

NATIONAL CLINICAL CARE COMMISSION

Operating Plan: 2018-2021

ABSTRACT

Public Law 115-80 states that the National Clinical Care Commission (the Commission) is required to submit to the Secretary of Health and Human Services and to the Congress an operating plan, due on January 31, 2019, for carrying out its activities. This document aims to provide a detailed overview of the Commission's plans over the next three years. The Commission is also charged that by not later than October 31, 2021, it submit a final report containing all its findings and recommendations regarding its focus - federal programs that address insulin-related disorders (e.g., Type 1 and Type 2 diabetes), including prevention, public health outreach and education, treatment, clinical care, and complications.

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Executive Summary

In November 2017, Congress passed the National Clinical Care Commission Act (P.L. 115-80) which established the National Clinical Care Commission (the Commission or NCCC) within the U.S Department of Health and Human Services (HHS). As stated in the Charter, the Commission is charged to evaluate and make recommendations to the Secretary of HHS and to Congress regarding “improvements to the coordination and leveraging of programs within the Department and other federal agencies related to awareness and clinical care for at least one, but not more than two, complex metabolic or autoimmune diseases resulting from issues related to insulin that represent a significant disease burden in the United States, which may include complications due to such diseases.” This charge is largely focused on diabetes, both Type 1 and Type 2, and includes prevention, public health outreach and education, treatment, clinical care, and complications.

Composed of 23 members, the Commission will conclude their work (sunset) in late 2021, three years from the date of the first meeting on October 31, 2018, unless it is extended by Congress. The Office of Disease Prevention and Health Promotion (ODPHP) was designated by the Assistant Secretary for Health to manage and support the Commission.

P.L. 115-80 specifies that the operating plan be finalized within the first 90 days of the inaugural meeting of the Commission. The plan to carry out the activities of the Commission includes:

- (1) A list of specific activities that the Commission plans to conduct for purposes of carrying out the duties described above;
- (2) A plan for completing the activities;
- (3) 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;
- (4) An explanation of Federal agency involvement and coordination needed to conduct such activities;
- (5) A budget for conducting such activities; and
- (6) Other information that the Commission deems appropriate.

This operating plan, therefore, outlines the approach to completing the work of the NCCC. It will accomplish this work through up to four meetings per year of the full Commission, and several meetings of subcommittees to support the full Commission. This document includes the list of Commission members and relevant entities who are involved in the work. A list of activities is included in this plan, along with a year-by-year design for the work. The first year is dedicated to establishing the Commission and its subcommittees, defining their scopes of work, and gathering information about relevant federal programs. In the second year, the Commission will delve into the details of the federal programs, looking for promising practices as well as for programmatic gaps, and understanding the degree to which federal programs are coordinated and how they might be optimally leveraged. The final year of the Commission’s work will be to refine particular aspects of subcommittee findings, review their reports with the

full Commission for its deliberation and actions, finalize the analysis, and develop recommendations. Full Commission meetings will be open to the public. Public comments will be solicited throughout the development of the Commission's recommendations. Written comments may be submitted to OHQ@hhs.gov.

Because funding was not appropriated by Congress for this Commission, the work of the Commission is funded through an HHS Joint Funding Agreement (JFA). This operating plan outlines the budgetary support provided over the three years by HHS agencies. For FY 18, four federal agencies and one OASH office will contribute to the JFA:

- Health Resources and Services Administration (HRSA)
- Centers for Disease Prevention and Health Promotion (CDC)
- Agency for Health Care Research and Quality (AHRQ)
- National Institutes for Health (NIH)
- Office of Minority Health (OMH)

In FY 19 – FY 21, in addition to the above agencies, the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), and the Indian Health Service (IHS), will contribute to the JFA. The JFA for FY 19 allows for approximately \$720,000 to execute the work of this Commission; \$583,000 is estimated for outside contracts. This amount is exclusive of federal salaries for up to 2.0 FTE.

