## **SENATE BILL 84**

J2, C3 1lr0522 (PRE–FILED) CF HB 135

By: Senators Young and Waldstreicher

Requested: September 14, 2020

Introduced and read first time: January 13, 2021

Assigned to: Education, Health, and Environmental Affairs

Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: February 14, 2021

CHAPTER \_\_\_\_\_

## 1 AN ACT concerning

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## Pharmacists – Administration of Self-Administered Medications and Maintenance Injectable Medications

FOR the purpose of authorizing a pharmacist who meets the requirements of certain regulations to administer maintenance injectable medications to a patient under certain circumstances; prohibiting a pharmacist from administering an initial dose of a maintenance injectable medication under a certain provision of this Act except under certain circumstances; prohibiting a pharmacist from administering a maintenance injectable medication unless the pharmacist provides the patient with a certain notice; requiring a pharmacist who charges a certain fee to provide a certain notice to a patient separate from any other forms or notices; prohibiting a pharmacist who charges a certain fee from collecting or attempting to collect the fee except under certain circumstances; requiring a pharmacist, to the extent practicable, to provide a certain form in a certain language or format to certain patients under certain circumstances; requiring the State Board of Pharmacy, on or before a certain date and in consultation with the State Board of Physicians and the State Board of Nursing, to adopt certain regulations for pharmacists to administer a maintenance injectable medication; establishing certain requirements for the regulations; requiring the Maryland Medical Assistance Program and the Maryland Children's Health Program to provide coverage for the administering of certain self-administered medications and maintenance injectable medications rendered by a licensed pharmacist to the same extent as the services rendered by any other licensed health care practitioner; requiring certain insurers, nonprofit health service plans, and health maintenance organizations to provide coverage for the

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

<u>Underlining</u> indicates amendments to bill.

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

1 2 3 4 5 6 7	administering administration of certain self-administered medications and maintenance injectable medications rendered by a licensed pharmacist to the same extent as the services rendered by any other licensed health care practitioner; altering a certain definition; defining a certain term; providing for the application of certain provisions of this Act; and generally relating to the administering of self-administered medications and maintenance injectable medications by pharmacists.
8	BY repealing and reenacting, with amendments,
9	Article – Health – General
10	Section 15–148(c)
11	Annotated Code of Maryland
12	(2019 Replacement Volume and 2020 Supplement)
13	BY repealing and reenacting, without amendments,
14	Article – Health Occupations
15	Section 12–101(a) and (c)
16	Annotated Code of Maryland
17	(2014 Replacement Volume and 2020 Supplement)
18	BY adding to
19	Article – Health Occupations
20	Section 12–101(o–1)
21	Annotated Code of Maryland
22	(2014 Replacement Volume and 2020 Supplement)
23	BY repealing and reenacting, with amendments,
24	Article – Health Occupations
25	Section 12–101(x)(1)(viii) and 12–509
26	Annotated Code of Maryland
27	(2014 Replacement Volume and 2020 Supplement)
28	BY adding to
29	Article – Insurance
30	Section 15–716
31	Annotated Code of Maryland
32	(2017 Replacement Volume and 2020 Supplement)
33	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
34	That the Laws of Maryland read as follows:
35	Article – Health – General

36 15–148.

37 (c) The Program and the Maryland Children's Health Program shall provide 38 coverage for services, TO THE SAME EXTENT AS SERVICES RENDERED BY ANY OTHER

- 1 LICENSED HEALTH CARE PRACTITIONER, rendered to an enrollee by a licensed 2 pharmacist under:
- 12 5093 **(1)** OF THE HEALTH **OCCUPATIONS** ARTICLE 4 **ADMINISTERING MEDICATIONS** SELF-ADMINISTERED OR **MAINTENANCE** 5 INJECTABLE MEDICATIONS; OR
- 6 **(2)** § 12–511 of the Health Occupations Article[, to the same extent as services rendered by any other licensed health care practitioner,] in screening an enrollee and prescribing contraceptives for the enrollee.

