0lr3150 CF SB 752

By: Delegates Johnson, Pendergrass, Acevero, Arikan, Hill, Kelly, Kerr, Kipke, Krebs, R. Lewis, Parrott, Saab, Shetty, Szeliga, and Valderrama

Introduced and read first time: February 7, 2020 Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

Public Health - Non-Controlled Substance Prescription Record System Program

4 FOR the purpose of establishing the NCS Prescription Record System Program under the $\mathbf{5}$ Maryland Health Care Commission; providing for the purpose of the Program; 6 requiring the Commission to implement the Program; requiring the Commission to 7 establish standards for selecting a certain prescription information system and any 8 other means for the transmission of certain information within the Program; 9 requiring that certain standards include certain requirements; requiring the 10 Commission to consider certain information to the extent practicable when making 11 a certain determination; requiring the Commission to make certain determinations; 12requiring a certain dispenser to submit certain information to the Program within a 13 certain period of time; prohibiting a dispenser from submitting certain information 14 to the Program; requiring a dispenser to submit certain information electronically 15using a certain method; requiring the State-designated health information exchange 16to accept and store certain information and make certain information available to 17certain persons; prohibiting the State-designated health information exchange from 18 charging a certain fee or other expense or making available or storing certain 19information; requiring each certain dispenser and prescriber to provide consumers 20certain information in a certain manner; requiring the Commission to post certain 21information on its website; establishing the NCS Prescription Record System 22Program Advisory Committee; providing for the purpose of the Advisory Committee; 23providing for the composition, chair, and terms of the Advisory Committee; requiring 24the Advisory Committee to meet at least quarterly; requiring the Advisory 25Committee to make certain recommendations; prohibiting a member of the Advisory 26Committee from receiving certain compensation, but authorizing the reimbursement 27of certain expenses; requiring the Commission, in consultation with the Secretary of 28Health, to adopt certain regulations; requiring the Commission to annually report to 29certain committees of the General Assembly on the Program beginning on a certain 30 date; defining certain terms; specifying the terms of the initial members of the

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW. [Brackets] indicate matter deleted from existing law.



$ \begin{array}{c} 1 \\ 2 \\ 3 \\ 4 \end{array} $	Advisory Committee; requiring the Commission to submit a certain plan to the General Assembly for approval; providing for the termination of certain provisions of this Act under certain circumstances; and generally relating to the NCS Prescription Record System Program.
$5 \\ 6 \\ 7 \\ 8 \\ 9 \\ 10$	BY adding to Article – Health – General Section 21–2D–01 through 21–2D–07 to be under the new subtitle "Subtitle 2D. NCS Prescription Record System Program" Annotated Code of Maryland (2019 Replacement Volume)
$\frac{11}{12}$	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:
13	Article – Health – General
14	SUBTITLE 2D. NCS PRESCRIPTION RECORD SYSTEM PROGRAM.
15	21–2 D –01.
$16\\17$	(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.
18 19	(B) "Advisory Committee" means the NCS Prescription Record System Program Advisory Committee.
20	(C) "COMMISSION" MEANS THE MARYLAND HEALTH CARE COMMISSION.
$21\\22\\23$	(D) (1) "DISPENSE" MEANS THE PROCEDURE THAT RESULTS IN THE RECEIPT OF A PRESCRIPTION OR NONPRESCRIPTION DRUG OR DEVICE BY A PATIENT OR THE PATIENT'S AGENT AND THAT ENTAILS:
24 25	(I) THE INTERPRETATION OF AN AUTHORIZED PRESCRIBER'S PRESCRIPTION FOR A DRUG OR DEVICE;
26 27	(II) THE SELECTION AND LABELING OF THE PRESCRIBED DRUG OR DEVICE IN ACCORDANCE WITH THE PRESCRIPTION; AND
28 29	(III) THE MEASURING AND PACKAGING OF THE PRESCRIBED DRUG OR DEVICE IN ACCORDANCE WITH FEDERAL AND STATE LAWS.
30	(2) "DISPENSE" DOES NOT INCLUDE:
31	(I) DIRECT ADMINISTRATION OF A PRESCRIPTION DRUG TO A

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1 PATIENT BY A HEALTH CARE PRACTITIONER; OR

2 (II) DISTRIBUTION OF A PRESCRIPTION DRUG SAMPLE TO A 3 PATIENT BY A HEALTH CARE PRACTITIONER.

