J2, J1 2lr0478

By: Senator Ready

AN ACT concerning

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Introduced and read first time: February 7, 2022

Assigned to: Education, Health, and Environmental Affairs

A BILL ENTITLED

2	Controlled Dangerous Substances and Treatment of Chronic Pain and

Long-Term Oxygen Use Patients (Continuity of Care Act of 2022)

5 FOR the purpose of altering certain requirements related to the provision of information 6 regarding opioid use disorder by the Maryland Department of Health, the 7 prescribing of opioids, and the filling of prescriptions for monitored prescription 8 drugs; establishing certain civil and criminal immunity; requiring a health care 9 provider to make a good-faith effort to maintain the previous dosage of and regimen 10 for a controlled dangerous substance and make certain referrals for a certain patient; 11 providing that a patient who experiences and is diagnosed with chronic pain or 12 receives long-term oxygen therapy may be administered ongoing treatment by 13 certain practitioners or providers; establishing requirements for prescribers who treat patients who experience chronic pain or receive long-term oxygen therapy; and 14 15 generally relating to controlled dangerous substances and the treatment of chronic 16 pain and long-term oxygen use patients.

- 17 BY repealing and reenacting, with amendments,
- 18 Article Health General
- 19 Section 8–407(a)(1) and 21–2A–04.2(e) and (f)
- 20 Annotated Code of Maryland
- 21 (2019 Replacement Volume and 2021 Supplement)
- 22 BY adding to
- 23 Article Health General
- 24 Section 21–2A–04.2(f)
- 25 Annotated Code of Maryland
- 26 (2019 Replacement Volume and 2021 Supplement)
- 27 BY repealing and reenacting, with amendments,
- 28 Article Health Occupations



1 2 3	Section 1–223 Annotated Code of Maryland (2021 Replacement Volume)
4 5 6 7 8 9	BY adding to Article – Health Occupations Section 1–223.1; and 1–1101 through 1–1103 to be under the new subtitle "Subtitle 11. Requirements for Prescribing Opioids for Chronic Pain and Long–Term Oxygen Therapy" Annotated Code of Maryland (2021 Replacement Volume)
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	8–407.
15 16	(a) The Department shall identify up-to-date, evidence-based, written information about opioid use disorder that:
17 18 19 20	(1) Has been reviewed, USING THE CURRENT VERSION OF THE AMERICAN PSYCHIATRIC ASSOCIATION'S "DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS", by medical experts and national and local organizations specializing in the treatment of opioid use disorder;
21	21–2A–04.2.
22 23 24	(e) If a pharmacist or pharmacist delegate has a reasonable belief that a patient may be seeking a monitored prescription drug for any purpose other than the treatment or an existing medical condition:
25 26 27 28	(1) (I) Before dispensing a monitored prescription drug to the patient the pharmacist or pharmacist delegate shall request prescription monitoring data to determine if the patient has received other prescriptions that indicate misuse, abuse, or diversion of a monitored prescription drug; [and]
29 30 31 32	(II) AFTER REVIEW OF THE PRESCRIPTION MONITORING DATA IF THE PHARMACIST OR PHARMACIST DELEGATE HAS A REASONABLE BELIEF THAT A PATIENT MAY BE SEEKING A MONITORED PRESCRIPTION DRUG FOR MISUSE ABUSE, OR DIVERSION, THE PHARMACIST OR PHARMACIST DELEGATE SHALL CONTACT THE PRESCRIBER TO VERIFY AND COMMUNICATE ANY POSSIBLE