Background

The National Clinical Care Commission (the Commission or NCCC) was established by Congress in November 2017 (P.L. 115-80) to evaluate and make recommendations to the Secretary of HHS and to Congress regarding “improvements to the coordination and leveraging of programs within the Department and other federal agencies related to awareness and clinical care for at least one, but not more than two, complex metabolic or autoimmune diseases resulting from issues related to insulin that represent a significant disease burden in the United States, which may include, complications due to such diseases.” This charge is largely focused on diabetes, both Type 1 and Type 2, and includes prevention, public health outreach and education, treatment, clinical care, and complications.

Unless extended by Congress, the Commission will sunset in 2021 - three years from the date of the first meeting on October 31, 2018. Because funding was not appropriated by Congress for this Commission, the work of the Commission is funded through an HHS Joint Funding Agreement (JFA). The Office of Disease Prevention and Health Promotion (ODPHP) was designated by the Assistant Secretary for Health to manage and support the Commission.

The Commission is composed of 23 voting members (see Appendix A), which includes 11 federal members and 12 non-federal members. The 11 federal members are individuals designated by the heads of the following federal agencies: The Centers for Medicare and Medicaid Services (CMS), the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), the Indian Health Service (IHS), the Department of Veterans Affairs (VA), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), the Department of Defense (DoD), the Department of Agriculture (USDA), and the Office of Minority Health (OMH).

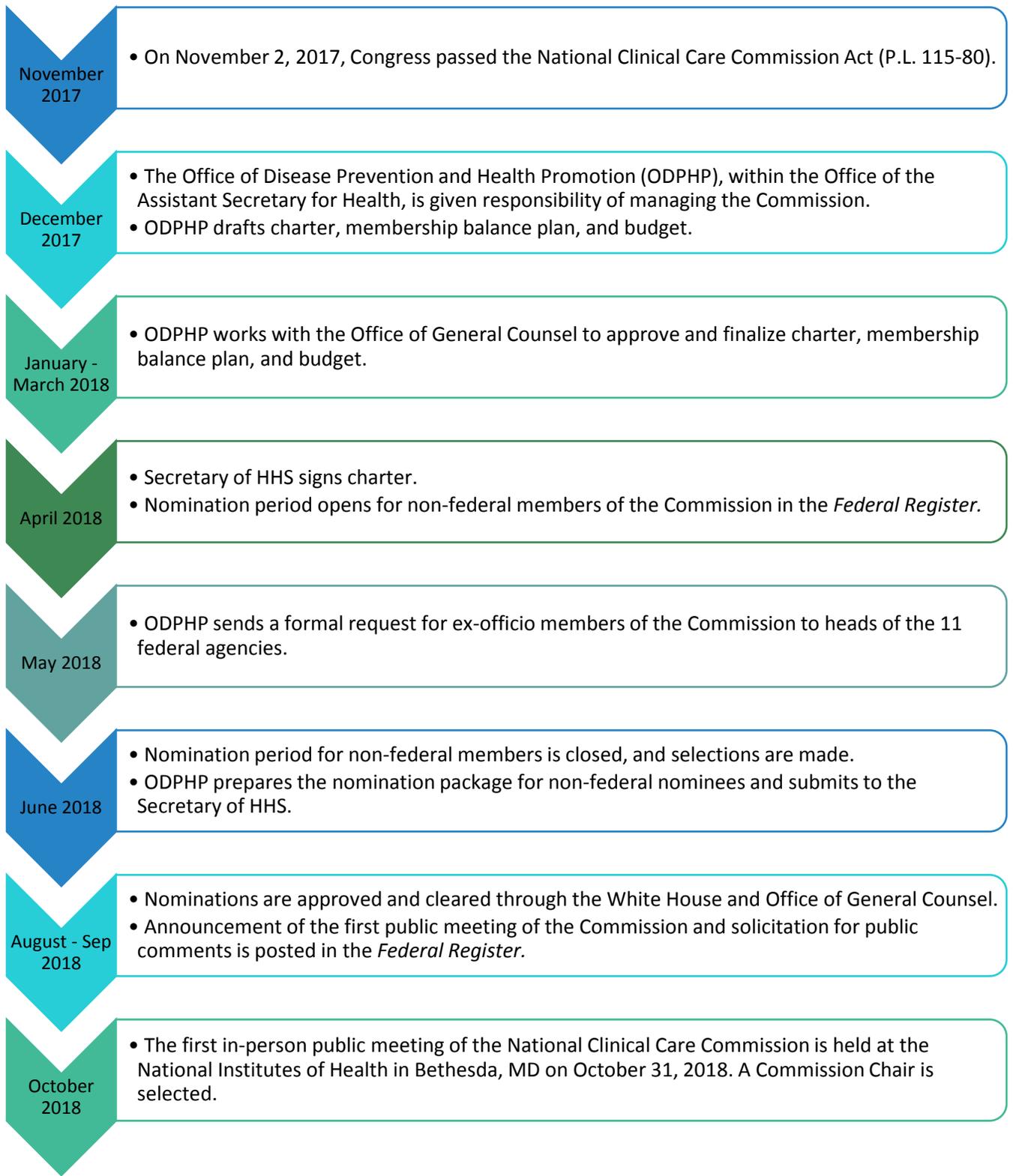
The 12 non-federal members are appointed as special government employees (SGEs) by the Secretary and are physician specialists, primary care physicians, non-physician health care professionals, patient advocates, national experts, and health care providers who serve individuals without health insurance.

