114TH CONGRESS
2D SESSION

H. R. 4063

AN ACT

To improve the use by the Secretary of Veterans Affairs of opioids in treating veterans, 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 ''Promoting Responsible Opioid Management and Incorporating Scientific Expertise Act'' or the ''Jason Simcakoski PROMISE Act''.

SEC. 2. IMPROVEMENT OF OPIOID SAFETY MEASURES BY DEPARTMENT OF VETERANS AFFAIRS.

(a) EXPANSION OF OPIOID SAFETY INITIATIVE.—

(1) INCLUSION OF ALL MEDICAL FACILITIES.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Veterans Affairs shall expand the Opioid Safety Initiative of the Department of Veterans Affairs to include all medical facilities of the Department.

(2) GUIDANCE.—The Secretary shall establish guidance that each health care provider of the Department of Veterans Affairs, before initiating opioid therapy to treat a patient as part of the comprehensive assessment conducted by the health care provider, use the Opioid Therapy Risk Report tool of the Department of Veterans Affairs (or any subsequent tool), which shall include information from the prescription drug monitoring program of each participating State as applicable, that includes the most recent information to date relating to the patient that accessed such program to assess the risk for adverse outcomes of opioid therapy for the patient,

including the concurrent use of controlled substances such as benzodiazepines, as part of the comprehensive assessment conducted by the health care provider.

(3) ENHANCED STANDARDS.—The Secretary shall establish enhanced standards with respect to the use of routine and random urine drug tests for all patients before and during opioid therapy to help prevent substance abuse, dependence, and diversion, including—

(A) that such tests occur not less frequently than once each year; and

(B) that health care providers appropriately order, interpret and respond to the results from such tests to tailor pain therapy, safeguards, and risk management strategies to each patient.

(b) PAIN MANAGEMENT EDUCATION AND TRAINING.—

(1) IN GENERAL.—In carrying out the Opioid Safety Initiative of the Department, the Secretary shall require all employees of the Department responsible for prescribing opioids to receive education and training described in paragraph (2).

(2) EDUCATION AND TRAINING.—Education and training described in this paragraph is education and training on pain management and safe opioid prescribing practices for purposes of safely and effectively managing patients with chronic pain, including education and training on the following:

(A) The implementation of and full compliance with the VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, including any update to such guideline.

(B) The use of evidence-based pain management therapies, including cognitive-behavioral therapy, non-opioid alternatives, and non-drug methods and procedures to managing pain and related health conditions including medical devices approved or cleared by the Food and Drug Administration for the treatment of patients with chronic pain and complementary alternative medicines.

(C) Screening and identification of patients with substance use disorder, including drug-seeking behavior, before prescribing opioids, assessment of risk potential for patients developing an addiction, and referral of patients to

appropriate addiction treatment professionals if addiction is identified or strongly suspected.

(D) Communication with patients on the potential harm associated with the use of opioids and other controlled substances, including the need to safely store and dispose of supplies relating to the use of opioids and other controlled substances.

(E) Such other education and training as the Secretary considers appropriate to ensure that veterans receive safe and high-quality pain management care from the Department.

(3) USE OF EXISTING PROGRAM.—In providing education and training described in paragraph (2), the Secretary shall use the Interdisciplinary Chronic Pain Management Training Team Program of the Department (or success program).

(c) PAIN MANAGEMENT TEAMS.—

(1) IN GENERAL.—In carrying out the Opioid Safety Initiative of the Department, the director of each medical facility of the Department shall identify and designate a pain management team of health care professionals, which may include board certified pain medicine specialists, responsible for coordinating and overseeing pain management therapy

at such facility for patients experiencing acute and chronic pain that is non-cancer related.

(2) ESTABLISHMENT OF PROTOCOLS.—

(A) IN GENERAL.—In consultation with the Directors of each Veterans Integrated Service Network, the Secretary shall establish standard protocols for the designation of pain management teams at each medical facility within the Department.

