

HOUSE BILL 1044

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7lr2766
CF SB 992

By: **Delegates Hill, Krebs, Lam, Morhaim, Turner, and Waldstreicher**

Introduced and read first time: February 8, 2017

Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 **Oncologists – Dispensing and Insurance Coverage of Orally Administered**
3 **Cancer Chemotherapy**

4 FOR the purpose of exempting a certain physician from the prohibition on dispensing
5 certain prescriptions when the physician has a substantial financial interest in a
6 pharmacy under certain circumstances; authorizing a licensed physician to
7 personally prepare and dispense a prescription written by a certain physician in the
8 same group practice; exempting certain associations that include an oncologist from
9 the prohibition on associating as a partner, a co-owner, or an employee of a certain
10 pharmacy; prohibiting a certain carrier from taking certain actions relating to an
11 oncologist's participation on the carrier's provider panel based solely on the
12 oncologist's dispensing of a certain prescription; requiring certain insurers, nonprofit
13 health service plans, and health maintenance organizations to allow an oncologist to
14 dispense a certain prescription to an insured or enrollee under certain
15 circumstances; prohibiting certain insurers, nonprofit health service plans, and
16 health maintenance organizations from imposing certain copayments, fees, or any
17 other conditions on an insured or enrollee who elects to fill a certain prescription
18 from a certain oncologist under certain circumstances; authorizing an oncologist to
19 apply to a certain insurer, nonprofit health service plan, or health maintenance
20 organization to be a certain pharmacy or other source to dispense or administer
21 prescription drugs for certain purposes and under certain circumstances; prohibiting
22 a certain insurer, nonprofit health service plan, and health maintenance
23 organization from unreasonably denying approval of an oncologist's application;
24 requiring certain insurers, nonprofit health service plans, and health maintenance
25 organizations to notify an oncologist of the reason for the denial under certain
26 circumstances; requiring the notification to be in writing and state a certain reason;
27 defining certain terms; making a technical correction; making stylistic changes; and
28 generally relating to dispensing and insurance coverage of orally administered
29 cancer chemotherapy.

30 BY repealing and reenacting, without amendments,

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 Article – Health Occupations
2 Section 12–102(a) and (b)
3 Annotated Code of Maryland
4 (2014 Replacement Volume and 2016 Supplement)

5 BY repealing and reenacting, with amendments,
6 Article – Health Occupations
7 Section 12–102(c), 12–313(b)(14), 12–401, 12–6B–09(14), and 14–404(a)(30)
8 Annotated Code of Maryland
9 (2014 Replacement Volume and 2016 Supplement)

10 BY repealing and reenacting, with amendments,
11 Article – Insurance
12 Section 15–112(i), 15–846, and 15–847
13 Annotated Code of Maryland
14 (2011 Replacement Volume and 2016 Supplement)

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

17 **Article – Health Occupations**

18 12–102.

19 (a) (1) In this section the following terms have the meanings indicated.

20 (2) “In the public interest” means the dispensing of drugs or devices by a
21 licensed dentist, physician, or podiatrist to a patient when a pharmacy is not conveniently
22 available to the patient.

23 (3) “Personally preparing and dispensing” means that the licensed dentist,
24 physician, or podiatrist:

25 (i) Is physically present on the premises where the prescription is
26 filled; and

27 (ii) Performs a final check of the prescription before it is provided to
28 the patient.

29 (b) This title does not limit the right of an individual to practice a health
30 occupation that the individual is authorized to practice under this article.

31 (c) (1) This subsection does not apply to a licensed dentist who obtains a
32 permit from the State Board of Dental Examiners under subsection (h) of this section.

33 (2) This title does not prohibit:

