

114TH CONGRESS
1ST SESSION

H. R. 6

AN ACT

To accelerate the discovery, development, and delivery of
21st century cures, and for other purposes.

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

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) **SHORT TITLE.**—This Act may be cited as the
3 “21st Century Cures Act”.

4 (b) **TABLE OF CONTENTS.**—The table of contents for
5 this Act is as follows:

- Sec. 1. Short title; table of contents.
Sec. 2. NIH and Cures Innovation Fund.

TITLE I—DISCOVERY

Subtitle A—National Institutes of Health Funding

- Sec. 1001. National Institutes of Health reauthorization.
Sec. 1002. Prize competitions.

Subtitle B—National Institutes of Health Planning and Administration

- Sec. 1021. NIH research strategic plan.
Sec. 1022. Increasing accountability at the National Institutes of Health.
Sec. 1023. Reducing administrative burdens of researchers.
Sec. 1024. Exemption for the National Institutes of Health from the Paperwork Reduction Act requirements.
Sec. 1025. NIH travel.
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Sec. 1029. Sense of Congress on increased inclusion of underrepresented communities in clinical trials.

Subtitle C—Supporting Young Emerging Scientists

- Sec. 1041. Improvement of loan repayment programs of the National Institutes of Health.
Sec. 1042. Report.

Subtitle D—Capstone Grant Program

- Sec. 1061. Capstone award.

Subtitle E—Promoting Pediatric Research Through the National Institutes of Health

- Sec. 1081. National pediatric research network.
Sec. 1082. Global pediatric clinical study network sense of Congress.
Sec. 1083. Appropriate age groupings in clinical research.

Subtitle F—Advancement of the National Institutes of Health Research and Data Access

- Sec. 1101. Standardization of data in Clinical Trial Registry Data Bank on eligibility for clinical trials.

Subtitle G—Facilitating Collaborative Research

- Sec. 1121. Clinical trial data system.
- Sec. 1122. National neurological diseases surveillance system.
- Sec. 1123. Data on natural history of diseases.
- Sec. 1124. Accessing, sharing, and using health data for research purposes.

Subtitle H—Council for 21st Century Cures

- Sec. 1141. Council for 21st Century Cures.

TITLE II—DEVELOPMENT

Subtitle A—Patient-Focused Drug Development

- Sec. 2001. Development and use of patient experience data to enhance structured risk-benefit assessment framework.

Subtitle B—Qualification and Use of Drug Development Tools

- Sec. 2021. Qualification of drug development tools.
- Sec. 2022. Accelerated approval development plan.

Subtitle C—FDA Advancement of Precision Medicine

- Sec. 2041. Precision medicine guidance and other programs of Food and Drug Administration.

Subtitle D—Modern Trial Design and Evidence Development

- Sec. 2061. Broader application of Bayesian statistics and adaptive trial designs.
- Sec. 2062. Utilizing evidence from clinical experience.
- Sec. 2063. Streamlined data review program.

Subtitle E—Expediting Patient Access

- Sec. 2081. Sense of Congress.
- Sec. 2082. Expanded access policy.
- Sec. 2083. Finalizing draft guidance on expanded access.

Subtitle F—Facilitating Responsible Manufacturer Communications

- Sec. 2101. Facilitating dissemination of health care economic information.
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Subtitle G—Antibiotic Drug Development

- Sec. 2121. Approval of certain drugs for use in a limited population of patients.
- Sec. 2122. Susceptibility test interpretive criteria for microorganisms.
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Subtitle H—Vaccine Access, Certainty, and Innovation

- Sec. 2141. Timely review of vaccines by the Advisory Committee on Immunization Practices.
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- Sec. 2162. Re-exportation among members of the European Economic Area.

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- Sec. 2181. Enhancing combination products review.

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- Sec. 2201. Priority review for breakthrough devices.

Subtitle M—Medical Device Regulatory Process Improvements

- Sec. 2221. Third-party quality system assessment.
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- Sec. 2223. Training and oversight in least burdensome appropriate means concept.
- Sec. 2224. Recognition of standards.
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- Sec. 2226. Advisory committee process.
- Sec. 2227. Humanitarian device exemption application.
- Sec. 2228. CLIA waiver study design guidance for in vitro diagnostics.

Subtitle N—Sensible Oversight for Technology Which Advances Regulatory Efficiency

- Sec. 2241. Health software.
- Sec. 2242. Applicability and inapplicability of regulation.
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- Sec. 2261. Protection of human subjects in research; applicability of rules.
- Sec. 2262. Use of non-local institutional review boards for review of investigational device exemptions and human device exemptions.
- Sec. 2263. Alteration or waiver of informed consent for clinical investigations.

Subtitle P—Improving Scientific Expertise and Outreach at FDA

- Sec. 2281. Silvio O. Conte Senior Biomedical Research Service.
- Sec. 2282. Enabling FDA scientific engagement.
- Sec. 2283. Reagan-Udall Foundation for the Food and Drug Administration.
- Sec. 2284. Collection of certain voluntary information exempted from Paperwork Reduction Act.
- Sec. 2285. Hiring authority for scientific, technical, and professional personnel.

Subtitle Q—Exempting From Sequestration Certain User Fees

- Sec. 2301. Exempting from sequestration certain user fees of Food and Drug Administration.

Subtitle R—Other Provisions

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TITLE III—DELIVERY

Subtitle A—Interoperability

Sec. 3001. Ensuring interoperability of health information technology.

Subtitle B—Telehealth

Sec. 3021. Telehealth services under the Medicare Program.

Subtitle C—Encouraging Continuing Medical Education for Physicians

Sec. 3041. Exempting from manufacturer transparency reporting certain transfers used for educational purposes.

Subtitle D—Disposable Medical Technologies

Sec. 3061. Treatment of certain items and devices.

Subtitle E—Local Coverage Decision Reforms

Sec. 3081. Improvements in the Medicare local coverage determination (LCD) process.

Subtitle F—Medicare Pharmaceutical and Technology Ombudsman

Sec. 3101. Medicare pharmaceutical and technology ombudsman.

Subtitle G—Medicare Site-of-Service Price Transparency

Sec. 3121. Medicare site-of-Service price transparency.

Subtitle H—Medicare Part D Patient Safety and Drug Abuse Prevention

Sec. 3141. Programs to prevent prescription drug abuse under Medicare parts C and D.

TITLE IV—MEDICAID, MEDICARE, AND OTHER REFORMS

Subtitle A—Medicaid and Medicare Reforms

Sec. 4001. Limiting Federal Medicaid reimbursement to States for durable medical equipment (DME) to Medicare payment rates.

Sec. 4002. Excluding authorized generics from calculation of average manufacturer price.

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. 4062. Outreach to historically black colleges and universities.

1 **SEC. 2. NIH AND CURES INNOVATION FUND.**

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

5 (b) AMOUNTS MADE AVAILABLE TO FUND.—

6 (1) IN GENERAL.—There is authorized to be
7 appropriated, and appropriated, to the NIH and
8 Cures Innovation Fund, out of any funds in the
9 Treasury not otherwise appropriated,
10 \$1,860,000,000 for each of fiscal years 2016
11 through 2020. The amounts appropriated to the
12 NIH and Cures Innovation Fund by the preceding
13 sentence shall be in addition to any amounts other-
14 wise made available to the Department of Health
15 and Human Services.

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

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

1 (i) not less than \$500,000,000 shall
2 be for the Accelerating Advancement Pro-
3 gram under subsection (d)(2);

4 (ii) not less than 35 percent of such
5 amounts remaining after subtracting the
6 allocation for the Accelerating Advance-
7 ment Program shall be for early stage in-
8 vestigators as defined in subsection (g);

9 (iii) not less than 20 percent of such
10 amounts remaining after subtracting the
11 allocation for the Accelerating Advance-
12 ment Program shall be for high-risk, high-
13 reward research under section 409L of the
14 Public Health Service Act, as added by
15 section 1028; and

16 (iv) not more than 10 percent of such
17 amounts (without subtracting the alloca-
18 tion for the Accelerating Advancement
19 Program) shall be for intramural research;
20 and

21 (B) \$110,000,000 shall be for carrying out
22 the provisions listed in subsection (e)(2).

23 (3) INAPPLICABILITY OF CERTAIN PROVI-
24 SIONS.—Amounts in the NIH and Cures Innovation

1 Fund (including amounts made available to the Na-
2 tional Institutes of Health) shall not be subject to—

3 (A) any transfer authority of the Secretary
4 of Health and Human Services or the Director
5 of the National Institutes of Health under sec-
6 tions 241, 402A(c), or 402A(d) of the Public
7 Health Service Act (42 U.S.C. 238j, 282a(c)
8 and (d)) or any other provision of law (other
9 than this section); or

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

13 (c) AUTHORIZED USES.—

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

20 (A) Research in which—

21 (i) a principal investigator has a spe-
22 cific project or specific objectives; and

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

25 (B) Research in which—

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

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

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

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

10 (E) The Accelerating Advancement Pro-
11 gram under subsection (d)(2).

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

14 (2) CURES DEVELOPMENT.—Amounts in the
15 NIH and Cures Innovation Fund that are allocated
16 pursuant to subsection (b)(2)(B) may only be used
17 for the purpose of carrying out the following provi-
18 sions:

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

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

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

4 (D) Section 2062 and the amendments
5 made by such section (relating to utilizing evi-
6 dence from clinical experience).

7 (E) Section 2161 (relating to grants for
8 studying the process of continuous drug manu-
9 facturing).

10 (F) Section 2201 and the amendments
11 made by such section (relating to priority re-
12 view for breakthrough devices).

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

16 (H) Sections 2241, 2242, and 2243 and
17 the amendments made by such sections (relat-
18 ing to health software).

19 (I) Section 513(j) of the Federal Food,
20 Drug, and Cosmetic Act, as added by section
21 2223 (relating to training and oversight in least
22 burdensome appropriate means concept).

23 (d) NIH INNOVATION FUND.—

24 (1) COORDINATION.—In conducting or sup-
25 porting biomedical research pursuant to funds allo-

1 cated pursuant to subsection (b)(2)(A), the Sec-
2 retary of Health and Human Services, acting
3 through the Director of the National Institutes of
4 Health, shall—

5 (A) ensure coordination among the na-
6 tional research institutes, the national centers,
7 and other departments, agencies, and offices of
8 the Federal Government; and

9 (B) minimize unnecessary duplication.

10 (2) ACCELERATING ADVANCEMENT PROGRAM.—

11 The Director of the National Institutes of Health
12 shall establish a program, to be known as the Accel-
13 erating Advancement Program, under which—

14 (A) the Director partners with national re-
15 search institutes and national centers to accom-
16 plish important biomedical research objectives;
17 and

18 (B) for every \$1 made available by the Di-
19 rector to a national research institute or na-
20 tional center for a research project, the insti-
21 tute or center makes \$1 available for such
22 project from funds that are not derived from
23 the NIH and Cures Innovation Fund.

24 (3) STRATEGIC PLAN.—

1 (A) IN GENERAL.—The Director of the
2 National Institutes of Health shall ensure that
3 scientifically based strategic planning is imple-
4 mented in support of research priorities, includ-
5 ing through development, use, and updating of
6 a research strategic plan that—

7 (i) is designed to increase the efficient
8 and effective focus of biomedical research
9 in a manner that leverages the best sci-
10 entific opportunities through a deliberative
11 planning process;

12 (ii) identifies areas, to be known as
13 strategic focus areas, in which the re-
14 sources of the NIH and Cures Innovation
15 Fund can contribute to the goals of ex-
16 panding knowledge to address, and find
17 more effective treatments for, unmet med-
18 ical needs in the United States, including
19 the areas of—

20 (I) biomarkers;

21 (II) precision medicine;

22 (III) infectious diseases, includ-
23 ing pathogens listed as a qualifying
24 pathogen under section 505E(f) of the
25 Federal Food, Drug, and Cosmetic

1 Act or listed or designated as a trop-
2 ical disease under section 524 of such
3 Act; and

4 (IV) antibiotics;

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

7 (iv) ensures that basic research re-
8 mains a priority.

9 (B) UPDATES AND REVIEWS.—The Direc-
10 tor of the National Institutes of Health shall re-
11 view and, as appropriate, update the research
12 strategic plan under subparagraph (A) not less
13 than every 18 months.

14 (e) TRANSFER AUTHORITY.—The Committee on Ap-
15 propriations of the Senate and the Committee on Appro-
16 priations of the House of Representatives may provide for
17 the transfer of funds in the NIH and Cures Innovation
18 Fund for the purposes specified in subsection (c).

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

21 (1) shall be used to supplement, not supplant,
22 amounts otherwise made available to the Depart-
23 ment of Health and Human Services;

24 (2) are subject to the requirements and limita-
25 tions of the most recently enacted regular or full-

1 year continuing appropriation Act or resolution (as
2 of the date of obligation) for programs of the Na-
3 tional Institutes of Health or the Food and Drug
4 Administration, as applicable; and

5 (3) notwithstanding any transfer authority in
6 any appropriation Act, shall not be used for any
7 purpose other than the purposes specified in sub-
8 section (c).

9 (g) DEFINITION.—In this subsection:

10 (1) The term “early stage investigator” means
11 an investigator who—

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

14 (B) has never been awarded, or has been
15 awarded only once, a substantial, competing
16 grant by the National Institutes of Health for
17 independent research; and

18 (C) is within 10 years of having com-
19 pleted—

20 (i) the investigator’s terminal degree;

21 or

22 (ii) a medical residency (or the equiva-
23 lent).

24 (2) The terms “national center” and “national
25 research institute” have the meanings given to those

1 terms in section 401(g) of the Public Health Service
2 Act (42 U.S.C. 281(g)).

3 **TITLE I—DISCOVERY**
4 **Subtitle A—National Institutes of**
5 **Health Funding**

6 **SEC. 1001. NATIONAL INSTITUTES OF HEALTH REAUTHOR-**
7 **IZATION.**

8 Section 402A(a)(1) of the Public Health Service Act
9 (42 U.S.C. 282a(a)(1)) is amended—

10 (1) in subparagraph (B), by striking at the end
11 “and”;

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

14 (3) by adding at the end the following new sub-
15 paragraphs:

16 “(D) \$31,811,000,000 for fiscal year
17 2016;

18 “(E) \$33,331,000,000 for fiscal year 2017;

19 and

20 “(F) \$34,851,000,000 for fiscal year
21 2018.”.

22 **SEC. 1002. PRIZE COMPETITIONS.**

23 Part B of title IV of the Public Health Service Act
24 (42 U.S.C. 284 et seq.) is amended by adding at the end
25 the following:

1 **“SEC. 409K. PRIZE COMPETITIONS FOR IMPROVING**
2 **HEALTH OUTCOMES AND REDUCING FED-**
3 **ERAL EXPENDITURES.**

4 “(a) **ESTABLISHMENT; GOALS.**—The Director of
5 NIH shall establish and implement an Innovation Prizes
6 Program for one or both of the following goals:

7 “(1) Identifying and funding areas of bio-
8 medical science that could realize significant ad-
9 vancements through the creation of a prize competi-
10 tion.

11 “(2) Improving health outcomes, particularly
12 with respect to human diseases and conditions for
13 which public and private investment in research is
14 disproportionately small relative to Federal Govern-
15 ment expenditures on prevention and treatment ac-
16 tivities, thereby reducing Federal expenditures on
17 health programs.

18 “(b) **DESIGN OF PRIZE COMPETITIONS.**—Not later
19 than 6 months after the date of enactment of this section,
20 the Director of NIH shall—

21 “(1) design prize competitions—

22 “(A) to cooperate with competitors to real-
23 ize innovations to identify and address areas of
24 biomedical science that could realize significant
25 advancements through the creation of a prize
26 competition; and

1 “(B) to award one or more prizes—

2 “(i) if appropriate, at the beginning of
3 or during the competitions, to the competi-
4 tors whose innovations are most promising
5 or demonstrate progress; and

6 “(ii) at the end of the competitions, to
7 the competitors whose innovations prove to
8 be the best solutions;

9 “(2) ensure that the design of such competi-
10 tions—

11 “(A) is realistic, given the amount of funds
12 to be awarded as prizes;

13 “(B) does not reflect any bias concerning
14 the type of innovations which will prove to be
15 the best solutions; and

16 “(C) allows any person to participate as a
17 competitor without regard to the person’s place
18 of incorporation, primary place of business, citi-
19 zenship, and residency, as applicable; and

20 “(3) submit to the Congress a report on the de-
21 sign of such competitions.