(B) CONSULTATION ON PRESCRIPTION OF OPIOIDS.—Each protocol established under subparagraph (A) shall ensure that any health care provider without expertise in prescribing analgesics or who has not completed the education and training under subsection (b), including a mental health care provider, does not prescribe opioids to a patient unless that health care provider—

(i) consults with a health care provider with pain management expertise or who is on the pain management team of the medical facility; and

(ii) refers the patient to the pain management team for any subsequent prescriptions and related therapy.

(3) REPORT.—

(A) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the director of each medical facility of the Department shall submit to the Under Secretary for Health and the director of the Veterans Integrated Service Network in which the medical facility is located a report identifying the health care professionals that have been designated as members of the pain management team at the medical facility pursuant to paragraph (1).

(B) ELEMENTS.—Each report submitted under subparagraph (A) with respect to a medical facility of the Department shall include—

(i) a certification as to whether all members of the pain management team at the medical facility have completed the education and training required under subsection (b);

(ii) a plan for the management and referral of patients to such pain management team if health care providers without expertise in prescribing analgesics prescribe opioid medications to treat acute

and chronic pain that is non-cancer related; and

(iii) a certification as to whether the medical facility—

(I) fully complies with the stepped-care model of pain management and other pain management policies contained in Directive 2009–053 of the Veterans Health Administration, or successor directive; or

(II) does not fully comply with such stepped-care model of pain management and other pain management policies but is carrying out a corrective plan of action to ensure such full compliance.

(d) TRACKING AND MONITORING OF OPIOID USE.—

(1) PRESCRIPTION DRUG MONITORING PROGRAMS OF STATES.—In carrying out the Opioid Safety Initiative and the Opioid Therapy Risk Report tool of the Department, the Secretary shall—

(A) ensure access by health care providers of the Department to information on controlled substances, including opioids and benzodiazepines, prescribed to veterans who re-

ceive care outside the Department through the prescription drug monitoring program of each State with such a program, including by seeking to enter into memoranda of understanding with States to allow shared access of such information between States and the Department;

(B) include such information in the Opioid Therapy Risk Report; and

(C) require health care providers of the Department to submit to the prescription drug monitoring program of each State information on prescriptions of controlled substances received by veterans in that State under the laws administered by the Secretary.

(2) REPORT ON TRACKING OF DATA ON OPIOID USE.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report on the feasibility and advisability of improving the Opioid Therapy Risk Report tool of the Department to allow for more advanced real-time tracking of and access to data on—

(A) the key clinical indicators with respect to the totality of opioid use by veterans;

(B) concurrent prescribing by health care providers of the Department of opioids in different health care settings, including data on concurrent prescribing of opioids to treat mental health disorders other than opioid use disorder; and

(C) mail-order prescriptions of opioid prescribed to veterans under the laws administered by the Secretary.

(e) AVAILABILITY OF OPIOID RECEPTOR ANTAGONISTS.—

(1) INCREASED AVAILABILITY AND USE.—

(A) IN GENERAL.—The Secretary shall maximize the availability of opioid receptor antagonists approved by the Food and Drug Administration, including naloxone, to veterans.

(B) AVAILABILITY, TRAINING, AND DISTRIBUTING.—In carrying out subparagraph (A), not later than 90 days after the date of the enactment of this Act, the Secretary shall—

(i) equip each pharmacy of the Department with opioid receptor antagonists approved by the Food and Drug Adminis-

tration to be dispensed to outpatients as needed; and

(ii) expand the Overdose Education and Naloxone Distribution program of the Department to ensure that all veterans in receipt of health care under laws administered by the Secretary who are at risk of opioid overdose may access such opioid receptor antagonists and training on the proper administration of such opioid receptor antagonists.

(C) VETERANS WHO ARE AT RISK.—For purposes of subparagraph (B), veterans who are at risk of opioid overdose include—

(i) veterans receiving long-term opioid therapy;

(ii) veterans receiving opioid therapy who have a history of substance use disorder or prior instances of overdose; and

(iii) veterans who are at risk as determined by a health care provider who is treating the veteran.

(2) REPORT.—Not later than 120 days after the date of the enactment of this Act, the Secretary shall submit to the Committee on Veterans' Affairs

of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report on carrying out paragraph (1), including an assessment of any remaining steps to be carried out by the Secretary to carry out such paragraph.

