Sec. 4003. Medicare payment incentive for the transition from traditional x-ray imaging to digital radiography and other Medicare imaging payment provision.
Sec. 4004. Treatment of infusion drugs furnished through durable medical equipment.
Sec. 4005. Extension and expansion of prior authorization for power mobility devices (PMDs) and accessories and prior authorization audit limitations.
Sec. 4006. Civil monetary penalties for violations related to grants, contracts, and other agreements.

Subtitle B—Other Reforms

Sec. 4041. SPR drawdown.

Subtitle C—Miscellaneous

Sec. 4061. Lyme disease and other tick-borne diseases.

SEC. 2. NIH AND CURES INNOVATION FUND.

(a) ESTABLISHMENT.—There is hereby established in the Treasury of the United States a fund to be known as the NIH and Cures Innovation Fund.

(b) AMOUNTS MADE AVAILABLE TO FUND.—

(1) IN GENERAL.—There is authorized to be appropriated, and appropriated, to the NIH and Cures Innovation Fund, out of any funds in the Treasury not otherwise appropriated, $1,860,000,000 for each of fiscal years 2016 through 2020. The amounts appropriated to the NIH and Cures Innovation Fund by the preceding sentence shall be in addition to any amounts otherwise made available to the Department of Health and Human Services.

(2) ALLOCATION OF AMOUNTS.—Of the amounts made available from the NIH and Cures Innovation Fund for a fiscal year—

(A) $1,750,000,000 shall be for biomedical research of the National Institutes of Health under subsection (c)(1), of which—

(i) not less than $500,000,000 shall be for the Accelerating Advancement Program under subsection (d)(2);

(ii) not less than 35 percent of such amounts remaining after subtracting the allocation for the Accelerating Advancement Program shall be for early stage investigators as defined in subsection (g);

(iii) not less than 20 percent of such amounts remaining after subtracting the allocation for the Accelerating Advancement Program shall be for high-risk, high-reward research under section 409K of the Public Health Service Act, as added by section 1028; and

(iv) not more than 10 percent of such amounts (without subtracting the allocation for the Accelerating Advancement

Program) shall be for intramural research; and

(B) $110,000,000 shall be for carrying out the provisions listed in subsection (c)(2).

(3) INAPPLICABILITY OF CERTAIN PROVISIONS.—Amounts in the NIH and Cures Innovation Fund (including amounts made available to the National Institutes of Health) shall not be subject to—

(A) any transfer authority of the Secretary of Health and Human Services or the Director of the National Institutes of Health under sections 241, 402A(c), or 402A(d) of the Public Health Service Act (42 U.S.C. 238j, 282a(c) and (d)) or any other provision of law (other than this section); or

(B) the Nonrecurring expenses fund under section 223 of division G of the Consolidated Appropriations Act, 2008 (42 U.S.C. 3514a).

(c) AUTHORIZED USES.—

(1) NIH BIOMEDICAL RESEARCH.—Amounts in the NIH and Cures Innovation Fund that are allocated pursuant to subsection (b)(2)(A) may only be used for the purpose of conducting or supporting biomedical research (including basic, translational, and clinical research) through the following:

(A) Research in which—

(i) a principal investigator has a specific project or specific objectives; and

(ii) funding is tied to pursuit of such project or objectives.

(B) Research in which—

(i) a principal investigator has shown promise in biomedical research; and

(ii) funding is not tied to a specific project or specific objectives.

(C) Research to be carried out by an early stage investigator (as defined in subsection (g)).

(D) Research to be carried out by a small business concern (as defined in section 3 of the Small Business Act).

(E) The Accelerating Advancement Program under subsection (d)(2).

(F) Development and implementation of the strategic plan under subsection (d)(3).

(2) CURES DEVELOPMENT.—Amounts in the NIH and Cures Innovation Fund that are allocated pursuant to subsection (b)(2)(B) may only be used for the purpose of carrying out the following provisions:

(A) Section 229A of the Public Health Service Act, as added by section 1123 (relating to data on natural history of diseases).

(B) Section 2001 and the amendments made by such section (relating to development and use of patient experience data to enhance structured risk-benefit assessment framework).

(C) Section 2021 and the amendments made by such section (relating to qualification of drug development tools).

(D) Section 2062 and the amendments made by such section (relating to utilizing evidence from clinical experience).

