

114TH CONGRESS
2D SESSION

S. 3457

To establish Centers for Medicare & Medicaid Services SBIR or STTR program grants which shall be known as Medicare commercialization grants.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 28, 2016

Mr. GARDNER (for himself and Mr. COONS) introduced the following bill;
which was read twice and referred to the Committee on Finance

A BILL

To establish Centers for Medicare & Medicaid Services SBIR or STTR program grants which shall be known as Medicare commercialization grants.

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 “Reducing Medicare
5 Costs through Innovation Act”.

6 **SEC. 2. MEDICARE COMMERCIALIZATION GRANTS.**

7 (a) DEFINITIONS.—In this section:

8 (1) The term—

1 (A) “Administrator” means the Adminis-
2 trator of the Centers for Medicare & Medicaid
3 Services; and

4 (B) “Secretary” means the Secretary of
5 Health and Human Services.

6 (2) The terms “commercialization”, “Phase I”,
7 “Phase II”, “Phase III”, “SBIR”, and “STTR”
8 have the meanings given those terms in section 9(e)
9 of the Small Business Act (15 U.S.C. 638(e)).

10 (3) The term “eligible medical product” means
11 a product—

12 (A) for which a grant recipient received a
13 Medicare commercialization grant;

14 (B) which will maintain or improve quality
15 of care while reducing costs (as determined by
16 the Secretary); and

17 (C)(i) that is a drug, as defined under sec-
18 tion 201(g)(1) of Federal Food, Drug, and Cos-
19 metic Act (21 U.S.C. 321(g)(1));

20 (ii) that is a biological product, as defined
21 in section 351 of the Public Health Service Act
22 (42 U.S.C. 262);

23 (iii) that is a combination product, as de-
24 scribed in section 503(g) of the Federal Food,
25 Drug, and Cosmetic Act (21 U.S.C. 353(g)); or

1 (iv) that is a device, as defined in section
 2 201(h) of the Federal Food, Drug, and Cos-
 3 metic Act (21 U.S.C. 321(h)), for which ap-
 4 proval under section 515 of such Act is re-
 5 quired.

6 (4) The term “eligible small business concern”
 7 means a small business concern that—

8 (A) has a focus on the diseases or condi-
 9 tions that are the top 10 cost drivers in the
 10 Medicare program under title XVIII of the So-
 11 cial Security Act (42 U.S.C. 1395 et seq.), as
 12 determined by the Secretary in accordance with
 13 subsection (b)(3);

14 (B) is otherwise eligible for a Centers for
 15 Medicare & Medicaid Services SBIR or STTR
 16 program grant;

17 (C) has completed Phase I activities; and

18 (D) has funding for Phase II activities.

19 (5) The term “small business concern” has the
 20 meaning given the term in section 3 of the Small
 21 Business Act (15 U.S.C. 632).

22 (b) MEDICARE COMMERCIALIZATION GRANTS.—

23 (1) ESTABLISHMENT OF PROGRAM.—The Sec-
 24 retary shall establish within the Centers for Medi-
 25 care & Medicaid Services SBIR or STTR program

1 a grant program referred to as the “Medicare com-
 2 mercialization grant program” through which the
 3 Secretary shall award grants to eligible small busi-
 4 ness concerns with approved applications to assist
 5 such small business concerns in Phase III activities
 6 related to developing novel eligible medical products
 7 and receiving approval or clearance by the Food and
 8 Drug Administration for such eligible medical prod-
 9 ucts in accordance with paragraph (2).

10 (2) APPROVAL PROCESS FOR GRANT RECIPI-
 11 ENT’S NOVEL DRUGS, DEVICES, OR DIAGNOSTICS.—
 12 A grantee may choose to submit an application for
 13 approval of novel drugs, devices, or diagnostics
 14 through a traditional approval process or through
 15 the pilot program for parallel review of medical
 16 products described in subsection (c).

17 (3) APPLICATIONS.—

18 (A) SOLICITATION OF APPLICATIONS.—

19 The Secretary shall issue an annual solicitation
 20 of applications for the grant program under
 21 paragraph (1), with a focus on the diseases or
 22 conditions that are the top 10 cost drivers in
 23 the Medicare program under title XVIII of the
 24 Social Security Act (42 U.S.C. 1395 et seq.), as

determined by the Secretary in accordance with subparagraph (B).

(B) COST DRIVERS IN MEDICARE.—The Secretary shall assess, in consultation with stakeholders, and take into consideration for purposes of determining such cost drivers and the eligibility of a small business concern, as described in subsection (a)(4)(A)—

(i) high volume medical procedures that are paid for under the Medicare program;

(ii) diseases or conditions that a high number of Medicare beneficiaries are affected by;

(iii) high cost medical procedures that are paid for under the Medicare program;

(iv) diseases or conditions that Medicare beneficiaries are affected by that result in a high cost to the Medicare program; and

(v) areas described in clauses (i) through (iv) for which there is a high potential for innovation or cost reduction.

