

HOUSE BILL 283

J2

(2lr1556)

ENROLLED BILL

— *Health and Government Operations/Education, Health, and Environmental Affairs* —

Introduced by **Chair, Health and Government Operations Committee** and **Delegate Elliott**

Read and Examined by Proofreaders:

Proofreader.

Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this _____ day of _____ at _____ o'clock, _____ M.

Speaker.

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

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.

Italics indicate opposite chamber/conference committee amendments.



1 physician–pharmacist agreements to be approved by the State Board of
 2 Physicians and the State Board of Pharmacy; repealing certain provisions that
 3 prohibit the State Board of Physicians and the State Board of Pharmacy from
 4 approving certain physician–pharmacist agreements under certain
 5 circumstances; repealing certain provisions relating to the time period during
 6 which a physician–pharmacist agreement is valid; requiring a certain physician
 7 and a certain pharmacist to submit a copy of a certain agreement to a certain
 8 board; requiring a therapy management contract to apply only to conditions for
 9 which protocols have been agreed to by certain parties; repealing a certain
 10 provision requiring ~~the establishment of~~ certain fees related to therapy
 11 management to be established in regulations; authorizing the State Board of
 12 Pharmacy to assess a certain fee established in regulation; repealing a
 13 requirement that certain regulations include provisions that establish a certain
 14 procedure; prohibiting certain regulations from requiring certain boards to
 15 approve certain physician–pharmacist agreements or the protocols specified in
 16 the agreements; requiring that an evaluation of the State Board of Pharmacy
 17 and the statutes and regulations that relate to the Board be performed on or
 18 before a certain date; providing for an extension of the renewal dates of certain
 19 permits; requiring the State Board of Pharmacy to submit certain reports to
 20 certain committees of the General Assembly on or before certain dates; altering
 21 a certain definition; making a conforming change; and generally relating to the
 22 State Board of Pharmacy.

23 BY repealing and reenacting, with amendments,
 24 Article – Health Occupations
 25 Section ~~12–204(d)~~, 12–407(a) and (b)(1), 12–6A–01(f), 12–6A–03, 12–6A–07,
 26 12–6A–10, 12–6C–06(a), and 12–802
 27 Annotated Code of Maryland
 28 (2009 Replacement Volume and 2011 Supplement)

29 BY repealing and reenacting, without amendments,
 30 Article – Health Occupations
 31 Section 12–6A–01(a)
 32 Annotated Code of Maryland
 33 (2009 Replacement Volume and 2011 Supplement)

34 BY repealing and reenacting, without amendments,
 35 Article – State Government
 36 Section 8–403(a)
 37 Annotated Code of Maryland
 38 (2009 Replacement Volume and 2011 Supplement)

39 BY repealing and reenacting, with amendments,
 40 Article – State Government
 41 Section 8–403(b)(45)
 42 Annotated Code of Maryland
 43 (2009 Replacement Volume and 2011 Supplement)

1 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
2 MARYLAND, That the Laws of Maryland read as follows:

3 **Article – Health Occupations**

4 ~~12-204.~~

5 ~~(d) (1) The Board may employ a staff in accordance with the budget of the~~
6 ~~Board.~~

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

8 ~~(3) STAFF HIRED AFTER SEPTEMBER 30, 2012, ARE IN THE~~
9 ~~EXECUTIVE SERVICE OR MANAGEMENT SERVICE OR ARE SPECIAL~~
10 ~~APPOINTMENTS IN THE STATE PERSONNEL MANAGEMENT SYSTEM.~~

11 ~~(4) THE BOARD, IN CONSULTATION WITH THE SECRETARY,~~
12 ~~SHALL DETERMINE THE APPROPRIATE JOB CLASSIFICATIONS AND GRADES FOR~~
13 ~~ALL STAFF.~~

14 12-407.

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

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

22 12-6A-01.

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

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

27 12-6A-03.

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

1 **[(b)** The Board of Physicians and the Board of Pharmacy may not approve a
2 physician–pharmacist agreement if the Boards find there is:

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

5 (2) A failure to satisfy requirements of:

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

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

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

12 **(B) (1) A LICENSED PHYSICIAN WHO HAS ENTERED INTO A**
13 **PHYSICIAN–PHARMACIST AGREEMENT SHALL SUBMIT TO THE BOARD OF**
14 **PHYSICIANS 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 **(2) A LICENSED PHARMACIST WHO HAS ENTERED INTO A**
19 **PHYSICIAN–PHARMACIST AGREEMENT SHALL SUBMIT TO THE BOARD OF**
20 **PHARMACY A COPY OF THE PHYSICIAN–PHARMACIST AGREEMENT AND ANY**
21 **SUBSEQUENT MODIFICATIONS MADE TO THE PHYSICIAN–PHARMACIST**
22 **AGREEMENT OR THE PROTOCOLS SPECIFIED IN THE PHYSICIAN–PHARMACIST**
23 **AGREEMENT.**

24 12–6A–07.