A charter approved by the HHS Secretary governs the Commission’s structure and activities. In compliance with the Federal Advisory Committee Act, Commission meetings are open to the public, and meeting materials and summaries are posted publicly. The Commission Chair, selected by the members of the Commission, conducts Commission meetings. The Chair is aided by the Designated Federal Officer at ODPHP.

P.L. 115-80 specified that the operating plan be finalized within the first 90 days of the inaugural meeting of the Commission. As stated, the plan to carry out the activities of the Commission includes:

- (1) A list of specific activities that the Commission plans to conduct for purposes of carrying out the duties described above;
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- (5) A budget for conducting such activities; and
- (6) Other information that the Commission deems appropriate.

Timeline Leading to the Inaugural Meeting



Charge to the Commission

The Commission shall evaluate and make recommendations, as appropriate, to the Secretary and to Congress regarding:

- (1) Federal programs of the US Department of Health and Human Services that focus on preventing and reducing the incidence of complex metabolic or autoimmune diseases resulting from issues related to insulin that represent a significant disease burden in the United States, which may include complications due to such diseases;
- (2) Current activities and gaps in Federal efforts to support clinicians in providing integrated, high-quality care to individuals with the diseases and complications;
- (3) The improvement in, and improved coordination of, Federal education and awareness activities related to the prevention and treatment of the diseases and complications, which may include the utilization of new and existing technologies;
- (4) Methods for outreach and dissemination of education and awareness materials that
 - (a) address the diseases and complications;
 - (b) are funded by the Federal Government; and
 - (c) are intended for health care professionals and the public; and
- (5) Whether there are opportunities for consolidation of inappropriately overlapping or duplicative Federal programs related to the diseases and complications.

List of Activities

The Commission plans to conduct the following activities for carrying out the duties of the charge:

- Subcommittee formation
- Inventory of federal programs and relevant policies
- Deeper discussion by subcommittees of pertinent themes
- Subject-matter expert interviews
- Subcommittee reports to full Commission
- Draft evaluation report with recommendations
- Public comments at all full Commission meetings and on draft recommendations
- Final report to Congress

To complement this work, which largely focuses on HHS programs, the Commission will explore its ability to extend its reach to those federal agencies beyond HHS that are directly related to diabetes prevention and control efforts. The Commission will look for approaches that improve care delivery and optimize person/patient and family engagement in education, prevention, treatment, and clinical care.

