

CO-PRESCRIBING TO REDUCE OVERDOSES ACT OF 2016

MAY 10, 2016.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

[To accompany H.R. 3680]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3680) to provide for the Secretary of Health and Human Services to carry out a grant program for co-prescribing opioid overdose reversal drugs, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

Purpose and Summary	Page 3
Background and Need for Legislation	3
Hearings	4
Committee Consideration	4
Committee Votes	4
Committee Oversight Findings	4
Statement of General Performance Goals and Objectives	5
New Budget Authority, Entitlement Authority, and Tax Expenditures	5
Earmark, Limited Tax Benefits, and Limited Tariff Benefits	5
Committee Cost Estimate	5
Congressional Budget Office Estimate	5
Federal Mandates Statement	7
Duplication of Federal Programs	7
Disclosure of Directed Rule Makings	7
Advisory Committee Statement	7
Applicability to Legislative Branch	7
Section-by-Section Analysis of the Legislation	7
Changes in Existing Law Made by the Bill, as Reported	8

The amendment is as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Co-Prescribing to Reduce Overdoses Act of 2016”.

SEC. 2. OPIOID OVERDOSE REVERSAL DRUGS PRESCRIBING GRANT PROGRAM.**(a) ESTABLISHMENT.—**

(1) **IN GENERAL.**—Not later than six months after the date of the enactment of this Act, the Secretary of Health and Human Services may establish, in accordance with this section, a five-year opioid overdose reversal drugs prescribing grant program (in this Act referred to as the “grant program”).

(2) **MAXIMUM GRANT AMOUNT.**—A grant made under this section may not be for more than \$200,000 per grant year.

(3) **ELIGIBLE ENTITY.**—For purposes of this section, the term “eligible entity” means a federally qualified health center (as defined in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)), an opioid treatment program under part 8 of title 42, Code of Federal Regulations, any practitioner dispensing narcotic drugs pursuant to section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)), or any other entity that the Secretary deems appropriate.

(4) **PRESCRIBING.**—For purposes of this section and section 3, the term “prescribing” means, with respect to an opioid overdose reversal drug, such as naloxone, the practice of prescribing such drug—

(A) in conjunction with an opioid prescription for patients at an elevated risk of overdose;

(B) in conjunction with an opioid agonist approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for the treatment of opioid abuse disorder;

(C) to the caregiver or a close relative of patients at an elevated risk of overdose from opioids; or

(D) in other circumstances, as identified by the Secretary, in which a provider identifies a patient is at an elevated risk for an intentional or unintentional drug overdose from heroin or prescription opioid therapies.

(b) **APPLICATION.**—To be eligible to receive a grant under this section, an eligible entity shall submit to the Secretary of Health and Human Services, in such form and manner as specified by the Secretary, an application that describes—

(1) the extent to which the area to which the entity will furnish services through use of the grant is experiencing significant morbidity and mortality caused by opioid abuse;

(2) the criteria that will be used to identify eligible patients to participate in such program; and

(3) how such program will work to try to identify State, local, or private funding to continue the program after expiration of the grant.

(c) **USE OF FUNDS.**—An eligible entity receiving a grant under this section may use the grant for any of the following activities, but may use not more than 20 percent of the grant funds for activities described in paragraphs (4) and (5):

(1) To establish a program for prescribing opioid overdose reversal drugs, such as naloxone.

(2) To train and provide resources for health care providers and pharmacists on the prescribing of opioid overdose reversal drugs, such as naloxone.

(3) To establish mechanisms and processes for tracking patients participating in the program described in paragraph (1) and the health outcomes of such patients.

(4) To purchase opioid overdose reversal drugs, such as naloxone, for distribution under the program described in paragraph (1).

(5) To offset the co-pays and other cost sharing associated with opioid overdose reversal drugs, such as naloxone, to ensure that cost is not a limiting factor for eligible patients.

(6) To conduct community outreach, in conjunction with community-based organizations, designed to raise awareness of prescribing practices, and the availability of opioid overdose reversal drugs, such as naloxone.