22 “(c) INNOVATION PRIZES ADVISORY BOARD.—

23 “(1) ESTABLISHMENT.—The Director of NIH
24 shall establish and maintain a board, to be known as

1 the I-Prize Board, to advise and assist the Director
2 of NIH in carrying out this section.

3 “(2) COMPOSITION; TERMS.—

4 “(A) COMPOSITION.—The I-Prize Board
5 shall be composed of nine voting members as
6 follows:

7 “(i) The Director of NIH (or the Di-
8 rector’s designee).

9 “(ii) Four members appointed by the
10 Director of NIH.

11 “(iii) One member appointed by the
12 Speaker of the House of Representatives.

13 “(iv) One member appointed by the
14 majority leader of the Senate.

15 “(v) One member appointed by the
16 minority leader of the House of Represent-
17 atives.

18 “(vi) One member appointed by the
19 minority leader in the Senate.

20 “(B) INCLUSION OF CERTAIN EXPERTS.—

21 The members of the I-Prize Board appointed
22 under clauses (ii) through (vi) of subparagraph
23 (A) shall, collectively, include medical, eco-
24 nomic, budgetary, innovation, or venture capital
25 experts from for-profit and not-for-profit pri-

1 vate sector entities with experience in awarding
2 prizes similar to the prizes under this section.

3 “(C) TERMS.—The appointed members of
4 the I-Prize Board shall each be appointed for a
5 term of 5 years.

6 “(D) APPOINTMENT OF INITIAL MEM-
7 BERS.—The initial appointed members of the I-
8 Prize Board shall be appointed not later than
9 120 days after the date of enactment of this
10 section.

11 “(3) RESPONSIBILITIES.—The I-Prize Board
12 shall be responsible for advising the Director of NIH
13 by—

14 “(A) identifying areas of biomedical
15 science that could realize significant advance-
16 ments through the creation of a prize competi-
17 tion;

18 “(B) making recommendations on estab-
19 lishing the criteria for prize competitions under
20 this section;

21 “(C) making recommendations on which
22 business organizations or other entities have
23 successfully met the criteria established for the
24 prize competition; and

1 “(D) gaining insight from researchers,
2 health economists, academia, and industry on
3 how to conduct prize competitions.

4 “(d) RESTRICTIONS.—

5 “(1) NO FINANCIAL CONFLICTS OF INTER-
6 EST.—Any member of the I-Prize Board, and any
7 officer or employee of the National Institutes of
8 Health responsible for carrying out this section, may
9 not personally or substantially participate in the
10 consideration or determination by the I-Prize Board
11 of any matter that would directly or predictably ef-
12 fect any financial interest of—

13 “(A) the individual or a relative (as such
14 term is defined in section 109(16) of the Ethics
15 in Government Act of 1978) of the individual;
16 or

17 “(B) of any business organization or other
18 entity—

19 “(i) of which the individual is an offi-
20 cer or employee;

21 “(ii) with respect to which the indi-
22 vidual is negotiating for employment; or

23 “(iii) in which the individual has any
24 other financial interest.

1 “(2) NO AWARDS TO COMPETITORS LIKELY TO
2 REAP FINANCIAL BENEFIT FROM INNOVATION.—The
3 Director of NIH may not, with respect to an innova-
4 tion, award a prize under this section to any indi-
5 vidual or entity that has a vested financial interest
6 in any product or procedure that is likely to be de-
7 veloped or marketed because of such innovation.

8 “(e) PROCESS OF AWARD.—The full monetary
9 amount of any prize awarded under this section shall be
10 made available to the prize winner not later than 90 days
11 after the date of such award.

12 “(f) SIMULATION.—The Director of NIH may—

13 “(1) award one or more contracts—

14 “(A) to perform a simulation of the prize
15 competitions to be conducted under this section,
16 based on the designs developed under sub-
17 section (b); and

18 “(B) to use the simulation to assess the ef-
19 fectiveness of the design; and

20 “(2) not later than 4 months after awarding
21 such one or more contracts, submit to the Congress
22 a report on the results of the simulation and assess-
23 ment.

24 “(g) IMPLEMENTATION OF PRIZE COMPETITIONS.—

1 “(1) IN GENERAL.—The Director of NIH may
2 enter into an agreement with one or more entities
3 described in section 501(c), and exempt from tax
4 under section 501(a), of the Internal Revenue Code
5 of 1986 to implement prize competitions based on
6 the designs developed under subsection (b).

7 “(2) MINIMUM PERCENTAGE FOR PRIZES.—If
8 the Director of NIH enters into an agreement under
9 paragraph (1) to provide funds or other assistance
10 (including in-kind contributions and testing or other
11 technical support) to an entity to implement a prize
12 competition under this section—

13 “(A) not more than 15 percent of such as-
14 sistance shall be for administration of the prize
15 competition; and

16 “(B) not less than 85 percent of such as-
17 sistance shall be for activities in direct support
18 of competitors such as demonstration, testing,
19 education, and prize awards.

20 “(h) TRACKING; REPORTING.—The Director of NIH
21 shall—

22 “(1) collect information on—

23 “(A) the medical efficacy of innovations
24 funded through the prize competitions under
25 this section; and

1 “(B) the actual and potential effect of the
2 innovations on Federal expenditures; and

3 “(2) not later than 1 year after the conclusion
4 of the prize competitions under this section, and not
5 later than the end of each of the 4 succeeding years,
6 submit to the Congress a report on the information
7 collected under paragraph (1).

8 “(i) INTELLECTUAL PROPERTY.—

9 “(1) PROHIBITION ON THE GOVERNMENT AC-
10 QUIRING INTELLECTUAL PROPERTY RIGHTS.—The
11 Federal Government may not gain an interest in in-
12 tellectual property developed by a participant in a
13 prize competition under this section without the
14 written consent of the participant.

15 “(2) LICENSES.—The Federal Government may
16 negotiate a license for the use of intellectual prop-
17 erty developed by a participant in a prize competi-
18 tion under this section.”.

19 **Subtitle B—National Institutes of**
20 **Health Planning and Adminis-**
21 **tration**

22 **SEC. 1021. NIH RESEARCH STRATEGIC PLAN.**

23 Section 402 of the Public Health Service Act (42
24 U.S.C. 282) is amended—

1 (1) in subsection (b), by amending paragraph
2 (5) to read as follows:

3 “(5) shall ensure that scientifically based stra-
4 tegic planning is implemented in support of research
5 priorities as determined by the agencies of the Na-
6 tional Institutes of Health, including through devel-
7 opment, use, and updating of the research strategic
8 plan under subsection (m);” and

9 (2) by adding at the end the following:

10 “(m) RESEARCH STRATEGIC PLAN.—

11 “(1) FIVE-YEAR PLANS FOR BIOMEDICAL RE-
12 SEARCH STRATEGY.—

13 “(A) IN GENERAL.—For each successive 5-
14 year period beginning with the period of fiscal
15 years 2016 through 2020, the Director of NIH,
16 in consultation with the entities described in
17 subparagraph (B), shall develop and maintain a
18 biomedical research strategic plan that—

19 “(i) is designed to increase the effi-
20 cient and effective focus of biomedical re-
21 search in a manner that leverages the best
22 scientific opportunities through a delibera-
23 tive planning process;

24 “(ii) identifies areas, to be known as
25 strategic focus areas, in which the re-

1 sources of the National Institutes of
2 Health can best contribute to the goal of
3 expanding knowledge on human health in
4 the United States through biomedical re-
5 search; and

6 “(iii) includes objectives for each such
7 strategic focus area.

8 “(B) ENTITIES DESCRIBED.—The entities
9 described in this subparagraph are the directors
10 of the national research institutes and national
11 centers, researchers, patient advocacy groups,
12 and industry leaders.

13 “(2) USE OF PLAN.—The Director of NIH and
14 the directors of the national research institutes and
15 national centers shall use the strategic plan—

16 “(A) to identify research opportunities;
17 and

18 “(B) to develop individual strategic plans
19 for the research activities of each of the na-
20 tional research institutes and national centers
21 that—

22 “(i) have a common template; and

23 “(ii) identify strategic focus areas in
24 which the resources of the national re-
25 search institutes and national centers can

1 best contribute to the goal of expanding
2 knowledge on human health in the United
3 States through biomedical research.

4 “(3) CONTENTS OF PLANS.—

5 “(A) STRATEGIC FOCUS AREAS.—The stra-
6 tegic focus areas identified pursuant to para-
7 graph (1)(A)(ii) shall—

8 “(i) be identified in a manner that—

9 “(I) considers the return on in-
10 vestment to the United States public
11 through the investments of the Na-
12 tional Institutes of Health in bio-
13 medical research; and

14 “(II) contributes to expanding
15 knowledge to improve the United
16 States public’s health through bio-
17 medical research; and

18 “(ii) include overarching and trans-
19 National Institutes of Health strategic
20 focus areas, to be known as Mission Pri-
21 ority Focus Areas, which best serve the
22 goals of preventing or eliminating the bur-
23 den of a disease or condition and scientif-
24 ically merit enhanced and focused research
25 over the next 5 years.

1 “(B) RARE AND PEDIATRIC DISEASES AND
2 CONDITIONS.—In developing and maintaining a
3 strategic plan under this subsection, the Direc-
4 tor of NIH shall ensure that rare and pediatric
5 diseases and conditions remain a priority.

6 “(C) WORKFORCE.—In developing and
7 maintaining a strategic plan under this sub-
8 section, the Director of NIH shall ensure that
9 maintaining the biomedical workforce of the fu-
10 ture, including the participation by scientists
11 from groups traditionally underrepresented in
12 the scientific workforce, remains a priority.

13 “(4) INITIAL PLAN.—Not later than 270 days
14 after the date of enactment of this subsection, the
15 Director of NIH and the directors of the national re-
16 search institutes and national centers shall—

17 “(A) complete the initial strategic plan re-
18 quired by paragraphs (1) and (2); and

19 “(B) make such initial strategic plan pub-
20 licly available on the website of the National In-
21 stitutes of Health.

22 “(5) REVIEW; UPDATES.—

23 “(A) PROGRESS REVIEWS.—Not less than
24 annually, the Director of NIH, in consultation
25 with the directors of the national research insti-

1 tutes and national centers, shall conduct
 2 progress reviews for each strategic focus area
 3 identified under paragraph (1)(A)(ii).

4 “(B) UPDATES.—Not later than the end of
 5 the 5-year period covered by the initial strategic
 6 plan under this subsection, and every 5 years
 7 thereafter, the Director of NIH, in consultation
 8 with the directors of the national research insti-
 9 tutes and national centers, stakeholders in the
 10 scientific field, advocates, and the public at
 11 large, shall—

12 “(i) conduct a review of the plan, in-
 13 cluding each strategic focus area identified
 14 under paragraph (2)(B); and

15 “(ii) update such plan in accordance
 16 with this section.”.

17 **SEC. 1022. INCREASING ACCOUNTABILITY AT THE NA-**
 18 **TIONAL INSTITUTES OF HEALTH.**

19 (a) APPOINTMENT AND TERMS OF DIRECTORS OF
 20 NATIONAL RESEARCH INSTITUTES AND NATIONAL CEN-
 21 TERS.—Subsection (a) of section 405 of the Public Health
 22 Service Act (42 U.S.C. 284) is amended to read as follows:

23 “(a) APPOINTMENT; TERMS.—

24 “(1) APPOINTMENT.—The Director of the Na-
 25 tional Cancer Institute shall be appointed by the

1 President and the directors of the other national re-
2 search institutes, as well as the directors of the na-
3 tional centers, shall be appointed by the Director of
4 NIH. The directors of the national research insti-
5 tutes, as well as national centers, shall report di-
6 rectly to the Director of NIH.

7 “(2) TERMS.—

8 “(A) IN GENERAL.—The term of office of
9 a director of a national research institute or na-
10 tional center shall be 5 years.

11 “(B) REMOVAL.—The director of a na-
12 tional research institute or national center may
13 be removed from office by the Director of NIH
14 prior to the expiration of such director’s 5-year
15 term.

16 “(C) REAPPOINTMENT.—At the end of the
17 term of a director of a national research insti-
18 tute or national center, the director may be re-
19 appointed. There is no limit on the number of
20 terms a director may serve.

21 “(D) VACANCIES.—If the office of a direc-
22 tor of a national research institute or national
23 center becomes vacant before the end of such
24 director’s term, the director appointed to fill the

1 vacancy shall be appointed for a 5-year term
2 starting on the date of such appointment.

3 “(E) TRANSITIONAL PROVISION.—Each di-
4 rector of a national research institute or na-
5 tional center serving on the date of enactment
6 of the 21st Century Cures Act is deemed to be
7 appointed for a 5-year term under this sub-
8 section starting on such date of enactment.”.

9 (b) COMPENSATION TO CONSULTANTS OR INDI-
10 VIDUAL SCIENTISTS.—Section 202 of the Departments of
11 Labor, Health and Human Services, and Education, and
12 Related Agencies Appropriations Act, 1993 (Public Law
13 102–394; 42 U.S.C. 238f note) is amended by striking
14 “portable structures;” and all that follows and inserting
15 “portable structures.”.

16 (c) REVIEW OF CERTAIN AWARDS BY DIRECTORS.—
17 Section 405(b) of the Public Health Service Act (42
18 U.S.C. 284(b)) is amended by adding at the end the fol-
19 lowing:

20 “(3) Before an award is made by a national research
21 institute or by a national center for a grant for a research
22 program or project (commonly referred to as an ‘R-series
23 grant’), other than an award constituting a noncompeting
24 renewal of such grant, or a noncompeting administrative

1 supplement to such grant, the director of such national
2 research institute or national center—

3 “(A) shall review and approve the award; and

4 “(B) shall take into consideration—

5 “(i) the mission of the national research
6 institute or national center and the scientific
7 priorities identified in the strategic plan under
8 section 402(m); and

9 “(ii) whether other agencies are funding
10 programs or projects to accomplish the same
11 goal.”.

12 (d) IOM STUDY ON DUPLICATION IN FEDERAL BIO-
13 MEDICAL RESEARCH.—The Secretary of Health and
14 Human Services shall enter into an arrangement with the
15 Institute of Medicine of the National Academies (or, if the
16 Institute declines, another appropriate entity) under which
17 the Institute (or other appropriate entity) not later than
18 2 years after the date of enactment of this Act will—

19 (1) complete a study on the extent to which bio-
20 medical research conducted or supported by Federal
21 agencies is duplicative; and

22 (2) submit a report to the Congress on the re-
23 sults of such study, including recommendations on
24 how to prevent such duplication.

1 **SEC. 1023. REDUCING ADMINISTRATIVE BURDENS OF RE-**
2 **SEARCHERS.**

3 (a) PLAN PREPARATION AND IMPLEMENTATION OF
4 MEASURES TO REDUCE ADMINISTRATIVE BURDENS.—
5 The Director of the National Institutes of Health shall
6 prepare a plan, including time frames, and implement
7 measures to reduce the administrative burdens of re-
8 searchers funded by the National Institutes of Health,
9 taking into account the recommendations, evaluations,
10 and plans researched by the following entities:

11 (1) The Scientific Management Review Board.

12 (2) The National Academy of Sciences.

13 (3) The 2007 and 2012 Faculty Burden Survey
14 conducted by The Federal Demonstration Partner-
15 ship.

16 (4) Relevant recommendations from the Re-
17 search Business Models Working Group.

18 (b) REPORT.—Not later than 2 years after the date
19 of enactment of this Act, the Director of the National In-
20 stitutes of Health shall submit to Congress a report on
21 the extent to which the Director has implemented meas-
22 ures pursuant to subsection (a).

1 **SEC. 1024. EXEMPTION FOR THE NATIONAL INSTITUTES OF**
2 **HEALTH FROM THE PAPERWORK REDUCTION**
3 **ACT REQUIREMENTS.**

4 Section 3518(e)(1) of title 44, United States Code,
5 is amended—

6 (1) in subparagraph (C), by striking “; or” and
7 inserting a semicolon;

8 (2) in subparagraph (D), by striking the period
9 at the end and inserting “; or”; and

10 (3) by inserting at the end the following new
11 subparagraph:

12 “(E) during the conduct of research by the Na-
13 tional Institutes of Health.”.

