

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Improving Medicare
5 Beneficiary Access to Innovative Diabetes Technologies
6 Act of 2021”.

1 **SEC. 2. ESTABLISHMENT OF HHS TASK FORCE ON COV-**
 2 **ERAGE AND PAYMENT FOR INNOVATIVE DIA-**
 3 **BETES TECHNOLOGIES AND SERVICES.**

4 (a) DEFINITIONS.—In this section:

5 (1) CMS.—The term “CMS” means the Cen-
 6 ters for Medicare & Medicaid Services.

7 (2) FDA.—The term “FDA” means the Food
 8 and Drug Administration.

9 (3) INNOVATIVE DIABETES TECHNOLOGIES AND
 10 SERVICES.—The term “innovative diabetes tech-
 11 nologies and services” means medical technologies
 12 and services for the treatment and management of
 13 diabetes for which coverage is not available under
 14 the Medicare fee-for-service program.

15 (4) MEDICARE.—The term “Medicare” means
 16 the program of health insurance for the aged and
 17 disabled established under title XVIII of the Social
 18 Security Act.

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

24 (6) SECRETARY.—The term “Secretary” means
 25 the Secretary of Health and Human Services.

26 (b) ESTABLISHMENT; MISSION.—

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

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

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

10 (B) make recommendations to support cur-
 11 rent and future access to innovative diabetes
 12 technologies and services under Medicare; and

13 (C) recommend changes to Medicare to en-
 14 sure appropriate access by Medicare bene-
 15 ficiaries to such innovative diabetes technologies
 16 and services.

17 (c) MEMBERSHIP.—

18 (1) APPOINTMENT.—The Secretary shall ap-
 19 point individuals with relevant expertise to the Task
 20 Force, which shall include the following voting mem-
 21 bers:

22 (A) CMS OFFICIALS.—

23 (i) The Director of the Center for
 24 Medicare.

1 (ii) Not more than 2 additional offi-
 2 cials or senior staff of CMS as the Sec-
 3 retary may specify.

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

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

9 (D) FDA OFFICIALS.—Not more than 2
 10 officials or senior staff from the Diabetes
 11 Branch of the Center for Devices and Radio-
 12 logical Health of FDA as the Commissioner of
 13 Food and Drugs may specify.

14 (E) PATIENT GROUPS.—Representatives
 15 of—

16 (i) Medicare beneficiaries;

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

20 (iii) individuals not described in clause

21 (i) or (ii) who have a diagnosis of diabetes.

22 (F) HEALTH CARE PROVIDERS.—Rep-
 23 resentatives of providers of services, physicians,
 24 and practitioners who treat individuals with a
 25 diagnosis of diabetes.

1 (G) MANUFACTURERS.—Representatives of
2 manufacturers of diabetes technologies, includ-
3 ing innovative diabetes technologies and serv-
4 ices.

5 (2) CO-CHAIRS.—

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

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

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

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

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

23 (3) COMPENSATION.—

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

4 (B) TRAVEL EXPENSES.—A member of the
 5 Task Force may be allowed travel expenses, in-
 6 cluding per diem in lieu of subsistence, at rates
 7 authorized for an employee of an agency under
 8 subchapter I of chapter 57 of title 5, United
 9 States Code, while away from the home or reg-
 10 ular place of business of the member in the per-
 11 formance of the duties of the Task Force.

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

16 (e) DUTIES.—The Task Force shall carry out the fol-
 17 lowing duties:

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

21 (A) identify innovative diabetes tech-
 22 nologies and services for the treatment of type
 23 I diabetes, type II diabetes, or both, that are in
 24 development or that have been cleared or ap-
 25 proved by FDA and that are wholly or partially

1 inaccessible to Medicare beneficiaries with dia-
2 betes under Medicare;

3 (B) develop and consider possible alter-
4 native approaches to enable Medicare bene-
5 ficiaries to access innovative diabetes tech-
6 nologies and services; and

7 (C) determine whether the existing admin-
8 istrative systems, benefit categories, and cov-
9 erage, coding and payment policies under Medi-
10 care would provide or impede access to, and ap-
11 propriate payment for, innovative diabetes tech-
12 nologies and services.

13 (2) ANALYSIS OF ACCESS DISPARITIES.—

14 (A) PRIVATE PAYOR POLICIES.—The Task
15 Force shall review coverage policies developed
16 by private payors for innovative diabetes tech-
17 nologies and services and determine whether
18 disparities exist between patients with diabetes
19 insured by private payors as compared to Medi-
20 care beneficiaries with diabetes.

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

1 with respect to innovative diabetes technologies
2 and services.

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

5 (A) CMS REGULATORY BARRIERS TO COV-
6 ERAGE.—The Task Force shall—

7 (i) identify all the categories of items
8 and services for which coverage is available
9 under Medicare whether established by
10 title XVIII of the Social Security Act or
11 otherwise (in this section referred to as
12 benefit categories) that may be used to
13 provide for coverage of diabetes tech-
14 nologies and services, including innovative
15 diabetes technologies and services;

16 (ii) review regulations and subregu-
17 latory guidance for the benefit categories
18 identified under clause (i) to identify poli-
19 cies that limit coverage of, and payment
20 for, diabetes technologies and services
21 under Medicare, especially innovative dia-
22 betes technologies and services; and

23 (iii) recommend specific changes to
24 such regulations and subregulatory guid-
25 ance to provide for coverage of, and pay-

1 ment for, innovative diabetes technologies
2 and services under Medicare.

3 (B) INTERAGENCY COLLABORATION.—The
4 Task Force shall identify strategies to improve
5 collaboration between FDA and CMS that fa-
6 cilitate expeditious clearance or approval of in-
7 novative diabetes technologies and services by
8 FDA and expeditious coverage of innovative di-
9 abetes technologies and services under Medi-
10 care.

11 (4) IDENTIFICATION OF STRATEGIES TO SUP-
12 PORT COVERAGE OF INNOVATIVE DIABETES TECH-
13 NOLOGIES AND SERVICES.—The Task Force shall
14 identify strategies not otherwise described in this
15 subsection to facilitate access to innovative diabetes
16 technologies and services by Medicare beneficiaries
17 as well as by other patients and their health care
18 providers.

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

22 (1) existing benefit categories under which in-
23 novative diabetes technologies and services should be
24 covered;

1 (2) legislative changes to title XVIII of the So-
2 cial Security Act and administrative changes to reg-
3 ulations promulgated and subregulatory guidance
4 issued with respect to existing benefit categories that
5 are necessary to provide for coverage of, and pay-
6 ment for, innovative diabetes technologies and serv-
7 ices;

8 (3) elimination of other unnecessary burdens
9 that impede coverage of, and payment for, innova-
10 tive diabetes technologies and services under Medi-
11 care;

12 (4) proposals for a new Medicare benefit cat-
13 egory to provide for coverage of innovative diabetes
14 technologies and services that cannot otherwise be
15 covered through administrative changes to regula-
16 tions and subregulatory guidance for existing benefit
17 categories, and specifications for any new benefit
18 category; and

19 (5) proposals to streamline interagency admin-
20 istrative processes through greater collaboration be-
21 tween FDA and CMS to facilitate prompt approval
22 or clearance and coverage under Medicare of innova-
23 tive diabetes technologies and services for Medicare
24 beneficiaries with diabetes.

25 (g) RESPONSE.—

1 (1) IN GENERAL.—With respect to each rec-
2 ommendation made by the Task Force under sub-
3 section (f), not later than 90 days after the date of
4 receipt of each such recommendation, the Secretary
5 shall make a determination whether to implement or
6 reject the recommendation.

7 (2) IMPLEMENTATION.—In the case of a deter-
8 mination by the Secretary to implement a rec-
9 ommendation under paragraph (1), the Secretary
10 shall provide the Task Force with a plan for such
11 implementation, including specific details about and
12 a timetable for the implementation.

13 (3) REJECTION.—In the case of a determina-
14 tion by the Secretary to reject a recommendation
15 under paragraph (1), the Secretary shall provide the
16 Task Force with—

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

19 (B) recommendations for alternative poli-
20 cies for consideration by the Task Force.

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

1 diabetes technologies and services as the Task Force de-
2 termines appropriate.

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

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

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