The Commission will also work to identify areas of priority as it explores current federal programs. This would facilitate the recognition of gaps in federal funding or areas of promising practices that are considered high priority. Such work is best done in subcommittees and then iteratively informed by federal programs and further discussion by the full Commission.

In summary, the Commission will use its first year of operation (2019) for inventory and information gathering on federal programs and relevant policies. The following years (2020 and 2021) will consist of analysis, discussion, refinement, and final recommendations.

Plan for Completing the Activities

Year 1: Information Gathering (CY 2019)

- The Commission first plans to conduct an inventory of federal programs and policies which focus on preventing and reducing the incidence of metabolic and autoimmune diseases resulting from issues related to insulin and their complications, largely Type 1 and Type 2 diabetes.
- The Commission will develop a matrix designed to target the relevant federal programs and policies and will seek answers to pertinent questions, such as scope, target populations, funding sources, effectiveness, and identification of potentially coordinated or consolidated programmatic resources.
- Once finalized, ODPHP will submit the matrix through the Strategic Work Information and Folder Transfer (SWIFT) for federal agencies to complete. ODPHP will be responsible for collecting, monitoring, and tracking all correspondence and compile the information into a comprehensive matrix.
- ODPHP anticipates a SWIFT deadline of February 2019.
- The NCCC plans to meet virtually in Q1 and Q4 of 2019, and in-person in Q2 and Q3 of 2019. The in-person meetings will be 1.5 days: a half-day for subcommittees and their preparation of reports to the full Commission meeting the next day. The subcommittees are expected to meet via conference calls at least twice before the summer and at least once before the Q3 in-person full NCCC meeting.

Year 2: Analysis (CY 2020)

- The NCCC plans to meet virtually in Q1 and Q4 of 2020, and in-person in Q2 and Q3 of 2020. The in-person meetings will be 1.5 days: a half-day for subcommittees and their preparation of reports to full Commission meeting the next day. The subcommittees are expected to meet via conference calls at least twice (up to monthly) before summer 2020, and at least once before the Q3 in-person full NCCC meeting.
- It is expected that during Year 2, the subcommittees' work will both broaden and deepen in their evaluation. This will likely require more frequent conference calls, subject matter expert interviews, and similar work to support and finish their evaluation of federal programs. Analyses will be well underway during this Year 2.

Year 3: Refinement and Recommendations (CY 2021)

- Year 3 of the NCCC will largely be devoted to finalizing the analysis and starting development of recommendations. There will be one virtual meeting in Q1 and two in-person meetings in Q3. These two in-person meetings will each last two full days, including subcommittee preparation for reports to the full Commission meeting the next day. Between the Q1 and Q3, the subcommittees are expected to meet via teleconference at least twice.
- By summer 2021 the NCCC will have draft recommendations, with finalization of the recommendations before the Q3 2021 in-person meeting. Subcommittees are expected to meet virtually at least once between Q2 and Q3.
- The Commission's recommendations will be submitted for public comment before the Report is finalized and cleared by federal agencies.
- September 2021 is planned to be the last NCCC meeting.
- By not later than October 2021, the Commission shall submit to the Secretary of HHS and Congress a final report containing all the findings and recommendations.

Subcommittee Meetings

- To effectively implement the duties of the Commission, the Commission will form at least 4 subcommittees in the areas of case finding, outreach & education, prevention, and treatment & complications. More subcommittees may be formed as the Commission progresses.
- Each subcommittee will identify a Chair, who will convene and conduct subcommittee meetings.
- Each subcommittee will be expected to meet via teleconference at least 1-2 times prior to each full Commission meeting.
- Each subcommittee will identify their scope, deliverables, meeting frequency, and support staffing (from within federal agencies and offices).
- Subcommittee meetings are not open to the public. Subcommittees report their activities and findings to the full Commission at public meetings for deliberation and action by the full Commission.