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

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

32 (c) A therapy management contract shall include:

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

4 (2) Notice to the patient indicating how the patient may terminate the
5 therapy management contract;

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

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

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

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

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

17 12-6A-10.

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

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

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

23 [(1)] (I) Define the criteria for physician-pharmacist agreements;
24 **AND**

25 [(2)] (II) Establish guidelines concerning the use of protocols,
26 including communication, documentation, and other relevant factors; and

27 [(3) Establish a procedure to allow for the approval, modification,
28 continuation, or disapproval of specific protocols by the Board of Physicians and the
29 Board of Pharmacy.]

1 **(2) MAY NOT REQUIRE THE BOARD OF PHYSICIANS OR THE**
2 **BOARD OF PHARMACY TO APPROVE A PHYSICIAN–PHARMACIST AGREEMENT OR**
3 **THE PROTOCOLS SPECIFIED IN A PHYSICIAN–PHARMACIST AGREEMENT.**

4 12–6C–06.

5 (a) A wholesale distributor permit expires on ~~[December 31]~~ **MAY 31** after
6 its effective date, unless the wholesale distributor permit is renewed for an additional
7 2–year term as provided in this section.

8 12–802.

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

12 Article – State Government

13 8–403.

14 (a) On or before December 15 of the 2nd year before the evaluation date of a
15 governmental activity or unit, the Legislative Policy Committee, based on a
16 preliminary evaluation, may waive as unnecessary the evaluation required under this
17 section.

18 (b) Except as otherwise provided in subsection (a) of this section, on or before
19 the evaluation date for the following governmental activities or units, an evaluation
20 shall be made of the following governmental activities or units and the statutes and
21 regulations that relate to the governmental activities or units:

22 (45) Pharmacy, State Board of (§ 12–201 of the Health Occupations
23 Article: July 1, ~~[2012]~~ **2022**);

24 SECTION 2. AND BE IT FURTHER ENACTED, That the State Board of
25 Pharmacy shall extend the renewal of permits required under §§ 12–407 and
26 12–6C–06 of the Health Occupations Article, as enacted by Section 1 of this Act, to
27 May 31, 2013, and May 31, 2014, respectively, for pharmacy permits and wholesale
28 distributor permits expiring on December 31, 2012, and December 31, 2013,
29 respectively, to accommodate the revised permit renewal date of May 31.

30 SECTION 3. AND BE IT FURTHER ENACTED, That, on or before December 1,
31 2012, the State Board of Pharmacy shall submit a report to the Senate Education,
32 Health, and Environmental Affairs Committee and the House Health and Government
33 Operations Committee, in accordance with § 2–1246 of the State Government Article,
34 on the implementation and use of the sanctioning guidelines required by Chapters 533
35 and 534 of the Acts of the General Assembly of 2010.

1 SECTION 4. AND BE IT FURTHER ENACTED, That, on or before October 1,
2 2013, the State Board of Pharmacy (Board) shall submit a report to the Senate
3 Education, Health, and Environmental Affairs Committee and the House Health and
4 Government Operations Committee, in accordance with § 2-1246 of the State
5 Government Article, on the implementation of nonstatutory recommendations
6 contained in the October 2011 sunset evaluation report on the Board, published by the
7 Department of Legislative Services, including:

8 (1) the impact of modifications made to the drug therapy management
9 program, including the number of physician-pharmacist agreements and the number
10 of drug therapy management protocols on file with the Board and the State Board of
11 Physicians;

12 (2) the Board's progress in further reducing the length of the
13 pharmacy technician registration process following implementation of the Board's new
14 Information Technology (IT) system, including information, for each full month
15 following implementation of the IT system, on the average wait time from the date of
16 application to the date of an applicant's registration or rejection;

17 (3) the status of the Board's contractual relationship with the
18 Pharmacists' Education and Advocacy Council (PEAC) and whether any statutory
19 changes are necessary to allow other vendors to compete with PEAC;

20 (4) the implementation of the Board's IT system, including both
21 positive and negative outcomes, and the effect, if any, of the IT system on the Board's
22 staffing needs; and

23 (5) the Board's 5-year financial outlook and an analysis of the Board's
24 ability to maintain a healthy fiscal outlook, including the effect of transfers from the
25 Board's fund balance under the Budget Reconciliation and Financing Acts of 2009,
26 2010, and 2011, costs associated with the Board's new database, and any additional
27 personnel costs resulting from the recommendations of the Department of Legislative
28 Services contained in the sunset evaluation report on the Board dated October 2011,
29 on the Board's ability to maintain an adequate fund balance.

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