4 (E) "DISPENSER" HAS THE MEANING STATED IN § 21–2A–01 OF THIS TITLE.

5 (F) "HEALTH CARE PRACTITIONER" MEANS AN INDIVIDUAL WHO IS 6 LICENSED, CERTIFIED, OR OTHERWISE AUTHORIZED UNDER THE HEALTH 7 OCCUPATIONS ARTICLE TO PROVIDE MEDICAL SERVICES IN THE ORDINARY 8 COURSE OF BUSINESS OR PRACTICE OF A PROFESSION.

9 (G) "NCS PRESCRIPTION DRUG" MEANS A PRESCRIPTION DRUG, AS 10 DEFINED IN § 21–201 OF THIS TITLE, THAT IS NOT A CONTROLLED DANGEROUS 11 SUBSTANCE UNDER TITLE 5, SUBTITLE 4 OF THE CRIMINAL LAW ARTICLE.

12 (H) "PHARMACIST" MEANS AN INDIVIDUAL WHO IS LICENSED UNDER TITLE 13 **12** OF THE HEALTH OCCUPATIONS ARTICLE TO DISPENSE A MONITORED 14 PRESCRIPTION DRUG.

15 (I) "PRESCRIBER" MEANS A LICENSED HEALTH CARE PRACTITIONER 16 AUTHORIZED BY LAW TO PRESCRIBE NCS PRESCRIPTION DRUGS.

17 (J) "PRESCRIBER DELEGATE" MEANS AN INDIVIDUAL WHO IS:

18 (1) AUTHORIZED BY A PRESCRIBER TO REQUEST OR ACCESS
 19 PRESCRIPTION MONITORING DATA; AND

20 (2) EMPLOYED BY OR UNDER CONTRACT WITH THE SAME 21 PROFESSIONAL PRACTICE AS THE PRESCRIBER.

(K) "PRESCRIPTION INFORMATION SYSTEM" MEANS THE SYSTEM AND ANY
 OTHER MEANS SELECTED BY THE COMMISSION FOR THE TRANSMISSION OF NCS
 PRESCRIPTION DRUG INFORMATION.

25 (L) "PROGRAM" MEANS THE NCS PRESCRIPTION RECORD SYSTEM 26 PROGRAM.

(M) "STATE-DESIGNATED HEALTH INFORMATION EXCHANGE" MEANS THE
HEALTH INFORMATION EXCHANGE DESIGNATED BY THE COMMISSION UNDER §
19–143 OF THIS ARTICLE.

30 **21–2D–02.**

1 (A) THERE IS AN NCS PRESCRIPTION RECORD SYSTEM PROGRAM UNDER 2 THE MARYLAND HEALTH CARE COMMISSION.

(B) THE PURPOSE OF THE PROGRAM IS TO IMPROVE PATIENT SAFETY AND
REDUCE HEALTH CARE COSTS BY ALLOWING A PRESCRIBER AND PRESCRIBER
DELEGATE TO ACCESS THE NCS PRESCRIPTION DRUG HISTORY OF A PATIENT,
INCLUDING DRUGS PRESCRIBED BY OTHER PRESCRIBERS.

7 (C) THE COMMISSION SHALL IMPLEMENT THE PROGRAM.