(7) To establish protocols to connect patients who have experienced a drug overdose with appropriate treatment, including medication assisted treatment and appropriate counseling and behavioral therapies.

(d) **EVALUATIONS BY RECIPIENTS.**—As a condition of receipt of a grant under this section, an eligible entity shall, for each year for which the grant is received, submit to the Secretary of Health and Human Services information on appropriate outcome measures specified by the Secretary to assess the outcomes of the program funded by the grant, including—

(1) the number of prescribers trained;

(2) the number of prescribers who have co-prescribed an opioid overdose reversal drug, such as naloxone, to at least one patient;

(3) the total number of prescriptions written for opioid overdose reversal drugs, such as naloxone;

(4) the percentage of patients at elevated risk who received a prescription for an opioid overdose reversal drug, such as naloxone;

(5) the number of patients reporting use of an opioid overdose reversal drug, such as naloxone; and

(6) any other outcome measures that the Secretary deems appropriate.

(e) **REPORTS BY SECRETARY.**—For each year of the grant program under this section, the Secretary of Health and Human Services shall submit to the appropriate committees of the House of Representatives and of the Senate a report aggregating the information received from the grant recipients for such year under subsection (d) and evaluating the outcomes achieved by the programs funded by grants made under this section.

SEC. 3. PROVIDING INFORMATION TO PRESCRIBERS IN CERTAIN FEDERAL HEALTH CARE AND MEDICAL FACILITIES ON BEST PRACTICES FOR PRESCRIBING OPIOID OVERDOSE REVERSAL DRUGS.

(a) **IN GENERAL.**—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the “Secretary”) may, as appropriate, provide information to prescribers within Federally qualified health centers (as defined in paragraph (4) of section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa))), and the health care facilities of the Indian Health Service, on best practices for prescribing opioid overdose reversal drugs, such as naloxone, for patients receiving chronic opioid therapy, patients being treated for opioid use disorders, and other patients that a provider identifies as having an elevated risk of overdose from heroin or prescription opioid therapies.

(b) **NOT ESTABLISHING A MEDICAL STANDARD OF CARE.**—The information on best practices provided under this section shall not be construed as constituting or establishing a medical standard of care for prescribing opioid overdose reversal drugs, such as naloxone, for patients described in subsection (a).

(c) **NO AUTHORIZATION OF ANY ADDITIONAL APPROPRIATIONS.**—The Secretary shall carry out this section through funds otherwise appropriated and nothing in this section shall be construed as authorizing the appropriations of additional funds to carry out this section.

(d) **ELEVATED RISK OF OVERDOSE DEFINED.**—In this section, the term “elevated risk of overdose” has the meaning given such term by the Secretary, which—

(1) may be based on the criteria provided in the Opioid Overdose Toolkit published by the Substance Abuse and Mental Health Services Administration (SAMHSA); and

(2) may include patients on a first course opioid treatment, patients using extended-release and long-acting opioid analgesics, and patients with a respiratory disease or other co-morbidities.

SEC. 4. AUTHORIZATION OF APPROPRIATIONS.

There is authorized to be appropriated to carry out this Act \$5,000,000 for the period of fiscal years 2017 through 2021.

SEC. 5. CUT-GO COMPLIANCE.

Subsection (f) of section 319D of the Public Health Service Act (42 U.S.C. 247d–4) is amended by inserting before the period at the end the following: “(except such dollar amount shall be reduced by \$5,000,000 for fiscal year 2018)”.

PURPOSE AND SUMMARY

H.R. 3680, the “Co-Prescribing to Reduce Overdoses Act of 2016,” was introduced by Rep. John Sarbanes (D–MD) on October 1, 2015. This legislation directs the Secretary of Health and Human Services to carry out a grant program for co-prescribing opioid overdose reversal drugs.

