific
20 and specifies the protocols that may be used.

21 12-6A-03.

22 (a) A licensed physician and a licensed pharmacist who wish to enter into
23 therapy management contracts shall have a physician-pharmacist agreement [that is
24 approved by the Board of Pharmacy and the Board of Physicians].

25 [(b) The Board of Physicians and the Board of Pharmacy may not approve a
26 physician-pharmacist agreement if the Boards find there is:

27 (1) Inadequate training, experience, or education of the physicians or
28 pharmacists to implement the protocol or protocols specified in the agreement; or

29 (2) A failure to satisfy requirements of:

30 (i) This title or Title 14 of this article; or

1 (ii) Regulations established by the Board of Physicians and the
2 Board of Pharmacy adopted under this subtitle.

3 (c) A physician–pharmacist agreement shall be valid for 2 years from the
4 date of its final approval by the Board of Physicians and the Board of Pharmacy unless
5 renewed in accordance with established regulations adopted under this subtitle.]

6 **(B) (1) A LICENSED PHYSICIAN WHO HAS ENTERED INTO A**
7 **PHYSICIAN–PHARMACIST AGREEMENT SHALL SUBMIT TO THE BOARD OF**
8 **PHYSICIANS A COPY OF THE PHYSICIAN–PHARMACIST AGREEMENT AND ANY**
9 **SUBSEQUENT MODIFICATIONS MADE TO THE PHYSICIAN–PHARMACIST**
10 **AGREEMENT OR THE PROTOCOLS SPECIFIED IN THE PHYSICIAN–PHARMACIST**
11 **AGREEMENT.**

12 **(2) A LICENSED PHARMACIST WHO HAS ENTERED INTO A**
13 **PHYSICIAN–PHARMACIST AGREEMENT SHALL SUBMIT TO THE BOARD OF**
14 **PHARMACY A COPY OF THE PHYSICIAN–PHARMACIST AGREEMENT AND ANY**
15 **SUBSEQUENT MODIFICATIONS MADE TO THE PHYSICIAN–PHARMACIST**
16 **AGREEMENT OR THE PROTOCOLS SPECIFIED IN THE PHYSICIAN–PHARMACIST**
17 **AGREEMENT.**

18 12–6A–07.

19 (a) A therapy management contract shall apply only to conditions for which
20 protocols have been [approved by the Board of Physicians and the Board of Pharmacy
21 under] **AGREED TO BY A LICENSED PHYSICIAN AND A LICENSED PHARMACIST IN**
22 **ACCORDANCE WITH** the regulations adopted under this subtitle.

23 (b) A therapy management contract shall terminate 1 year from the date of
24 its signing, unless renewed by the licensed physician, licensed pharmacist, and
25 patient.

26 (c) A therapy management contract shall include:

27 (1) A statement that none of the parties involved in the therapy
28 management contract have been coerced, given economic incentives, excluding normal
29 reimbursement for services rendered, or involuntarily required to participate;

30 (2) Notice to the patient indicating how the patient may terminate the
31 therapy management contract;

32 (3) A procedure for periodic review by the physician, of the drugs
33 modified pursuant to the agreement or changed with the consent of the physician; and

34 (4) Reference to [an approved] A protocol, which will be provided to
35 the patient upon request.

1 (d) Any party to the therapy management contract may terminate the
2 contract at any time.

3 [(e) Fees paid to the Board of Physicians and Board of Pharmacy related to
4 therapy management shall be established in regulations.]

5 **(E) THE BOARD OF PHARMACY MAY ASSESS A FEE, AS ESTABLISHED IN**
6 **REGULATION, FOR APPROVAL OF A PHARMACIST TO ENTER INTO A**
7 **PHYSICIAN-PHARMACIST AGREEMENT.**

8 12-6A-10.

9 (a) Subject to subsection (b) of this section, the Board of Pharmacy, together
10 with the Board of Physicians, shall jointly develop and adopt regulations to implement
11 the provisions of this subtitle.

12 (b) The regulations adopted under subsection (a) of this section:

13 **(1) [shall] SHALL** include provisions that:

14 **[(1) (I) Define the criteria for physician-pharmacist agreements;**
15 **AND**

16 **[(2) (II) Establish guidelines concerning the use of protocols,**
17 **including communication, documentation, and other relevant factors; and**

18 **[(3) Establish a procedure to allow for the approval, modification,**
19 **continuation, or disapproval of specific protocols by the Board of Physicians and the**
20 **Board of Pharmacy.]**

21 **(2) MAY NOT REQUIRE THE BOARD OF PHYSICIANS OR THE**
22 **BOARD OF PHARMACY TO APPROVE A PHYSICIAN-PHARMACIST AGREEMENT OR**
23 **THE PROTOCOLS SPECIFIED IN A PHYSICIAN-PHARMACIST AGREEMENT.**

24 12-6C-06.

25 (a) A wholesale distributor permit expires on [December 31] **MAY 31** after
26 its effective date, unless the wholesale distributor permit is renewed for an additional
27 2-year term as provided in this section.

28 12-802.

29 Subject to the evaluation and reestablishment provisions of the Program
30 Evaluation Act, this title and all rules and regulations adopted under this title shall
31 terminate and be of no effect after July 1, [2013] **2023**.

1 Information Technology (IT) system, including information, for each full month
2 following implementation of the IT system, on the average wait time from the date of
3 application to the date of an applicant’s registration or rejection;

4 (3) the status of the Board’s contractual relationship with the
5 Pharmacists’ Education and Advocacy Council (PEAC) and whether any statutory
6 changes are necessary to allow other vendors to compete with PEAC;

7 (4) the implementation of the Board’s IT system, including both
8 positive and negative outcomes, and the effect, if any, of the IT system on the Board’s
9 staffing needs; and

10 (5) the Board’s 5–year financial outlook and an analysis of the Board’s
11 ability to maintain a healthy fiscal outlook, including the effect of transfers from the
12 Board’s fund balance under the Budget Reconciliation and Financing Acts of 2009,
13 2010, and 2011, costs associated with the Board’s new database, and any additional
14 personnel costs resulting from the recommendations of the Department of Legislative
15 Services contained in the sunset evaluation report on the Board dated October 2011,
16 on the Board’s ability to maintain an adequate fund balance.

17 SECTION 5. AND BE IT FURTHER ENACTED, That this Act shall take effect
18 July 1, 2012.

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.