8 **21–2D–03.**

9 (A) THE COMMISSION SHALL ESTABLISH BY REGULATION STANDARDS FOR 10 SELECTING A PRESCRIPTION INFORMATION SYSTEM THAT MAY ELECTRONICALLY 11 TRANSMIT NCS PRESCRIPTION DRUG INFORMATION, AND ANY OTHER MEANS FOR 12 THE TRANSMISSION OF NCS PRESCRIPTION DRUG INFORMATION WITHIN THE 13 PROGRAM.

14 (B) THE STANDARDS DEVELOPED UNDER SUBSECTION (A) OF THIS SECTION 15 SHALL REQUIRE A PRESCRIPTION INFORMATION SYSTEM TO:

16 (1) MEET THE PRIVACY AND SECURITY CONTROL AND TECHNICAL 17 PERFORMANCE STANDARDS ESTABLISHED BY THE COMMISSION;

18 (2) COMPLY WITH EACH REQUIRED PRIVACY AND SECURITY 19 CONTROL AND TECHNICAL PERFORMANCE STANDARD DURING THE PERIOD OF 20 RECOGNITION BY THE COMMISSION;

21 (3) ACCEPT NCS PRESCRIPTION DRUG INFORMATION SUBMITTED 22 BY DISPENSERS;

(4) TRANSMIT THE NCS PRESCRIPTION DRUG INFORMATION
 SUBMITTED BY DISPENSERS TO THE STATE-DESIGNATED HEALTH INFORMATION
 EXCHANGE; AND

26(5)MEET AND MAINTAIN COMPLIANCE WITH ANY OTHER STANDARD27ESTABLISHED BY THE COMMISSION.

28 (C) TO THE EXTENT PRACTICABLE, WHEN DETERMINING WHETHER TO 29 SELECT A PRESCRIPTION INFORMATION SYSTEM, THE COMMISSION SHALL:

- 30
- (1) CONSIDER THE EXTENT TO WHICH THE PRESCRIPTION

1	INFORMATION SYSTEM IS BEING USED BY DISPENSERS AND PRESCRIBERS; AND
$2 \\ 3$	(2) MINIMIZE ANY ADVERSE IMPACTS OF IMPLEMENTATION ON DISPENSERS AND PRESCRIBERS.
4	21–2D–04.
5	(A) THE COMMISSION SHALL DETERMINE:
6	(1) THE CATEGORIES OF PRESCRIBERS AND DISPENSERS WHO ARE:
7 8	(I) REQUIRED TO PARTICIPATE IN AND COMPLY WITH THE REQUIREMENTS OF THE PROGRAM; AND
9	(II) EXCLUDED FROM PARTICIPATING IN THE PROGRAM;
$10\\11\\12$	(2) THE TIME PERIOD WITHIN WHICH A DISPENSER SHALL TRANSMIT INFORMATION ON A DISPENSED NCS PRESCRIPTION DRUG TO A PRESCRIPTION INFORMATION SYSTEM; AND
$\frac{13}{14}$	(3) THE METHOD BY WHICH PATIENTS MAY OPT OUT OF THE PROGRAM.
$15\\16\\17\\18$	(B) (1) (I) EXCEPT AS PROVIDED IN SUBPARAGRAPH (II) OF THIS PARAGRAPH, AFTER DISPENSING AN NCS PRESCRIPTION DRUG, A DISPENSER SHALL SUBMIT ALL REQUIRED INFORMATION ON THE PRESCRIPTION TO THE PROGRAM WITHIN THE TIME PERIOD ESTABLISHED BY THE COMMISSION.
19 20 21	(II) A DISPENSER MAY NOT SUBMIT INFORMATION ON AN NCS PRESCRIPTION DRUG FROM A PRESCRIBER WHO IS EXCLUDED FROM THE PROGRAM.
$22 \\ 23 \\ 24$	(2) A DISPENSER SHALL SUBMIT THE REQUIRED INFORMATION ON A DISPENSED NCS PRESCRIPTION DRUG UNDER PARAGRAPH (1) OF THIS SUBSECTION ELECTRONICALLY USING A PRESCRIPTION INFORMATION SYSTEM.
25 26	(C) (1) EXCEPT AS PROVIDED IN PARAGRAPH (2)(II) OF THIS SUBSECTION, THE STATE-DESIGNATED HEALTH INFORMATION EXCHANGE SHALL:
27 28 29	(I) ACCEPT AND STORE NCS PRESCRIPTION DRUG INFORMATION SUBMITTED THROUGH A PRESCRIPTION INFORMATION SYSTEM UNDER THIS SUBTITLE; AND