Full Commission meetings (open to the public)

- The inaugural October 31, 2018 meeting of the Commission featured presentations from ODPHP, the Centers for Disease Control and Prevention, the Indian Health Service, the National Institutes of Health, and the Veterans Affairs. The presentations highlighted existing federal efforts in diabetes in these agencies.
- Future meetings of the Commission will feature similar presentations from remaining agencies: Office of Minority Health, Food and Drug Administration, Department of Agriculture, Department of Defense, Agency for Healthcare Research and Quality, and the Health Resources and Services Administration.
- The Commission will evaluate the programs discussed, and, along with the SWIFT data call, determine the need for further exploration/explanation of these programs and policies.
- In its final year the Commission will complete its evaluation and make recommendations via its Report to Congress, due in October 2021.

Public Comment

- Members of the public are welcome to submit oral and written comments to the Commission for consideration.
- Written comments are allowed throughout the lifecycle of the Commission and may be submitted to OHQ@hhs.gov.
- A solicitation for oral comments is announced with the publication of each *Federal Register* notice prior to each full committee meeting.
- Written comments are also solicited from targeted organizations and individuals.
- All comments, oral and written, are provided to members of the Commission along with all relevant materials.

List of Members

To ensure that the Commission's activities run smoothly, various individuals are needed to manage and support its operations. The Federal Advisory Committee Act (P.L. 92-463) (FACA) was established to outline the general responsibilities of federal official involvement with the committee management. The information below is divided into two sections: Management and Support. These will describe the roles and responsibilities of each individual under these titles. A list of members can be found in Appendix A.

Management:

The **Designated Federal Officer (DFO)** serves as the FACA authority, and ensures compliance with FACA and any other applicable laws and regulations. The DFO is responsible for opening, attending, and adjourning committee meetings, approving agendas, maintaining required records on cost and membership, ensuring efficient operations, maintaining records for availability to the public, and providing copies of committee reports to the Committee Management Officer for forwarding to the Library of Congress. The DFO also reviews members' conflict of interest statements to determine if and when any member(s) should be recused from any given topic. Prior to each meeting, the DFO will notify the public of meetings and ensure that all meeting notices are published in the *Federal Register*.

The **Committee Management Officer (CMO)** will coordinate all committee management activities for the agency, including submission of required documents and reports, coordination of *Federal Register* notices and timely publication, preparation and coordination of invitation letters to members who are selected to serve by the Secretary.

Support:

In the absence of a DFO at a committee or subcommittee meeting, a **DFO alternate/representative** will be present at each committee or subcommittee meeting, and is secondarily responsible for completing DFO tasks as specified. If simultaneous subcommittee meetings are to be held, each subcommittee shall have a federal employee in attendance, serving as the DFO.

A number of **support staff**, including staff from ODPHP and other offices when applicable will support the Commission in a variety of ways. Any federal staff supporting subcommittees and public meetings will serve as an additional federal staff member on subcommittee calls. Additionally, they will attend the public meetings of the Commission (two in-person, two virtual meetings per year) to assist in meeting management, and attend the in-person subcommittee break-out sessions. Additional support items include website maintenance and content development, meeting planning and management, public comments, and communications/publication clearance. Support staff may also include individuals from contractors or non-federal member organizations to assist with administrative duties, such as meeting notes and calendar invites.

A **science writer** will be responsible for developing an outline of the Committee's final report and working with subcommittee leads to determine deadlines for completing sections of the final report. The science writer will provide editorial input, including final copy editing, to ensure the final report is well-organized, free of critical errors or typos, and written in one voice. The science writer will attend all public Commission meetings and when appropriate, subcommittee meetings.

Consultants and **outside** experts may be involved for a short amount of time to help with a specific question or set of questions, or be involved through the duration of a subcommittee's work, depending on the needs of the subcommittee. Consultants participate in subcommittee meetings, but do not deliberate with the full Commission in the public meetings.