## 9 Article - Health Occupations

- 10 12-101.
- 11 (a) In this title the following words have the meanings indicated.
- 12 (c) "Biological product" has the meaning stated in 42 U.S.C. § 262.
- 13 (O-1) (1) "MAINTENANCE INJECTABLE MEDICATION" MEANS A 14 MEDICATION THAT:
- 15 (I) IS ADMINISTERED BY INJECTION OTHER THAN 16 INTRAVENOUSLY; AND
- 17 (II) <u>1.</u> TREATS A CHRONIC NEED, CONDITION, OR DISORDER; 18 OR
- 19 <u>2. Treats a sexually transmitted infection and</u> 20 is not a vaccine.
- 21 (2) "MAINTENANCE INJECTABLE MEDICATION" INCLUDES A 22 MEDICATION FOR THE TREATMENT OF A PSYCHIATRIC DISORDER OR SUBSTANCE 23 USE DISORDER, CONTRACEPTION, AND VITAMINS.
- 24 (x) (1) "Practice pharmacy" means to engage in any of the following activities:
- 25 (viii) Administering vaccinations in accordance with § 12–508 of this 26 title or self-administered drugs **OR MAINTENANCE INJECTABLE MEDICATIONS** in accordance with § 12–509 of this title;
- 28 12–509.

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1 2 3	(A) In addition to the authority granted to a pharmacist under § 12–508 of this subtitle, a pharmacist, in accordance with regulations adopted by the Board, may administer [a]:
4 5	(1) $\bf A$ self-administered drug to a patient that is prescribed by an authorized prescriber; $\bf AND$
6 7 8	(2) SUBJECT TO SUBSECTION (B) SUBSECTIONS (B) AND (C) OF THIS SECTION, A MAINTENANCE INJECTABLE MEDICATION THAT IS NOT A BIOLOGICAL PRODUCT TO A PATIENT:
9	(I) THAT IS PRESCRIBED BY AN AUTHORIZED PRESCRIBER;
10 11	(II) IN ACCORDANCE WITH A STANDING ORDER ISSUED BY AN AUTHORIZED PUBLIC HEALTH OFFICIAL; OR
12 13	(III) IN ACCORDANCE WITH A PROTOCOL UNDER SUBTITLE 6A OF THIS TITLE.
14 15 16 17	(B) A PHARMACIST MAY NOT ADMINISTER AN INITIAL DOSE OF A MAINTENANCE INJECTABLE MEDICATION PRODUCT UNDER SUBSECTION (A)(2) OF THIS SECTION UNLESS THE PHARMACIST RECEIVES WRITTEN APPROVAL FROM THE PRESCRIBER.
18 19 20	(C) (1) A PHARMACIST MAY NOT ADMINISTER A MAINTENANCE INJECTABLE MEDICATION UNDER SUBSECTION (A)(2) OF THIS SECTION UNLESS THE PHARMACIST PROVIDES THE PATIENT WITH THE FOLLOWING WRITTEN NOTICE:
21	"IMPORTANT FINANCIAL INFORMATION
22 23	Notice of Pharmacist's Maintenance Injectable Medication Administration Fee and Medical Billing Disclosure
24	A. MAINTENANCE INJECTABLE MEDICATION ADMINISTRATION FEE.
25 26 27 28	THE PHARMACIST MAY CHARGE A SEPARATE FEE FOR ADMINISTERING A MAINTENANCE INJECTABLE MEDICATION THAT IS IN ADDITION TO THE COST OF YOUR MAINTENANCE INJECTABLE MEDICATION. THE PHARMACIST WILL INITIAL THE STATEMENT BELOW THAT APPLIES TO YOU.
29	THE PHARMACIST DOES NOT CHARGE A SEPARATE FEE FOR

ADMINISTERING A MAINTENANCE INJECTABLE MEDICATION.