(II) MAKE NCS PRESCRIPTION DRUG 1 INFORMATION $\mathbf{2}$ AVAILABLE TO PRESCRIBERS, PHARMACISTS, PRESCRIBER DELEGATES, AND 3 PHARMACIST DELEGATES IN ACCORDANCE WITH REGULATIONS. 4 (2) THE STATE-DESIGNATED HEALTH INFORMATION EXCHANGE $\mathbf{5}$ MAY NOT: 6 CHARGE ANY OF THE FOLLOWING A FEE OR OTHER **(I)** 7 EXPENSE FOR THE TRANSMISSION OR RETRIEVAL OF NCS PRESCRIPTION DRUG

8 INFORMATION WITHIN THE PROGRAM:

9 **1.** A DISPENSER OR PRESCRIBER; OR

10 2. A PRESCRIPTION INFORMATION SYSTEM; OR

11 (II) MAKE AVAILABLE OR STORE NCS PRESCRIPTION DRUG 12 INFORMATION FOR ANY INDIVIDUAL WHO HAS OPTED OUT OF THE PROGRAM OR 13 THE STATE-DESIGNATED HEALTH INFORMATION EXCHANGE.

14 **21–2D–05.**

15 (A) EACH DISPENSER AND PRESCRIBER WHO PARTICIPATES IN THE 16 PROGRAM SHALL PROVIDE CONSUMERS, BY AN APPROPRIATE METHOD:

17 (1) NOTICE THAT INFORMATION ON AN NCS PRESCRIPTION DRUG 18 DISPENSED OR PRESCRIBED BY THE DISPENSER OR PRESCRIBER WILL BE 19 SUBMITTED TO THE PROGRAM UNLESS THE CONSUMER OPTS OUT OF THE 20 PROGRAM OR THE PRESCRIBER IS EXCLUDED FROM THE PROGRAM;

21 (2) A DESCRIPTION OF HOW THE PROGRAM MAY USE THE RECORD 22 OF A DISPENSED OR PRESCRIBED NCS PRESCRIPTION DRUG;

(3) NOTICE THAT NCS PRESCRIPTION DRUG INFORMATION WILL BE
SHARED WITH HEALTH CARE PRACTITIONERS ENGAGED IN THE PATIENT'S CARE
UNLESS THE CONSUMER OPTS OUT OF THE PROGRAM OR THE HEALTH CARE
PRACTITIONER IS EXCLUDED FROM THE PROGRAM;

27(4)THE WEBSITE THROUGH WHICH THE PATIENT MAY OPT OUT OF28PARTICIPATION IN THE PROGRAM; AND

29 (5) ANY INFORMATION REQUIRED BY THE COMMISSION, AFTER 30 CONSULTATION WITH THE ADVISORY COMMITTEE.

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1 (B) THE COMMISSION SHALL POST INFORMATION ON THE PROGRAM ON 2 ITS WEBSITE, INCLUDING:

3 (1) A DESCRIPTION OF HOW AN INDIVIDUAL CAN OPT OUT OF THE 4 PROGRAM; AND

5 (2) A LINK TO THE FORM THAT MUST BE USED BY A CONSUMER TO 6 OPT OUT OF THE PROGRAM LOCATED ON THE WEBSITE OF THE 7 STATE-DESIGNATED HEALTH INFORMATION EXCHANGE.