BACKGROUND AND NEED FOR LEGISLATION

In 1999, there were 6.1 overdose deaths per 100,000 Americans involving opioid analgesics and heroin. By 2014, that number doubled to 14.7 overdose deaths. The rate of overdose for individuals aged 24 to 34 nearly tripled going from 8.1 overdose deaths per

100,000 to 23.1 overdose deaths.¹ Naloxone is an opioid antagonist that can prevent opioid overdose deaths by binding to the opioid receptors in the body and preventing the overdose. The World Health Organization estimated that if naloxone was more widely available in the United States, 20,000 overdose deaths could be prevented annually.² This legislation is a first step in promoting wider access of naloxone or other opioid overdose reversal drugs that may come to market.

HEARINGS

The Subcommittee on Health held a hearing on H.R. 3680 on October 8, 2015. The Subcommittee received testimony from:

- Mr. Michael Botticelli, Director, National Drug Control Policy, Executive Office of the President;
- Dr. Richard Frank, Assistant Secretary for Planning and Evaluation, Department of Health and Human Services;
- Mr. Jack Riley, Deputy Administrator, Drug Enforcement Administration;
- Dr. Allen Anderson, President, American Orthopaedic Society for Sports Medicine;
- Dr. Paul Halverson, Dean, Indiana University, Richard M. Fairbanks School of Public Health;
- Dr. Kenneth Katz, Lehigh Valley Health Network, Department of Emergency Medicine, Section of Medical Toxicology;
- Dr. Chapman Sledge, Chief Medical Officer, Cumberland Heights; and,
- Dr. Robert Corey Waller, Chair, Legislative Advocacy Committee, American Society of Addiction Medicine.

COMMITTEE CONSIDERATION

On April 20, 2016, the Subcommittee on Health met in open markup session and forwarded H.R. 3680, as amended, to the full Committee by a voice vote. On April 26, 27, and 28, 2016, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 3680 reported to the House, as amended, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 3680 reported.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held a hearing and made findings that are reflected in this report.

¹<http://www.cdc.gov/nchs/data/has/has15.pdf>.

²<http://www.reuters.com/article/us-health-who-naloxone-idUSKBN0IO12420141104>.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The goal of this legislation is to provide grants to states to encourage the co-prescribing of opioid overdose reversal drugs for individuals identified as being at risk for overdose.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 3680 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that H.R. 3680 contains no earmarks, limited tax benefits, or limited tariff benefits.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

H.R. 3680—Co-Prescribing To Reduce Overdoses Act of 2015

Summary: H.R. 3680 would authorize the Secretary of Health and Human Services (MIS) to establish a grant program to provide funds to eligible entities to develop guidelines and to provide resources for prescribing drugs that reverse opioid overdoses. The bill also would authorize the Secretary of MS to provide information to prescribers and health care facilities of the Indian Health Service on best practices for prescribing certain drugs to patients with an elevated risk of opioid use disorders. Additionally, H.R. 3680 would reduce amounts authorized to be appropriated for certain existing activities related to bioterrorism and public health emergencies by the Centers for Disease Control and Prevention (CDC). Assuming appropriation actions consistent with the bill, CB0 estimates that implementing H.R. 3680 would reduce net discretionary costs by \$1 million over the 2017–2021 period.

Pay-as-you-go procedures do not apply because enacting H.R. 3680 would not affect direct spending or revenues. CB0 estimates that enacting H.R. 3680 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2027.

H.R. 3680 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would not affect the budgets of state, local, or tribal governments.

Estimated cost to the Federal Government: The estimated budgetary effect of H.R. 3680 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2017	2018	2019	2020	2021	2017–2021
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Health and Human Services:						
Authorization Level	1	1	1	1	1	5
Estimated Outlays	*	1	1	1	1	4
Centers for Disease Control and Prevention:						
Authorization Level	0	–5	0	0	0	–5
Estimated Outlays	0	–2	–2	–1	*	–5
Total Changes:						
Authorization Level	1	–4	1	1	1	0
Estimated Outlays	*	–1	–1	*	1	–1

Notes: * = between –\$500,000 and \$500,000; details may not add to totals because of rounding.

Basis of estimate: For this estimate, CBO assumes that H.R. 3680 will be enacted near the end of fiscal year 2016 and that spending will follow historical patterns for similar programs.