14 **SEC. 1025. NIH TRAVEL.**

15 It is the sense of Congress that participation in or
16 sponsorship of scientific conferences and meetings is es-
17 sential to the mission of the National Institutes of Health.

18 **SEC. 1026. OTHER TRANSACTIONS AUTHORITY.**

19 Section 480 of the Public Health Service Act (42
20 U.S.C. 287a) is amended—

21 (1) in subsection (b), by striking “the appro-
22 priation of funds as described in subsection (g)” and
23 inserting “the availability of funds as described in
24 subsection (f)”;

25 (2) in subsection (e)(3), by amending subpara-
26 graph (C) to read as follows:

1 “(C) OTHER TRANSACTIONS AUTHORITY.—

2 The Director of the Center shall have other
3 transactions authority in entering into trans-
4 actions to fund projects in accordance with the
5 terms and conditions of this section.”;

6 (3) by striking subsection (f); and

7 (4) by redesignating subsection (g) as sub-
8 section (f).

9 **SEC. 1027. NCATS PHASE IIB RESTRICTION.**

10 Section 479 of the Public Health Service Act (42
11 U.S.C. 287) is amended—

12 (1) prior to making the amendments under
13 paragraph (2), by striking “IIB” each place it ap-
14 pears and inserting “III”; and

15 (2) by striking “IIA” each place it appears and
16 inserting “IIB”.

17 **SEC. 1028. HIGH-RISK, HIGH-REWARD RESEARCH.**

18 Part B of title IV of the Public Health Service Act
19 (42 U.S.C. 284 et seq.), as amended by section 1002 of
20 this Act, is amended by adding at the end the following:

21 **“SEC. 409L. HIGH-RISK, HIGH-REWARD RESEARCH PRO-**
22 **GRAM.**

23 “The director of each national research institute
24 shall, as appropriate—

1 “(1) establish programs to conduct or support
2 research projects that pursue innovative approaches
3 to major contemporary challenges in biomedical re-
4 search that involve inherent high risk, but have the
5 potential to lead to breakthroughs; and

6 “(2) set aside a specific percentage of funding,
7 to be determined by the Director of NIH for each
8 national research institute, for such projects.”.

9 **SEC. 1029. SENSE OF CONGRESS ON INCREASED INCLUSION**
10 **OF UNDERREPRESENTED COMMUNITIES IN**
11 **CLINICAL TRIALS.**

12 It is the sense of Congress that the National Institute
13 on Minority Health and Health Disparities (NIMHD)
14 should include within its strategic plan ways to increase
15 representation of underrepresented communities in clinical
16 trials.

17 **Subtitle C—Supporting Young**
18 **Emerging Scientists**

19 **SEC. 1041. IMPROVEMENT OF LOAN REPAYMENT PRO-**
20 **GRAMS OF THE NATIONAL INSTITUTES OF**
21 **HEALTH.**

22 (a) IN GENERAL.—Part G of title IV of the Public
23 Health Service Act (42 U.S.C. 288 et seq.) is amended—

1 (1) by redesignating the second section 487F
2 (42 U.S.C. 288–6; relating to pediatric research loan
3 repayment program) as section 487G; and

4 (2) by inserting after section 487G, as so redesi-
5 gnated, the following:

6 **“SEC. 487H. LOAN REPAYMENT PROGRAM.**

7 “(a) IN GENERAL.—The Secretary shall establish a
8 program, based on workforce and scientific needs, of en-
9 tering into contracts with qualified health professionals
10 under which such health professionals agree to engage in
11 research in consideration of the Federal Government
12 agreeing to pay, for each year of engaging in such re-
13 search, not more than \$50,000 of the principal and inter-
14 est of the educational loans of such health professionals.

15 “(b) ADJUSTMENT FOR INFLATION.—Beginning with
16 respect to fiscal year 2017, the Secretary may increase
17 the maximum amount specified in subsection (a) by an
18 amount that is determined by the Secretary, on an annual
19 basis, to reflect inflation.

20 “(c) LIMITATION.—The Secretary may not enter into
21 a contract with a health professional pursuant to sub-
22 section (a) unless such professional has a substantial
23 amount of educational loans relative to income.

24 “(d) APPLICABILITY OF CERTAIN PROVISIONS RE-
25 GARDING OBLIGATED SERVICE.—Except to the extent in-

1 consistent with this section, the provisions of sections
2 338B, 338C, and 338E shall apply to the program estab-
3 lished under this section to the same extent and in the
4 same manner as such provisions apply to the National
5 Health Service Corps Loan Repayment Program estab-
6 lished under section 338B.

7 “(e) AVAILABILITY OF APPROPRIATIONS.—Amounts
8 appropriated for a fiscal year for contracts under sub-
9 section (a) are authorized to remain available until the ex-
10 piration of the second fiscal year beginning after the fiscal
11 year for which the amounts were appropriated.”.

12 (b) UPDATE OF OTHER LOAN REPAYMENT PRO-
13 GRAMS.—

14 (1) Section 464z-5(a) of the Public Health
15 Service Act (42 U.S.C.285t-2(a)) is amended—

16 (A) by striking “\$35,000” and inserting
17 “\$50,000”; and

18 (B) by adding at the end the following new
19 sentence: “Subsection (b) of section 487H shall
20 apply with respect to the maximum amount
21 specified in this subsection in the same manner
22 as it applies to the maximum amount specified
23 in subsection (a) of such section.”.

24 (2) Section 487A(a) of such Act (42 U.S.C.
25 288-1(a)) is amended—

1 (A) by striking “\$35,000” and inserting
2 “\$50,000”; and

3 (B) by adding at the end the following new
4 sentence: “Subsection (b) of section 487H shall
5 apply with respect to the maximum amount
6 specified in this subsection in the same manner
7 as it applies to the maximum amount specified
8 in subsection (a) of such section.”.

9 (3) Section 487B(a) of such Act (42 U.S.C.
10 288–2(a)) is amended—

11 (A) by striking “\$35,000” and inserting
12 “\$50,000”; and

13 (B) by adding at the end the following new
14 sentence: “Subsection (b) of section 487H shall
15 apply with respect to the maximum amount
16 specified in this subsection in the same manner
17 as it applies to the maximum amount specified
18 in such subsection (a) of such section.”.

19 (4) Section 487C(a)(1) of such Act (42 U.S.C.
20 288–3(a)(1)) is amended—

21 (A) by striking “\$35,000” and inserting
22 “\$50,000”; and

23 (B) by adding at the end the following new
24 sentence: “Subsection (b) of section 487H shall
25 apply with respect to the maximum amount

1 specified in this paragraph in the same manner
2 as it applies to the maximum amount specified
3 in such subsection (a) of such section.”.

4 (5) Section 487E(a)(1) of such Act (42 U.S.C.
5 288–5(a)(1)) is amended—

6 (A) by striking “\$35,000” and inserting
7 “\$50,000”; and

8 (B) by adding at the end the following new
9 sentence: “Subsection (b) of section 487H shall
10 apply with respect to the maximum amount
11 specified in this paragraph in the same manner
12 as it applies to the maximum amount specified
13 in such subsection (a) of such section.”.

14 (6) Section 487F(a) of such Act (42 U.S.C.
15 288–5a(a)), as added by section 205 of Public Law
16 106–505, is amended—

17 (A) by striking “\$35,000” and inserting
18 “\$50,000”; and

19 (B) by adding at the end the following new
20 sentence: “Subsection (b) of section 487H shall
21 apply with respect to the maximum amount
22 specified in this subsection in the same manner
23 as it applies to the maximum amount specified
24 in such subsection (a) of such section.”.

1 (7) Section 487G of such Act (42 U.S.C. 288–
2 6, as redesignated by subsection (a)(1)), is further
3 amended—

4 (A) in subsection (a)(1), by striking
5 “\$35,000” and inserting “\$50,000”; and

6 (B) in subsection (b), by adding at the end
7 the following new sentence: “Subsection (b) of
8 section 487H shall apply with respect to the
9 maximum amount specified in subsection (a)(1)
10 in the same manner as it applies to the max-
11 imum amount specified in such subsection (a)
12 of such section.”.

13 **SEC. 1042. REPORT.**

14 Not later than 18 months after the date of the enact-
15 ment of this Act, the Director of the National Institutes
16 of Health shall submit to Congress a report on efforts of
17 the National Institutes of Health to attract, retain, and
18 develop emerging scientists, including underrepresented
19 individuals in the sciences, such as women and other mi-
20 norities.

1 **Subtitle D—Capstone Grant**
2 **Program**

3 **SEC. 1061. CAPSTONE AWARD.**

4 Part G of title IV of the Public Health Service Act
5 (42 U.S.C. 288 et seq.) is amended by adding at the end
6 the following:

7 **“SEC. 490. CAPSTONE AWARD.**

8 “(a) **IN GENERAL.**—The Secretary may make awards
9 (each of which, hereafter in this section, referred to as
10 a ‘Capstone Award’) to support outstanding scientists who
11 have been funded by the National Institutes of Health.

12 “(b) **PURPOSE.**—Capstone Awards shall be made to
13 facilitate the successful transition or conclusion of re-
14 search programs, or for other purposes, as determined by
15 the Director of NIH, in consultation with the directors
16 of the national research institutes and national centers.

17 “(c) **DURATION AND AMOUNT.**—The duration and
18 amount of each Capstone Award shall be determined by
19 the Director of NIH in consultation with the directors of
20 the national research institutes and national centers.

21 “(d) **LIMITATION.**—Individuals who have received a
22 Capstone Award shall not be eligible to have principle in-
23 vestigator status on subsequent awards from the National
24 Institutes of Health.”.

1 **Subtitle E—Promoting Pediatric**
2 **Research Through the National**
3 **Institutes of Health**

4 **SEC. 1081. NATIONAL PEDIATRIC RESEARCH NETWORK.**

5 Section 409D(d) of the Public Health Service Act (42
6 U.S.C. 284h(d)) is amended—

7 (1) in paragraph (1)—

8 (A) by striking “in consultation with the
9 Director of the Eunice Kennedy Shriver Na-
10 tional Institute of Child Health and Human
11 Development and in collaboration with other
12 appropriate national research institutes and na-
13 tional centers that carry out activities involving
14 pediatric research” and inserting “in collabora-
15 tion with the national research institutes and
16 national centers that carry out activities involv-
17 ing pediatric research”;

18 (B) by striking subparagraph (B);

19 (C) by striking “may be comprised of, as
20 appropriate” and all that follows through “the
21 pediatric research consortia” and inserting
22 “may be comprised of, as appropriate, the pedi-
23 atric research consortia”; and

24 (D) by striking “; or” at the end and in-
25 serting a period; and

1 (2) in paragraph (1), paragraph (2)(A), the
2 first sentence of paragraph (2)(E), and paragraph
3 (4), by striking “may” each place it appears and in-
4 serting “shall”.

5 **SEC. 1082. GLOBAL PEDIATRIC CLINICAL STUDY NETWORK**
6 **SENSE OF CONGRESS.**

7 It is the sense of Congress that—

8 (1) the National Institutes of Health should en-
9 courage a global pediatric clinical study network
10 through the allocation of grants, contracts, or coop-
11 erative agreements to supplement the salaries of new
12 and early investigators who participate in the global
13 pediatric clinical study network;

14 (2) National Institutes of Health grants, con-
15 tracts, or cooperative agreements should be awarded,
16 solely for the purpose of supplementing the salaries
17 of new and early investigators, to entities that par-
18 ticipate in the global pediatric clinical study net-
19 work;

20 (3) the Food and Drug Administration should
21 engage the European Medicines Agency and other
22 foreign regulatory entities during the formation of
23 the global pediatric clinical study network to encour-
24 age their participation; and

1 (4) once a global pediatric clinical study net-
2 work is established and becomes operational, the
3 Food and Drug Administration should continue to
4 engage the European Medicines Agency and other
5 foreign regulatory entities to encourage and facili-
6 tate their participation in the network with the goal
7 of enhancing the global reach of the network.

8 **SEC. 1083. APPROPRIATE AGE GROUPINGS IN CLINICAL RE-**
9 **SEARCH.**

10 (a) INPUT FROM EXPERTS.—Not later than 180
11 days after the date of enactment of this Act, the Director
12 of the National Institutes of Health shall convene a work-
13 shop of experts on pediatrics and experts on geriatrics to
14 provide input on—

15 (1) appropriate age groupings to be included in
16 research studies involving human subjects; and

17 (2) acceptable scientific justifications for ex-
18 cluding participants from a range of age groups
19 from human subjects research studies.

20 (b) GUIDELINES.—Not later than 180 days after the
21 conclusion of the workshop under subsection (a), the Di-
22 rector of the National Institutes of Health shall publish
23 guidelines—

1 (1) addressing the consideration of age as an
2 inclusion variable in research involving human sub-
3 jects; and

4 (2) identifying criteria for justifications for any
5 age-related exclusions in such research.

6 (c) PUBLIC AVAILABILITY OF FINDINGS AND CON-
7 CLUSIONS.—The Director of the National Institutes of
8 Health shall—

9 (1) make the findings and conclusions resulting
10 from the workshop under subsection (a) available to
11 the public on the website of the National Institutes
12 of Health; and

13 (2) not less than biennially, disclose to the pub-
14 lic on such website the number of children included
15 in research that is conducted or supported by the
16 National Institutes of Health, disaggregated by de-
17 velopmentally appropriate age group, race, and gen-
18 der.

19 **Subtitle F—Advancement of the**
20 **National Institutes of Health Re-**
21 **search and Data Access**

22 **SEC. 1101. STANDARDIZATION OF DATA IN CLINICAL TRIAL**
23 **REGISTRY DATA BANK ON ELIGIBILITY FOR**
24 **CLINICAL TRIALS.**

25 (a) STANDARDIZATION.—

1 (1) IN GENERAL.—Section 402(j) of the Public
2 Health Service Act (42 U.S.C. 282(j)) is amended—

3 (A) by redesignating paragraph (7) as
4 paragraph (8); and

5 (B) by inserting after paragraph (6) the
6 following:

7 “(7) STANDARDIZATION.—The Director of NIH
8 shall—

9 “(A) ensure that the registry and results
10 data bank is easily used by the public;

11 “(B) ensure that entries in the registry
12 and results data bank are easily compared;

13 “(C) ensure that information required to
14 be submitted to the registry and results data
15 bank, including recruitment information under
16 paragraph (2)(A)(ii)(II), is submitted by per-
17 sons and posted by the Director of NIH in a
18 standardized format and includes at least—

19 “(i) the disease or indication being
20 studied;

21 “(ii) inclusion criteria such as age,
22 gender, diagnosis or diagnoses, laboratory
23 values, or imaging results; and

1 “(iii) exclusion criteria such as spe-
2 cific diagnosis or diagnoses, laboratory val-
3 ues, or prohibited medications; and

4 “(D) to the extent possible, in carrying out
5 this paragraph, make use of standard health
6 care terminologies, such as the International
7 Classification of Diseases or the Current Proce-
8 dural Terminology, that facilitate electronic
9 matching to data in electronic health records or
10 other relevant health information tech-
11 nologies.”.

12 (2) CONFORMING AMENDMENT.—Clause (iv) of
13 section 402(j)(2)(B) of the Public Health Service
14 Act (42 U.S.C. 282(j)(2)(B)) is hereby stricken.

15 (b) CONSULTATION.—Not later than 90 days after
16 the date of enactment of this Act, the Secretary of Health
17 and Human Services shall consult with stakeholders (in-
18 cluding patients, researchers, physicians, industry rep-
19 resentatives, health information technology providers, the
20 Food and Drug Administration, and standard setting or-
21 ganizations such as CDISC that have experience working
22 with Federal agencies to standardize health data submis-
23 sions) to receive advice on enhancements to the clinical
24 trial registry data bank under section 402(j) of the Public
25 Health Service Act (42 U.S.C. 282(j)) (including enhance-

1 ments to usability, functionality, and search capability)
2 that are necessary to implement paragraph (7) of section
3 402(j) of such Act, as added by subsection (a).

4 (c) APPLICABILITY.—Not later than 18 months after
5 the date of enactment of this Act, the Secretary of Health
6 and Human Services shall begin implementation of para-
7 graph (7) of section 402(j) of the Public Health Service
8 Act, as added by subsection (a).