Federal Agency Involvement

The representation of other federal agencies within HHS and three non-HHS departments (USDA, DoD, and the VA) on the Commission will help to guide the programmatic and policy evaluation by the full Commission over the life of the Commission. Each federal member will serve as the appropriate expert for his/her agency, or will designate subject matter experts within their agency to provide relevant information to the Commission. The DFO will assist and support this process, as directed by the Chair for the Commission. When and where appropriate, other support staff may assist in administration aspects of the Commission, such as scheduling subcommittee meetings and calls, distributing reports and informative materials, and providing focused research on relevant aspects of federal programs under the charge of the Commission. Those staff will not be involved in decision-making roles, as that is the purview of the full Commission.

Budget

The Commission is a congressionally mandated advisory committee, but funds were not appropriated. ODPHP requested funding through a Joint Funding Agreement to support the establishment and management of the Commission. Funds are necessary given the size and scope of this Federal Advisory Committee. The Assistant Secretary for Health recommended for FY18 that the OMH, AHRQ, CDC, NIH, and HRSA contribute funds to support the establishment of the Commission. At that time, IHS and FDA were not included in the budget request for FY18 because they are funded through a different appropriations bill. In subsequent years (FY19, FY20, and FY21), each of the agencies, including CMS, HIS, and FDA, will contribute funds through a Joint Funding Agreement.

The funds support the management of the Commission, including:

- Project management for the Commission and subcommittees
- Meeting support and logistics including planning, registration, meeting materials, webcasting, teleconference calls, audio-visual and technical equipment/support
- Website design, maintenance, and updates, including development and maintenance of database for public comments and analysis, blogs, and posting of public documents
- SharePoint website (design, maintenance) and access (licenses) by Commission members to files and documents relevant to the work of the Commission
- Travel and per diem for members to attend public Commission meetings
- Funding for support staff
- Travel and per diem for non-member consultants
- Promotion and outreach for meetings and public comments
- Rent for the meeting location
- Support for research including environmental scans, literature reviews, and analysis
- Meeting reports and final Report to Congress in 2021.

The Commission is required by P.L. 115-80 to meet at least twice a year but no more than four times a year. Two in-person meetings and two virtual meetings are planned for each year.

JFA funding will continue in FY 2019 - FY 2021 at the approved level. Costs will be incurred for the writing of the final report to the Secretary of HHS and to the Congress, no later than the end of FY2021.

Description of Costs (per fiscal year)	Cost
Federal Staff (up to 2.0 FTE)	\$283,000
Travel & per diem	\$25,000
Contractual (e.g., website, venue rental, events planning, user charges, graphics, printing, ORISE fellow, webcasting (audiovisual), environmental scans and research, note-taking, and contract for report to Congress	\$583,000
Consultants	\$5,000
TOTAL	\$896,000
Outside contract totals (less federal salaries and travel)	\$583,000

The estimated annual cost for operating the Commission, excluding travel expenses for members, consultants, and staff salary support is \$583,000. The estimated annual federal staff support required for the Commission is 2.0 FTEs at an estimated annual cost of \$283,000.

Other information that the Commission deems appropriate

As the Commission's work evolves, further information about federal programs and activities covered under the charge of the Commission may be needed to complete the evaluation and to allow a synthesis of the findings by the Commission. This could enhance, strengthen, and clarify the final recommendations within the report to Congress.

Appendix A: List of Members

Federal Members:

Ann Albright, PhD, RDN

Director, Division of Diabetes Translation
Centers for Disease Control and Prevention

Ann Bullock, MD

Director, Division of Diabetes Treatment and Prevention
Office of Clinical and Preventive Services
Indian Health Service

William Chong, MD

Acting Deputy Director, Division of Metabolism and Endocrinology Products
Office of New Drugs, Center for Drug Evaluation and Research
Food and Drug Administration

Paul Conlin, MD

Chief, Medical Service
Veterans Affairs Boston Healthcare System

Naomi Fukagawa, MD, PhD

Director, Beltsville Human Nutrition Research Center
United States Department of Agriculture

Barbara Linder, MD, PhD

Senior Advisor, Childhood Diabetes Research
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health

Aaron Lopata, MD, MPP

Chief Medical Officer, Maternal and Child Health Bureau
Office of the Associate Administrator
Health Resources and Services Administration

Barry Marx, MD, FAAP

Director, Office of Clinician Engagement
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services

Donald Shell, MD, MA

Director, Disease Prevention, Disease Management and Population Health Policy & Oversight
OASD (HA) Health Services Policy and Oversight Defense Health Headquarters
Department of Defense

Howard Tracer, MD

Medical Officer, U.S. Preventive Services Task Force Program
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality

CAPT David Wong, MD, FAAP

Medical Officer, Office of Minority Health
Office of the Assistant Secretary for Health

Special Government Employees:

Shari Bolen, MD, MPH

Associate Division Director of Internal Medicine
The MetroHealth System
Cleveland, Ohio

John Boltri, MD, FAAFP

Chair and Professor, Department of Family and Community Medicine
Northeast Ohio Medical University College of Medicine
Rootstown, Ohio

J. William (Bill) Cook, MD

Chair, Board of Directors
Ascension Medical Group
Baltimore, MD

Ayotunde Dokun, MD, PhD, FACE

Chief of Endocrine Service, Division of Endocrinology, Diabetes and Metabolism
Regional One Health System
Memphis, Tennessee

Jasmine Gonzalvo, PharmD, BCPS, BC-ADM, CDE, LDE

Clinical Associate Professor
Purdue University College of Pharmacy
Indianapolis, Indiana

M. Carol Greenlee, MD, FACP, FACE
Faculty Co-Chair
Center for Medicare and Medicaid Innovation (CMMI) Transforming Clinical Practice
Initiative (TCPI)
Grand Junction, Colorado

Meredith Hawkins, MD, MS
Director, Global Diabetes Institute
Albert Einstein College of Medicine
Bronx, New York

William Herman, MD, MPH (*Commission Chair*)
Professor of Internal Medicine and Epidemiology
Director, Michigan Center for Diabetes Translational Research
University of Michigan
Ann Arbor, Michigan

Shannon Idzik, DNP, ANP-BC, FAAN, FAANP
Associate Dean and Professor, Doctor of Nursing Practice Program
University of Maryland Baltimore School of Nursing
Baltimore, Maryland

Ellen Leake
Chair, Juvenile Diabetes Research Foundation (JDRF) International Board of Directors
Jackson, Mississippi

Dean Schillinger, MD
Chief, UCSF Division of General Internal Medicine
San Francisco General Hospital
San Francisco, California

David Strogatz, PhD, MSPH
Director, Center for Rural Community Health
Bassett Research Institute, Bassett Health Care Network
Cooperstown, New York

Federal Management Employee:

Clydette Powell, MD, MPH, FAAP
Designated Federal Officer
Office of Disease Prevention and Health Promotion
Office of the Assistant Secretary for Health
Department of Health and Human Services
Washington, DC

Appendix B: Abbreviations

AHRQ	Agency for Healthcare Research and Quality
CDC	Centers of Disease Control and Prevention
CMO	Committee Management Officer
CMS	Centers for Medicare and Medicaid Services
CY	Calendar Year
DFO	Designated Federal Officer
DoD	Department of Defense
FACA	Federal Advisory Committee Act
FDA	Food and Drug Administration
FY	Fiscal Year
HHS	U.S. Department of Health and Human Services
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
JFA	Joint Funding Agreement
NIH	National Institutes of Health
OASH	Office of the Assistant Secretary for Health
ODPHP	Office of Disease Control and Prevention
OMH	Office of Minority Health
ORISE	Oak Ridge Institute for Science and Education
PL	Public Law
USDA	U.S. Department of Agriculture
VA	Department of Veterans Affairs