(E) Section 2161 (relating to grants for studying the process of continuous drug manufacturing).

(F) Section 2201 and the amendments made by such section (relating to priority review for breakthrough devices).

(G) Section 2221 and the amendments made by such section (relating to third-party quality system assessments).

(H) Sections 2241, 2242, and 2243 and the amendments made by such sections (relating to health software).

(I) Section 513(j) of the Federal Food, Drug, and Cosmetic Act, as added by section 2223 (relating to training and oversight in least burdensome appropriate means concept).

(d) NIH INNOVATION FUND.—

(1) COORDINATION.—In conducting or supporting biomedical research pursuant to funds allocated pursuant to subsection (b)(2)(A), the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall—

(A) ensure coordination among the national research institutes, the national centers, and other departments, agencies, and offices of the Federal Government; and

(B) minimize unnecessary duplication.

(2) ACCELERATING ADVANCEMENT PROGRAM.—The Director of the National Institutes of Health shall establish a program, to be known as the Accelerating Advancement Program, under which—

(A) the Director partners with national research institutes and national centers to accomplish important biomedical research objectives; and

(B) for every $1 made available by the Director to a national research institute or national center for a research project, the institute or center makes $1 available for such project from funds that are not derived from the NIH and Cures Innovation Fund.

(3) STRATEGIC PLAN.—

(A) IN GENERAL.—The Director of the National Institutes of Health shall ensure that scientifically based strategic planning is implemented in support of research priorities, including through development, use, and updating of a research strategic plan that—

(i) is designed to increase the efficient and effective focus of biomedical research in a manner that leverages the best scientific opportunities through a deliberative planning process;

(ii) identifies areas, to be known as strategic focus areas, in which the resources of the NIH and Cures Innovation Fund can contribute to the goals of expanding knowledge to address, and find more effective treatments for, unmet med-

ical needs in the United States, including the areas of—

(I) biomarkers;

(II) precision medicine;

(III) infectious diseases, including pathogens listed as a qualifying pathogen under section 505E(f) of the Federal Food, Drug, and Cosmetic Act or listed or designated as a tropical disease under section 524 of such Act; and

(IV) antibiotics;

(iii) includes objectives for each such strategic focus area; and

(iv) ensures that basic research remains a priority.

(B) UPDATES AND REVIEWS.—The Director of the National Institutes of Health shall review and, as appropriate, update the research strategic plan under subparagraph (A) not less than every 18 months.

(e) TRANSFER AUTHORITY.—The Committee on Appropriations of the Senate and the Committee on Appropriations of the House of Representatives may provide for

the transfer of funds in the NIH and Cures Innovation Fund for the purposes specified in subsection (c).

(f) SUPPLEMENT, NOT SUPPLANT; LIMITATIONS.—Funds appropriated by subsection (b)—

(1) shall be used to supplement, not supplant, amounts otherwise made available to the Department of Health and Human Services;

(2) are subject to the requirements and limitations of the most recently enacted regular or full-year continuing appropriation Act or resolution (as of the date of obligation) for programs of the National Institutes of Health or the Food and Drug Administration, as applicable; and

(3) notwithstanding any transfer authority in any appropriation Act, shall not be used for any purpose other than the purposes specified in subsection (c).

(g) DEFINITION.—In this subsection:

(1) The term ''early stage investigator'' means an investigator who—

(A) will be the principal investigator or the program director of the proposed research;

(B) has never been awarded, or has been awarded only once, a substantial, competing

grant by the National Institutes of Health for independent research; and

(C) is within 10 years of having completed—

(i) the investigator's terminal degree; or

(ii) a medical residency (or the equivalent).

(2) The terms ''national center'' and ''national research institute'' have the meanings given to those terms in section 401(g) of the Public Health Service Act (42 U.S.C. 281(g)).

TITLE I—DISCOVERY

Subtitle A—National Institutes of Health Funding

SEC. 1001. NATIONAL INSTITUTES OF HEALTH REAUTHORIZATION.

Section 402A(a)(1) of the Public Health Service Act (42 U.S.C. 282a(a)(1)) is amended—

(1) in subparagraph (B), by striking at the end ''and'';

(2) in subparagraph (C), by striking at the end the period and inserting a semicolon; and

(3) by adding at the end the following new subparagraphs: