

NATIONAL CLINICAL CARE COMMISSION ACT

NOVEMBER 14, 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. 1192]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 1192) to amend the Public Health Service Act to foster more effective implementation and coordination of clinical care for people with pre-diabetes, diabetes, and the chronic diseases and conditions that result from diabetes, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

CONTENTS

| | Page |
|---|------|
| Purpose and Summary | 4 |
| Background and Need for Legislation | 4 |
| Hearings | 4 |
| Committee Consideration | 4 |
| Committee Votes | 5 |
| Committee Oversight Findings | 5 |
| 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 | 5 |
| Duplication of Federal Programs | 5 |
| Disclosure of Directed Rule Makings | 6 |
| Advisory Committee Statement | 6 |
| Applicability to Legislative Branch | 6 |
| Section-by-Section Analysis of the Legislation | 6 |
| Changes in Existing Law Made by the Bill, as Reported | 6 |

The amendments are as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “National Clinical Care Commission Act”.

SEC. 2. ESTABLISHMENT OF THE NATIONAL CLINICAL CARE COMMISSION.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following new section:

“SEC. 399V-7. NATIONAL CLINICAL CARE COMMISSION.

“(a) **ESTABLISHMENT.**—There is hereby established, within the Department of Health and Human Services, a National Clinical Care Commission (in this section referred to as the ‘Commission’) to evaluate, and recommend solutions regarding better coordination and leveraging of, programs within the Department and other Federal agencies that relate in any way to supporting appropriate clinical care (such as any interactions between physicians and other health care providers and their patients related to treatment and care management) for individuals with—

- “(1) a complex metabolic or autoimmune disease;
- “(2) a disease resulting from insulin deficiency or insulin resistance; or
- “(3) complications caused by any such disease.

“(b) MEMBERSHIP.—

“(1) **IN GENERAL.**—The Commission shall be composed of the following voting members:

“(A) The heads (or their designees) of the following Federal agencies and departments:

- “(i) The Centers for Medicare & Medicaid Services.
- “(ii) The Agency for Healthcare Research and Quality.
- “(iii) The Centers for Disease Control and Prevention.
- “(iv) The Indian Health Service.
- “(v) The Department of Veterans Affairs.
- “(vi) The National Institutes of Health.
- “(vii) The Food and Drug Administration.
- “(viii) The Health Resources and Services Administration.
- “(ix) The Department of Defense.

“(B) Twelve additional voting members appointed under paragraph (2).

“(C) Such additional voting members as may be appointed by the Secretary, at the Secretary’s discretion, from among the heads (or their designees) of governmental or nongovernmental entities that impact clinical care of individuals with any of the diseases and complications described in subsection (a).

“(2) **ADDITIONAL MEMBERS.**—The Commission shall include additional voting members appointed by the Secretary, in consultation with national medical societies and patient advocacy organizations with expertise in the care and epidemiology of any of the diseases and complications described in subsection (a), including one or more such members from each of the following categories:

- “(A) Clinical endocrinologists.
- “(B) Physician specialties (other than as described in subparagraph (A)) that play a role in diseases and complications described in subsection (a), such as cardiologists, nephrologists, and eye care professionals.
- “(C) Primary care physicians.
- “(D) Non-physician health care professionals, such as certified diabetes educators, registered dietitians and nutrition professionals, nurses, nurse practitioners, and physician assistants.
- “(E) Patient advocates.
- “(F) National experts in the duties listed under subsection (c).
- “(G) Health care providers furnishing services to a patient population that consists of a high percentage (as specified by the Secretary) of individuals who are enrolled in a State plan under title XIX of the Social Security Act or who are not covered under a health plan or health insurance coverage.

“(3) **CHAIRPERSON.**—The voting members of the Commission shall select a chairperson from the members appointed under paragraph (2) from the category under paragraph (2)(A).

“(4) **MEETINGS.**—The Commission shall meet at least twice, and not more than 4 times, a year.

“(5) **BOARD TERMS.**—Members of the Commission appointed pursuant to subparagraph (B) or (C) of paragraph (1), including the chairperson, shall serve for a 3-year term. A vacancy on the Commission shall be filled in the same manner as the original appointments.