(f) INCLUSION OF CERTAIN INFORMATION AND CAPABILITIES IN OPIOID THERAPY RISK REPORT TOOL OF THE DEPARTMENT.—

(1) INFORMATION.—The Secretary shall include in the Opioid Therapy Risk Report tool of the Department—

(A) information on the most recent time the tool was accessed by a health care provider of the Department with respect to each veteran; and

(B) information on the results of the most recent urine drug test for each veteran.

(2) CAPABILITIES.—The Secretary shall include in the Opioid Therapy Risk Report tool the ability of the health care providers of the Department to determine whether a health care provider of the Department prescribed opioids to a veteran without checking the information in the tool with respect to the veteran.

(g) NOTIFICATIONS OF RISK IN COMPUTERIZED HEALTH RECORD.—The Secretary shall modify the computerized patient record system of the Department to ensure that any health care provider that accesses the record of a veteran, regardless of the reason the veteran seeks care from the health care provider, will be immediately notified whether the veteran—

(1) is receiving opioid therapy and has a history of substance use disorder or prior instances of overdose;

(2) has a history of opioid abuse; or

(3) is at risk of becoming an opioid abuser as determined by a health care provider who is treating the veteran.

(h) DEFINITIONS.—In this section:

(1) The term ''controlled substance'' has the meaning given that term in section 102 of the Controlled Substances Act (21 U.S.C. 802).

(2) The term ''State'' means each of the several States, territories, and possessions of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

SEC. 3. STRENGTHENING OF JOINT WORKING GROUP ON PAIN MANAGEMENT OF THE DEPARTMENT OF VETERANS AFFAIRS AND THE DEPARTMENT OF DEFENSE.

(a) IN GENERAL.—Not later than 90 days after the date of enactment of this Act, the Secretary of Veterans Affairs and the Secretary of Defense shall ensure that the Pain Management Working Group of the Health Executive Committee of the Department of Veterans Affairs–Department of Defense Joint Executive Committee (Pain Management Working Group) established under section 320 of title 38, United States Code, includes a focus on the following:

(1) The opioid prescribing practices of health care providers of each Department.

(2) The ability of each Department to manage acute and chronic pain among individuals receiving health care from the Department, including training health care providers with respect to pain management.

(3) The use by each Department of complementary and integrative health and complementary alternative medicines in treating such individuals.

(4) The concurrent use by health care providers of each Department of opioids and prescription

drugs to treat mental health disorders, including benzodiazepines.

(5) The practice by health care providers of each Department of prescribing opioids to treat mental health disorders.

(6) The coordination in coverage of and consistent access to medications prescribed for patients transitioning from receiving health care from the Department of Defense to receiving health care from the Department of Veterans Affairs.

(7) The ability of each Department to identify and treat substance use disorders among individuals receiving health care from that Department.

(b) COORDINATION AND CONSULTATION.—The Secretary of Veterans Affairs and the Secretary of Defense shall ensure that the working group described in subsection (a)—

(1) coordinates the activities of the working group with other relevant working groups established under section 320 of title 38, United States Code;

(2) consults with other relevant Federal agencies with respect to the activities of the working group; and

(3) consults with the Department of Veterans Affairs and the Department of Defense with respect to, reviews, and comments on the VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, or any successor guideline, before any update to the guideline is released.

(c) CLINICAL PRACTICE GUIDELINES.—

(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Veterans Affairs and the Secretary of Defense shall issue an update to the VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain.

(2) MATTERS INCLUDED.—In conducting the update under subsection (a), the Pain Management Working Group, in coordination with the Clinical Practice Guideline VA/DOD Management of Opioid Therapy for Chronic Pain Working Group, shall examine whether the Clinical Practical Guideline should include the following:

(A) Enhanced guidance with respect to—

(i) the coadministration of an opioid and other drugs, including benzodiazepines, that may result in life-limiting drug interactions;

(ii) the treatment of patients with current acute psychiatric instability or substance use disorder or patients at risk of suicide; and

(iii) the use of opioid therapy to treat mental health disorders other than opioid use disorder.