9 **Subtitle G—Facilitating**
10 **Collaborative Research**

11 **SEC. 1121. CLINICAL TRIAL DATA SYSTEM.**

12 (a) ESTABLISHMENT.—The Secretary, acting
13 through the Commissioner of Food and Drugs and the Di-
14 rector of the National Institutes of Health, shall enter into
15 a cooperative agreement, contract, or grant for a period
16 of 7 years, to be known as the Clinical Trial Data System
17 Agreement, with one or more eligible entities to implement
18 a pilot program with respect to all clinical trial data ob-
19 tained from qualified clinical trials for purposes of reg-
20 istered users conducting further research on such data.

21 (b) APPLICATION.—Eligible entities seeking to enter
22 into a cooperative agreement, contract, or grant with the
23 Secretary under this section shall submit to the Secretary
24 an application in such time and manner, and containing
25 such information, as the Secretary may require in accord-

1 ance with this section. The Secretary shall not enter into
2 a cooperative agreement, contract, or grant under this sec-
3 tion with an eligible entity unless such entity submits an
4 application including the following:

5 (1) A certification that the eligible entity is not
6 currently and does not plan to be involved in spon-
7 soring, operating, or participating in a clinical trial
8 nor collaborating with another entity for the pur-
9 poses of sponsoring, operating, or participating in a
10 clinical trial.

11 (2) Information demonstrating that the eligible
12 entity can compile clinical trial data in standardized
13 formats using terminologies and standards that have
14 been developed by recognized standards developing
15 organizations with input from diverse stakeholder
16 groups, and information demonstrating that the eli-
17 gible entity can de-identify clinical trial data con-
18 sistent with the requirements of section 164.514 of
19 title 45, Code of Federal Regulations (or successor
20 regulations).

21 (3) A description of the system the eligible enti-
22 ty will use to store and maintain such data, and in-
23 formation demonstrating that this system will com-
24 ply with applicable standards and requirements for
25 ensuring the security of the clinical trial data.

1 (4) A certification that the eligible entity will
2 allow only registered users to access and use de-
3 identified clinical trial data, gathered from qualified
4 clinical trials, and that the eligible entity will allow
5 each registered user to access and use such data
6 only after such registered user agrees in writing to
7 the terms described in (e)(4)(B), and such other
8 carefully controlled contractual terms as may be de-
9 fined by the Secretary.

10 (5) Evidence demonstrating the ability of the
11 eligible entity to ensure that registered users dis-
12 seminate the results of the research conducted in ac-
13 cordance with this section to interested parties to
14 serve as a guide to future medical product develop-
15 ment or scientific research.

16 (6) The plan of the eligible entity for securing
17 funding for the activities it would conduct under the
18 clinical trial data system agreement from govern-
19 mental sources and private foundations, entities, and
20 individuals.

21 (7) Evidence demonstrating a proven track
22 record of—

23 (A) being a neutral third party in working
24 with medical product manufacturers, academic

1 institutions, and the Food and Drug Adminis-
2 tration; and

3 (B) having the ability to protect confiden-
4 tial data.

5 (8) An agreement that the eligible entity will
6 work with the Comptroller General of the United
7 States for purposes of the study and report under
8 subsection (d).

9 (c) EXTENSION, EXPANSION, TERMINATION.—The
10 Secretary, acting through the Commissioner of Food and
11 Drugs and the Director of the National Institutes of
12 Health, upon the expiration of the 7-year period referred
13 to in subsection (a), may extend (including permanently),
14 expand, or terminate the pilot program established under
15 such subsection, in whole or in part.

16 (d) STUDY AND REPORT.—

17 (1) IN GENERAL.—The Comptroller General of
18 the United States shall conduct a study and issue a
19 report to the Congress and the Secretary with re-
20 spect to the pilot program established under sub-
21 section (a), not later than 6 years after the date on
22 which the pilot program is established under sub-
23 section (a).

24 (2) STUDY.—The study under paragraph (1)
25 shall—

1 (A) review the effectiveness of the pilot
2 program established under subsection (a); and

3 (B) be designed to formulate recommenda-
4 tions on improvements to the program.

5 (3) REPORT.—The report under paragraph (1)
6 shall contain at least the following information:

7 (A) The new discoveries, research inquir-
8 ies, or clinical trials that have resulted from ac-
9 cessing clinical trial data under the pilot pro-
10 gram established under subsection (a).

11 (B) The number of times scientists have
12 accessed such data, disaggregated by research
13 area and clinical trial phase.

14 (C) An analysis of whether the program
15 has helped to reduce adverse events in clinical
16 trials.

17 (D) An analysis of whether scientists have
18 raised any concerns about the burden of having
19 to share data with the system established under
20 the program and, if so, a description of such
21 concerns.

22 (E) An analysis of privacy and data integ-
23 rity practices used in the program.

24 (e) DEFINITIONS.—In this section:

1 (1) The term “eligible entity” means an entity
2 that has experienced personnel with clinical and
3 other technical expertise in the biomedical sciences
4 and biomedical ethics and that is—

5 (A) an institution of higher education (as
6 such term is defined in section 1001 of the
7 Higher Education Act of 1965 (20 U.S.C.
8 1001)) or a consortium of such institutions; or

9 (B) an organization described in section
10 501(c)(3) of title 26 of the Internal Revenue
11 Code of 1986 and exempt from tax under sec-
12 tion 501(a) of such title.

13 (2) The term “medical product” means a drug
14 (as defined in section 201(g) of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 331(g))), a de-
16 vice (as defined in section 201(h) of such Act (21
17 U.S.C. 331(h))), a biological product (as defined in
18 section 351 of the Public Health Service Act (42
19 U.S.C. 262)), or any combination thereof.

20 (3) The term “qualified clinical trial” means a
21 clinical trial sponsored solely by an agency of the
22 Department of Health and Human Services with re-
23 spect to a medical product—

24 (A) that—

1 (i) was approved or cleared under sec-
2 tion 505, 510(k), or 515, or has an exemp-
3 tion for investigational use in effect under
4 section 505 or 520(m), of the Federal
5 Food, Drug, and Cosmetic Act (42 U.S.C.
6 301 et seq.); or

7 (ii) was licensed under section 351 of
8 the Public Health Service Act (42 U.S.C.
9 262) or has an exemption for investiga-
10 tional use in effect under such section 351;
11 or

12 (B) that is an investigational product for
13 which the original development was discon-
14 tinued and with respect to which—

15 (i) no additional work to support ap-
16 proval, licensure, or clearance of such med-
17 ical product is being or is planned to be
18 undertaken by the sponsor of the original
19 development program, its successors, as-
20 signs, or collaborators; and

21 (ii) the sponsor of the original inves-
22 tigational development program has pro-
23 vided its consent to the Secretary for inclu-
24 sion of data regarding such product in the
25 system established under this section.

1 (4) The term “registered user” means a sci-
2 entific or medical researcher who has—

3 (A) a legitimate biomedical research pur-
4 pose for accessing information from the clinical
5 trials data system and has appropriate quali-
6 fications to conduct such research; and

7 (B) agreed in writing not to transfer to
8 any other person that is not a registered user
9 de-identified clinical trial data from qualified
10 clinical trials accessed through an eligible enti-
11 ty, use such data for reasons not specified in
12 the research proposal, or seek to re-identify
13 qualified clinical trial participants.

14 (5) The term “Secretary” means the Secretary
15 of Health and Human Services.

16 **SEC. 1122. NATIONAL NEUROLOGICAL DISEASES SURVEIL-**
17 **LANCE SYSTEM.**

18 Part P of title III of the Public Health Service Act
19 (42 U.S.C. 280g et seq.) is amended by adding at the end
20 the following:

21 **“SEC. 399V-6 SURVEILLANCE OF NEUROLOGICAL DISEASES.**

22 “(a) IN GENERAL.—The Secretary, acting through
23 the Director of the Centers for Disease Control and Pre-
24 vention and in coordination with other agencies as deter-
25 mined appropriate by the Secretary, shall—

1 “(1) enhance and expand infrastructure and ac-
2 tivities to track the epidemiology of neurological dis-
3 eases, including multiple sclerosis and Parkinson’s
4 disease; and

5 “(2) incorporate information obtained through
6 such activities into a statistically sound, scientifically
7 credible, integrated surveillance system, to be known
8 as the National Neurological Diseases Surveillance
9 System.

10 “(b) RESEARCH.—The Secretary shall ensure that
11 the National Neurological Diseases Surveillance System is
12 designed in a manner that facilitates further research on
13 neurological diseases.

14 “(c) CONTENT.—In carrying out subsection (a), the
15 Secretary—

16 “(1) shall provide for the collection and storage
17 of information on the incidence and prevalence of
18 neurological diseases in the United States;

19 “(2) to the extent practicable, shall provide for
20 the collection and storage of other available informa-
21 tion on neurological diseases, such as information
22 concerning—

23 “(A) demographics and other information
24 associated or possibly associated with neuro-

1 logical diseases, such as age, race, ethnicity,
2 sex, geographic location, and family history;

3 “(B) risk factors associated or possibly as-
4 sociated with neurological diseases, including
5 genetic and environmental risk factors; and

6 “(C) diagnosis and progression markers;

7 “(3) may provide for the collection and storage
8 of information relevant to analysis on neurological
9 diseases, such as information concerning—

10 “(A) the epidemiology of the diseases;

11 “(B) the natural history of the diseases;

12 “(C) the prevention of the diseases;

13 “(D) the detection, management, and
14 treatment approaches for the diseases; and

15 “(E) the development of outcomes meas-
16 ures; and

17 “(4) may address issues identified during the
18 consultation process under subsection (d).

19 “(d) CONSULTATION.—In carrying out this section,
20 the Secretary shall consult with individuals with appro-
21 priate expertise, including—

22 “(1) epidemiologists with experience in disease
23 surveillance or registries;

24 “(2) representatives of national voluntary
25 health associations that—

1 “(A) focus on neurological diseases, includ-
2 ing multiple sclerosis and Parkinson’s disease;
3 and

4 “(B) have demonstrated experience in re-
5 search, care, or patient services;

6 “(3) health information technology experts or
7 other information management specialists;

8 “(4) clinicians with expertise in neurological
9 diseases; and

10 “(5) research scientists with experience con-
11 ducting translational research or utilizing surveil-
12 lance systems for scientific research purposes.

13 “(e) GRANTS.—The Secretary may award grants to,
14 or enter into contracts or cooperative agreements with,
15 public or private nonprofit entities to carry out activities
16 under this section.

17 “(f) COORDINATION WITH OTHER FEDERAL, STATE,
18 AND LOCAL AGENCIES.—Subject to subsection (h), the
19 Secretary shall make information and analysis in the Na-
20 tional Neurological Diseases Surveillance System avail-
21 able, as appropriate—

22 “(1) to Federal departments and agencies, such
23 as the National Institutes of Health, the Food and
24 Drug Administration, the Centers for Medicare &
25 Medicaid Services, the Agency for Healthcare Re-

1 search and Quality, the Department of Veterans Af-
2 fairs, and the Department of Defense; and

3 “(2) to State and local agencies.

4 “(g) PUBLIC ACCESS.—Subject to subsection (h), the
5 Secretary shall make information and analysis in the Na-
6 tional Neurological Diseases Surveillance System avail-
7 able, as appropriate, to the public, including researchers.

8 “(h) PRIVACY.—The Secretary shall ensure that pri-
9 vacy and security protections applicable to the National
10 Neurological Diseases Surveillance System are at least as
11 stringent as the privacy and security protections under
12 HIPAA privacy and security law (as defined in section
13 3009(a)(2)).

14 “(i) REPORT.—Not later than 4 years after the date
15 of the enactment of this section, the Secretary shall sub-
16 mit a report to the Congress concerning the implementa-
17 tion of this section. Such report shall include information
18 on—

19 “(1) the development and maintenance of the
20 National Neurological Diseases Surveillance System;

21 “(2) the type of information collected and
22 stored in the System;

23 “(3) the use and availability of such informa-
24 tion, including guidelines for such use; and

1 “(4) the use and coordination of databases that
2 collect or maintain information on neurological dis-
3 eases.

4 “(j) DEFINITION.—In this section, the term ‘national
5 voluntary health association’ means a national nonprofit
6 organization with chapters, other affiliated organizations,
7 or networks in States throughout the United States.

8 “(k) AUTHORIZATION OF APPROPRIATIONS.—To
9 carry out this section, there is authorized to be appro-
10 priated \$5,000,000 for each of fiscal years 2016 through
11 2020.”.

12 **SEC. 1123. DATA ON NATURAL HISTORY OF DISEASES.**

13 (a) SENSE OF CONGRESS.—It is the sense of the Con-
14 gress that studies on the natural history of diseases can
15 help to facilitate and expedite the development of medical
16 products for such diseases.

17 (b) AUTHORITY.—Part A of title II of the Public
18 Health Service Act (42 U.S.C. 202 et seq.) is amended
19 by adding at the end the following:

20 **“SEC. 229A. DATA ON NATURAL HISTORY OF DISEASES.**

21 “(a) IN GENERAL.—The Secretary, acting through
22 the Commissioner of Food and Drugs, may, for the pur-
23 poses described in subsection (b)—

1 “(1) participate in public-private partnerships
2 engaged in one or more activities specified in sub-
3 section (c); and

4 “(2) award grants to patient advocacy groups
5 or other organizations determined appropriate by the
6 Secretary.

7 “(b) PURPOSES DESCRIBED.—The purposes de-
8 scribed in this subsection are to establish or facilitate the
9 collection, maintenance, analysis, and interpretation of
10 data regarding the natural history of diseases, with a par-
11 ticular focus on rare diseases.

12 “(c) ACTIVITIES OF PUBLIC-PRIVATE PARTNER-
13 SHIPS.—The activities of public-private partnerships in
14 which the Secretary may participate for purposes of this
15 section include—

16 “(1) cooperating with other entities that spon-
17 sor or maintain disease registries, including disease
18 registries and disease registry platforms for rare dis-
19 eases;

20 “(2) developing or enhancing a secure informa-
21 tion technology system that—

22 “(A) has the capacity to support data
23 needs across a wide range of disease studies;

24 “(B) is easily modified as knowledge is
25 gained during such studies; and

1 “(C) is capable of handling increasing
2 amounts of data as more studies are carried
3 out; and

4 “(3) providing advice to clinical researchers, pa-
5 tient advocacy groups, and other entities with re-
6 spect to—

7 “(A) the design and conduct of disease
8 studies;

9 “(B) the modification of any such ongoing
10 studies; and

11 “(C) addressing associated patient privacy
12 issues.

13 “(d) AVAILABILITY OF DATA ON NATURAL HISTORY
14 OF DISEASES.—Data relating to the natural history of
15 diseases obtained, aggregated, or otherwise maintained by
16 a public-private partnership in which the Secretary par-
17 ticipates under subsection (a) shall be made available, con-
18 sistent with otherwise applicable Federal and State pri-
19 vacy laws, to the public (including patient advocacy
20 groups, researchers, and drug developers) to help to facili-
21 tate and expedite medical product development programs.

22 “(e) CONFIDENTIALITY.—Notwithstanding sub-
23 section (d), nothing in this section authorizes the disclo-
24 sure of any information that is a trade secret or commer-
25 cial or financial information that is privileged or confiden-

1 tial and subject to section 552(b)(4) of title 5, United
 2 States Code, or section 1905 of title 18, United States
 3 Code.

4 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
 5 is authorized to be appropriated to carry out this section
 6 \$5,000,000 for each of fiscal years 2016 through 2020.”.

7 **SEC. 1124. ACCESSING, SHARING, AND USING HEALTH DATA**
 8 **FOR RESEARCH PURPOSES.**

9 (a) IN GENERAL.—(1) The HITECH Act (title XIII
 10 of division A of Public Law 111–5) is amended by adding
 11 at the end of subtitle D of such Act (42 U.S.C. 17921
 12 et seq.) the following:

13 **“PART 4—ACCESSING, SHARING, AND USING**
 14 **HEALTH DATA FOR RESEARCH PURPOSES**

15 **“SEC. 13441. REFERENCES.**

16 “In this part:

17 “(1) THE RULE.—References to ‘the Rule’ refer
 18 to part 160 or part 164, as appropriate, of title 45,
 19 Code of Federal Regulations (or any successor regu-
 20 lation).