“(c) DUTIES.—The Commission shall—

“(1) evaluate programs of the Department of Health and Human Services regarding the utilization of diabetes screening benefits, annual wellness visits, and other preventive health benefits that may reduce the incidence of the dis-

eases and complications described in subsection (a), including explaining problems regarding such utilization and related data collection mechanisms;

“(2) identify current activities and critical gaps in Federal efforts to support clinicians in providing integrated, high-quality care to individuals with any of the diseases and complications described in subsection (a);

“(3) make recommendations regarding the coordination of clinically-based activities that are being supported by the Federal Government with respect to the diseases and complications described in subsection (a);

“(4) make recommendations regarding the development and coordination of federally funded clinical practice support tools for physicians and other health care professionals in caring for and managing the care of individuals with any of the diseases and complications described in subsection (a), specifically with regard to implementation of new treatments and technologies;

“(5) evaluate programs described in subsection (a) that are in existence as of the date of the enactment of this section and determine if such programs are meeting the needs identified in paragraph (2) and, if such programs are determined as not meeting such needs, recommend programs that would be more appropriate;

“(6) recommend, with respect to the diseases and complications described in subsection (a), clinical pathways for new technologies and treatments, including future data collection activities, that may be developed and then used to evaluate—

“(A) various care models and methods; and

“(B) the impact of such models and methods on quality of care as measured by appropriate care parameters (such as A1C, blood pressure, and cholesterol levels);

“(7) evaluate and expand education and awareness activities provided to physicians and other health care professionals regarding clinical practices for the prevention of the diseases and complications described in subsection (a);

“(8) review and recommend appropriate methods for outreach and dissemination of educational resources that—

“(A) regard the diseases and complications described in subsection (a);

“(B) are funded by the Federal Government; and

“(C) are intended for health care professionals and the public; and

“(9) carry out other activities, such as activities relating to the areas of public health and nutrition, that the Commission deems appropriate with respect to the diseases and complications described in subsection (a).

“(d) OPERATING PLAN.—

“(1) INITIAL PLAN.—Not later than 90 days after its first meeting, the Commission shall submit to the Secretary and the Congress an operating plan for carrying out the activities of the Commission as described in subsection (c). Such operating plan may include—

“(A) a list of specific activities that the Commission plans to conduct for purposes of carrying out the duties described in each of the paragraphs in subsection (c);

“(B) a plan for completing the activities;

“(C) a list of members of the Commission and other individuals who are not members of the Commission who will need to be involved to conduct such activities;

“(D) an explanation of Federal agency involvement and coordination needed to conduct such activities;

“(E) a budget for conducting such activities;

“(F) a plan for evaluating the value and potential impact of the Commission’s work and recommendations, including the possible continuation of the Commission for the purposes of overseeing their implementation; and

“(G) other information that the Commission deems appropriate.

“(2) UPDATES.—The Commission shall periodically update the operating plan under paragraph (1) and submit such updates to the Secretary and the Congress.

“(e) FINAL REPORT.—By not later than 3 years after the date of the Commission’s first meeting, the Commission shall submit to the Secretary and the Congress a final report containing all of the findings and recommendations required by this section. Not later than 120 days after the submission of the final report, the Secretary shall review the plan required by subsection (d)(1)(F) and submit to the Congress a recommendation on whether the Commission should be reauthorized to operate after fiscal year 2019.

“(f) SUNSET.—The Commission shall terminate at the end of fiscal year 2019.”.

Amend the title so as to read:

A bill to amend the Public Health Service Act to foster more effective implementation and coordination of clinical care for people with a complex metabolic or autoimmune disease, a disease resulting from insulin deficiency or insulin resistance, or complications caused by such a disease, and for other purposes.

PURPOSE AND SUMMARY

H.R. 1192 was introduced on March 2, 2015, by Rep. Pete Olson (R–TX). H.R. 1192 establishes a clinical care commission to evaluate and recommend solutions regarding better coordinating and leveraging of Federal programs related to complex metabolic or autoimmune disorders, a disease resulting from insulin deficiency or resistance, or complications caused by any such disease.

BACKGROUND AND NEED FOR LEGISLATION

Metabolic disorders take a large toll on human health each year. Complications from these disorders can lead to catastrophic health outcomes, such as limb amputation and kidney failure, and the treatment of metabolic disorders and their complications costs billions of dollars each year.