- 1 \_\_\_\_\_ THE PHARMACIST'S CHARGES A SEPARATE FEE FOR ADMINISTRATING A
  2 MAINTENANCE INJECTABLE MEDICATION IN THE AMOUNT OF \$ ...
- 3 IF YOUR HEALTH BENEFIT PLAN DOES NOT COVER ALL OR PART OF THE
- 4 PHARMACIST'S MAINTENANCE INJECTABLE MEDICATION ADMINISTRATION FEE,
- 5 YOU MAY BE RESPONSIBLE FOR PAYING THE BALANCE. THE PHARMACIST WILL
- 6 INITIAL THE SECTION BELOW THAT IS APPLICABLE TO YOUR INSURANCE COVERAGE.
- 7 PLEASE READ THE INITIALED SECTION AND ASK THE PHARMACIST ANY QUESTIONS
- 8 YOU MAY HAVE.
- 9 SECTION 1. THIS SECTION APPLIES TO YOU. YOU HAVE A PLAN THAT LIKELY
- 10 DOES NOT COVER THE MAINTENANCE INJECTABLE MEDICATION ADMINISTRATION
- 11 FEE. YOU MUST PAY THE MAINTENANCE INJECTABLE MEDICATION
- 12 <u>ADMINISTRATION FEE IN FULL IF YOU CHOOSE TO HAVE THE MAINTENANCE</u>
- 13 INJECTABLE MEDICATION ADMINISTERED HERE. THE PHARMACIST WILL SUBMIT A
- 14 CLAIM ON YOUR BEHALF. IF YOUR PLAN PAYS THE PHARMACIST ALL OR PART OF
- 15 THE FEE, THE PHARMACIST WILL ISSUE YOU A REFUND WITHIN 30 DAYS AFTER
- 16 RECEIPT OF PAYMENT FROM YOUR PLAN.
- 17 \_\_\_\_ SECTION 2. THIS SECTION APPLIES TO YOU. YOUR PLAN FULLY COVERS THE
- 18 MAINTENANCE INJECTABLE MEDICATION ADMINISTRATION FEE. YOU OWE \$0 FOR
- 19 THE MAINTENANCE INJECTABLE MEDICATION ADMINISTRATION FEE. YOU WILL NOT
- 20 BE BILLED TODAY OR IN THE FUTURE FOR TODAY'S MAINTENANCE INJECTABLE
- 21 MEDICATION ADMINISTRATION FEE.
- 22 \_\_\_\_ SECTION 3. THIS SECTION APPLIES TO YOU. YOU HAVE A PLAN THAT COVERS
- 23 ALL OR PART OF THE MAINTENANCE INJECTABLE MEDICATION ADMINISTRATION
- 24 FEE BUT THE PHARMACIST DOES NOT HAVE A CONTRACT WITH YOUR PLAN SO YOU
- 25 MAY BE RESPONSIBLE FOR ALL OR PART OF THE FEE. YOU MUST PAY \$ TODAY
- 26 TO HAVE THE MAINTENANCE INJECTABLE MEDICATION ADMINISTERED. IF YOU
- 27 HAVE OVERPAID, THE PHARMACIST WILL ISSUE YOU A REFUND WITHIN 30 DAYS
- 28 AFTER RECEIPT OF PAYMENT FROM YOUR PLAN.
- YOU COULD SAVE MONEY BY HAVING YOUR MAINTENANCE INJECTABLE
- 30 MEDICATION ADMINISTERED BY A HEALTH CARE PROVIDER WHO HAS A CONTRACT
- 31 WITH YOUR PLAN. BEFORE HAVING THE MAINTENANCE INJECTABLE MEDICATION
- 32 ADMINISTERED AT THIS TIME, YOU SHOULD CONTACT YOUR PLAN TO DETERMINE
- ADMINISTERED AT THIS TIME, TOU SHOULD CONTACT TOUR TEAN TO DETERMINE
- 33 YOUR COST FOR THE MAINTENANCE INJECTABLE MEDICATION ADMINISTRATION
- 34 FEE IF DELIVERED BY A HEALTH CARE PROVIDER WHO HAS A CONTRACT WITH YOUR
- 35 PLAN. YOU SHOULD ASK WHAT YOU WOULD PAY OUT-OF-POCKET FOR A
- 36 COPAYMENT, COINSURANCE, OR A DEDUCTIBLE.
- 37 \_\_\_\_ SECTION 4. THIS SECTION APPLIES TO YOU. THE PHARMACIST DOES HAVE A
- 38 CONTRACT WITH YOUR PLAN AND THERE IS COVERAGE FOR THE PHARMACIST'S

1	MAINTENANCE INJECTABLE MEDICATION ADMINISTRATION FEE. THE PHARMACIST
2	HAS CONTACTED YOUR PLAN AND WAS INFORMED THAT YOUR OUT-OF-POCKET
3	EXPENSES FOR THE MAINTENANCE INJECTABLE MEDICATION ADMINISTRATION FEB
4	WILL BE:
5	COPAYMENT
6	COINSURANCE
7	<u>DEDUCTIBLE</u>
8	TOTAL
9	B. PAYMENT REQUIRED.
10	I AGREE TO PAY THE TOTAL PAYMENT FOR WHICH I AM RESPONSIBLE TODAY IN THE
10 11	AMOUNT OF \$ THE PHARMACIST WILL SUBMIT A CLAIM ON MY BEHALF AND 1
12	WILL BE REFUNDED ANY OVERPAYMENT WITHIN 30 DAYS AFTER THE PHARMACIST'S
13	RECEIPT OF PAYMENT FROM MY PLAN.
10	INDUCTION AND THE WAY
14	C. INFORMED CONSENT REQUIRED.
15	THE PHARMACIST MAY NOT COLLECT OR ATTEMPT TO COLLECT
16	PAYMENT FOR A MAINTENANCE INJECTABLE MEDICATION
17	ADMINISTRATION FEE FROM YOU UNLESS THIS FORM IS PROPERLY
18	COMPLETED BY THE PHARMACIST AND SIGNED BY YOU. THE
19	PHARMACIST IS REQUIRED TO PROVIDE A COPY OF THIS COMPLETED
20	FORM TO YOU.
21	Py cigning this eodm i acknowledge that I was drowned this complete
22	BY SIGNING THIS FORM, I ACKNOWLEDGE THAT I WAS PROVIDED THIS COMPLETED FORM BEFORE BEING ADMINISTERED A MAINTENANCE INJECTABLE MEDICATION
23	TODAY.
24	
25	<u>SIGNATURE</u>
26	D. COMPLAINTS AND ADDITIONAL INFORMATION.
27	IF YOU HAVE A COMPLAINT RELATING TO THE MAINTENANCE INJECTABLE
28	MEDICATION ADMINISTRATION FEE OR SERVICE, PLEASE FIRST CONTACT THE
29	PHARMACIST.
30	IF THE COMPLAINT IS UNRESOLVED, YOU MAY THEN FILE THE COMPLAINT WITH THE
31	STATE BOARD OF PHARMACY.