21 “(2) PART 164.—References to a specified sec-
 22 tion of ‘part 164’, refer to such specified section of
 23 part 164 of title 45, Code of Federal Regulations (or
 24 any successor section).

1 **“SEC. 13442. DEFINING HEALTH DATA RESEARCH AS PART**
2 **OF HEALTH CARE OPERATIONS.**

3 “(a) IN GENERAL.—Subject to subsection (b), the
4 Secretary shall revise or clarify the Rule to allow the use
5 and disclosure of protected health information by a cov-
6 ered entity for research purposes, including studies whose
7 purpose is to obtain generalizable knowledge, to be treated
8 as the use and disclosure of such information for health
9 care operations described in subparagraph (1) of the defi-
10 nition of health care operations in section 164.501 of part
11 164.

12 “(b) MODIFICATIONS TO RULES FOR DISCLOSURES
13 FOR HEALTH CARE OPERATIONS.—In applying section
14 164.506 of part 164 to the disclosure of protected health
15 information described in subsection (a)—

16 “(1) the Secretary shall revise or clarify the
17 Rule so that the disclosure may be made by the cov-
18 ered entity to only—

19 “(A) another covered entity for health care
20 operations (as defined in section 164.501 of
21 part 164);

22 “(B) a business associate that has entered
23 into a contract under section 164.504(e) of part
24 164 with a disclosing covered entity to perform
25 health care operations; or

1 “(C) a business associate that has entered
2 into a contract under section 164.504(e) of part
3 164 for the purpose of data aggregation (as de-
4 fined in section 164.501 of part 164); and

5 “(2) the Secretary shall further revise or clarify
6 the Rule so that the limitation specified by section
7 164.506(e)(4) of part 164 does not apply to disclo-
8 sures that are described by subsection (a).

9 “(c) **RULE OF CONSTRUCTION.**—This section shall
10 not be construed as prohibiting or restricting a use or dis-
11 closure of protected health information for research pur-
12 poses that is otherwise permitted under part 164.

13 **“SEC. 13443. TREATING DISCLOSURES OF PROTECTED**
14 **HEALTH INFORMATION FOR RESEARCH SIMI-**
15 **LARLY TO DISCLOSURES OF SUCH INFORMA-**
16 **TION FOR PUBLIC HEALTH PURPOSES.**

17 “(a) **REMUNERATION.**—The Secretary shall revise or
18 clarify the Rule so that disclosures of protected health in-
19 formation for research purposes are not subject to the lim-
20 itation on remuneration described in section
21 164.502(a)(5)(ii)(B)(2)(ii) of part 164.

22 “(b) **PERMITTED USES AND DISCLOSURES.**—The
23 Secretary shall revise or clarify the Rule so that research
24 activities, including comparative research activities, re-
25 lated to the quality, safety, or effectiveness of a product

1 or activity that is regulated by the Food and Drug Admin-
2 istration are included as public health activities for pur-
3 poses of which a covered entity may disclose protected
4 health information to a person described in section
5 164.512(b)(1)(iii) of part 164.

6 **“SEC. 13444. PERMITTING REMOTE ACCESS TO PROTECTED**
7 **HEALTH INFORMATION BY RESEARCHERS.**

8 “The Secretary shall revise or clarify the Rule so that
9 subparagraph (B) of section 164.512(i)(1)(ii) of part 164
10 (prohibiting the removal of protected health information
11 by a researcher) does not prohibit remote access to health
12 information by a researcher so long as—

13 “(1) appropriate security and privacy safe-
14 guards are maintained by the covered entity and the
15 researcher; and

16 “(2) the protected health information is not
17 copied or otherwise retained by the researcher.

18 **“SEC. 13445. ALLOWING ONE-TIME AUTHORIZATION OF USE**
19 **AND DISCLOSURE OF PROTECTED HEALTH**
20 **INFORMATION FOR RESEARCH PURPOSES.**

21 “(a) IN GENERAL.—The Secretary shall revise or
22 clarify the Rule to specify that an authorization for the
23 use or disclosure of protected health information, with re-
24 spect to an individual, for future research purposes shall

1 be deemed to contain a sufficient description of the pur-
2 pose of the use or disclosure if the authorization—

3 “(1) sufficiently describes the purposes such
4 that it would be reasonable for the individual to ex-
5 pect that the protected health information could be
6 used or disclosed for such future research;

7 “(2) either—

8 “(A) states that the authorization will ex-
9 pire on a particular date or on the occurrence
10 of a particular event; or

11 “(B) states that the authorization will re-
12 main valid unless and until it is revoked by the
13 individual; and

14 “(3) provides instruction to the individual on
15 how to revoke such authorization at any time.

16 “(b) REVOCATION OF AUTHORIZATION.—The Sec-
17 retary shall revise or clarify the Rule to specify that, if
18 an individual revokes an authorization for future research
19 purposes such as is described by subsection (a), the cov-
20 ered entity may not make any further uses or disclosures
21 based on that authorization, except, as provided in para-
22 graph (b)(5) of section 164.508 of part 164, to the extent
23 that the covered entity has taken action in reliance on the
24 authorization.”.

1 (2) The table of sections in section 13001(b) of such
2 Act is amended by adding at the end of the items relating
3 to subtitle D the following new items:

“PART 4—ACCESSING, SHARING, AND USING HEALTH DATA FOR RESEARCH
PURPOSES

“Sec. 13441. References.

“Sec. 13442. Defining health data research as part of health care operations.

“Sec. 13443. Treating disclosures of protected health information for research
similarly to disclosures of such information for public health
purposes.

“Sec. 13444. Permitting remote access to protected health information by re-
searchers.

“Sec. 13445. Allowing one-time authorization of use and disclosure of protected
health information for research purposes.”.

4 (b) REVISION OF REGULATIONS.—Not later than 12
5 months after the date of the enactment of this Act, the
6 Secretary of Health and Human Services shall revise and
7 clarify the provisions of title 45, Code of Federal Regula-
8 tions, for consistency with part 4 of subtitle D of the
9 HITECH Act, as added by subsection (a).

10 **Subtitle H—Council for 21st**
11 **Century Cures**

12 **SEC. 1141. COUNCIL FOR 21ST CENTURY CURES.**

13 Title II of the Public Health Service Act (42 U.S.C.
14 202 et seq.) is amended by adding at the end the fol-
15 lowing:

16 **“PART E—COUNCIL FOR 21ST CENTURY CURES**

17 **“SEC. 281. ESTABLISHMENT.**

18 “A nonprofit corporation to be known as the Council
19 for 21st Century Cures (referred to in this part as the
20 ‘Council’) shall be established in accordance with this sec-

1 tion. The Council shall be a public-private partnership
2 headed by an Executive Director (referred to in this part
3 as the ‘Executive Director’), appointed by the members
4 of the Board of Directors. The Council shall not be an
5 agency or instrumentality of the United States Govern-
6 ment.

7 **“SEC. 281A. PURPOSE.**

8 “The purpose of the Council is to accelerate the dis-
9 covery, development, and delivery in the United States of
10 innovative cures, treatments, and preventive measures for
11 patients.

12 **“SEC. 281B. DUTIES.**

13 “For the purpose described in section 281A, the
14 Council shall—

15 “(1) foster collaboration and coordination
16 among the entities that comprise the Council, includ-
17 ing academia, government agencies, industry, health
18 care payors and providers, patient advocates, and
19 others engaged in the cycle of discovery, develop-
20 ment, and delivery of life-saving and health-enhanc-
21 ing innovative interventions;

22 “(2) undertake communication and dissemina-
23 tion activities;

24 “(3) publish information on the activities fund-
25 ed under section 281D;

1 “(4) establish a strategic agenda for accel-
2 erating the discovery, development, and delivery in
3 the United States of innovative cures, treatments,
4 and preventive measures for patients;

5 “(5) identify gaps and opportunities within and
6 across the discovery, development, and delivery cycle;

7 “(6) develop and propose recommendations
8 based on the gaps and opportunities so identified;

9 “(7) facilitate the interoperability of the compo-
10 nents of the discovery, development, and delivery
11 cycle;

12 “(8) propose recommendations that will facili-
13 tate precompetitive collaboration;

14 “(9) identify opportunities to work with, but
15 not duplicate the efforts of, nonprofit organizations
16 and other public-private partnerships; and

17 “(10) identify opportunities for collaboration
18 with organizations operating outside of the United
19 States, such as the Innovative Medicines Initiative of
20 the European Union.

21 **“SEC. 281C. ORGANIZATION; ADMINISTRATION.**

22 “(a) BOARD OF DIRECTORS.—

23 “(1) ESTABLISHMENT.—

24 “(A) IN GENERAL.—The Council shall
25 have a Board of Directors (in this part referred

1 to as the ‘Board of Directors’), which shall be
2 composed of the ex officio members under sub-
3 paragraph (B) and the appointed members
4 under subparagraph (C). All members of the
5 Board shall be voting members.

6 “(B) EX OFFICIO MEMBERS.—The ex offi-
7 cio members of the Board shall be the following
8 individuals or their designees:

9 “(i) The Director of the National In-
10 stitutes of Health.

11 “(ii) The Commissioner of Food and
12 Drugs.

13 “(iii) The Administrator of the Cen-
14 ters for Medicare & Medicaid Services.

15 “(iv) The heads of five other Federal
16 agencies deemed by the Secretary to be en-
17 gaged in biomedical research and develop-
18 ment.

19 “(C) APPOINTED MEMBERS.—The ap-
20 pointed members of the Board shall consist of
21 17 individuals, of whom—

22 “(i) eight shall be appointed by the
23 Comptroller General of the United States
24 from a list of nominations submitted by
25 leading trade associations—

1 “(I) four of whom shall be rep-
2 representatives of the biopharmaceutical
3 industry;

4 “(II) two of whom shall be rep-
5 representatives of the medical device in-
6 dustry; and

7 “(III) two of whom shall be rep-
8 representatives of the information and
9 digital technology industry; and

10 “(ii) nine shall be appointed by the
11 Comptroller General of the United States,
12 after soliciting nominations—

13 “(I) two of whom shall be rep-
14 representatives of academic researchers;

15 “(II) three of whom shall be rep-
16 representatives of patients;

17 “(III) two of whom shall be rep-
18 representatives of health care providers;
19 and

20 “(IV) two of whom shall be rep-
21 representatives of health care plans and
22 insurers.

23 “(D) CHAIR.—The Chair of the Board
24 shall be selected by the members of the Board

1 by majority vote from among the members of
2 the Board.

3 “(2) TERMS AND VACANCIES.—

4 “(A) IN GENERAL.—The term of office of
5 each member of the Board appointed under
6 paragraph (1)(C) shall be 5 years.

7 “(B) VACANCY.—Any vacancy in the mem-
8 bership of the Board—

9 “(i) shall not affect the power of the
10 remaining members to execute the duties
11 of the Board; and

12 “(ii) shall be filled by appointment by
13 the appointed members described in para-
14 graph (1)(C) by majority vote.

15 “(C) PARTIAL TERM.—If a member of the
16 Board does not serve the full term applicable
17 under subparagraph (A), the individual ap-
18 pointed under subparagraph (B) to fill the re-
19 sulting vacancy shall be appointed for the re-
20 mainder of the term of the predecessor of the
21 individual.

22 “(3) RESPONSIBILITIES.—Not later than 90
23 days after the date on which the Council is incor-
24 porated and its Board of Directors is fully con-

1 stituted, the Board of Directors shall establish by-
2 laws and policies for the Council that—

3 “(A) are published in the Federal Register
4 and available for public comment;

5 “(B) establish policies for the selection
6 and, as applicable, appointment of—

7 “(i) the officers, employees, agents,
8 and contractors of the Council; and

9 “(ii) the members of any committees
10 of the Council;

11 “(C) establish policies, including ethical
12 standards, for the conduct of programs and
13 other activities under section 281D; and

14 “(D) establish specific duties of the Execu-
15 tive Director.

16 “(4) MEETINGS.—

17 “(A) IN GENERAL.—The Board of Direc-
18 tors shall—

19 “(i) meet on a quarterly basis; and

20 “(ii) submit to Congress, and make
21 publicly available, the minutes of such
22 meetings.

23 “(B) AGENDA.—The Board of Directors
24 shall, not later than 3 months after the incorpo-
25 ration of the Council—

1 “(i) issue an agenda (in this part re-
2 ferred to as the ‘agenda’) outlining how
3 the Council will achieve the purpose de-
4 scribed in section 281A; and

5 “(ii) annually thereafter, in consulta-
6 tion with the Executive Director, review
7 and update such agenda.

8 “(b) APPOINTMENT AND INCORPORATION.—Not
9 later than 6 months after the date of enactment of the
10 21st Century Cures Act—

11 “(1) the Comptroller General of the United
12 States shall appoint the appointed members of the
13 Board of Directors under subsection (a)(1)(C); and

14 “(2) the ex officio members of the Board of Di-
15 rectors under subsection (a)(1)(B) shall serve as
16 incorporators and shall take whatever actions are
17 necessary to incorporate the Council.

18 “(c) NONPROFIT STATUS.—In carrying out this part,
19 the Board of Directors shall establish such policies and
20 bylaws, and the Executive Director shall carry out such
21 activities, as may be necessary to ensure that the Council
22 maintains status as an organization that—

23 “(1) is described in subsection (c)(3) of section
24 501 of the Internal Revenue Code of 1986; and

1 “(2) is, under subsection (a) of such section, ex-
2 empt from taxation.

3 “(d) EXECUTIVE DIRECTOR.—The Executive Direc-
4 tor shall—

5 “(1) be the chief executive officer of the Coun-
6 cil; and

7 “(2) subject to the oversight of the Board of
8 Directors, be responsible for the day-to-day manage-
9 ment of the Council.

10 **“SEC. 281D. OPERATIONAL ACTIVITIES AND ASSISTANCE.**

11 “(a) IN GENERAL.—The Council shall establish a
12 sufficient operational infrastructure to fulfill the duties
13 specified in section 281B.

14 “(b) PRIVATE SECTOR MATCHING FUNDS.—The
15 Council may accept financial or in-kind support from par-
16 ticipating entities or private foundations or organizations
17 when such support is deemed appropriate.

18 **“SEC. 281E. TERMINATION; REPORT.**

19 “(a) IN GENERAL.—The Council shall terminate on
20 September 30, 2023.

21 “(b) REPORT.—Not later than 1 year after the date
22 on which the Council is established and each year there-
23 after, the Executive Director shall submit to the appro-
24 priate congressional committees a report on the perform-
25 ance of the Council. In preparing such report, the Council

1 shall consult with a nongovernmental consultant with ap-
 2 propriate expertise.

3 **“SEC. 281F. FUNDING.**

4 “For the each of fiscal years 2016 through 2023,
 5 there is authorized to be appropriated \$10,000,000 to the
 6 Council for purposes of carrying out the duties of the
 7 Council under this part.”.

8 **TITLE II—DEVELOPMENT**
 9 **Subtitle A—Patient-Focused Drug**
 10 **Development**

11 **SEC. 2001. DEVELOPMENT AND USE OF PATIENT EXPERI-**
 12 **ENCE DATA TO ENHANCE STRUCTURED RISK-**
 13 **BENEFIT ASSESSMENT FRAMEWORK.**

14 (a) IN GENERAL.—Section 505 of the Federal Food,
 15 Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

16 (1) in subsection (d), by striking “The Sec-
 17 retary shall implement” and all that follows through
 18 “premarket approval of a drug.”; and

19 (2) by adding at the end the following new sub-
 20 sections:

21 “(x) STRUCTURED RISK-BENEFIT ASSESSMENT
 22 FRAMEWORK.—

23 “(1) IN GENERAL.—The Secretary shall imple-
 24 ment a structured risk-benefit assessment frame-
 25 work in the new drug approval process—

1 “(A) to facilitate the balanced consider-
2 ation of benefits and risks; and

3 “(B) to develop and implement a con-
4 sistent and systematic approach to the discus-
5 sion of, regulatory decisionmaking with respect
6 to, and the communication of, the benefits and
7 risks of new drugs.

8 “(2) RULE OF CONSTRUCTION.—Nothing in
9 paragraph (1) shall alter the criteria for evaluating
10 an application for premarket approval of a drug.