There are numerous programs across the Federal government related to metabolic disorders. Some focus on prevention, while others focus on the treatment of such conditions. Improving such efforts, including the coordination among Federal activities related to metabolic disorders, provides an opportunity to reduce costs while enhancing health outcomes.

HEARINGS

The Subcommittee on Health held a hearing on H.R. 1192 on September 8, 2016. The hearing was entitled “Examining Legislation to Improve Public Health” and witnesses included the following:

- Sonja L. Banks, President and COO, Sickle Cell Disease Association of America, Inc.;
- General Arthur Dean, Chairman and CEO, Community Anti-Drug Coalitions of America;
- Jonathan Leffert, President-Elect, American Association of Clinical Endocrinologists;
- Brad Marino, Chair, Pediatric Congenital Heart Association; and
- R. Sean Morrison, Director, National Palliative Care Research Center.

COMMITTEE CONSIDERATION

On September 12 and 13, 2016, the Subcommittee on Health met in open markup session and forwarded H.R. 1192 to the full Committee, as amended, by a voice vote.

On September 20 and 21, 2016, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 1192 reported to the House, without amendment, 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. 1192 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.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

This legislation establishes a clinical care commission to evaluate and recommend solutions regarding better coordinating and leveraging of Federal programs that relate to complex metabolic or autoimmune disorders, a disease resulting from insulin deficiency or resistance, or complications caused by any such disease.

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. 1192 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. 1192 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. At the time this report was filed, the estimate was not available.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

At the time this report was filed, the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not available.

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. 1192 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. 1192 specifically directs to be completed no rule making 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 provides that the Act may be cited as the “National Clinical Care Commission Act”.

Section 2. Establishment of the National Clinical Care Commission

Section 2 establishes a National Clinical Care Commission within the Department of Health and Human Services. The Commission will evaluate and recommend solutions regarding better coordination and leveraging of programs within the Department of Health and Human Services and other Federal agencies that relate to supporting appropriate clinical care for individuals with a complex metabolic or autoimmune disease, a disease resulting from insulin deficiency or resistance, or complications by any such disease.

The Commission will sunset at the end of fiscal year 2019.

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 P—ADDITIONAL PROGRAMS

* * * * *

SEC. 399V-7. NATIONAL CLINICAL CARE COMMISSION.

(a) *ESTABLISHMENT.*—There is hereby established, within the Department of Health and Human Services, a National Clinical Care Commission (in this section referred to as the “Commission”) to evaluate, and recommend solutions regarding better coordination and leveraging of, programs within the Department and other Federal agencies that relate in any way to supporting appropriate clinical care (such as any interactions between physicians and other health care providers and their patients related to treatment and care management) for individuals with—

- (1) a complex metabolic or autoimmune disease;
- (2) a disease resulting from insulin deficiency or insulin resistance; or
- (3) complications caused by any such disease.

(b) *MEMBERSHIP.*—

(1) *IN GENERAL.*—The Commission shall be composed of the following voting members:

(A) The heads (or their designees) of the following Federal agencies and departments:

- (i) The Centers for Medicare & Medicaid Services.
- (ii) The Agency for Healthcare Research and Quality.
- (iii) The Centers for Disease Control and Prevention.
- (iv) The Indian Health Service.
- (v) The Department of Veterans Affairs.
- (vi) The National Institutes of Health.
- (vii) The Food and Drug Administration.
- (viii) The Health Resources and Services Administration.
- (ix) The Department of Defense.

(B) Twelve additional voting members appointed under paragraph (2).

(C) Such additional voting members as may be appointed by the Secretary, at the Secretary’s discretion, from among the heads (or their designees) of governmental or non-governmental entities that impact clinical care of individuals with any of the diseases and complications described in subsection (a).

(2) *ADDITIONAL MEMBERS.*—The Commission shall include additional voting members appointed by the Secretary, in consultation with national medical societies and patient advocacy organizations with expertise in the care and epidemiology of any of the diseases and complications described in subsection (a), including one or more such members from each of the following categories:

- (A) Clinical endocrinologists.
- (B) Physician specialties (other than as described in subparagraph (A)) that play a role in diseases and complications described in subsection (a), such as cardiologists, nephrologists, and eye care professionals.
- (C) Primary care physicians.
- (D) Non-physician health care professionals, such as certified diabetes educators, registered dietitians and nutrition

professionals, nurses, nurse practitioners, and physician assistants.