- 1 (i) A licensed veterinarian from:
- 2 1. Personally preparing and dispensing the veterinarian's
3 prescriptions; or
- 4 2. Dispensing, in accordance with § 2-313(c) of the
5 Agriculture Article, compounded nonsterile preparations or compounded sterile
6 preparations provided by a pharmacy;
- 7 (ii) A licensed dentist, physician, or podiatrist from personally
8 preparing and dispensing the dentist's, physician's, or podiatrist's prescriptions when:
- 9 1. The dentist, physician, or podiatrist:
- 10 A. Has applied to the board of licensure in this State which
11 licensed the dentist, physician, or podiatrist;
- 12 B. Has demonstrated to the satisfaction of that board that the
13 dispensing of prescription drugs or devices by the dentist, physician, or podiatrist is in the
14 public interest;
- 15 C. Has received a written permit from that board to dispense
16 prescription drugs or devices except that a written permit is not required in order to
17 dispense starter dosages or samples without charge; and
- 18 D. Posts a sign conspicuously positioned and readable
19 regarding the process for resolving incorrectly filled prescriptions or includes written
20 information regarding the process with each prescription dispensed;
- 21 2. The person for whom the drugs or devices are prescribed
22 is a patient of the prescribing dentist, physician, or podiatrist;
- 23 3. **[The] EXCEPT AS PROVIDED IN §§ 12-313(B)(14) AND**
24 **12-6B-09(14) OF THIS TITLE AND § 14-404(A)(30) OF THIS ARTICLE, THE** dentist,
25 physician, or podiatrist does not have a substantial financial interest in a pharmacy; and
- 26 4. The dentist, physician, or podiatrist:
- 27 A. Complies with the dispensing and labeling requirements
28 of this title;
- 29 B. Records the dispensing of the prescription drug or device
30 on the patient's chart;
- 31 C. Allows the Division of Drug Control to enter and inspect
32 the dentist's, physician's, or podiatrist's office at all reasonable hours and in accordance
33 with § 12-102.1 of this subtitle;

1 D. On inspection by the Division of Drug Control, signs and
2 dates an acknowledgment form provided by the Division of Drug Control relating to the
3 requirements of this section;

4 E. Except for starter dosages or samples without charge,
5 provides the patient with a written prescription, maintains prescription files in accordance
6 with § 12–403(c)(13) of this title, and maintains a separate file for Schedule II prescriptions;

7 F. Does not direct patients to a single pharmacist or
8 pharmacy in accordance with § 12–403(c)(8) of this title;

9 G. Does not receive remuneration for referring patients to a
10 pharmacist or pharmacy;

11 H. Complies with the child resistant packaging requirements
12 regarding prescription drugs under Title 22, Subtitle 3 of the Health – General Article;

13 I. Complies with drug recalls;

14 J. Maintains biennial inventories and complies with any
15 other federal and State record–keeping requirements relating to controlled dangerous
16 substances;

17 K. Purchases prescription drugs from a pharmacy or
18 wholesale distributor who holds a permit issued by the Board of Pharmacy, as verified by
19 the Board of Pharmacy;

20 L. Annually reports to the respective board of licensure
21 whether the dentist, physician, or podiatrist has personally prepared and dispensed
22 prescription drugs within the previous year; and

23 M. Completes ten continuing education credits over a 5–year
24 period relating to the preparing and dispensing of prescription drugs, offered by the
25 Accreditation Council for Pharmacy Education (ACPE) or as approved by the Secretary, in
26 consultation with each respective board of licensure, as a condition of permit renewal;

27 (iii) A licensed physician who complies with the requirements of item
28 (ii) of this paragraph from personally preparing and dispensing a prescription written by:

29 1. A physician assistant in accordance with a delegation
30 agreement that complies with Title 15, Subtitle 3 of this article; [or]

31 2. A nurse practitioner who is authorized to practice under
32 Title 8, Subtitle 3 of this article and is working with the physician in the same office setting;
33 or

1 **3. A PHYSICIAN IN THE SAME GROUP PRACTICE WHO IS**
2 **BOARD-CERTIFIED OR BOARD-ELIGIBLE IN THE SAME SPECIALTY AS THE**
3 **DISPENSING PHYSICIAN; OR**

4 (iv) A hospital-based clinic from dispensing prescriptions to its
5 patients.

6 12-313.

7 (b) Subject to the hearing provisions of § 12-315 of this subtitle, the Board, on the
8 affirmative vote of a majority of its members then serving, may deny a license to any
9 applicant for a pharmacist's license, reprimand any licensee, place any licensee on
10 probation, or suspend or revoke a license of a pharmacist if the applicant or licensee:

11 (14) Except as to an association that has remained in continuous existence
12 since July 1, 1963, **OR AN ASSOCIATION BETWEEN AN ONCOLOGIST AND A**
13 **PHARMACIST FOR THE OPERATION OF A PHARMACY**, associates as a partner, [coowner]
14 **A CO-OWNER**, or **AN** employee of a pharmacy that is owned wholly or substantially by an
15 authorized prescriber or group of authorized prescribers;

16 12-401.

17 (a) A person shall hold a pharmacy permit issued by the Board before the person
18 may establish or operate a pharmacy in this State.

19 (b) A separate pharmacy permit is required for each pharmacy that a person
20 establishes or operates.

