117TH CONGRESS
1ST SESSION

S. _____

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 SENATE OF THE UNITED STATES

Mr. MANCHIN (for himself and Mr. SCOTT of South Carolina) introduced the following bill; which was read twice and referred to the Committee on _____

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Non-Opioid Directive Act''.

SEC. 2. NON-OPIOID PAIN MANAGEMENT FORM.

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

"SEC. 553. NON-OPIOID PAIN MANAGEMENT DIRECTIVE.

"(a) DEVELOPMENT OF FORM.—

"(1) IN GENERAL.—The Secretary shall develop a non-opioid pain management form indicating to health care professionals, providers of services, and emergency medical services personnel that, except as provided in subsection (c) or in rules promulgated by the Secretary under subsection (e), an individual who has executed the form or who has had a form executed on the individual's behalf must not be administered (with the exception of intraoperative opioid use) an opioid or offered a prescription for an opioid for pain management, including post-surgical pain.

"(2) CONTENTS OF FORM.—The Secretary shall include on the non-opioid pain management form instructions on how the form may be revoked and any other information that the Secretary determines relevant.

"(3) PUBLIC AVAILABILITY OF FORM.—The Secretary shall—

"(A) make the form available to the public on the website of the Department of Health and Human Services;

"(B) require each group health plan or health insurance issuer to make the form available to each enrollee; and

"(C) require each group health plan or health insurance issuer to include a notice of the individual's choice for non-opioid pain management to health care providers, professionals, and such other entities as the Secretary may require for use during any preauthorization process, including any prior authorization relating to an occupational injury or a workers' compensation claim.

"(b) EXECUTION, USE, AND REVOCATION OF FORM.—

"(1) EXECUTION.—A non-opioid pain management form may be executed by—

"(A) an individual, on his or her own behalf; or

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

"(2) INCLUSION IN MEDICAL RECORD.—

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

"(B) ELECTRONIC MEDICAL RECORDS.—

"(i) IN GENERAL.—The Secretary shall establish procedures to ensure that any executed form is included in any electronic medical record relating to the individual.

"(ii) REQUIREMENTS.—The procedures established under clause (i) shall—

"(I) require health care providers and such other entities as the Secretary may specify to include each individual's choice to exercise a non-opioid pain management directive in a clear part in the medical records in a similar manner as it would display allergies to treatments;

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

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

''(III) require group health plans and health insurance issuers to provide a copy of the non-opioid pain management form during annual enrollment, specifically asking the individual to opt-in or opt-out.

''(3) REVOCATION.—

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

''(B) BY AN AUTHORIZED REPRESENTATIVE.—A patient advocate or guardian may revoke a non-opioid pain management form on behalf of an individual at any time by issuing the revocation in writing and providing notice

of the revocation to the individual's health care professional.

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

''(c) EXCEPTION FOR EMERGENCIES.—

''(1) IN GENERAL.—A health care professional who is authorized to dispense a particular opioid under the Controlled Substances Act and is authorized to dispense controlled substances by the State in which the health care professional practices may administer that opioid to an individual who has executed a non-opioid pain management form or who has had a non-opioid pain management form executed on their behalf if—

''(A) the individual is—

''(i) receiving emergency treatment in a hospital or outside of a hospital; or

''(ii) receiving the opioid through intraoperative use during surgery; and

"(B) in the treating health care professional's opinion, after due consideration of other options and inquiring about a history of opioid use, the administration of the opioid is medically necessary to treat the individual.

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

"(d) LIMITATION ON LIABILITY.—

"(1) IN GENERAL.—Except as otherwise provided by law, the individuals and entities described in paragraph (2) shall not be subject to civil or criminal liability or professional disciplinary action for failing to administer, prescribe, or dispense an opioid, or for the inadvertent administration of an opioid, to an individual who has executed a non-opioid pain management form or who has had a non-opioid pain management form executed on his or her behalf, if the failure to act or act was done reasonably and in good faith.

''(2) INDIVIDUALS AND ENTITIES DESCRIBED.—The individuals and entities described in this paragraph are the following:

''(A) A health care professional whose scope of practice includes the prescribing, administering, or dispensing of a controlled substance.

''(B) A provider of services.

''(C) An employee of a health care professional.

''(D) An employee of a provider of services.

''(E) Emergency and intraoperative medical services personnel.

''(e) REGULATIONS.—The Secretary shall promulgate such rules and regulations as may be required to implement this section, including the following:

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

''(2) Procedures to revoke a non-opioid pain management form.

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

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

''(4) Exceptions for administering or prescribing an opioid to an individual who has executed a non-opioid pain management form or who has had a non-opioid pain management form executed on his or her behalf if the opioid is administered or prescribed to treat the individual for a substance use disorder.

''(5) Exceptions for administering or prescribing an opioid to an individual who has executed a non-opioid pain management form or who has had a non-opioid pain management form executed on his or her behalf if the individual is a hospice patient.

''(6) The rules promulgated under this section must allow a health care professional or provider of services to incorporate a non-opioid pain management form into an existing patient form or into other documentation used by the health care professional or provider of services.

''(f) DEFINITIONS.—In this section:

''(1) GROUP HEALTH PLAN; HEALTH INSURANCE ISSUER.—The terms 'group health plan' and 'health insurance issuer' have the meanings given such terms in section 2791.

''(2) GUARDIAN.—The term 'guardian' means a person with the powers and duties to make medical treatment decisions on behalf of a patient to the extent granted by court order.

''(3) NON-OPIOID PAIN MANAGEMENT FORM.—The term 'non-opioid pain management form' means the non-opioid pain management form developed by the Secretary under subsection (a).

''(4) PATIENT ADVOCATE.—The term 'patient advocate' means an individual designated to make medical treatment decisions for a patient.

''(5) PROVIDER OF SERVICES.—The term 'provider of services' has the meaning given such term in section 1861(u) of the Social Security Act.''.

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