8 **21–2D–06.**

9 (A) THERE IS AN NCS PRESCRIPTION RECORD SYSTEM PROGRAM 10 ADVISORY COMMITTEE.

11 **(B)** THE PURPOSE OF THE ADVISORY COMMITTEE IS TO PROVIDE 12 CLINICAL AND OPERATIONAL RECOMMENDATIONS TO THE COMMISSION IN THE 13 DEVELOPMENT AND IMPLEMENTATION OF THE PROGRAM.

- 14 (C) THE ADVISORY COMMITTEE CONSISTS OF:
- 15 (1) THE FOLLOWING MEMBERS DESIGNATED BY THE COMMISSION:

16 (I) ONE PRIMARY CARE PHYSICIAN LICENSED AND 17 PRACTICING IN THE STATE, NOMINATED BY THE MARYLAND ACADEMY OF FAMILY 18 MEDICINE;

19 (II) ONE PRIMARY CARE PHYSICIAN LICENSED AND 20 PRACTICING IN THE STATE, NOMINATED BY THE MARYLAND CHAPTER OF THE 21 AMERICAN COLLEGE OF PHYSICIANS;

22 (III) ONE PHYSICIAN LICENSED AND PRACTICING IN THE 23 STATE, NOMINATED BY MEDCHI;

(IV) ONE EMERGENCY MEDICINE PHYSICIAN LICENSED AND
 PRACTICING IN THE STATE, NOMINATED BY THE MARYLAND AMERICAN COLLEGE
 OF EMERGENCY PHYSICIANS;

27 (V) ONE ENDOCRINOLOGIST LICENSED AND PRACTICING IN 28 THE STATE WHO TREATS PATIENTS WITH DIABETES, NOMINATED BY THE 29 MID-ATLANTIC CHAPTER OF THE AMERICAN COLLEGE OF CLINICAL 30 ENDOCRINOLOGISTS;

	8 HOUSE BILL 1486
$\frac{1}{2}$	(VI) ONE PSYCHIATRIST LICENSED AND PRACTICING IN THE STATE, NOMINATED BY THE MARYLAND PSYCHIATRIC SOCIETY;
3	(VII) ONE MEMBER NOMINATED BY THE ATTORNEY GENERAL;
4 5 6	(VIII) ONE MEMBER WITH EXPERTISE IN HEALTH INFORMATION TECHNOLOGY, NOMINATED BY THE MARYLAND CHAPTER OF THE HEALTHCARE INFORMATION AND MANAGEMENT SYSTEMS SOCIETY;
7 8	(IX) ONE PHARMACIST LICENSED AND PRACTICING IN THE STATE, NOMINATED BY THE MARYLAND PHARMACISTS ASSOCIATION;
9 10	(X) ONE REPRESENTATIVE OF THE PRESCRIPTION DRUG MONITORING PROGRAM, NOMINATED BY THE SECRETARY OF HEALTH;
11 12 13	(XI) ONE RESIDENT OF THE STATE WHO HAS EXPERIENCE WITH HEALTH ISSUES IMPACTING CONSUMERS, NOMINATED BY THE SECRETARY OF HEALTH; AND
$\begin{array}{c} 14\\ 15\\ 16\end{array}$	(XII) ONE RESIDENT OF THE STATE WHO HAS EXPERTISE IN HEALTH INFORMATION TECHNOLOGY AND CYBERSECURITY, NOMINATED BY THE SECRETARY OF INFORMATION TECHNOLOGY; AND
17 18	(2) ONE MEMBER OF THE COMMISSION, DESIGNATED BY THE CHAIR OF THE COMMISSION.
19 20 21	(D) THE MEMBER OF THE COMMISSION DESIGNATED TO SERVE ON THE ADVISORY COMMITTEE SHALL SERVE AS THE CHAIR OF THE ADVISORY COMMITTEE.
$\frac{22}{23}$	(E) (1) THE TERM OF A MEMBER DESIGNATED UNDER SUBSECTION (C)(1) OF THIS SECTION IS 4 YEARS.
24 25 26	(2) THE TERMS OF MEMBERS DESIGNATED UNDER SUBSECTION (C)(1) OF THIS SECTION ARE STAGGERED AS REQUIRED BY THE TERMS PROVIDED FOR MEMBERS OF THE ADVISORY COMMITTEE ON OCTOBER 1, 2020.
27 28 29	(3) AT THE END OF A TERM, A MEMBER DESIGNATED UNDER SUBSECTION (C)(1) OF THIS SECTION CONTINUES TO SERVE UNTIL A SUCCESSOR IS DESIGNATED AND QUALIFIES.
$\begin{array}{c} 30\\ 31 \end{array}$	(4) A MEMBER WHO IS DESIGNATED AFTER A TERM HAS BEGUN SERVES ONLY FOR THE REST OF THE TERM AND UNTIL A SUCCESSOR IS