(B) Enhanced guidance with respect to the treatment of patients with behaviors or comorbidities, such as post-traumatic stress disorder or other psychiatric disorders, or a history of substance abuse or addiction, that requires a consultation or comanagement of opioid therapy with one or more specialists in pain management, mental health, or addictions.

(C) Enhanced guidance with respect to health care providers—

(i) conducting an effective assessment for patients beginning or continuing opioid therapy, including understanding and setting realistic goals with respect to achieving and maintaining an expected level of pain relief, improved function, or a clinically appropriate combination of both; and

(ii) effectively assessing whether opioid therapy is achieving or maintaining the established treatment goals of the patient or whether the patient and health care provider should discuss adjusting, augmenting, or discontinuing the opioid therapy.

(D) Guidelines to govern the methodologies used by health care providers of the Department of Veterans Affairs and the Department of Defense to taper opioid therapy when adjusting or discontinuing the use of opioid therapy.

(E) Guidelines with respect to appropriate case management for patients receiving opioid therapy who transition between inpatient and outpatient health care settings, which may include the use of care transition plans.

(F) Guidelines with respect to appropriate case management for patients receiving opioid therapy who transition from receiving care during active duty to post-military health care networks.

(G) Guidelines with respect to providing options, before initiating opioid therapy, for pain management therapies without the use of

opioids and options to augment opioid therapy with other clinical and complementary and integrative health services to minimize opioid dependence.

(H) Guidelines with respect to the provision of evidence-based non-opioid treatments within the Department of Veterans Affairs and the Department of Defense, including medical devices and other therapies approved or cleared by the Food and Drug Administration for the treatment of chronic pain as an alternative to or to augment opioid therapy.

SEC. 4. REVIEW, INVESTIGATION, AND REPORT ON USE OF OPIOIDS IN TREATMENT BY DEPARTMENT OF VETERANS AFFAIRS.

(a) COMPTROLLER GENERAL REPORT.—

(1) IN GENERAL.—Not later than 2 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report on the Opioid Safety Initiative of the Department of Veterans Affairs and the opioid prescribing practices of health care providers of the Department.

(2) ELEMENTS.—The report submitted under paragraph (1) shall include the following:

(A) Recommendations on such improvements to the Opioid Safety Initiative of the Department as the Comptroller General considers appropriate.

(B) Information with respect to—

(i) deaths resulting from sentinel events involving veterans prescribed opioids by a health care provider of the Department;

(ii) overall prescription rates and prescriptions indications of opioids to treat non-cancer, non-palliative, and non-hospice care patients;

(iii) the prescription rates and prescriptions indications of benzodiazepines and opioids concomitantly by health care providers of the Department;

(iv) the practice by health care providers of the Department of prescribing opioids to treat patients without any pain, including to treat patients with mental health disorders other than opioid use disorder; and

(v) the effectiveness of opioid therapy for patients receiving such therapy, including the effectiveness of long-term opioid therapy.

(C) An evaluation of processes of the Department in place to oversee opioid use among veterans, including procedures to identify and remedy potential over-prescribing of opioids by health care providers of the Department.

(D) An assessment of the implementation by the Secretary of the VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain.

(b) QUARTERLY PROGRESS REPORT ON IMPLEMENTATION OF COMPTROLLER GENERAL RECOMMENDATIONS.—Not later than 2 years after the date of the enactment of this Act, and not later than 30 days after the end of each quarter thereafter, the Secretary of Veterans Affairs shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a progress report detailing the actions by the Secretary during the period covered by the report to address any outstanding findings and recommendations by the Comptroller General of the United

States under subsection (a) with respect to the Veterans Health Administration.

(c) ANNUAL REVIEW OF PRESCRIPTION RATES.—Not later than 1 year after the date of the enactment of this Act, and not less frequently than annually for the following 5 years, the Secretary shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report, with respect to each medical facility of the Department of Veterans Affairs, to collect and review information on opioids prescribed by health care providers at the facility to treat non-cancer, non-palliative, and non-hospice care patients that contains, for the 1-year period preceding the submission of the report, the following:

(1) The number of patients and the percentage of the patient population of the Department who were prescribed benzodiazepines and opioids concurrently by a health care provider of the Department.