11 “(y) DEVELOPMENT AND USE OF PATIENT EXPERI-
12 ENCE DATA TO ENHANCE STRUCTURED RISK-BENEFIT
13 ASSESSMENT FRAMEWORK.—

14 “(1) IN GENERAL.—Not later than 2 years
15 after the date of the enactment of this subsection,
16 the Secretary shall establish and implement proc-
17 esses under which—

18 “(A) an entity seeking to develop patient
19 experience data may submit to the Secretary—

20 “(i) initial research concepts for feed-
21 back from the Secretary; and

22 “(ii) with respect to patient experience
23 data collected by the entity, draft guidance
24 documents, completed data, and sum-
25 maries and analyses of such data;

1 “(B) the Secretary may request such an
2 entity to submit such documents, data, and
3 summaries and analyses; and

4 “(C) patient experience data may be devel-
5 oped and used to enhance the structured risk-
6 benefit assessment framework under subsection
7 (x).

8 “(2) PATIENT EXPERIENCE DATA.—In this sub-
9 section, the term ‘patient experience data’ means
10 data collected by patients, parents, caregivers, pa-
11 tient advocacy organizations, disease research found-
12 ations, medical researchers, research sponsors, or
13 other parties determined appropriate by the Sec-
14 retary that is intended to facilitate or enhance the
15 Secretary’s risk-benefit assessments, including infor-
16 mation about the impact of a disease or a therapy
17 on patients’ lives.”.

18 (b) GUIDANCE.—

19 (1) IN GENERAL.—The Secretary of Health and
20 Human Services shall publish guidance on the imple-
21 mentation of subsection (y) of section 505 of the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 355), as added by subsection (a). Such guidance
24 shall include—

1 (A) with respect to draft guidance docu-
2 ments, data, or summaries and analyses sub-
3 mitted to the Secretary under paragraph (1)(A)
4 of such subsection, guidance—

5 (i) specifying the timelines for the re-
6 view of such documents, data, or sum-
7 maries and analyses by the Secretary; and

8 (ii) on how the Secretary will use such
9 documents, data, or summaries and anal-
10 yses to update any guidance documents
11 published under this subsection or publish
12 new guidance;

13 (B) with respect to the collection and anal-
14 ysis of patient experience data (as defined in
15 paragraph (2) of such subsection (y)), guidance
16 on—

17 (i) methodological considerations for
18 the collection of patient experience data,
19 which may include structured approaches
20 to gathering information on—

21 (I) the experience of a patient liv-
22 ing with a particular disease;

23 (II) the burden of living with or
24 managing the disease;

1 (III) the impact of the disease on
2 daily life and long-term functioning;
3 and

4 (IV) the effect of current thera-
5 peutic options on different aspects of
6 the disease; and

7 (ii) the establishment and mainte-
8 nance of registries designed to increase un-
9 derstanding of the natural history of a dis-
10 ease;

11 (C) methodological approaches that may be
12 used to assess patients' beliefs with respect to
13 the benefits and risks in the management of the
14 patient's disease; and

15 (D) methodologies, standards, and poten-
16 tial experimental designs for patient-reported
17 outcomes.

18 (2) TIMING.—Not later than 3 years after the
19 date of the enactment of this Act, the Secretary of
20 Health and Human Services shall issue draft guid-
21 ance on the implementation of subsection (y) of sec-
22 tion 505 of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 355), as added by subsection (a).
24 The Secretary shall issue final guidance on the im-
25 plementation of such subsection not later than 1

1 year after the date on which the comment period for
2 the draft guidance closes.

3 (3) WORKSHOPS.—

4 (A) IN GENERAL.—Not later than 6
5 months after the date of the enactment of this
6 Act and once every 6 months during the fol-
7 lowing 12-month period, the Secretary of
8 Health and Human Services shall convene a
9 workshop to obtain input regarding methodolo-
10 gies for developing the guidance under para-
11 graph (1), including the collection of patient ex-
12 perience data.

13 (B) ATTENDEES.—A workshop convened
14 under this paragraph shall include—

15 (i) patients;

16 (ii) representatives from patient advo-
17 cacy organizations, biopharmaceutical com-
18 panies, and disease research foundations;

19 (iii) representatives of the reviewing
20 divisions of the Food and Drug Adminis-
21 tration; and

22 (iv) methodological experts with sig-
23 nificant expertise in patient experience
24 data.

1 (4) PUBLIC MEETING.—Not later than 90 days
2 after the date on which the draft guidance is pub-
3 lished under this subsection, the Secretary of Health
4 and Human Services shall convene a public meeting
5 to solicit input on the guidance.

6 **Subtitle B—Qualification and Use**
7 **of Drug Development Tools**

8 **SEC. 2021. QUALIFICATION OF DRUG DEVELOPMENT**
9 **TOOLS.**

10 (a) FINDINGS.—Congress finds the following:

11 (1) Development of new drugs has become in-
12 creasingly challenging and resource intensive.

13 (2) Development of drug development tools can
14 benefit the availability of new medical therapies by
15 helping to translate scientific discoveries into clinical
16 applications.

17 (3) Biomedical research consortia (as defined in
18 section 507(f) of the Federal Food, Drug, and Cos-
19 metic Act, as added by subsection (c)) can play a
20 valuable role in helping to develop and qualify drug
21 development tools.

22 (b) SENSE OF CONGRESS.—It is the sense of Con-
23 gress that—

1 (1) Congress should promote and facilitate a
2 collaborative effort among the biomedical research
3 consortia described in subsection (a)(3)—

4 (A) to develop, through a transparent pub-
5 lic process, data standards and scientific ap-
6 proaches to data collection accepted by the
7 medical and clinical research community for
8 purposes of qualifying drug development tools;

9 (B) to coordinate efforts toward developing
10 and qualifying drug development tools in key
11 therapeutic areas; and

12 (C) to encourage the development of acces-
13 sible databases for collecting relevant drug de-
14 velopment tool data for such purposes; and

15 (2) an entity seeking to qualify a drug develop-
16 ment tool should be encouraged, in addition to con-
17 sultation with the Secretary, to consult with bio-
18 medical research consortia and other individuals and
19 entities with expert knowledge and insights that may
20 assist the requestor and benefit the process for such
21 qualification.

22 (c) QUALIFICATION OF DRUG DEVELOPMENT

23 TOOLS.—Chapter V of the Federal Food, Drug, and Cos-
24 metic Act is amended by inserting after section 506F the
25 following new section:

1 **“SEC. 507. QUALIFICATION OF DRUG DEVELOPMENT**
2 **TOOLS.**

3 “(a) PROCESS FOR QUALIFICATION.—

4 “(1) IN GENERAL.—The Secretary shall estab-
5 lish a process for the qualification of drug develop-
6 ment tools for a proposed context of use under
7 which—

8 “(A)(i) a requestor initiates such process
9 by submitting a letter of intent to the Sec-
10 retary; and

11 “(ii) the Secretary accepts or declines to
12 accept such letter of intent;

13 “(B)(i) if the Secretary accepts the letter
14 of intent, a requestor submits a qualification
15 plan to the Secretary; and

16 “(ii) the Secretary accepts or declines to
17 accept the qualification plan; and

18 “(C)(i) if the Secretary accepts the quali-
19 fication plan, the requestor submits to the Sec-
20 retary a full qualification package;

21 “(ii) the Secretary determines whether to
22 accept such qualification package for review;
23 and

24 “(iii) if the Secretary accepts such quali-
25 fication package for review, the Secretary con-

1 ducts such review in accordance with this sec-
2 tion.

3 “(2) ACCEPTANCE AND REVIEW OF SUBMIS-
4 SIONS.—

5 “(A) IN GENERAL.—The succeeding provi-
6 sions of this paragraph shall apply with respect
7 to the treatment of a letter of intent, a quali-
8 fication plan, or a full qualification package
9 submitted under paragraph (1) (referred to in
10 this paragraph as ‘qualification submissions’).

11 “(B) ACCEPTANCE FACTORS; NONACCEPT-
12 ANCE.—The Secretary shall determine whether
13 to accept a qualification submission based on
14 factors which may include the scientific merit of
15 the submission and the available resources of
16 the Food and Drug Administration to review
17 the qualification submission. A determination
18 not to accept a submission under paragraph (1)
19 shall not be construed as a final determination
20 by the Secretary under this section regarding
21 the qualification of a drug development tool for
22 its proposed context of use.

23 “(C) PRIORITIZATION OF QUALIFICATION
24 REVIEW.—The Secretary may prioritize the re-
25 view of a full qualification package submitted

1 under paragraph (1) with respect to a drug de-
2 velopment tool, based on factors determined ap-
3 propriate by the Secretary, including—

4 “(i) as applicable, the severity, rarity,
5 or prevalence of the disease or condition
6 targeted by the drug development tool and
7 the availability or lack of alternative treat-
8 ments for such disease or condition; and

9 “(ii) the identification, by the Sec-
10 retary or by biomedical research consortia
11 and other expert stakeholders, of such a
12 drug development tool and its proposed
13 context of use as a public health priority.

14 “(D) ENGAGEMENT OF EXTERNAL EX-
15 PERTS.—The Secretary may, for purposes of
16 the review of qualification submissions, through
17 the use of cooperative agreements, grants, or
18 other appropriate mechanisms, consult with bio-
19 medical research consortia and may consider
20 the recommendations of such consortia with re-
21 spect to the review of any qualification plan
22 submitted under paragraph (1) or the review of
23 any full qualification package under paragraph
24 (3).

1 “(3) REVIEW OF FULL QUALIFICATION PACK-
2 AGE.—The Secretary shall—

3 “(A) conduct a comprehensive review of a
4 full qualification package accepted under para-
5 graph (1)(C); and

6 “(B) determine whether the drug develop-
7 ment tool at issue is qualified for its proposed
8 context of use.

9 “(4) QUALIFICATION.—The Secretary shall de-
10 termine whether a drug development tool is qualified
11 for a proposed context of use based on the scientific
12 merit of a full qualification package reviewed under
13 paragraph (3).

14 “(b) EFFECT OF QUALIFICATION.—

15 “(1) IN GENERAL.—A drug development tool
16 determined to be qualified under subsection (a)(4)
17 for a proposed context of use specified by the re-
18 questor may be used by any person in such context
19 of use for the purposes described in paragraph (2).

20 “(2) USE OF A DRUG DEVELOPMENT TOOL.—
21 Subject to paragraph (3), a drug development tool
22 qualified under this section may be used for—

23 “(A) supporting or obtaining approval or
24 licensure (as applicable) of a drug or biological
25 product (including in accordance with section

1 506(c)) under section 505 of this Act or section
2 351 of the Public Health Service Act; or

3 “(B) supporting the investigational use of
4 a drug or biological product under section
5 505(i) of this Act or section 351(a)(3) of the
6 Public Health Service Act.

7 “(3) RESCISSION OR MODIFICATION.—

8 “(A) IN GENERAL.—The Secretary may re-
9 scind or modify a determination under this sec-
10 tion to qualify a drug development tool if the
11 Secretary determines that the drug development
12 tool is not appropriate for the proposed context
13 of use specified by the requestor. Such a deter-
14 mination may be based on new information that
15 calls into question the basis for such qualifica-
16 tion.

17 “(B) MEETING FOR REVIEW.—If the Sec-
18 retary rescinds or modifies under subparagraph
19 (A) a determination to qualify a drug develop-
20 ment tool, the requestor involved shall, on re-
21 quest, be granted a meeting with the Secretary
22 to discuss the basis of the Secretary’s decision
23 to rescind or modify the determination before
24 the effective date of the rescission or modifica-
25 tion.

1 “(c) TRANSPARENCY.—

2 “(1) IN GENERAL.—Subject to paragraph (3),
3 the Secretary shall make publicly available, and up-
4 date on at least a biannual basis, on the Internet
5 website of the Food and Drug Administration the
6 following:

7 “(A) Information with respect to each
8 qualification submission under the qualification
9 process under subsection (a), including—

10 “(i) the stage of the review process
11 applicable to the submission;

12 “(ii) the date of the most recent
13 change in stage status;

14 “(iii) whether the external scientific
15 experts were utilized in the development of
16 a qualification plan or the review of a full
17 qualification package; and

18 “(iv) submissions from requestors
19 under the qualification process under sub-
20 section (a), including any data and evi-
21 dence contained in such submissions, and
22 any updates to such submissions.

23 “(B) The Secretary’s formal written deter-
24 minations in response to such qualification sub-
25 missions.

1 “(C) Any rescissions or modifications
2 under subsection (b)(3) of a determination to
3 qualify a drug development tool.

4 “(D) Summary reviews that document con-
5 clusions and recommendations for determina-
6 tions to qualify drug development tools under
7 subsection (a).

8 “(E) A comprehensive list of—

9 “(i) all drug development tools quali-
10 fied under subsection (a); and

11 “(ii) all surrogate endpoints which
12 were the basis of approval or licensure (as
13 applicable) of a drug or biological product
14 (including in accordance with section
15 506(e)) under section 505 of this Act or
16 section 351 of the Public Health Service
17 Act.

18 “(2) RELATION TO TRADE SECRETS ACT.—In-
19 formation made publicly available by the Secretary
20 under paragraph (1) shall be considered a disclosure
21 authorized by law for purposes of section 1905 of
22 title 18, United States Code.

23 “(3) APPLICABILITY.—Nothing in this section
24 shall be construed as authorizing the Secretary to
25 disclose any information contained in an application

1 submitted under section 505 of this Act or section
2 351 of the Public Health Service Act that is con-
3 fidential commercial or trade secret information sub-
4 ject to section 552(b)(4) of title 5, United States
5 Code, or section 1905 of title 18, United States
6 Code.

7 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
8 tion shall be construed—

9 “(1) to alter the standards of evidence under
10 subsection (c) or (d) of section 505, including the
11 substantial evidence standard in such subsection (d),
12 or under section 351 of the Public Health Service
13 Act (as applicable); or

14 “(2) to limit the authority of the Secretary to
15 approve or license products under this Act or the
16 Public Health Service Act, as applicable (as in effect
17 before the date of the enactment of the 21st Century
18 Cures Act).

19 “(e) DEFINITIONS.—In this section:

20 “(1) BIOMARKER.—(A) The term ‘biomarker’
21 means a characteristic (such as a physiologic,
22 pathologic, or anatomic characteristic or measure-
23 ment) that is objectively measured and evaluated as
24 an indicator of normal biologic processes, pathologic

1 processes, or biological responses to a therapeutic
2 intervention; and

3 “(B) such term includes a surrogate endpoint.

4 “(2) BIOMEDICAL RESEARCH CONSORTIA.—The
5 term ‘biomedical research consortia’ means collabo-
6 rative groups that may take the form of public-pri-
7 vate partnerships and may include government agen-
8 cies, institutions of higher education (as defined in
9 section 101(a) of the Higher Education Act of
10 1965), patient advocacy groups, industry representa-
11 tives, clinical and scientific experts, and other rel-
12 evant entities and individuals.

13 “(3) CLINICAL OUTCOME ASSESSMENT.—(A)
14 The term ‘clinical outcome assessment’ means a
15 measurement of a patient’s symptoms, overall men-
16 tal state, or the effects of a disease or condition on
17 how the patient functions; and

18 “(B) such term includes a patient-reported out-
19 come.

20 “(4) CONTEXT OF USE.—The term ‘context of
21 use’ means, with respect to a drug development tool,
22 the circumstances under which the drug development
23 tool is to be used in drug development and regu-
24 latory review.

1 “(5) DRUG DEVELOPMENT TOOL.—The term
2 ‘drug development tool’ includes—

3 “(A) a biomarker;

4 “(B) a clinical outcome assessment; and

5 “(C) any other method, material, or meas-
6 ure that the Secretary determines aids drug de-
7 velopment and regulatory review for purposes of
8 this section.

9 “(6) PATIENT-REPORTED OUTCOME.—The term
10 ‘patient-reported outcome’ means a measurement
11 based on a report from a patient regarding the sta-
12 tus of the patient’s health condition without amend-
13 ment or interpretation of the patient’s report by a
14 clinician or any other person.

15 “(7) QUALIFICATION.—The terms ‘qualifica-
16 tion’ and ‘qualified’ mean a determination by the
17 Secretary that a drug development tool and its pro-
18 posed context of use can be relied upon to have a
19 specific interpretation and application in drug devel-
20 opment and regulatory review under this Act.