(E) Patient advocates.

(F) National experts in the duties listed under subsection (c).

(G) Health care providers furnishing services to a patient population that consists of a high percentage (as specified by the Secretary) of individuals who are enrolled in a State plan under title XIX of the Social Security Act or who are not covered under a health plan or health insurance coverage.

(3) CHAIRPERSON.—The voting members of the Commission shall select a chairperson from the members appointed under paragraph (2) from the category under paragraph (2)(A).

(4) MEETINGS.—The Commission shall meet at least twice, and not more than 4 times, a year.

(5) BOARD TERMS.—Members of the Commission appointed pursuant to subparagraph (B) or (C) of paragraph (1), including the chairperson, shall serve for a 3-year term. A vacancy on the Commission shall be filled in the same manner as the original appointments.

(c) DUTIES.—The Commission shall—

(1) evaluate programs of the Department of Health and Human Services regarding the utilization of diabetes screening benefits, annual wellness visits, and other preventive health benefits that may reduce the incidence of the diseases and complications described in subsection (a), including explaining problems regarding such utilization and related data collection mechanisms;

(2) identify current activities and critical gaps in Federal efforts to support clinicians in providing integrated, high-quality care to individuals with any of the diseases and complications described in subsection (a);

(3) make recommendations regarding the coordination of clinically-based activities that are being supported by the Federal Government with respect to the diseases and complications described in subsection (a);

(4) make recommendations regarding the development and coordination of federally funded clinical practice support tools for physicians and other health care professionals in caring for and managing the care of individuals with any of the diseases and complications described in subsection (a), specifically with regard to implementation of new treatments and technologies;

(5) evaluate programs described in subsection (a) that are in existence as of the date of the enactment of this section and determine if such programs are meeting the needs identified in paragraph (2) and, if such programs are determined as not meeting such needs, recommend programs that would be more appropriate;

(6) recommend, with respect to the diseases and complications described in subsection (a), clinical pathways for new technologies and treatments, including future data collection activities, that may be developed and then used to evaluate—

(A) various care models and methods; and

(B) the impact of such models and methods on quality of care as measured by appropriate care parameters (such as A1C, blood pressure, and cholesterol levels);

(7) evaluate and expand education and awareness activities provided to physicians and other health care professionals regarding clinical practices for the prevention of the diseases and complications described in subsection (a);

(8) review and recommend appropriate methods for outreach and dissemination of educational resources that—

(A) regard the diseases and complications described in subsection (a);

(B) are funded by the Federal Government; and

(C) are intended for health care professionals and the public; and

(9) carry out other activities, such as activities relating to the areas of public health and nutrition, that the Commission deems appropriate with respect to the diseases and complications described in subsection (a).

(d) OPERATING PLAN.—

(1) INITIAL PLAN.—Not later than 90 days after its first meeting, the Commission shall submit to the Secretary and the Congress an operating plan for carrying out the activities of the Commission as described in subsection (c). Such operating plan may include—

(A) a list of specific activities that the Commission plans to conduct for purposes of carrying out the duties described in each of the paragraphs in subsection (c);

(B) a plan for completing the activities;

(C) a list of members of the Commission and other individuals who are not members of the Commission who will need to be involved to conduct such activities;

(D) an explanation of Federal agency involvement and coordination needed to conduct such activities;

(E) a budget for conducting such activities;

(F) a plan for evaluating the value and potential impact of the Commission's work and recommendations, including the possible continuation of the Commission for the purposes of overseeing their implementation; and

(G) other information that the Commission deems appropriate.

(2) UPDATES.—The Commission shall periodically update the operating plan under paragraph (1) and submit such updates to the Secretary and the Congress.

(e) FINAL REPORT.—By not later than 3 years after the date of the Commission's first meeting, the Commission shall submit to the Secretary and the Congress a final report containing all of the findings and recommendations required by this section. Not later than 120 days after the submission of the final report, the Secretary shall review the plan required by subsection (d)(1)(F) and submit to the Congress a recommendation on whether the Commission should be reauthorized to operate after fiscal year 2019.

(f) SUNSET.—The Commission shall terminate at the end of fiscal year 2019.

* * * * *

○