(2) The number of patients and the percentage of the patient population of the Department without any pain who were prescribed opioids by a health care provider of the Department, including those who were prescribed benzodiazepines and opioids concurrently.

(3) The number of non-cancer, non-palliative, and non-hospice care patients and the percentage of such patients who were treated with opioids by a health care provider of the Department on an inpatient-basis and who also received prescription opioids by mail from the Department while being treated on an inpatient-basis.

(4) The number of non-cancer, non-palliative, and non-hospice care patients and the percentage of such patients who were prescribed opioids concurrently by a health care provider of the Department and a health care provider that is not health care provider of the Department.

(5) With respect to each medical facility of the Department, information on opioids prescribed by health care providers at the facility to treat non-cancer, non-palliative, and non-hospice care patients, including information on—

(A) the prescription rate at which each health care provider at the facility prescribed benzodiazepines and opioids concurrently to such patients and the aggregate such prescription rate for all health care providers at the facility;

(B) the prescription rate at which each health care provider at the facility prescribed benzodiazepines or opioids to such patients to treat conditions for which benzodiazepines or opioids are not approved treatment and the aggregate such prescription rate for all health care providers at the facility;

(C) the prescription rate at which each health care provider at the facility prescribed or dispensed mail-order prescriptions of opioids to such patients while such patients were being treated with opioids on an inpatient-basis and the aggregate of such prescription rate for all health care providers at the facility; and

(D) the prescription rate at which each health care provider at the facility prescribed opioids to such patients who were also concurrently prescribed opioids by a health care provider that is not a health care provider of the Department and the aggregate of such prescription rates for all health care providers at the facility.

(6) With respect to each medical facility of the Department, the number of times a pharmacist at the facility overrode a critical drug interaction warn-

ing with respect to an interaction between opioids and another medication before dispensing such medication to a veteran.

(d) INVESTIGATION OF PRESCRIPTION RATES.—If the Secretary determines that a prescription rate with respect to a health care provider or medical facility of the Department conflicts with or is otherwise inconsistent with the standards of appropriate and safe care, the Secretary shall—

(1) immediately notify the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives of such determination, including information relating to such determination, prescription rate, and health care provider or medical facility, as the case may be; and

(2) through the Office of the Medical Inspector of the Veterans Health Administration, conduct a full investigation of the health care provider or medical facility, as the case may be.

(e) PRESCRIPTION RATE DEFINED.—In this section, the term ''prescription rate'' means, with respect to a health care provider or medical facility of the Department, each of the following:

(1) The number of patients treated with opioids by the health care provider or at the medical facility, as the case may be, divided by the total number of pharmacy users of that health care provider or medical facility.

(2) The average number of morphine equivalents per day prescribed by the health care provider or at the medical facility, as the case may be, to patients being treated with opioids.

(3) Of the patients being treated with opioids by the health care provider or at the medical facility, as the case may be, the average number of prescriptions of opioids per patient.

SEC. 5. MANDATORY DISCLOSURE OF CERTAIN VETERAN INFORMATION TO STATE CONTROLLED SUBSTANCE MONITORING PROGRAMS.

Section 5701(l) of title 38, United States Code, is amended by striking ''may'' and inserting ''shall''.

SEC. 6. MODIFICATION TO LIMITATION ON AWARDS AND BONUSES.

Section 705 of the Veterans Access, Choice, and Accountability Act of 2014 (Public Law 113–146; 38 U.S.C. 703 note) is amended to read as follows:

''SEC. 705. LIMITATION ON AWARDS AND BONUSES PAID TO EMPLOYEES OF DEPARTMENT OF VETERANS AFFAIRS.

''The Secretary of Veterans Affairs shall ensure that the aggregate amount of awards and bonuses paid by the Secretary in a fiscal year under chapter 45 or 53 of title 5, United States Code, or any other awards or bonuses authorized under such title or title 38, United States Code, does not exceed the following amounts:

''(1) With respect to each of fiscal years 2017 through 2021, $230,000,000.

''(2) With respect to each of fiscal years 2022 through 2024, $360,000,000.''.

Passed the House of Representatives May 10, 2016.

Attest:

Clerk.

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