Health and Human Services

The bill would require the Secretary of HHS to award grants to states to develop guidelines for prescribing drugs that help reverse opioid overdoses and to other eligible entities to establish and support programs for prescribing such drugs. The bill would authorize the appropriation of \$5 million over the 2017–2021 period for those purposes. Assuming availability of appropriated funds, CBO estimates that implementing the grant program would cost of \$4 million over the 2017–2021 period.

Centers for Disease Control and Prevention

Under current law, an authorization of appropriation of \$138 million exists for 2018 for CDC activities related to bioterrorism and public health emergencies. H.R. 3680 would reduce the authorized amount by \$5 million in 2018. Assuming future appropriations are reduced accordingly, CBO estimates that implementing this provision would result in \$5 million less in discretionary outlays for those activities over 2017–2021 period.

Pay-As-You-Go considerations: None.

Increase in long-term direct spending and deficits: CBO estimates that enacting H.R. 3680 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2027.

Intergovernmental and private-sector impact: H.R. 3680 contains no intergovernmental or private-sector mandates as defined in UMRA. Any costs incurred by states or local governments that apply for grants authorized by the bill would be incurred voluntarily as a condition of federal assistance.

Estimate prepared by: Federal costs: Ellen Werble; Impact on state, local, and tribal governments: Leo Lex; Impact on the private sector: Amy Petz.

Estimate approved by: Holly Harvey; Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 3680 establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 3680 specifically directs to be completed 0 rule makings within the meaning of 5 U.S.C. 551.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 states that the legislation may be cited as the “Co-Prescribing to Reduce Overdoses Act of 2016.”

Section 2. Opioid overdose reversal drugs prescribing grant program

Section 2 directs the Secretary of Health and Human Services to establish a five-year opioid overdose reversal drugs prescribing grant program.

Rural health care clinics, federally qualified health centers, eligible opioid treatment programs, or physicians who dispense or prescribe certain drugs under DATA 2000, or any other entity that the Secretary deems appropriate would be eligible under the grant program.

Additionally, this section defines prescribing of an opioid overdose reversal drug to mean in conjunction with an opioid prescription for patients at increased risk for overdose, in conjunction with an opioid agonist such as methadone used for treatment of an opioid use disorder, to the caregiver or close relative of someone at risk of overdose, or in circumstances as defined by the Secretary.

To be eligible to receive a grant under this section, the potential grantee must describe the following: the mortality and morbidity in the area the grantee will be providing services that is a result of opioid abuse, the criteria to identify eligible patients for participa-

tion, and how the program will work to identify other sources of funding to continue the program after the grant expires.

Grants awarded by the Secretary under this section may be used to establish a program for prescribing and training, to provide resources for health care providers and pharmacists on the prescribing of opioid overdose reversal drugs, to establish ways to track patients' health outcomes in the program, to purchase opioid overdose reversal drugs, to offset the copays or cost sharing to these drugs, to conduct community outreach, or to establish protocols to connect patients who have experienced a drug overdose with appropriate treatment.

All grants awarded under this section will be evaluated on six criteria: the number of prescribers trained, the number of prescribers who have co-prescribed an opioid overdose reversal drug, the total number of prescriptions written, the percentage of patients at an elevated risk who received a prescription for an overdose reversal drug, the number of patients reporting using the drug, and any other outcome measures the Secretary deems appropriate.

Finally, this section mandates a report from the Secretary for each year of the grant program on the outcomes achieved by the grants funded.

Section 3. Providing information to prescribers in certain federal health care and medical facilities on best practices for prescribing naloxone

This section authorizes the Secretary to provide information to prescribers in federally qualified health centers and Indian Health Service facilities on best practices for prescribing naloxone. This section does not establish a medical standard of care, and there is no additional authorization of appropriation for this section to be carried out.

This section also elucidates the term "elevated risk of overdose" which meaning may be based on the Opioid Overdose Toolkit published by the Substance Abuse and Mental Health Services Administration and may include patients on a first course opioid treatment, those using extended-release or long acting opioids, or patients with respiratory disease or other comorbidities.