(C) APPLICATION REQUIREMENT.—Each eligible small business concern that applies for

1 a Medicare commercialization grant shall in-
2 clude in the application for such grant a de-
3 scription of each source of funding for the eligi-
4 ble business concern and the amount of funding
5 from each such source.

6 (4) DURATION.—An eligible small business con-
7 cern may receive a Medicare commercialization grant
8 for a period of not less than 1 year and not more
9 than 3 years.

10 (5) NO LIMIT ON NUMBER OF RECIPIENTS.—
11 The Secretary shall not limit the number of eligible
12 small business concerns that may receive a Medicare
13 commercialization grant.

14 (6) PERIODIC ASSESSMENT.—At the completion
15 of the third year for which grants are awarded
16 under this subsection, the Secretary shall prepare an
17 assessment containing information about the cost re-
18 ductions and improvements in care that result from
19 such grants, including—

20 (A) a general assessment of the cost driv-
21 ers that the grants were intended to address;

22 (B) information about the novel eligible
23 medical products that the grantees developed or
24 received approval or clearance for with the aid
25 of grant funding under this subsection; and

1 (C) the potential for a reduction in costs
2 that may result if such novel eligible medical
3 products were used nationwide.

4 (7) REPORT.—The Secretary shall prepare and
5 submit to Congress, at the completion of the third
6 year for which grants are awarded under this sub-
7 section and following the assessment described in
8 paragraph (6), a summary report containing the in-
9 formation described in paragraph (6). The Secretary
10 shall also post each such report on the website of the
11 Department of Health and Human Services.

12 (8) FUNDING.—To carry out the grant program
13 under this subsection, the Secretary shall use
14 amounts allocated for the SBIR and STTR pro-
15 grams of the Department of Health and Human
16 Services under subsections (f) and (n), respectively,
17 of section 9 of the Small Business Act (15 U.S.C.
18 638).

19 (9) COLLABORATION.—The Secretary shall col-
20 laborate with the heads of other divisions within the
21 Department of Health and Human Services as the
22 Secretary determines necessary to carry out this
23 subsection.

24 (c) PILOT PROGRAM FOR PARALLEL REVIEW OF
25 MEDICAL PRODUCTS.—

(1) IN GENERAL.—Not later than 60 days after the date of enactment of this section, the Secretary and the Administrator shall jointly establish a pilot program for parallel review of eligible medical products that is similar to the “Pilot Program for Parallel Review of Medical Products” described in the notice of the Centers for Medicare & Medicaid Services, published in the Federal Register on October 11, 2011 (76 Fed. Reg. 62808) (referred to in this subsection as the “pilot program”). Such pilot program shall not affect the applicable criteria or standards for approving, clearing, or classifying medical products under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) and shall not affect the criteria and standards relating to determinations about a reimbursement designation or a national coverage determination under the Medicare program under title XVIII of the Social Security Act.

(2) PURPOSE.—The purposes of the pilot program are to—

(A) reduce the timeline of the review processes for purposes of approval by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) and

1 a reimbursement designation and a national
2 coverage determination under the Medicare pro-
3 gram under title XVIII of the Social Security
4 Act for certain medical products developed by
5 Medicare commercialization grant recipients;
6 and

7 (B) increase the efficiency of, and commu-
8 nication between, the Department of Health
9 and Human Services and the Centers for Medi-
10 care & Medicaid Services.

11 (3) ELIGIBLE PARTICIPANTS.—The pilot pro-
12 gram established under this subsection shall be
13 available—

14 (A) only to recipients of a Medicare com-
15 mercialization grant under this subsection (b)
16 who choose to participate in such pilot program;
17 and

18 (B) only for the review of eligible medical
19 products.

20 (4) PARALLEL REVIEW PROCESS.—As part of
21 the pilot program—

22 (A) to the extent practicable, the Secretary
23 and the Administrator shall notify participating
24 grant recipients of the data that may be nec-

1 essary for the grant recipient to submit at the
2 beginning of the review process; and

3 (B) the Administrator shall begin review
4 for purposes of a reimbursement designation
5 and a national coverage determination under
6 the Medicare program under title XVIII of the
7 Social Security Act for an eligible medical prod-
8 uct while the Secretary of Health and Human
9 Services is reviewing that eligible medical prod-
10 uct for approval under the Federal Food, Drug,
11 and Cosmetic Act (21 U.S.C. 301).

12 (5) ALLOCATION OF RESOURCES.—The Admin-
13 istrator shall allocate the resources necessary to
14 carry out the pilot program.

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