21 “(8) REQUESTOR.—The term ‘requestor’ means
22 an entity or entities, including a drug sponsor or a
23 biomedical research consortia, seeking to qualify a
24 drug development tool for a proposed context of use
25 under this section.

1 “(9) SURROGATE ENDPOINT.—The term ‘surro-
2 gate endpoint’ means a marker, such as a laboratory
3 measurement, radiographic image, physical sign, or
4 other measure, that is not itself a direct measure-
5 ment of clinical benefit, and—

6 “(A) is known to predict clinical benefit
7 and could be used to support traditional ap-
8 proval of a drug or biological product; or

9 “(B) is reasonably likely to predict clinical
10 benefit and could be used to support the accel-
11 erated approval of a drug or biological product
12 in accordance with section 506(c).

13 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
14 are authorized to be appropriated to carry out this section,
15 \$10,000,000 for each of fiscal years 2016 through 2020.”.

16 (d) GUIDANCE.—

17 (1) IN GENERAL.—The Secretary of Health and
18 Human Services shall, in consultation with bio-
19 medical research consortia (as defined in subsection
20 (f) of section 507 the Federal Food, Drug, and Cos-
21 metic Act (as added by subsection (c))) and other
22 interested parties through a collaborative public
23 process, issue guidance to implement such section
24 507 that—

1 (A) provides a conceptual framework de-
2 scribing appropriate standards and scientific
3 approaches to support the development of bio-
4 markers delineated under the taxonomy estab-
5 lished under paragraph (3);

6 (B) makes recommendations for dem-
7 onstrating that a surrogate endpoint is reason-
8 ably likely to predict clinical benefit for the pur-
9 pose of supporting the accelerated approval of
10 a drug under section 506(c) of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C.
12 356(c));

13 (C) with respect to the qualification proc-
14 ess under such section 507—

15 (i) describes the requirements that en-
16 tities seeking to qualify a drug develop-
17 ment tool under such section shall observe
18 when engaging in such process;

19 (ii) outlines reasonable timeframes for
20 the Secretary's review of letters, qualifica-
21 tion plans, or full qualification packages
22 submitted under such process; and

23 (iii) establishes a process by which
24 such entities or the Secretary may consult
25 with biomedical research consortia and

1 other individuals and entities with expert
2 knowledge and insights that may assist the
3 Secretary in the review of qualification
4 plans and full qualification submissions
5 under such section; and

6 (D) includes such other information as the
7 Secretary determines appropriate.

8 (2) TIMING.—Not later than 24 months after
9 the date of the enactment of this Act, the Secretary
10 of Health and Human Services shall issue draft
11 guidance under paragraph (1) on the implementa-
12 tion of section 507 of the Federal Food, Drug, and
13 Cosmetic Act (as added by subsection (c)). The Sec-
14 retary shall issue final guidance on the implementa-
15 tion of such section not later than 6 months after
16 the date on which the comment period for the draft
17 guidance closes.

18 (3) TAXONOMY.—

19 (A) IN GENERAL.—For purposes of in-
20 forming guidance under this subsection, the
21 Secretary of Health and Human Services shall,
22 in consultation with biomedical research con-
23 sortia and other interested parties through a
24 collaborative public process, establish a tax-
25 onomy for the classification of biomarkers (and

1 related scientific concepts) for use in drug de-
2 velopment.

3 (B) PUBLIC AVAILABILITY.—Not later
4 than 12 months after the date of the enactment
5 of this Act, the Secretary of Health and Human
6 Services shall make such taxonomy publicly
7 available in draft form for public comment. The
8 Secretary shall finalize the taxonomy not later
9 than 12 months after the close of the public
10 comment period.

11 (e) MEETING AND REPORT.—

12 (1) MEETING.—Not later than 12 months after
13 the date of the enactment of this Act, the Secretary
14 of Health and Human Services shall convene a pub-
15 lic meeting to describe and solicit public input re-
16 garding the qualification process under section 507
17 of the Federal Food, Drug, and Cosmetic Act, as
18 added by subsection (c).

19 (2) REPORT.—Not later than 5 years after the
20 date of the enactment of this Act, the Secretary
21 shall make publicly available on the Internet website
22 of the Food and Drug Administration a report. Such
23 report shall include, with respect to the qualification
24 process under section 507 of the Federal Food,

1 Drug, and Cosmetic Act, as added by subsection (c),
2 information on—

3 (A) the number of requests submitted, as
4 a letter of intent, for qualification of a drug de-
5 velopment tool (as defined in subsection (f) of
6 such section);

7 (B) the number of such requests accepted
8 and determined to be eligible for submission of
9 a qualification plan or full qualification package
10 (as such terms are defined in such subsection),
11 respectively;

12 (C) the number of such requests for which
13 external scientific experts were utilized in the
14 development of a qualification plan or review of
15 a full qualification package;

16 (D) the number of qualification plans and
17 full qualification packages, respectively, sub-
18 mitted to the Secretary; and

19 (E) the drug development tools qualified
20 through such qualification process, specified by
21 type of tool, such as a biomarker or clinical out-
22 come assessment (as such terms are defined in
23 subsection (f) of such section 507).

1 **SEC. 2022. ACCELERATED APPROVAL DEVELOPMENT PLAN.**

2 (a) IN GENERAL.—Section 506 of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 356) is amended by
4 adding the following subsection:

5 “(g) ACCELERATED APPROVAL DEVELOPMENT
6 PLAN.—

7 “(1) IN GENERAL.—In the case of a drug that
8 the Secretary determines may be eligible for acceler-
9 ated approval in accordance with subsection (c), the
10 sponsor of such drug may request, at any time after
11 the submission of an application for the investigation
12 of the drug under section 505(i) of this Act or sec-
13 tion 351(a)(3) of the Public Health Service Act, that
14 the Secretary agree to an accelerated approval devel-
15 opment plan described in paragraph (2).

16 “(2) PLAN DESCRIBED.—A plan described in
17 this paragraph, with respect to a drug described in
18 paragraph (1), is an accelerated approval develop-
19 ment plan, which shall include agreement on—

20 “(A) the surrogate endpoint to be assessed
21 under such plan;

22 “(B) the design of the study that will uti-
23 lize the surrogate endpoint; and

24 “(C) the magnitude of the effect of the
25 drug on the surrogate endpoint that is the sub-
26 ject of the agreement that would be sufficient

1 to form the primary basis of a claim that the
2 drug is effective.

3 “(3) MODIFICATION; TERMINATION.—The Sec-
4 retary may require the sponsor of a drug that is the
5 subject of an accelerated approval development plan
6 to modify or terminate the plan if additional data or
7 information indicates that—

8 “(A) the plan as originally agreed upon is
9 no longer sufficient to demonstrate the safety
10 and effectiveness of the drug involved; or

11 “(B) the drug is no longer eligible for ac-
12 celerated approval under subsection (c).

13 “(4) SPONSOR CONSULTATION.—If the Sec-
14 retary requires the modification or termination of an
15 accelerated approval development plan under para-
16 graph (3), the sponsor shall be granted a request for
17 a meeting to discuss the basis of the Secretary’s de-
18 cision before the effective date of the modification or
19 termination.

20 “(5) DEFINITION.—In this section, the term
21 ‘accelerated approval development plan’ means a de-
22 velopment plan agreed upon by the Secretary and
23 the sponsor submitting the plan that contains study
24 parameters for the use of a surrogate endpoint
25 that—

1 “(A) is reasonably likely to predict clinical
2 benefit; and

3 “(B) is intended to be the basis of the ac-
4 celerated approval of a drug in accordance with
5 subsection (c).”.

6 (b) TECHNICAL AMENDMENTS.—Section 506 of the
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356)
8 is amended—

9 (1) by striking “(f) AWARENESS EFFORTS” and
10 inserting “(e) AWARENESS EFFORTS”; and

11 (2) by striking “(e) CONSTRUCTION” and in-
12 serting “(f) CONSTRUCTION”.

13 **Subtitle C—FDA Advancement of** 14 **Precision Medicine**

15 **SEC. 2041. PRECISION MEDICINE GUIDANCE AND OTHER** 16 **PROGRAMS OF FOOD AND DRUG ADMINIS-** 17 **TRATION.**

18 Chapter V of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 351 et seq.) is amended by adding at the
20 end the following:

21 **“Subchapter J—Precision Medicine**

22 **“SEC. 591. GENERAL AGENCY GUIDANCE ON PRECISION** 23 **MEDICINE.**

24 “(a) IN GENERAL.—The Secretary shall issue and
25 periodically update guidance to assist sponsors in the de-

1 velopment of a precision drug or biological product. Such
2 guidance shall—

3 “(1) define the term ‘precision drug or biologi-
4 cal product’; and

5 “(2) address the topics described in subsection
6 (b).

7 “(b) CERTAIN ISSUES.—The topics to be addressed
8 by guidance under subsection (a) are—

9 “(1) the evidence needed to support the use of
10 biomarkers (as defined in section 507(e)) that iden-
11 tify subsets of patients as likely responders to thera-
12 pies in order to streamline the conduct of clinical
13 trials;

14 “(2) recommendations for the design of studies
15 to demonstrate the validity of a biomarker as a pre-
16 dictor of drug or biological product response;

17 “(3) the manner and extent to which a benefit-
18 risk assessment may be affected when clinical trials
19 are limited to patient population subsets that are
20 identified using biomarkers;

21 “(4) the development of companion diagnostics
22 in the context of a drug development program; and

23 “(5) considerations for developing biomarkers
24 that inform prescribing decisions for a drug or bio-
25 logical product, and when information regarding a

1 biomarker may be included in the approved prescrip-
2 tion labeling for a precision drug or biological prod-
3 uct.

4 “(c) DATE CERTAIN FOR INITIAL GUIDANCE.—The
5 Secretary shall issue guidance under subsection (a) not
6 later than 18 months after the date of the enactment of
7 the 21st Century Cures Act.

8 **“SEC. 592. PRECISION MEDICINE REGARDING ORPHAN-**
9 **DRUG AND EXPEDITED-APPROVAL PRO-**
10 **GRAMS.**

11 “(a) IN GENERAL.—In the case of a precision drug
12 or biological product that is the subject of an application
13 submitted under section 505(b)(1), or section 351(a) of
14 the Public Health Service Act, for the treatment of a seri-
15 ous or life-threatening disease or condition and has been
16 designated under section 526 as a drug for a rare disease
17 or condition, the Secretary may—

18 “(1) consistent with applicable standards for
19 approval, rely upon data or information previously
20 submitted by the sponsor of the precision drug or bi-
21 ological product, or another sponsor, provided that
22 the sponsor of the precision drug or biological prod-
23 uct has obtained a contractual right of reference to
24 such other sponsor’s data and information, in an ap-
25 plication approved under section 505(c) or licensed

1 under section 351(a) of the Public Health Service
2 Act, as applicable—

3 “(A) for a different drug or biological
4 product; or

5 “(B) for a different indication for such
6 precision drug or biological product,

7 in order to expedite clinical development for a preci-
8 sion drug or biological product that is using the
9 same or similar approach as that used to support
10 approval of the prior approved application or license,
11 as appropriate; and

12 “(2) as appropriate, consider the application for
13 approval of such precision drug or biological product
14 to be eligible for expedited review and approval pro-
15 grams described in section 506, including acceler-
16 ated approval in accordance with subsection (c) of
17 such section.

18 “(b) RULE OF CONSTRUCTION.—Nothing in this sec-
19 tion shall be construed to—

20 “(1) limit the authority of the Secretary to ap-
21 prove products pursuant to this Act and the Public
22 Health Service Act as authorized prior to the date
23 of enactment of this section; or

24 “(2) confer any new rights, beyond those au-
25 thorized under this Act prior to enactment of this

1 section, with respect to a sponsor’s ability to ref-
2 erence information contained in another application
3 submitted under section 505(b)(1) of this Act or sec-
4 tion 351(a) of the Public Health Service Act.”.

5 **Subtitle D—Modern Trial Design**
6 **and Evidence Development**

7 **SEC. 2061. BROADER APPLICATION OF BAYESIAN STATIS-**
8 **TICS AND ADAPTIVE TRIAL DESIGNS.**

9 (a) PROPOSALS FOR USE OF INNOVATIVE STATIS-
10 TICAL METHODS IN CLINICAL PROTOCOLS FOR DRUGS
11 AND BIOLOGICAL PRODUCTS.—For purposes of assisting
12 sponsors in incorporating adaptive trial design and
13 Bayesian methods into proposed clinical protocols and ap-
14 plications for new drugs under section 505 of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 355) and bio-
16 logical products under section 351 of the Public Health
17 Service Act (42 U.S.C. 262), the Secretary shall conduct
18 a public meeting and issue guidance in accordance with
19 subsection (b).

20 (b) GUIDANCE ADDRESSING USE OF ADAPTIVE
21 TRIAL DESIGNS AND BAYESIAN METHODS.—

22 (1) IN GENERAL.—The Secretary of Health and
23 Human Services, acting through the Commissioner
24 of Food and Drugs (in this subsection referred to as
25 the “Secretary”), shall—

1 (A) update and finalize the draft guidance
2 addressing the use of adaptive trial design for
3 drugs and biological products; and

4 (B) issue draft guidance on the use of
5 Bayesian methods in the development and regu-
6 latory review and approval or licensure of drugs
7 and biological products.

8 (2) CONTENTS.—The guidances under para-
9 graph (1) shall address—

10 (A) the use of adaptive trial designs and
11 Bayesian methods in clinical trials, including
12 clinical trials proposed or submitted to help to
13 satisfy the substantial evidence standard under
14 section 505(d) of the Federal Food, Drug, and
15 Cosmetic Act (21 U.S.C. 355(d));

16 (B) how sponsors may obtain feedback
17 from the Secretary on technical issues related
18 to modeling and simulations prior to—

19 (i) completion of such modeling or
20 simulations; or

21 (ii) the submission of resulting infor-
22 mation to the Secretary;

23 (C) the types of quantitative and quali-
24 tative information that should be submitted for
25 review; and

1 (D) recommended analysis methodologies.

2 (3) PUBLIC MEETING.—Prior to updating or
3 developing the guidances required by paragraph (1),
4 the Secretary shall consult with stakeholders, includ-
5 ing representatives of regulated industry, academia,
6 patient advocacy organizations, and disease research
7 foundations, through a public meeting to be held not
8 later than 1 year after the date of enactment of this
9 Act.

10 (4) SCHEDULE.—The Secretary shall publish—

11 (A) the final guidance required by para-
12 graph (1)(A) not later than 18 months after the
13 date of the public meeting required by para-
14 graph (3); and

15 (B) the guidance required by paragraph
16 (1)(B) not later than 48 months after the date
17 of the public meeting required by paragraph
18 (3).

19 **SEC. 2062. UTILIZING EVIDENCE FROM CLINICAL EXPERI-**
20 **ENCE.**

21 Chapter V of the Federal Food, Drug, and Cosmetic
22 Act is amended by inserting after section 505E of such
23 Act (21 U.S.C. 355f) the following:

1 **“SEC. 505F. UTILIZING EVIDENCE FROM CLINICAL EXPERI-**
2 **ENCE.**

3 “(a) IN GENERAL.—The Secretary shall establish a
4 program to evaluate the potential use of evidence from
5 clinical experience—

6 “(1) to help to support the approval of a new
7 indication for a drug approved under section 505(b);
8 and

9 “(2) to help to support or satisfy postapproval
10 study requirements.

11 “(b) EVIDENCE FROM CLINICAL EXPERIENCE DE-
12 FINED.—In this section, the term ‘evidence from clinical
13 experience’ means data regarding the usage, or the poten-
14 tial benefits or risks, of a drug derived from sources other
15 than randomized clinical trials, including from observa-
16 tional studies, registries, and therapeutic use.

17 “(c) PROGRAM FRAMEWORK.—

18 “(1) IN GENERAL.—Not later than 18 months
19 after the date of enactment of this section, the Sec-
20 retary shall establish a draft framework for imple-
21 mentation of the program under this section.

22 “(2) CONTENTS OF FRAMEWORK.—The frame-
23 work shall include information describing—

24 “(A) the current sources of data developed
25 through clinical experience, including ongoing

1 safety surveillance, registry, claims, and pa-
2 tient-centered outcomes research activities;

3 “(B) the gaps in current data collection ac-
4 tivities;

5 “(C) the current standards and methodolo-
6 gies for collection and analysis of data gen-
7 erated through clinical experience; and

8 “(D) the priority areas, remaining chal-
9 lenges, and potential pilot opportunities that
10 the program established under this section will
11 address.