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CONCERNS; AND

- WAS FOR THE PURPOSE OF THE TREATMENT OF AN EXISTING MEDICAL CONDITION, 1 2 THE PHARMACIST OR PHARMACIST DELEGATE SHALL FILL THE PRESCRIPTION AS 3 WRITTEN; AND 4 The pharmacist shall have the responsibility described in 21 C.F.R. § (2) 1306.04. 5 6 **(F)** A PHARMACIST OR LICENSED PHARMACY MAY NOT BE HELD LIABLE IN 7 A CIVIL OR CRIMINAL ACTION SOLELY FOR DISPENSING AN OPIOID IF THE 8 PHARMACIST OR LICENSED PHARMACY COMPLIED WITH THE REQUIREMENTS OF 9 THIS SECTION. 10 [(f)] (G) The Secretary may adopt regulations to provide additional clinical, 11 technical, or administrative exemptions based on new standards of practice. 12 **Article – Health Occupations** 1-223.13 14 In this section, "controlled dangerous substance" has the meaning stated in § 15 5–101 of the Criminal Law Article. 16 On treatment for pain, a health care provider, based on the clinical judgment (b) 17 of the health care provider, shall prescribe: 18 (1) The lowest effective dose of an opioid; and 19 A quantity that is no greater than the quantity needed for the expected 20 duration of pain severe enough to require an opioid that is a controlled dangerous substance 21unless the opioid is prescribed to treat: 22 A substance–related disorder; (i) 23 (ii) Pain associated with a cancer diagnosis; 24(iii) Pain experienced while the patient is receiving end-of-life, 25 hospice, or palliative care services; or 26 (iv) Chronic pain. 27 The dosage, quantity, and duration of an opioid prescribed under subsection
- (c) The dosage, quantity, and duration of an opioid prescribed under subsection (b) of this section shall be based on [an evidence–based clinical guideline for prescribing controlled dangerous substances] THE PRESCRIBER'S CLINICAL JUDGMENT AFTER CONSIDERATION OF AN EVIDENCE–BASED CLINICAL GUIDELINE that is appropriate for:

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(1)

ELECTRONIC

- 1 (1) The health care service delivery setting for the patient; 2 The type of health care services required by the patient; and (2) 3 (3) The age and health status of the patient. 4 (1) When a patient is prescribed an opioid under subsection (b) of this section, the patient shall be advised of the benefits and risks associated with the opioid. 5 6 When a patient is co-prescribed a benzodiazepine with an opioid that 7 is prescribed under subsection (b) of this section, the patient shall be advised of the benefits 8 and risks associated with the benzodiazepine and the co-prescription of the 9 benzodiazepine. 10 A violation of subsection (b) or (d) of this section is grounds for POSSIBLE disciplinary action [by] AT THE DISCRETION OF the health occupations board that 11 regulates the health care provider who commits the ALLEGED violation. 12 13 1-223.1. IN THIS SECTION, "CONTROLLED DANGEROUS SUBSTANCE" HAS THE 14 MEANING STATED IN § 5–101 OF THE CRIMINAL LAW ARTICLE. 15 16 **(B)** A HEALTH CARE PROVIDER SHALL MAKE A GOOD-FAITH EFFORT TO 17 MAINTAIN A PREVIOUSLY PRESCRIBED DOSAGE OF AND REGIMEN FOR A 18 CONTROLLED DANGEROUS SUBSTANCE AND MAKE ANY TIMELY REFERRALS NECESSARY TO ENSURE A PATIENT'S CONTINUED CARE FOR A PATIENT WHO: 19 20 LOSES ACCESS TO THE PATIENT'S HEALTH CARE PROVIDER WHO **(1)** MANAGES THE PATIENT'S CONTROLLED DANGEROUS SUBSTANCE; AND 2122**(2)** SEEKS A CONTINUANCE OF A PRESCRIPTION. 23(C) A HEALTH CARE PROVIDER MAY ACCESS INFORMATION RELATING TO 24PREVIOUS DOSAGES AND REGIMENS FOR CONTROLLED 25 SUBSTANCES BY REVIEWING PRESCRIPTION MONITORING DATA IF:
- A REGIMEN FOR CONTROLLED DANGEROUS SUBSTANCES IS 28**(2)** 29 NECESSARY.

