II

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.

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 ''Reducing Medicare Costs through Innovation Act''.

SEC. 2. MEDICARE COMMERCIALIZATION GRANTS.

(a) DEFINITIONS.—In this section:

(1) The term—

(A) ''Administrator'' means the Administrator of the Centers for Medicare & Medicaid Services; and

(B) ''Secretary'' means the Secretary of Health and Human Services.

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

(3) The term ''eligible medical product'' means a product—

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

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

(C)(i) that is a drug, as defined under section 201(g)(1) of Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1));

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

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

(iv) that is a device, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)), for which approval under section 515 of such Act is required.

(4) The term ''eligible small business concern'' means a small business concern that—

(A) has a focus on the diseases or conditions that are the top 10 cost drivers in the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), as determined by the Secretary in accordance with subsection (b)(3);

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

(C) has completed Phase I activities; and

(D) has funding for Phase II activities.

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

(b) MEDICARE COMMERCIALIZATION GRANTS.—

(1) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish within the Centers for Medicare & Medicaid Services SBIR or STTR program

a grant program referred to as the ''Medicare commercialization grant program'' through which the Secretary shall award grants to eligible small business concerns with approved applications to assist such small business concerns in Phase III activities related to developing novel eligible medical products and receiving approval or clearance by the Food and Drug Administration for such eligible medical products in accordance with paragraph (2).

(2) APPROVAL PROCESS FOR GRANT RECIPIENT'S NOVEL DRUGS, DEVICES, OR DIAGNOSTICS.—A grantee may choose to submit an application for approval of novel drugs, devices, or diagnostics through a traditional approval process or through the pilot program for parallel review of medical products described in subsection (c).

(3) APPLICATIONS.—

(A) SOLICITATION OF APPLICATIONS.—The Secretary shall issue an annual solicitation of applications for the grant program under paragraph (1), with a focus on the diseases or conditions that are the top 10 cost drivers in the Medicare program under title XVIII of the 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

a Medicare commercialization grant shall include in the application for such grant a description of each source of funding for the eligible business concern and the amount of funding from each such source.

(4) DURATION.—An eligible small business concern may receive a Medicare commercialization grant for a period of not less than 1 year and not more than 3 years.

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

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

(A) a general assessment of the cost drivers that the grants were intended to address;

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

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

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

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

(9) COLLABORATION.—The Secretary shall collaborate with the heads of other divisions within the Department of Health and Human Services as the Secretary determines necessary to carry out this subsection.

(c) PILOT PROGRAM FOR PARALLEL REVIEW OF 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

a reimbursement designation and a national coverage determination under the Medicare program under title XVIII of the Social Security Act for certain medical products developed by Medicare commercialization grant recipients; and

(B) increase the efficiency of, and communication between, the Department of Health and Human Services and the Centers for Medicare & Medicaid Services.

(3) ELIGIBLE PARTICIPANTS.—The pilot program established under this subsection shall be available—

(A) only to recipients of a Medicare commercialization grant under this subsection (b) who choose to participate in such pilot program; and

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

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

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

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

(B) the Administrator shall begin review for purposes of a reimbursement designation and a national coverage determination under the Medicare program under title XVIII of the Social Security Act for an eligible medical product while the Secretary of Health and Human Services is reviewing that eligible medical product for approval under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301).

(5) ALLOCATION OF RESOURCES.—The Administrator shall allocate the resources necessary to carry out the pilot program.

○