117TH CONGRESS
1ST SESSION

S. 2146

To establish within the Office of the Secretary of Health and Human Services a special task force on ensuring Medicare beneficiary access to innovative diabetes technologies and services.

IN THE SENATE OF THE UNITED STATES

JUNE 21, 2021

Ms. COLLINS (for herself and Mrs. SHAHEEN) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To establish within the Office of the Secretary of Health and Human Services a special task force on ensuring Medicare beneficiary access to innovative diabetes technologies and services.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Improving Medicare Beneficiary Access to Innovative Diabetes Technologies Act of 2021''.

SEC. 2. ESTABLISHMENT OF HHS TASK FORCE ON COVERAGE AND PAYMENT FOR INNOVATIVE DIABETES TECHNOLOGIES AND SERVICES.

(a) DEFINITIONS.—In this section:

(1) CMS.—The term ''CMS'' means the Centers for Medicare & Medicaid Services.

(2) FDA.—The term ''FDA'' means the Food and Drug Administration.

(3) INNOVATIVE DIABETES TECHNOLOGIES AND SERVICES.—The term ''innovative diabetes technologies and services'' means medical technologies and services for the treatment and management of diabetes for which coverage is not available under the Medicare fee-for-service program.

(4) MEDICARE.—The term ''Medicare'' means the program of health insurance for the aged and disabled established under title XVIII of the Social Security Act.

(5) MEDICARE BENEFICIARY.—The term ''Medicare beneficiary'' means an individual who is entitled to benefits under part A of title XVIII of the Social Security Act, or enrolled under part B of such title, or both.

(6) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(b) ESTABLISHMENT; MISSION.—

(1) ESTABLISHMENT.—There is established within the Office of the Secretary the Task Force on Innovative Diabetes Technologies and Services (in this section referred to as the ''Task Force'').

(2) MISSION.—The mission of the Task Force is to—

(A) advise the Secretary with respect to accessibility to innovative diabetes technologies and services under Medicare;

(B) make recommendations to support current and future access to innovative diabetes technologies and services under Medicare; and

(C) recommend changes to Medicare to ensure appropriate access by Medicare beneficiaries to such innovative diabetes technologies and services.

(c) MEMBERSHIP.—

(1) APPOINTMENT.—The Secretary shall appoint individuals with relevant expertise to the Task Force, which shall include the following voting members:

(A) CMS OFFICIALS.—

(i) The Director of the Center for Medicare.

(ii) Not more than 2 additional officials or senior staff of CMS as the Secretary may specify.

(B) BENEFICIARY OMBUDSMAN.—The Medicare Beneficiary Ombudsman.

(C) PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN.—The Medicare Pharmaceutical and Technology Ombudsman.

(D) FDA OFFICIALS.—Not more than 2 officials or senior staff from the Diabetes Branch of the Center for Devices and Radiological Health of FDA as the Commissioner of Food and Drugs may specify.

(E) PATIENT GROUPS.—Representatives of—

(i) Medicare beneficiaries;

(ii) individuals enrolled under a State plan under title XIX of the Social Security Act (or a waiver of such a plan); and

(iii) individuals not described in clause (i) or (ii) who have a diagnosis of diabetes.

(F) HEALTH CARE PROVIDERS.—Representatives of providers of services, physicians, and practitioners who treat individuals with a diagnosis of diabetes.

(G) MANUFACTURERS.—Representatives of manufacturers of diabetes technologies, including innovative diabetes technologies and services.

(2) CO-CHAIRS.—

(A) IN GENERAL.—Of the members of the Task Force—

(i) one co-chair shall be the Director of the Center for Medicare; and

(ii) one co-chair shall be designated by the Secretary from among voting members appointed under subparagraph (E), (F), or (G) of paragraph (1).

(B) ROTATION OF NON-GOVERNMENT CO-CHAIR.—The Secretary shall rotate designations of co-chairs under subparagraph (A)(ii) from among voting members appointed under subparagraph (E), (F), or (G) of paragraph (1).

(C) TERM OF SERVICE FOR NON-GOVERNMENT CO-CHAIR.—Each co-chair designated under subparagraph (A)(ii) shall serve a term of 2 years.

(3) COMPENSATION.—

(A) IN GENERAL.—Except as provided in subparagraph (B), members of the Task Force shall serve without compensation.

(B) TRAVEL EXPENSES.—A member of the Task Force may be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for an employee of an agency under subchapter I of chapter 57 of title 5, United States Code, while away from the home or regular place of business of the member in the performance of the duties of the Task Force.

(d) MEETINGS.—The Secretary shall convene the Task Force not less frequently than 4 times each year. The Secretary shall convene the first meeting of the Task Force no later than July 1, 2022.