PHYSICAL

RECORDS,

INCLUDING

OR

DOCUMENTATION OF PREVIOUS DOSAGES, ARE UNAVAILABLE; AND

30 (D) A REFERRAL MADE UNDER SUBSECTION (B) OF THIS SECTION MAY

1	INCLUDE:
2	(1) MENTAL HEALTH MEDICATION MANAGEMENT;
3	(2) PAIN MEDICATION MANAGEMENT; AND
4	(3) A REFERRAL TO A NEW HEALTH CARE PROVIDER.
5 6 7 8 9	(E) A HEALTH CARE PROVIDER WHO PROVIDES TREATMENT UNDER THIS SECTION MAY NOT BE HELD LIABLE IN A CIVIL OR CRIMINAL ACTION IF THE HEALTH CARE PROVIDER MAKES A GOOD-FAITH EFFORT TO COMPLY WITH THE PROVISIONS OF THIS SECTION FOR 90 DAYS AFTER THE DAY OF THE FIRST VISIT OF THE PATIENT AT WHICH THE HEALTH CARE PROVIDER IS CONTINUING PREVIOUS DOSES OF OR A REGIMEN FOR A CONTROLLED DANGEROUS SUBSTANCE.
11 12	SUBTITLE 11. REQUIREMENTS FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN AND LONG-TERM OXYGEN THERAPY.
13	1–1101.
14 15	(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.
16	(B) (1) "CHRONIC PAIN" MEANS A CONDITION:
17 18	(I) IN WHICH A PATIENT'S PAIN PERSISTS BEYOND THE USUAL COURSE OF AN ACUTE DISEASE OR HEALING OF AN INJURY; OR
19 20 21	
22	(2) "CHRONIC PAIN" INCLUDES:
23 24	(I) INTERMITTENT EPISODIC PAIN THAT MIGHT REQUIRE PERIODIC TREATMENT; AND
25	(II) PAIN DESCRIBED AS:
26	1. CHRONIC EPISODIC;
27	2. CHRONIC RELAPSING:

- 3. HIGH IMPACT; OR
- 2 4. Intractable.
- 3 (3) "CHRONIC PAIN" DOES NOT INCLUDE TREATMENT FOR PAIN 4 FROM TERMINAL ILLNESS, AS DEFINED IN § 21–2A–01 OF THIS ARTICLE.
- 5 (C) "PRESCRIBER" MEANS A LICENSED HEALTH CARE PRACTITIONER WHO 6 IS AUTHORIZED UNDER LAW TO PRESCRIBE AN OPIOID.
- 7 **1–1102**.
- 8 (A) (1) A PATIENT WHO EXPERIENCES CHRONIC PAIN OR RECEIVES 9 LONG-TERM OXYGEN THERAPY MAY BE ADMINISTERED ONGOING TREATMENT BY:
- 10 (I) A HEALTH CARE PRACTITIONER WHO SPECIALIZES IN THE 11 TREATMENT OF CHRONIC PAIN OR LONG-TERM OXYGEN THERAPY;
- 12 (II) A LICENSED HEALTH CARE PRACTITIONER WHO 13 SPECIALIZES IN THE ILLNESS OR INJURY FROM WHICH THE PATIENT SUFFERS; OR
- 14 (III) THE PATIENT'S PRIMARY CARE PROVIDER.
- 15 (2) A PRIMARY CARE PROVIDER WHO ADMINISTERS TREATMENT FOR
 16 A PATIENT'S CHRONIC PAIN OR LONG—TERM OXYGEN THERAPY UNDER PARAGRAPH
 17 (1) OF THIS SUBSECTION SHALL DOCUMENT WHETHER THE PRIMARY CARE
 18 PROVIDER CONSULTED WITH A HEALTH CARE PRACTITIONER WHO SPECIALIZES IN
 19 THE TREATMENT OF THE PATIENT'S SPECIFIC ILLNESS OR INJURY OR A PAIN
 20 MANAGEMENT PRACTITIONER.
- 21 (B) A DIAGNOSIS OF CHRONIC PAIN MADE BY A PRESCRIBER AND SUPPORTED BY WRITTEN DOCUMENTATION OF THE DIAGNOSIS BY THE TREATING PRESCRIBER SHALL BE CONSIDERED PROOF THAT A PATIENT SUFFERS FROM CHRONIC PAIN.
- 25 (C) A PRESCRIBER WHO PROVIDES TREATMENT TO A PATIENT WHO 26 EXPERIENCES CHRONIC PAIN OR RECEIVES LONG—TERM OXYGEN THERAPY:
- 27 (1) SHALL MAKE ALL DECISIONS REGARDING THE TREATMENT OF A
 28 PATIENT EXPERIENCING CHRONIC PAIN OR RECEIVING LONG—TERM OXYGEN
 29 THERAPY, INCLUDING THE DECISION OF WHETHER THE TREATMENT REQUIRES THE
 30 PRESCRIPTION OF OPIOIDS;

