

117TH CONGRESS
1ST SESSION

H. R. 4098

To develop a non-opioid pain management directive indicating to health care professionals and emergency medical services personnel that an individual with respect to whom a form has been executed must not be administered an opioid or offered a prescription for an opioid, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 23, 2021

Mr. MCKINLEY (for himself, Ms. BLUNT ROCHESTER, Mr. CURTIS, and Mr. O'HALLERAN) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To develop a non-opioid pain management directive indicating to health care professionals and emergency medical services personnel that an individual with respect to whom a form has been executed must not be administered an opioid or offered a prescription for an opioid, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Non-Opioid Directive
5 Act”.

1 **SEC. 2. NON-OPIOID PAIN MANAGEMENT FORM.**

2 (a) IN GENERAL.—Title V of the Public Health Serv-
3 ice Act (42 U.S.C. 290aa et seq.) is amended by inserting
4 after section 552 of such Act the following:

5 **“SEC. 553. NON-OPIOID PAIN MANAGEMENT DIRECTIVE.**

6 “(a) DEVELOPMENT OF FORM.—

7 “(1) IN GENERAL.—The Secretary shall develop
8 a non-opioid pain management form indicating to
9 health care professionals, providers of services, and
10 emergency medical services personnel that, except as
11 provided in subsection (c) or in rules promulgated by
12 the Secretary under subsection (e), an individual
13 who has executed the form or who has had a form
14 executed on the individual’s behalf must not be ad-
15 ministered (with the exception of intraoperative
16 opioid use) an opioid or offered a prescription for an
17 opioid for pain management, including post-surgical
18 pain.

19 “(2) CONTENTS OF FORM.—The Secretary shall
20 include on the non-opioid pain management form in-
21 structions on how the form may be revoked and any
22 other information that the Secretary determines rel-
23 evant.

24 “(3) PUBLIC AVAILABILITY OF FORM.—The
25 Secretary shall—

1 “(A) make the form available to the public
2 on the website of the Department of Health and
3 Human Services;

4 “(B) require each group health plan or
5 health insurance issuer to make the form avail-
6 able to each enrollee; and

7 “(C) require each group health plan or
8 health insurance issuer to include a notice of
9 the individual’s choice for non-opioid pain man-
10 agement to health care providers, professionals,
11 and such other entities as the Secretary may re-
12 quire for use during any preauthorization proc-
13 ess, including any prior authorization relating
14 to an occupational injury or a workers’ com-
15 pensation claim.

16 “(b) EXECUTION, USE, AND REVOCATION OF
17 FORM.—

18 “(1) EXECUTION.—A non-opioid pain manage-
19 ment form may be executed by—

20 “(A) an individual, on his or her own be-
21 half; or

22 “(B) a guardian or patient advocate of an
23 individual on behalf of the individual, in the
24 case of an individual who is a minor or who is
25 incapacitated (as determined by the Secretary).

1 “(2) INCLUSION IN MEDICAL RECORD.—

2 “(A) IN GENERAL.—If a non-opioid pain
3 management form is executed by or on behalf
4 of an individual and is presented to a health
5 care professional, the health care professional
6 shall make a copy of the form and include the
7 copy in the individual’s medical record.

8 “(B) ELECTRONIC MEDICAL RECORDS.—

9 “(i) IN GENERAL.—The Secretary
10 shall establish procedures to ensure that
11 any executed form is included in any elec-
12 tronic medical record relating to the indi-
13 vidual.

14 “(ii) REQUIREMENTS.—The proce-
15 dures established under clause (i) shall—

16 “(I) require health care providers
17 and such other entities as the Sec-
18 retary may specify to include each in-
19 dividual’s choice to exercise a non-
20 opioid pain management directive in a
21 clear part in the medical records in a
22 similar manner as it would display al-
23 lergies to treatments;

24 “(II) if an individual chooses to
25 use the non-opioid directive, permit

1 the individual to report the existence
2 of a non-opioid pain management
3 form to their employer or group
4 health plan or health insurance issuer
5 to serve as notice to the health plan
6 or issuer and any pharmacy benefit
7 manager; and

8 “(III) require group health plans
9 and health insurance issuers to pro-
10 vide a copy of the non-opioid pain
11 management form during annual en-
12 rollment, specifically asking the indi-
13 vidual to opt-in or opt-out.

14 “(3) REVOCATION.—

15 “(A) BY THE INDIVIDUAL.—An individual
16 may revoke a non-opioid pain management form
17 executed by themselves at any time and in any
18 manner by which they are able to communicate
19 their intent to revoke the form.

20 “(B) BY AN AUTHORIZED REPRESENTA-
21 TIVE.—A patient advocate or guardian may re-
22 voke a non-opioid pain management form on
23 behalf of an individual at any time by issuing
24 the revocation in writing and providing notice

1 of the revocation to the individual’s health care
2 professional.