Section 4. Authorization of appropriations

Section 4 authorizes an appropriation of \$5,000,000 for the period of fiscal years 2017 to 2021.

Section 5. Cut-Go compliance

Section 5 reduces the authorization of Section 319D of the Public Health Service Act by \$5,000,000 for fiscal year 2018 to bring the legislation into compliance with Cut-Go. This reduction in authorization is equal to the authorization of appropriations in section 4.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

* * * * *

PART B—FEDERAL-STATE COOPERATION

* * * * *

SEC. 319D. REVITALIZING THE CENTERS FOR DISEASE CONTROL AND PREVENTION.

(a) FACILITIES; CAPACITIES.—

(1) FINDINGS.—Congress finds that the Centers for Disease Control and Prevention has an essential role in defending against and combatting public health threats domestically and abroad and requires secure and modern facilities, and expanded and improved capabilities related to bioterrorism and other public health emergencies, sufficient to enable such Centers to conduct this important mission.

(2) FACILITIES.—

(A) IN GENERAL.—The Director of the Centers for Disease Control and Prevention may design, construct, and equip new facilities, renovate existing facilities (including laboratories, laboratory support buildings, scientific communication facilities, transshipment complexes, secured and isolated parking structures, office buildings, and other facilities and infrastructure), and upgrade security of such facilities, in order to better conduct the capacities described in section 319A, and for supporting public health activities.

(B) MULTIYEAR CONTRACTING AUTHORITY.—For any project of designing, constructing, equipping, or renovating any facility under subparagraph (A), the Director of the Centers for Disease Control and Prevention may enter into a single contract or related contracts that collectively include the full scope of the project, and the solicitation and contract shall contain the clause “availability of funds” found at section 52.232–18 of title 48, Code of Federal Regulations.

(3) IMPROVING THE CAPACITIES OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION.—The Secretary shall expand, enhance, and improve the capabilities of the Centers for Disease Control and Prevention relating to preparedness for and responding effectively to bioterrorism and other public health emergencies. Activities that may be carried out under the preceding sentence include—

(A) expanding or enhancing the training of personnel;

(B) improving communications facilities and networks, including delivery of necessary information to rural areas;

(C) improving capabilities for public health surveillance and reporting activities, taking into account the integrated system or systems of public health alert communications and surveillance networks under subsection (b); and

(D) improving laboratory facilities related to bioterrorism and other public health emergencies, including increasing the security of such facilities.

(b) NATIONAL COMMUNICATIONS AND SURVEILLANCE NETWORKS.—

(1) IN GENERAL.—The Secretary, directly or through awards of grants, contracts, or cooperative agreements, shall provide for the establishment of an integrated system or systems of public health alert communications and surveillance networks between and among—

(A) Federal, State, and local public health officials;

(B) public and private health-related laboratories, hospitals, poison control centers, and other health care facilities; and

(C) any other entities determined appropriate by the Secretary.

(2) REQUIREMENTS.—The Secretary shall ensure that networks under paragraph (1) allow for the timely sharing and discussion, in a secure manner, of essential information concerning bioterrorism or another public health emergency, or recommended methods for responding to such an attack or emergency, allowing for coordination to maximize all-hazards medical and public health preparedness and response and to minimize duplication of effort.

(3) STANDARDS.—Not later than one year after the date of the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Secretary, in cooperation with health care providers and State and local public health officials, shall establish any additional technical and reporting standards (including standards for interoperability) for networks under paragraph (1) and update such standards as necessary.

(c) MODERNIZING PUBLIC HEALTH SITUATIONAL AWARENESS AND BIOSURVEILLANCE.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, the Secretary, in collaboration with State, local, and tribal public health officials, shall establish a near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems to share data and information to enhance early detection of rapid response to, and management of, potentially catastrophic infectious disease outbreaks, novel emerging threats, and other public health emergencies that originate domestically or abroad. Such network shall be built on existing State situational awareness systems or enhanced systems that enable such connectivity.