- 1 SHALL ADMINISTER CARE SUFFICIENT TO TREAT A PATIENT **(2)** 2BASED ON ONGOING, OBJECTIVE EVALUATIONS OF A PATIENT WITHOUT FEAR OF 3 REPRIMAND OR DISCIPLINE; AND 4 MAY NOT MAKE A DETERMINATION BASED ON SPECIFIC MORPHINE MILLIGRAM EQUIVALENT GUIDELINES WHEN ORDERING, PRESCRIBING, 5 6 DISPENSING, ADMINISTERING, OR PURCHASING CONTROLLED DANGEROUS SUBSTANCES, INCLUDING OPIOIDS. 8 A PRESCRIBER WHO PROVIDES TREATMENT TO A PATIENT WHO (D) 9 EXPERIENCES CHRONIC PAIN OR RECEIVES LONG-TERM OXYGEN THERAPY SHALL: 10 **(1)** DOCUMENT IN THE PATIENT'S MEDICAL RECORD THE PATIENT'S 11 MEDICAL CONDITION AND TREATMENT; 12**(2)** IF OPIOIDS ARE ADMINISTERED, ADMINISTER THE OPIOIDS IN THE LOWEST AMOUNT NECESSARY TO CONTROL THE PATIENT'S CHRONIC PAIN; 13 IF OPIOIDS ARE PRESCRIBED: 14 **(3)** 15 **(I)** PRESCRIBE THE OPIOIDS IN A MEASURED AND MONITORED 16 MANNER; 17 (II)CLOSELY MONITOR THE PATIENT'S PRESCRIPTION; AND 18 (III) TITRATE THE PATIENT'S PRESCRIPTION TO THE LOWEST 19 EFFECTIVE DOSE OF THE PRESCRIPTION FOR THE DURATION OF THE PATIENT'S CHRONIC PAIN OR LONG-TERM OXYGEN THERAPY, AS NECESSARY, THROUGH 20 ONGOING, OBJECTIVE EVALUATIONS TO ACHIEVE ONGOING, SUCCESSFUL 2122TREATMENT; AND 23 **(4)** CONTINUE TREATMENT FOR A PATIENT WHO: 24**(I)** IS ON A MANAGED AND MONITORED REGIMEN OF OPIOID 25TREATMENT; 26 (II)HAS INCREASED FUNCTIONALITY AND QUALITY OF LIFE AS 27 A RESULT OF THE TREATMENT; AND
- 29 **(E)** A PRESCRIBER WHO PROVIDES TREATMENT UNDER THIS SECTION MAY 30 NOT BE HELD LIABLE IN A CIVIL OR CRIMINAL ACTION IF THE PRESCRIBER MAKES A

(III) SHOWS NO INDICATION OF MISUSE OR DIVERSION.

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- 1 GOOD-FAITH EFFORT TO COMPLY WITH THIS SECTION.
- 2 **1–1103.**
- 3 (A) ON OR BEFORE JANUARY 1, 2023, THE DEPARTMENT SHALL ADOPT 4 REGULATIONS TO CARRY OUT THIS SUBTITLE.
- 5 (B) THE REGULATIONS ADOPTED BY THE DEPARTMENT UNDER 6 SUBSECTION (A) OF THIS SECTION SHALL:
- 7 (1) TAKE INTO CONSIDERATION THE INDIVIDUALIZED NEEDS OF 8 PATIENTS WHO RECEIVE TREATMENT IN ACCORDANCE WITH THIS SUBTITLE;
- 9 (2) REQUIRE PRESCRIBERS WHO ACT IN GOOD FAITH TO USE THEIR 10 BEST JUDGMENT, NOTWITHSTANDING ANY STATUTE OR RULE TO THE CONTRARY, TO 11 MANAGE A PATIENT'S CHRONIC PAIN;
- 12 (3) ENSURE THAT PATIENTS WHO RECEIVE TREATMENT IN
 13 ACCORDANCE WITH THIS SUBTITLE ARE TREATED WITH DIGNITY AND NOT UNDULY
 14 DENIED THE MEDICATIONS NEEDED TO TREAT THE PATIENT'S CHRONIC PAIN; AND
- 15 (4) ENSURE THAT PRESCRIBERS MAY CO-PRESCRIBE
 16 BENZODIAZEPINE AS MEDICALLY APPROPRIATE IN ADDITION TO TREATMENT IN
 17 ACCORDANCE WITH THIS SUBTITLE.
- SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect 19 October 1, 2022.