3 “(4) NOTIFICATION REQUIREMENT.—In the
4 case of a non-opioid pain management form executed
5 by a patient advocate or guardian on behalf of an
6 individual pursuant to paragraph (1)(B), any health
7 care professional who copied and included the form
8 in the individual’s medical record shall notify the pa-
9 tient of such form upon the patient turning 18, or
10 regaining capacity, as applicable.

11 “(c) EXCEPTION FOR EMERGENCIES.—

12 “(1) IN GENERAL.—A health care professional
13 who is authorized to dispense a particular opioid
14 under the Controlled Substances Act and is author-
15 ized to dispense controlled substances by the State
16 in which the health care professional practices may
17 administer that opioid to an individual who has exe-
18 cuted a non-opioid pain management form or who
19 has had a non-opioid pain management form exe-
20 cuted on their behalf if—

21 “(A) the individual is—

22 “(i) receiving emergency treatment in
23 a hospital or outside of a hospital; or

24 “(ii) receiving the opioid through
25 intraoperative use during surgery; and

1 “(B) in the treating health care profes-
2 sional’s opinion, after due consideration of
3 other options and inquiring about a history of
4 opioid use, the administration of the opioid is
5 medically necessary to treat the individual.

6 “(2) PROVISION OF INFORMATION ON ADVERSE
7 EVENTS, OPIOID USE DISORDER, AND TREATMENT
8 SERVICES.—If an opioid is administered under this
9 subsection, the health care professional shall ensure
10 that the individual is provided with information on
11 adverse events, opioid use disorder, and treatment
12 services of opioid use disorder.

13 “(d) LIMITATION ON LIABILITY.—

14 “(1) IN GENERAL.—Except as otherwise pro-
15 vided by law, the individuals and entities described
16 in paragraph (2) shall not be subject to civil or
17 criminal liability or professional disciplinary action
18 for failing to administer, prescribe, or dispense an
19 opioid, or for the inadvertent administration of an
20 opioid, to an individual who has executed a non-
21 opioid pain management form or who has had a non-
22 opioid pain management form executed on his or her
23 behalf, if the failure to act or act was done reason-
24 ably and in good faith.

1 “(2) INDIVIDUALS AND ENTITIES DE-
2 SCRIBED.—The individuals and entities described in
3 this paragraph are the following:

4 “(A) A health care professional whose
5 scope of practice includes the prescribing, ad-
6 ministering, or dispensing of a controlled sub-
7 stance.

8 “(B) A provider of services.

9 “(C) An employee of a health care profes-
10 sional.

11 “(D) An employee of a provider of services.

12 “(E) Emergency and intraoperative med-
13 ical services personnel.

14 “(e) REGULATIONS.—The Secretary shall promulgate
15 such rules and regulations as may be required to imple-
16 ment this section, including the following:

17 “(1) Procedures to record a non-opioid pain
18 management form in a medical record, including an
19 electronic medical record.

20 “(2) Procedures to revoke a non-opioid pain
21 management form.

22 “(3) Procedures to ensure that the recording,
23 disclosure, or distribution of data relating to a non-
24 opioid pain management form or the transmission of
25 a non-opioid pain management form complies with

1 State and Federal confidentiality and consent laws,
2 rules, and regulations.

3 “(4) Exceptions for administering or pre-
4 scribing an opioid to an individual who has executed
5 a non-opioid pain management form or who has had
6 a non-opioid pain management form executed on his
7 or her behalf if the opioid is administered or pre-
8 scribed to treat the individual for a substance use
9 disorder.

10 “(5) Exceptions for administering or pre-
11 scribing an opioid to an individual who has executed
12 a non-opioid pain management form or who has had
13 a non-opioid pain management form executed on his
14 or her behalf if the individual is a hospice patient.

15 “(6) The rules promulgated under this section
16 must allow a health care professional or provider of
17 services to incorporate a non-opioid pain manage-
18 ment form into an existing patient form or into
19 other documentation used by the health care profes-
20 sional or provider of services.

21 “(f) DEFINITIONS.—In this section:

22 “(1) GROUP HEALTH PLAN; HEALTH INSUR-
23 ANCE ISSUER.—The terms ‘group health plan’ and
24 ‘health insurance issuer’ have the meanings given
25 such terms in section 2791.

1 “(2) GUARDIAN.—The term ‘guardian’ means a
2 person with the powers and duties to make medical
3 treatment decisions on behalf of a patient to the ex-
4 tent granted by court order.

5 “(3) NON-OPIOID PAIN MANAGEMENT FORM.—
6 The term ‘non-opioid pain management form’ means
7 the non-opioid pain management form developed by
8 the Secretary under subsection (a).

9 “(4) PATIENT ADVOCATE.—The term ‘patient
10 advocate’ means an individual designated to make
11 medical treatment decisions for a patient.

12 “(5) PROVIDER OF SERVICES.—The term ‘pro-
13 vider of services’ has the meaning given such term
14 in section 1861(u) of the Social Security Act.”.

15 (b) EFFECTIVE DATE.—Section 553 of the Public
16 Health Service Act, as added by subsection (a), shall take
17 effect on January 1, 2022.

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