(e) DUTIES.—The Task Force shall carry out the following duties:

(1) IDENTIFICATION OF INNOVATIVE DIABETES TECHNOLOGIES AND SERVICES.—The Task Force shall—

(A) identify innovative diabetes technologies and services for the treatment of type I diabetes, type II diabetes, or both, that are in development or that have been cleared or approved by FDA and that are wholly or partially

inaccessible to Medicare beneficiaries with diabetes under Medicare;

(B) develop and consider possible alternative approaches to enable Medicare beneficiaries to access innovative diabetes technologies and services; and

(C) determine whether the existing administrative systems, benefit categories, and coverage, coding and payment policies under Medicare would provide or impede access to, and appropriate payment for, innovative diabetes technologies and services.

(2) ANALYSIS OF ACCESS DISPARITIES.—

(A) PRIVATE PAYOR POLICIES.—The Task Force shall review coverage policies developed by private payors for innovative diabetes technologies and services and determine whether disparities exist between patients with diabetes insured by private payors as compared to Medicare beneficiaries with diabetes.

(B) CASE STUDIES.—The Task Force shall recommend to the Secretary the development of real-world patient case studies and health care provider case studies that identify barriers to access, and access disparities, under Medicare

with respect to innovative diabetes technologies and services.

(3) IDENTIFICATION OF CHANGES IN RELEVANT FDA APPROVAL AND CMS COVERAGE POLICIES.—

(A) CMS REGULATORY BARRIERS TO COVERAGE.—The Task Force shall—

(i) identify all the categories of items and services for which coverage is available under Medicare whether established by title XVIII of the Social Security Act or otherwise (in this section referred to as benefit categories) that may be used to provide for coverage of diabetes technologies and services, including innovative diabetes technologies and services;

(ii) review regulations and subregulatory guidance for the benefit categories identified under clause (i) to identify policies that limit coverage of, and payment for, diabetes technologies and services under Medicare, especially innovative diabetes technologies and services; and

(iii) recommend specific changes to such regulations and subregulatory guidance to provide for coverage of, and pay-

ment for, innovative diabetes technologies and services under Medicare.

(B) INTERAGENCY COLLABORATION.—The Task Force shall identify strategies to improve collaboration between FDA and CMS that facilitate expeditious clearance or approval of innovative diabetes technologies and services by FDA and expeditious coverage of innovative diabetes technologies and services under Medicare.

(4) IDENTIFICATION OF STRATEGIES TO SUPPORT COVERAGE OF INNOVATIVE DIABETES TECHNOLOGIES AND SERVICES.—The Task Force shall identify strategies not otherwise described in this subsection to facilitate access to innovative diabetes technologies and services by Medicare beneficiaries as well as by other patients and their health care providers.

(f) RECOMMENDATIONS.—Not less frequently than annually, the Task Force shall make recommendations to the Secretary with respect to—

(1) existing benefit categories under which innovative diabetes technologies and services should be covered;

(2) legislative changes to title XVIII of the Social Security Act and administrative changes to regulations promulgated and subregulatory guidance issued with respect to existing benefit categories that are necessary to provide for coverage of, and payment for, innovative diabetes technologies and services;

(3) elimination of other unnecessary burdens that impede coverage of, and payment for, innovative diabetes technologies and services under Medicare;

(4) proposals for a new Medicare benefit category to provide for coverage of innovative diabetes technologies and services that cannot otherwise be covered through administrative changes to regulations and subregulatory guidance for existing benefit categories, and specifications for any new benefit category; and

(5) proposals to streamline interagency administrative processes through greater collaboration between FDA and CMS to facilitate prompt approval or clearance and coverage under Medicare of innovative diabetes technologies and services for Medicare beneficiaries with diabetes.

(g) RESPONSE.—

(1) IN GENERAL.—With respect to each recommendation made by the Task Force under subsection (f), not later than 90 days after the date of receipt of each such recommendation, the Secretary shall make a determination whether to implement or reject the recommendation.

(2) IMPLEMENTATION.—In the case of a determination by the Secretary to implement a recommendation under paragraph (1), the Secretary shall provide the Task Force with a plan for such implementation, including specific details about and a timetable for the implementation.

(3) REJECTION.—In the case of a determination by the Secretary to reject a recommendation under paragraph (1), the Secretary shall provide the Task Force with—

(A) a detailed explanation of the rationale for the determination; and

(B) recommendations for alternative policies for consideration by the Task Force.

(h) REPORT.—The Secretary shall submit an annual report to Congress that describes the activities of the Task Force for the year involved. Each such report shall include such recommendations for improving access to innovative

diabetes technologies and services as the Task Force determines appropriate.

(i) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.), other than section 14 of such Act, shall apply to the Task Force.

(j) RULE OF CONSTRUCTION.—The deliberations of the Task Force shall not be construed as interfering with or impeding any decision, determination, rulemaking, or issuance of subregulatory guidance by the Secretary that provides for coverage of, and payment for, innovative diabetes technologies and services.

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