(2) STRATEGY AND IMPLEMENTATION PLAN.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, the Secretary shall submit to the appropriate committees of Congress a coordinated strategy and an accompanying implementation plan that identifies and demonstrates the measurable steps the Secretary will carry out to—

- (A) develop, implement, and evaluate the network described in paragraph (1), utilizing the elements described in paragraph (3);
 - (B) modernize and enhance biosurveillance activities; and
 - (C) improve information sharing, coordination, and communication among disparate biosurveillance systems supported by the Department of Health and Human Services.
- (3) ELEMENTS.—The network described in paragraph (1) shall include data and information transmitted in a standardized format from—
- (A) State, local, and tribal public health entities, including public health laboratories;
 - (B) Federal health agencies;
 - (C) zoonotic disease monitoring systems;
 - (D) public and private sector health care entities, hospitals, pharmacies, poison control centers or professional organizations in the field of poison control, community health centers, health centers and clinical laboratories, to the extent practicable and provided that such data are voluntarily provided simultaneously to the Secretary and appropriate State, local, and tribal public health agencies; and
 - (E) such other sources as the Secretary may deem appropriate.
- (4) RULE OF CONSTRUCTION.—Paragraph (3) shall not be construed as requiring separate reporting of data and information from each source listed.
- (5) REQUIRED ACTIVITIES.—In establishing and operating the network described in paragraph (1), the Secretary shall—
- (A) utilize applicable interoperability standards as determined by the Secretary, and in consultation with the Office of the National Coordinator for Health Information Technology, through a joint public and private sector process;
 - (B) define minimal data elements for such network;
 - (C) in collaboration with State, local, and tribal public health officials, integrate and build upon existing State, local, and tribal capabilities, ensuring simultaneous sharing of data, information, and analyses from the network described in paragraph (1) with State, local, and tribal public health agencies; and
 - (D) in collaboration with State, local, and tribal public health officials, develop procedures and standards for the collection, analysis, and interpretation of data that States, regions, or other entities collect and report to the network described in paragraph (1).
- (6) CONSULTATION WITH THE NATIONAL BIODEFENSE SCIENCE BOARD.—In carrying out this section and consistent with section 319M, the National Biodefense Science Board shall provide expert advice and guidance, including recommendations, regarding the measurable steps the Secretary should take to modernize and enhance biosurveillance activities pursuant to the efforts of the Department of Health and Human Services to ensure comprehensive, real-time, all-hazards biosurveillance

capabilities. In complying with the preceding sentence, the National Biodefense Science Board shall—

(A) identify the steps necessary to achieve a national bio-surveillance system for human health, with international connectivity, where appropriate, that is predicated on State, regional, and community level capabilities and creates a networked system to allow for two-way information flow between and among Federal, State, and local government public health authorities and clinical health care providers;

(B) identify any duplicative surveillance programs under the authority of the Secretary, or changes that are necessary to existing programs, in order to enhance and modernize such activities, minimize duplication, strengthen and streamline such activities under the authority of the Secretary, and achieve real-time and appropriate data that relate to disease activity, both human and zoonotic; and

(C) coordinate with applicable existing advisory committees of the Director of the Centers for Disease Control and Prevention, including such advisory committees consisting of representatives from State, local, and tribal public health authorities and appropriate public and private sector health care entities and academic institutions, in order to provide guidance on public health surveillance activities.

(d) STATE AND REGIONAL SYSTEMS TO ENHANCE SITUATIONAL AWARENESS IN PUBLIC HEALTH EMERGENCIES.—

(1) IN GENERAL.—To implement the network described in subsection (c), the Secretary may award grants to States or consortia of States to enhance the ability of such States or consortia of States to establish or operate a coordinated public health situational awareness system for regional or Statewide early detection of, rapid response to, and management of potentially catastrophic infectious disease outbreaks and public health emergencies, in collaboration with appropriate public health agencies, sentinel hospitals, clinical laboratories, pharmacies, poison control centers, other health care organizations, and animal health organizations within such States.