21 **(C) NOTWITHSTANDING ANY OTHER PROVISION OF LAW, AN ONCOLOGIST,**
22 **AS DEFINED IN § 15-846 OF THE INSURANCE ARTICLE, MAY OWN, ESTABLISH, OR**
23 **OPERATE A PHARMACY IN THE STATE IF THE PHARMACY DISPENSES PRESCRIPTION**
24 **DRUGS ONLY TO PATIENTS OF THE ONCOLOGIST OR AN ONCOLOGIST IN THE SAME**
25 **GROUP PRACTICE.**

26 12-6B-09.

27 Subject to the hearing provision of § 12-315 of this title, the Board may deny a
28 pharmacy technician's registration to any applicant, reprimand a registered pharmacy
29 technician, place any pharmacy technician's registration on probation, or suspend or revoke
30 a pharmacy technician's registration if the applicant or pharmacy technician registrant:

31 (14) Except as to an association that has remained in continuous existence
32 since July 1, 1963, **OR AN ASSOCIATION BETWEEN AN ONCOLOGIST AND A PHARMACY**
33 **TECHNICIAN FOR THE OPERATION OF A PHARMACY**, associates as a partner, **A**
34 **co-owner**, or **AN** employee of a pharmacy that is owned wholly or substantially by an
35 authorized prescriber or group of authorized prescribers;

1 14-404.

2 (a) Subject to the hearing provisions of § 14-405 of this subtitle, a disciplinary
3 panel, on the affirmative vote of a majority of the quorum of the disciplinary panel, may
4 reprimand any licensee, place any licensee on probation, or suspend or revoke a license if
5 the licensee:

6 (30) Except as to an association that has remained in continuous existence
7 since July 1, 1963, **OR AN ASSOCIATION BETWEEN AN ONCOLOGIST AND A PHARMACY**
8 **TECHNICIAN FOR THE OPERATION OF A PHARMACY:**

9 (i) Associates with a pharmacist as a partner or co-owner of a
10 pharmacy for the purpose of operating a pharmacy;

11 (ii) Employs a pharmacist for the purpose of operating a pharmacy;
12 or

13 (iii) Contracts with a pharmacist for the purpose of operating a
14 pharmacy;

15 **Article - Insurance**

16 15-112.

17 (i) (1) A carrier may not deny an application for participation or terminate
18 participation on its provider panel solely on the basis of the license, certification, or other
19 authorization of the provider to provide health care services if the carrier provides health
20 care services within the provider's lawful scope of practice.

21 (2) Notwithstanding paragraph (1) of this subsection, a carrier may reject
22 an application for participation or terminate participation on its provider panel based on
23 the participation on the provider panel of a sufficient number of similarly qualified
24 providers.

25 **(3) A CARRIER MAY NOT DENY AN APPLICATION FROM AN**
26 **ONCOLOGIST FOR PARTICIPATION OR TERMINATE PARTICIPATION OF AN**
27 **ONCOLOGIST ON ITS PROVIDER PANEL BASED SOLELY ON THE ONCOLOGIST'S**
28 **DISPENSING OF A COVERED ORALLY ADMINISTERED CANCER CHEMOTHERAPY**
29 **PRESCRIPTION TO PATIENTS OF THE ONCOLOGIST.**

30 **[(3)] (4)** A violation of this subsection does not create a new cause of
31 action.

32 15-846.

1 (a) (1) In this section[, “cancer] **THE FOLLOWING WORDS HAVE THE**
2 **MEANINGS INDICATED.**

3 (2) **“CANCER chemotherapy”** means medication that is prescribed by a
4 licensed physician to kill or slow the growth of cancer cells.

5 (3) **“ONCOLOGIST” MEANS A LICENSED PHYSICIAN WHO IS:**

6 (I) **BOARD–CERTIFIED OR BOARD–ELIGIBLE IN MEDICAL**
7 **ONCOLOGY, RADIATION ONCOLOGY, HEMATOLOGY, OR ANOTHER ONCOLOGY**
8 **SPECIALTY RECOGNIZED BY THE AMERICAN BOARD OF MEDICAL SPECIALTIES; OR**

9 (II) **A SURGEON WHO CONSULTS ON OR TREATS A PATIENT**
10 **PRIMARILY FOR A CANCER DIAGNOSIS.**

11 (4) **“PROVIDER PANEL” HAS THE MEANING STATED IN § 15–112 OF**
12 **THIS TITLE.**

13 (b) This section applies to:

14 (1) insurers and nonprofit health service plans that provide coverage for
15 both orally administered cancer chemotherapy and cancer chemotherapy that is
16 administered intravenously or by injection under health insurance policies or contracts that
17 are issued or delivered in the State; and

18 (2) health maintenance organizations that provide coverage for both orally
19 administered cancer chemotherapy and cancer chemotherapy that is administered
20 intravenously or by injection under contracts that are issued or delivered in the State.