- 1 IF YOU NEED ADDITIONAL INFORMATION REGARDING YOUR MAINTENANCE
- 2 <u>INJECTABLE MEDICATION ADMINISTRATION FEE CHARGES OR IF YOU NEED</u>
- 3 ASSISTANCE MEDIATING A MAINTENANCE INJECTABLE MEDICATION
- 4 ADMINISTRATION FEE COMPLAINT AGAINST A PHARMACIST, CONTACT THE HEALTH
- 5 EDUCATION AND ADVOCACY UNIT OF THE OFFICE OF THE ATTORNEY GENERAL.
- 6 TO REQUEST THIS NOTICE IN AN ALTERNATIVE FORMAT, PLEASE CONTACT THE
- 7 STATE BOARD OF PHARMACY.".
- 8 (2) If a pharmacist charges all or part of a fee for
- 9 ADMINISTERING A MAINTENANCE INJECTABLE MEDICATION UNDER SUBSECTION
- 10 (A)(2) OF THIS SECTION, THE PHARMACIST:
- 11 (I) SHALL PROVIDE THE PATIENT WITH THE WRITTEN NOTICE
- 12 REQUIRED UNDER PARAGRAPH (1) OF THIS SUBSECTION SEPARATE FROM ANY
- 13 OTHER FORMS OR NOTICES; AND
- 14 (II) MAY NOT COLLECT OR ATTEMPT TO COLLECT PAYMENT
- 15 FROM A PATIENT UNLESS THE PHARMACIST PROVIDES THE PATIENT, BEFORE
- 16 ADMINISTERING THE MAINTENANCE INJECTABLE MEDICATION, WITH:
- 1. A PROPERLY COMPLETED NOTICE AS REQUIRED
- 18 UNDER PARAGRAPH (1) OF THIS SUBSECTION; AND
- 19 2. A COPY OF THE COMPLETED AND SIGNED NOTICE
- 20 REQUIRED UNDER PARAGRAPH (1) OF THIS SUBSECTION.
- 21 (3) If A PATIENT DOES NOT SPEAK ENGLISH OR REQUESTS THE
- 22 NOTICE REQUIRED UNDER PARAGRAPH (1) OF THIS SUBSECTION IN AN
- 23 ALTERNATIVE FORMAT, THE PHARMACIST SHALL, TO THE EXTENT PRACTICABLE,
- 24 PROVIDE THE NOTICE IN A LANGUAGE OR FORMAT THAT IS UNDERSTANDABLE TO
- 25 THE PATIENT.
- 26 (C) (D) (1) On or before September 1, 2022, the Board, in
- 27 CONSULTATION WITH THE STATE BOARD OF PHYSICIANS AND THE STATE BOARD
- 28 OF NURSING, SHALL ADOPT REGULATIONS ESTABLISHING STANDARD PROCEDURES:
- 29 (I) THAT A PHARMACIST MUST USE TO ADMINISTER A
- 30 MAINTENANCE INJECTABLE MEDICATION AFTER AN INITIAL DOSE IS ADMINISTERED
- 31 BY THE PRESCRIBER;