THE ADVISORY COMMITTEE SHALL: (1) (2) (1) (2) three members in 2023; (1)(2)three members in 2024;

 $\mathbf{2}$ (5) A MEMBER DESIGNATED UNDER SUBSECTION (C)(1) OF THIS SECTION MAY SERVE NOT MORE THAN TWO CONSECUTIVE 4-YEAR TERMS. 3

- 4 **(F)** THE ADVISORY COMMITTEE SHALL MEET AT LEAST QUARTERLY.
- $\mathbf{5}$ (G)

DESIGNATED AND QUALIFIES.

6 Make policy and operational recommendations to the 7 COMMISSION REGARDING THE ESTABLISHMENT AND OPERATION OF THE 8 **PROGRAM; AND**

9 MAKE RECOMMENDATIONS REGARDING WHICH HEALTH CARE 10 PRACTITIONERS WHO DISPENSE OR PRESCRIBE NCS PRESCRIPTION DRUGS 11 SHOULD BE EXCLUDED FROM THE PROGRAM.

A MEMBER OF THE ADVISORY COMMITTEE: 12**(H)**

13MAY NOT RECEIVE COMPENSATION AS A MEMBER OF THE 14**ADVISORY COMMITTEE: BUT**

IS ENTITLED TO REIMBURSEMENT FOR EXPENSES UNDER THE 15STANDARD STATE TRAVEL REGULATIONS, AS PROVIDED IN THE STATE BUDGET. 16

21-2D-07. 17

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18 (A) THE COMMISSION, IN CONSULTATION WITH THE SECRETARY, SHALL 19 ADOPT REGULATIONS TO IMPLEMENT THIS SUBTITLE.

BEGINNING JANUARY 1, 2021, THE COMMISSION SHALL ANNUALLY 20**(B)** REPORT TO THE SENATE FINANCE COMMITTEE AND THE HOUSE HEALTH AND 2122**GOVERNMENT OPERATIONS COMMITTEE, IN ACCORDANCE WITH § 2–1257 OF THE** STATE GOVERNMENT ARTICLE, ON THE PROGRAM. 23

SECTION 2. AND BE IT FURTHER ENACTED, That the terms of the initial 2425members of the NCS Prescription Record System Program Advisory Committee shall expire as follows: 26

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- 28
- 29(3)three members in 2025; and

1 (4) four members in 2026.

2 SECTION 3. AND BE IT FURTHER ENACTED, That:

3 (a) The Maryland Health Care Commission shall submit a plan for funding the 4 NCS Prescription Record System Program to the General Assembly for approval.

5 (b) If the Maryland Health Care Commission does not submit a plan in 6 accordance with this section or the General Assembly does not approve a plan submitted 7 by the Maryland Health Care Commission on or before April 15, 2022, Sections 1 and 2 of 8 this Act, with no further action required by the General Assembly, shall be abrogated and 9 of no further force and effect.

10 SECTION 4. AND BE IT FURTHER ENACTED, That this Act shall take effect 11 October 1, 2020.

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