(2) ELIGIBILITY.—To be eligible to receive a grant under paragraph (1), the State or consortium of States shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including an assurance that the State or consortium of States will submit to the Secretary—

(A) reports of such data, information, and metrics as the Secretary may require;

(B) a report on the effectiveness of the systems funded under the grant; and

(C) a description of the manner in which grant funds will be used to enhance the timelines and comprehensiveness of efforts to detect, respond to, and manage potentially catastrophic infectious disease outbreaks and public health emergencies.

(3) USE OF FUNDS.—A State or consortium of States that receives an award under this subsection—

(A) shall establish, enhance, or operate a coordinated public health situational awareness system for regional or Statewide early detection of, rapid response to, and management of potentially catastrophic infectious disease outbreaks and public health emergencies;

(B) may award grants or contracts to entities described in paragraph (1) within or serving such State to assist such entities in improving the operation of information technology systems, facilitating the secure exchange of data and information, and training personnel to enhance the operation of the system described in subparagraph (A); and

(C) may conduct a pilot program for the development of multi-State telehealth network test beds that build on, enhance, and securely link existing State and local telehealth programs to prepare for, monitor, respond to, and manage the events of public health emergencies, facilitate coordination and communication among medical, public health, and emergency response agencies, and provide medical services through telehealth initiatives within the States that are involved in such a multi-State telehealth network test bed.

(4) LIMITATION.—Information technology systems acquired or implemented using grants awarded under this section must be compliant with—

(A) interoperability and other technological standards, as determined by the Secretary; and

(B) data collection and reporting requirements for the network described in subsection (c).

(5) INDEPENDENT EVALUATION.—Not later than 3 years after the date of enactment of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, the Government Accountability Office shall conduct an independent evaluation, and submit to the Secretary and the appropriate committees of Congress a report concerning the activities conducted under this subsection and subsection (c).

(e) TELEHEALTH ENHANCEMENTS FOR EMERGENCY RESPONSE.—

(1) EVALUATION.—The Secretary, in consultation with the Federal Communications Commission and other relevant Federal agencies, shall—

(A) conduct an inventory of telehealth initiatives in existence on the date of enactment of the Pandemic and All-Hazards Preparedness Act, including—

- (i) the specific location of network components;
- (ii) the medical, technological, and communications capabilities of such components;
- (iii) the functionality of such components; and
- (iv) the capacity and ability of such components to handle increased volume during the response to a public health emergency;

(B) identify methods to expand and interconnect the regional health information networks funded by the Secretary, the State and regional broadband networks funded through the rural health care support mechanism pilot

program funded by the Federal Communications Commission, and other telehealth networks;

(C) evaluate ways to prepare for, monitor, respond rapidly to, or manage the events of, a public health emergency through the enhanced use of telehealth technologies, including mechanisms for payment or reimbursement for use of such technologies and personnel during public health emergencies;

(D) identify methods for reducing legal barriers that deter health care professionals from providing telemedicine services, such as by utilizing State emergency health care professional credentialing verification systems, encouraging States to establish and implement mechanisms to improve interstate medical licensure cooperation, facilitating the exchange of information among States regarding investigations and adverse actions, and encouraging States to waive the application of licensing requirements during a public health emergency;

(E) evaluate ways to integrate the practice of telemedicine within the National Disaster Medical System; and

(F) promote greater coordination among existing Federal interagency telemedicine and health information technology initiatives.

(2) REPORT.—Not later than 12 months after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall prepare and submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding the findings and recommendations pursuant to subparagraphs (A) through (F) of paragraph (1).

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, \$138,300,000 for each of fiscal years 2014 through 2018 (*except such dollar amount shall be reduced by \$5,000,000 for fiscal year 2018*).

(g) DEFINITION.—For purposes of this section the term “bio-surveillance” means the process of gathering near real-time biological data that relates to human and zoonotic disease activity and threats to human or animal health, in order to achieve early warning and identification of such health threats, early detection and prompt ongoing tracking of health events, and overall situational awareness of disease activity.

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