- 1 (II) THAT A PHARMACIST MUST USE TO ADMINISTER AN INITIAL
- 2 DOSE OF A MAINTENANCE INJECTABLE MEDICATION IF THE ADMINISTRATION OF
- 3 THE INITIAL DOSE IS AUTHORIZED UNDER SUBSECTION (B) OF THIS SECTION; AND
- 4 (III) FOR COMMUNICATING TO THE PRESCRIBER WHETHER A
- 5 MEDICATION WAS ADMINISTERED TO A SPECIFIC PATIENT AND RELEVANT
- 6 INFORMATION ABOUT THE PATIENT'S CONDITION.
- 7 (2) THE REGULATIONS SHALL REQUIRE A PHARMACIST TO:
- 8 (I) EXCEPT AS PROVIDED IN PARAGRAPH (3) OF THIS
- 9 SUBSECTION, COMPLETE A TRAINING PROGRAM APPROVED BY THE BOARD FOR:
- 10 1. Administering maintenance injectable
- 11 MEDICATIONS; AND
- 12 **2.** MANAGING THE POPULATIONS THE PHARMACIST
- 13 SERVES, THE MEDICATIONS BEING ADMINISTERED, AND THE CURRENT GUIDELINES
- 14 RELATING TO THESE POPULATIONS AND MEDICATIONS;
- 15 (II) FOLLOW THE STANDARD PROCEDURES ESTABLISHED BY
- 16 THE BOARD; AND
- 17 (III) AFTER ADMINISTERING A MAINTENANCE INJECTABLE
- 18 **MEDICATION**:
- 1. Notify the prescriber that the maintenance
- 20 INJECTABLE MEDICATION WAS ADMINISTERED AND OF ANY RELEVANT DETAILS
- 21 ABOUT THE PATIENT'S CONDITION;
- 22 PROVIDE THE PATIENT WITH A WRITTEN RECORD OF
- 23 THE MAINTENANCE INJECTABLE MEDICATION ADMINISTERED;
- 24 RECORD IN ANY ELECTRONIC OR WRITTEN HEALTH
- 25 RECORD ON THE PATIENT MAINTAINED BY THE PHARMACIST:
- A. THE ADMINISTERING OF THE MAINTENANCE
- 27 INJECTABLE MEDICATION; AND
- 28 B. Any pertinent details about the patient's
- 29 CONDITION; AND
- 30 4. NOTIFY THE PATIENT OF THE NEED TO ATTEND ANY
- 31 UPCOMING APPOINTMENTS THE PATIENT HAS SCHEDULED WITH THE PRESCRIBER.

$1 \\ 2$	(3) THE REGULATIONS SHALL WAIVE THE REQUIREMENT TO COMPLETE A TRAINING PROGRAM FOR A PHARMACIST WHO ALREADY HAS
3	UNDERGONE THE TRAINING AS PART OF THE PHARMACIST'S FORMAL EDUCATIONAL
4	PROGRAM.
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5	Article – Insurance
6	15–716.
7	(A) THIS SECTION APPLIES TO INDIVIDUAL, GROUP, OR BLANKET HEALTH
8	INSURANCE POLICIES AND CONTRACTS DELIVERED OR ISSUED FOR DELIVERY IN
9	THE STATE BY INSURERS, NONPROFIT HEALTH SERVICE PLANS, AND HEALTH
10	MAINTENANCE ORGANIZATIONS FOR THAT PROVIDE COVERAGE FOR PATIENT
11	ASSESSMENT REGARDING, AND ADMINISTRATION OF, SELF-ADMINISTERED
12	MEDICATIONS AND MAINTENANCE INJECTABLE MEDICATIONS.
13	(B) AN ENTITY SUBJECT TO THIS SECTION SHALL PROVIDE COVERAGE FOR
14	SERVICES RENDERED BY A LICENSED PHARMACIST UNDER § 12-509 OF THE
15	HEALTH OCCUPATIONS ARTICLE TO AN INDIVIDUAL WHO IS COVERED UNDER A
16	POLICY OR CONTRACT ISSUED OR DELIVERED BY THE ENTITY, TO THE SAME EXTENT
17	AS SERVICES RENDERED BY ANY OTHER LICENSED HEALTH CARE PRACTITIONER, IN
18	ADMINISTERING THE ADMINISTRATION OF SELF-ADMINISTERED MEDICATIONS OR
19	MAINTENANCE INJECTABLE MEDICATIONS.
20	SECTION 2. AND BE IT FURTHER ENACTED, That § 15–716 of the Insurance
$\frac{21}{21}$	Article, as enacted by Section 1 of this Act, shall apply to all policies and contracts issued,
22	delivered, or renewed in the State on or after January 1, 2022.
23 24	SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2021.
	Approved:
	Governor.
	President of the Senate.
	Speaker of the House of Delegates.