21 (c) An entity subject to this section may not impose dollar limits, copayments,
22 deductibles, or coinsurance requirements on coverage for orally administered cancer
23 chemotherapy that are less favorable to an insured or enrollee than the dollar limits,
24 copayments, deductibles, or coinsurance requirements that apply to coverage for cancer
25 chemotherapy that is administered intravenously or by injection.

26 (d) An entity subject to this section may not reclassify cancer chemotherapy or
27 increase a copayment, deductible, coinsurance requirement, or other out–of–pocket expense
28 imposed on cancer chemotherapy to achieve compliance with this section.

29 (E) **AN ENTITY SUBJECT TO THIS SECTION SHALL ALLOW AN ONCOLOGIST**
30 **TO DISPENSE A COVERED ORALLY ADMINISTERED CANCER CHEMOTHERAPY**
31 **PRESCRIPTION TO AN INSURED OR ENROLLEE IF:**

1 **[(3)] (4)** “Managed care system” means a system of cost containment
2 methods that an insurer, a nonprofit health service plan, or a health maintenance
3 organization uses to review and preauthorize drugs prescribed by a health care provider
4 for a covered individual to control utilization, quality, and claims.

5 **(5) “ONCOLOGIST” MEANS A LICENSED PHYSICIAN WHO IS:**

6 **(I) BOARD–CERTIFIED OR BOARD–ELIGIBLE IN MEDICAL**
7 **ONCOLOGY, RADIATION ONCOLOGY, HEMATOLOGY, OR ANOTHER ONCOLOGY**
8 **SPECIALTY RECOGNIZED BY THE AMERICAN BOARD OF MEDICAL SPECIALTIES; OR**

9 **(II) A SURGEON WHO CONSULTS ON OR TREATS A PATIENT**
10 **PRIMARILY FOR A CANCER DIAGNOSIS.**

11 **[(4)] (6)** (i) “Rare medical condition” means a disease or condition that
12 affects fewer than:

- 13 1. 200,000 individuals in the United States; or
- 14 2. approximately 1 in 1,500 individuals worldwide.

15 (ii) “Rare medical condition” includes:

- 16 1. cystic fibrosis;
- 17 2. hemophilia; and
- 18 3. multiple myeloma.

19 **[(5)] (7)** “Specialty drug” means a prescription drug that:

20 (i) is prescribed for an individual with a complex or chronic medical
21 condition or a rare medical condition;

22 (ii) costs \$600 or more for up to a 30–day supply;

23 (iii) is not typically stocked at retail pharmacies; and

24 (iv) 1. requires a difficult or unusual process of delivery to the
25 patient in the preparation, handling, storage, inventory, or distribution of the drug; or

26 2. requires enhanced patient education, management, or
27 support, beyond those required for traditional dispensing, before or after administration of
28 the drug.

29 (b) This section applies to:

1 (1) insurers and nonprofit health service plans that provide coverage for
2 prescription drugs under individual, group, or blanket health insurance policies or
3 contracts that are issued or delivered in the State; and

4 (2) health maintenance organizations that provide coverage for
5 prescription drugs under individual or group contracts that are issued or delivered in the
6 State.

7 (c) (1) Subject to paragraph (2) of this subsection, an entity subject to this
8 section may not impose a copayment or coinsurance requirement on a covered specialty
9 drug that exceeds \$150 for up to a 30-day supply of the specialty drug.

10 (2) On July 1 of each year, the limit on the copayment or coinsurance
11 requirement on a covered specialty drug shall increase by a percentage equal to the
12 percentage change from the preceding year in the medical care component of the March
13 Consumer Price Index for All Urban Consumers, Washington-Baltimore, from the U.S.
14 Department of Labor, Bureau of Labor Statistics.

15 (d) Subject to § 15-805 of this subtitle and notwithstanding § 15-806 of this
16 subtitle, nothing in this article or regulations adopted under this article precludes an entity
17 subject to this section from requiring a covered specialty drug to be obtained through:

18 (1) a designated pharmacy or other source authorized under the Health
19 Occupations Article to dispense or administer prescription drugs; or

20 (2) a pharmacy participating in the entity's provider network, if the entity
21 determines that the pharmacy:

22 (i) meets the entity's performance standards; and

23 (ii) accepts the entity's network reimbursement rates.

24 (e) (1) A pharmacy registered under § 340B of the federal Public Health
25 Services Act may apply to an entity subject to this section to be a designated pharmacy
26 under subsection (d)(1) of this section for the purpose of enabling the pharmacy's patients
27 with HIV, AIDS, or hepatitis C to receive the copayment or coinsurance maximum provided
28 for in subsection (c) of this section if:

29 (i) the pharmacy is owned by a federally qualified health center, as
30 defined in 42 U.S.C. § 254B;

31 (ii) the federally qualified health center provides integrated and
32 coordinated medical and pharmaceutical services to HIV positive, AIDS, and hepatitis C
33 patients; and

1 (iii) the prescription drugs are covered specialty drugs for the
2 treatment of HIV, AIDS, or hepatitis C.

3 (2) An entity subject to this section may not unreasonably withhold
4 approval of a pharmacy's application under paragraph (1) of this subsection.

5 **(F) (1) AN ONCOLOGIST MAY APPLY TO AN ENTITY SUBJECT TO THIS**
6 **SECTION TO BE A DESIGNATED PHARMACY OR OTHER SOURCE UNDER SUBSECTION**
7 **(D)(1) OF THIS SECTION TO DISPENSE OR ADMINISTER PRESCRIPTION DRUGS FOR**
8 **THE PURPOSES OF IMPROVING PATIENT ACCESS AND ADHERENCE AND ENABLING**
9 **THE ONCOLOGIST'S PATIENTS DIAGNOSED WITH CANCER TO RECEIVE THE**
10 **COPAYMENT OR COINSURANCE MAXIMUM PROVIDED FOR IN SUBSECTION (C) OF**
11 **THIS SECTION IF:**

12 **(I) THE ONCOLOGIST DISPENSES ORALLY ADMINISTERED**
13 **CANCER CHEMOTHERAPY IN ACCORDANCE WITH § 12-102 OF THE HEALTH**
14 **OCCUPATIONS ARTICLE;**

15 **(II) THE PRESCRIPTION DRUGS DISPENSED BY THE**
16 **ONCOLOGIST UNDER THIS SUBSECTION ARE ORALLY ADMINISTERED CANCER**
17 **CHEMOTHERAPY SPECIALTY DRUGS; AND**

18 **(III) THE ONCOLOGIST ACCEPTS THE ENTITY'S NETWORK**
19 **REIMBURSEMENT RATES.**

20 **(2) AN ENTITY SUBJECT TO THIS SECTION MAY NOT UNREASONABLY**
21 **DENY APPROVAL OF AN ONCOLOGIST'S APPLICATION UNDER PARAGRAPH (1) OF**
22 **THIS SUBSECTION.**

23 **(3) (I) IF AN ENTITY SUBJECT TO THIS SECTION DENIES APPROVAL**
24 **OF AN ONCOLOGIST'S APPLICATION UNDER PARAGRAPH (1) OF THIS SUBSECTION,**
25 **THE ENTITY SHALL NOTIFY THE ONCOLOGIST OF THE REASON FOR THE DENIAL.**

26 **(II) THE NOTIFICATION REQUIRED UNDER SUBPARAGRAPH (I)**
27 **OF THIS PARAGRAPH SHALL BE IN WRITING AND STATE THE SPECIFIC REASON FOR**
28 **THE DENIAL.**

29 **[(f)] (G)** An entity subject to this section may provide coverage for specialty
30 drugs through a managed care system.

31 **[(g)] (H)** (1) A determination by an entity subject to this section that a
32 prescription drug is not a specialty drug is considered a coverage decision under §
33 15-10D-01 of this title.

1 (2) For complaints filed with the Commissioner under this subsection, if
2 the entity made its determination that a prescription drug is not a specialty drug on the
3 basis that the prescription drug did not meet the criteria listed in subsection (a)(5)(i) of this
4 section:

5 (i) the Commissioner may seek advice from an independent review
6 organization or medical expert on the list compiled under § 15–10A–05(b) of this title; and

7 (ii) the expenses for any advice provided by an independent review
8 organization or medical expert shall be paid for as provided under § 15–10A–05(h) of this
9 title.

10 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
11 October 1, 2017.