12 “(3) CONSULTATION.—

13 “(A) IN GENERAL.—In developing the pro-
14 gram framework under this subsection, the Sec-
15 retary shall consult with regulated industry,
16 academia, medical professional organizations,
17 representatives of patient advocacy organiza-
18 tions, disease research foundations, and other
19 interested parties.

20 “(B) PROCESS.—The consultation under
21 subparagraph (A) may be carried out through
22 approaches such as—

23 “(i) a public-private partnership with
24 the entities described in such subparagraph
25 in which the Secretary may participate; or

1 “(ii) a contract, grant, or other ar-
2 rangement, as determined appropriate by
3 the Secretary with such a partnership or
4 an independent research organization.

5 “(d) PROGRAM IMPLEMENTATION.—The Secretary
6 shall, not later than 24 months after the date of enact-
7 ment of this section and in accordance with the framework
8 established under subsection (c), implement the program
9 to evaluate the potential use of evidence from clinical expe-
10 rience.

11 “(e) GUIDANCE FOR INDUSTRY.—The Secretary
12 shall—

13 “(1) utilize the program established under sub-
14 section (a), its activities, and any subsequent pilots
15 or written reports, to inform a guidance for industry
16 on—

17 “(A) the circumstances under which spon-
18 sors of drugs and the Secretary may rely on
19 evidence from clinical experience for the pur-
20 poses described in subsection (a)(1) or (a)(2);
21 and

22 “(B) the appropriate standards and meth-
23 odologies for collection and analysis of evidence
24 from clinical experience submitted for such pur-
25 poses;

1 “(2) not later than 36 months after the date of
2 enactment of this section, issue draft guidance for
3 industry as described in paragraph (1); and

4 “(3) not later than 48 months after the date of
5 enactment of this section, after providing an oppor-
6 tunity for public comment on the draft guidance,
7 issue final guidance.

8 “(f) RULE OF CONSTRUCTION.—

9 “(1) Subject to paragraph (2), nothing in this
10 section prohibits the Secretary from using evidence
11 from clinical experience for purposes not specified in
12 this section, provided the Secretary determines that
13 sufficient basis exists for any such nonspecified use.

14 “(2) This section shall not be construed to
15 alter—

16 “(A) the standards of evidence under—

17 “(i) subsection (c) or (d) of section
18 505, including the substantial evidence
19 standard in such subsection (d); or

20 “(ii) section 351(a) of the Public
21 Health Service Act; or

22 “(B) the Secretary’s authority to require
23 postapproval studies or clinical trials, or the
24 standards of evidence under which studies or
25 trials are evaluated.

1 **“SEC. 505G. COLLECTING EVIDENCE FROM CLINICAL EXPERIENCE THROUGH TARGETED EXTENSIONS**
2 **OF THE SENTINEL SYSTEM.**

3
4 “(a) IN GENERAL.—The Secretary shall, in parallel
5 to implementing the program established under section
6 505F and in order to build capacity for utilizing the evi-
7 dence from clinical experience described in that section,
8 identify and execute pilot demonstrations to extend exist-
9 ing use of the Sentinel System surveillance infrastructure
10 authorized under section 505(k).

11 “(b) PILOT DEMONSTRATIONS.—

12 “(1) IN GENERAL.—The Secretary—

13 “(A) shall design and implement pilot dem-
14 onstrations to utilize data captured through the
15 Sentinel System surveillance infrastructure au-
16 thorized under section 505(k) for purposes of,
17 as appropriate—

18 “(i) generating evidence from clinical
19 experience to improve characterization or
20 assessment of risks or benefits of a drug
21 approved under section 505(c);

22 “(ii) protecting the public health; or

23 “(iii) advancing patient-centered care;

24 and

25 “(B) may make strategic linkages with
26 sources of complementary public health data

1 and infrastructure the Secretary determines ap-
2 propriate and necessary.

3 “(2) CONSULTATION.—In developing the pilot
4 demonstrations under this subsection, the Secretary
5 shall—

6 “(A) consult with regulated industry, aca-
7 demia, medical professional organizations, rep-
8 resentatives of patient advocacy organizations,
9 disease research foundations, and other inter-
10 ested parties through a public process; and

11 “(B) develop a framework to promote ap-
12 propriate transparency and dialogue about re-
13 search conducted under these pilot demonstra-
14 tions, including by—

15 “(i) providing adequate notice to a
16 sponsor of a drug approved under section
17 505 or section 351 of the Public Health
18 Service Act of the Secretary’s intent to
19 conduct analyses of such sponsor’s drug or
20 drugs under these pilot demonstrations;

21 “(ii) providing adequate notice of the
22 findings related to analyses described in
23 clause (i) and an opportunity for the spon-
24 sor of such drug or drugs to comment on
25 such findings; and

1 “(iii) ensuring the protection from
2 public disclosure of any information that is
3 a trade secret or confidential information
4 subject to section 552(b)(4) of title 5,
5 United States Code, or section 1905 of
6 title 18, United States Code.

7 “(3) HIPAA PRIVACY RULE; HUMAN SUBJECT
8 RESEARCH REGULATION.—The Secretary may deem
9 such pilot demonstrations—

10 “(A) public health activities, for purposes
11 of which a use or disclosure of protected health
12 information would be permitted as described in
13 section 164.512(b)(1) of title 45, Code of Fed-
14 eral Regulations (or any successor regulation);
15 and

16 “(B) outside the scope of ‘research’ as de-
17 fined in section 46.102(d) of title 45, Code of
18 Federal Regulations (or any successor regula-
19 tion).

20 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
21 are authorized to be appropriated to carry out this section
22 \$3,000,000 for each of fiscal years 2016 through 2020.”.

23 **SEC. 2063. STREAMLINED DATA REVIEW PROGRAM.**

24 (a) IN GENERAL.—Chapter V of the Federal Food,
25 Drug, and Cosmetic Act, as amended by section 2062, is

1 further amended by inserting after section 505G of such
2 Act the following:

3 **“SEC. 505H. STREAMLINED DATA REVIEW PROGRAM.**

4 “(a) IN GENERAL.—The Secretary shall establish a
5 streamlined data review program under which a holder of
6 an approved application submitted under section
7 505(b)(1) or under section 351(a) of the Public Health
8 Service Act may, to support the approval or licensure (as
9 applicable) of the use of the drug that is the subject of
10 such approved application for a new qualified indication,
11 submit qualified data summaries.

12 “(b) ELIGIBILITY.—In carrying out the streamlined
13 data review program under subsection (a), the Secretary
14 may authorize the holder of the approved application to
15 include one or more qualified data summaries described
16 in subsection (a) in a supplemental application if—

17 “(1) the drug has been approved under section
18 505(c) of this Act or licensed under section 351(a)
19 of the Public Health Service Act for one or more in-
20 dications, and such approval or licensure remains in
21 effect;

22 “(2) the supplemental application is for ap-
23 proval or licensure (as applicable) under such section
24 505(c) or 351(a) of the use of the drug for a new

1 qualified indication under such section 505(c) or
2 351(a);

3 “(3) there is an existing database acceptable to
4 the Secretary regarding the safety of the drug devel-
5 oped for one or more indications of the drug ap-
6 proved under such section 505(c) or licensed under
7 such section 351(a);

8 “(4) the supplemental application incorporates
9 or supplements the data submitted in the application
10 for approval or licensure referred to in paragraph
11 (1); and

12 “(5) the full data sets used to develop the quali-
13 fied data summaries are submitted, unless the Sec-
14 retary determines that the full data sets are not re-
15 quired.

16 “(c) PUBLIC AVAILABILITY OF INFORMATION ON
17 PROGRAM.—The Secretary shall post on the public website
18 of the Food and Drug Administration and update annu-
19 ally—

20 “(1) the number of applications reviewed under
21 the streamlined data review program;

22 “(2) the average time for completion of review
23 under the streamlined data review program versus
24 other review of applications for new indications; and

1 “(3) the number of applications reviewed under
2 the streamlined data review program for which the
3 Food and Drug Administration made use of full
4 data sets in addition to the qualified data summary.

5 “(d) DEFINITIONS.—In this section:

6 “(1) The term ‘qualified indication’ means—

7 “(A) an indication for the treatment of
8 cancer, as determined appropriate by the Sec-
9 retary; or

10 “(B) such other types of indications as the
11 Secretary determines to be subject to the
12 streamlined data review program under this
13 section.

14 “(2) The term ‘qualified data summary’ means
15 a summary of clinical data intended to demonstrate
16 safety and effectiveness with respect to a qualified
17 indication for use of a drug.”.

18 (b) SENSE OF CONGRESS.—It is the sense of Con-
19 gress that the streamlined data review program under sec-
20 tion 505H of the Federal Food, Drug, and Cosmetic Act,
21 as added by subsection (a), should enable the Food and
22 Drug Administration to make approval decisions for cer-
23 tain supplemental applications based on qualified data
24 summaries (as defined in such section 505H).

1 (c) GUIDANCE; REGULATIONS.—The Commissioner
2 of Food and Drugs—

3 (1) shall—

4 (A) issue final guidance for implementation
5 of the streamlined data review program estab-
6 lished under section 505H of the Federal Food,
7 Drug, and Cosmetic Act, as added by sub-
8 section (a), not later than 24 months after the
9 date of enactment of this Act; and

10 (B) include in such guidance the process
11 for expanding the types of indications to be
12 subject to the streamlined data review program,
13 as authorized by section 505H(c)(1)(B) of such
14 Act; and

15 (2) in addition to issuing guidance under para-
16 graph (1), may issue such regulations as may be
17 necessary for implementation of the program.

18 **Subtitle E—Expediting Patient**
19 **Access**

20 **SEC. 2081. SENSE OF CONGRESS.**

21 It is the sense of Congress that the Food and Drug
22 Administration should continue to expedite the approval
23 of drugs designated as breakthrough therapies pursuant
24 to section 506(a) of the Federal Food, Drug, and Cos-
25 metic Act (21 U.S.C. 356(a)) by approving drugs so des-

1 ignited as early as possible in the clinical development
2 process, regardless of the phase of development, provided
3 that the Secretary of Health and Human Services deter-
4 mines that an application for such a drug meets the stand-
5 ards of evidence of safety and effectiveness under section
6 505 of such Act (21 U.S.C. 355), including the substantial
7 evidence standard under subsection (d) of such section or
8 under section 351(a) of the Public Health Service Act (42
9 U.S.C. 262(a)).

10 **SEC. 2082. EXPANDED ACCESS POLICY.**

11 Chapter V of the Federal Food, Drug, and Cosmetic
12 Act is amended by inserting after section 561 (21 U.S.C.
13 360bbb) the following:

14 **“SEC. 561A. EXPANDED ACCESS POLICY REQUIRED FOR IN-**
15 **VESTIGATIONAL DRUGS.**

16 “(a) IN GENERAL.—The manufacturer or distributor
17 of one or more investigational drugs for the diagnosis,
18 monitoring, or treatment of one or more serious diseases
19 or conditions shall make publicly available the policy of
20 the manufacturer or distributor on evaluating and re-
21 sponding to requests submitted under section 561(b) for
22 provision of such a drug. A manufacturer or distributor
23 may satisfy the requirement of the preceding sentence by
24 posting such policy as generally applicable to all of such
25 manufacturer’s or distributor’s investigational drugs.

1 “(b) CONTENT OF POLICY.—A policy described in
2 subsection (a) shall include making publicly available—

3 “(1) contact information for the manufacturer
4 or distributor to facilitate communication about re-
5 quests described in subsection (a);

6 “(2) procedures for making such requests;

7 “(3) the general criteria the manufacturer or
8 distributor will consider or use to approve such re-
9 quests; and

10 “(4) the length of time the manufacturer or dis-
11 tributor anticipates will be necessary to acknowledge
12 receipt of such requests.

13 “(c) NO GUARANTEE OF ACCESS.—The posting of
14 policies by manufacturers and distributors under sub-
15 section (a) shall not serve as a guarantee of access to any
16 specific investigational drug by any individual patient.

17 “(d) REVISED POLICY.—A manufacturer or dis-
18 tributor that has made a policy publicly available as re-
19 quired by this section may revise the policy at any time.

20 “(e) APPLICATION.—This section shall apply to a
21 manufacturer or distributor with respect to an investiga-
22 tional drug beginning on the later of—

23 “(1) the date that is 60 days after the date of
24 enactment of the 21st Century Cures Act; or

1 “(2) the first initiation of a phase 2 or phase
2 3 study (as such terms are defined in section
3 312.21(b) and (c) of title 21, Code of Federal Regu-
4 lations (or any successor regulations)) with respect
5 to such investigational new drug.”.

6 **SEC. 2083. FINALIZING DRAFT GUIDANCE ON EXPANDED**
7 **ACCESS.**

8 (a) **IN GENERAL.**—Not later than 12 months after
9 the date of enactment of this Act, the Secretary of Health
10 and Human Services shall finalize the draft guidance enti-
11 tled “Expanded Access to Investigational Drugs for Treat-
12 ment Use—Qs & As” and dated May 2013.

13 (b) **CONTENTS.**—The final guidance referred to in
14 subsection (a) shall clearly define how the Secretary of
15 Health and Human Services interprets and uses adverse
16 drug event data reported by investigators in the case of
17 data reported from use under a request submitted under
18 section 561(b) of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 360bbb(b)).

1 **Subtitle F—Facilitating Respon-**
2 **sible Manufacturer Communica-**
3 **tions**

4 **SEC. 2101. FACILITATING DISSEMINATION OF HEALTH**
5 **CARE ECONOMIC INFORMATION.**

6 Section 502(a) of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 352(a)) is amended—

8 (1) by striking “(a) If its” and inserting
9 “(a)(1) If its”;

10 (2) by striking “a formulary committee, or
11 other similar entity, in the course of the committee
12 or the entity carrying out its responsibilities for the
13 selection of drugs for managed care or other similar
14 organizations” and inserting “a payor, formulary
15 committee, or other similar entity with knowledge
16 and expertise in the area of health care economic
17 analysis, carrying out its responsibilities for the se-
18 lection of drugs for coverage or reimbursement”;

19 (3) by striking “directly relates” and inserting
20 “relates”;

21 (4) by striking “and is based on competent and
22 reliable scientific evidence. The requirements set
23 forth in section 505(a) or in section 351(a) of the
24 Public Health Service Act shall not apply to health
25 care economic information provided to such a com-

1 mittee or entity in accordance with this paragraph”
2 and inserting “, is based on competent and reliable
3 scientific evidence, and includes, where applicable, a
4 conspicuous and prominent statement describing any
5 material differences between the health care eco-
6 nomic information and the labeling approved for the
7 drug under section 505 or under section 351 of the
8 Public Health Service Act. The requirements set
9 forth in section 505(a) or in subsections (a) and (k)
10 of section 351 of the Public Health Service Act shall
11 not apply to health care economic information pro-
12 vided to such a payor, committee, or entity in ac-
13 cordance with this paragraph”; and

14 (5) by striking “In this paragraph, the term”
15 and all that follows and inserting the following:

16 “(2)(A) For purposes of this paragraph, the term
17 ‘health care economic information’ means any analysis (in-
18 cluding the clinical data, inputs, clinical or other assump-
19 tions, methods, results, and other components underlying
20 or comprising the analysis) that identifies, measures, or
21 describes the economic consequences, which may be based
22 on the separate or aggregated clinical consequences of the
23 represented health outcomes, of the use of a drug. Such
24 analysis may be comparative to the use of another drug,
25 to another health care intervention, or to no intervention.

1 “(B) Such term does not include any analysis that
2 relates only to an indication that is not approved under
3 section 505 or under section 351 of the Public Health
4 Service Act for such drug.”.

5 **SEC. 2102. FACILITATING RESPONSIBLE COMMUNICATION**
6 **OF SCIENTIFIC AND MEDICAL DEVELOP-**
7 **MENTS.**

8 (a) GUIDANCE.—Not later than 18 months after the
9 date of enactment of this Act, the Secretary of Health and
10 Human Services shall issue draft guidance on facilitating
11 the responsible dissemination of truthful and nonmis-
12 leading scientific and medical information not included in
13 the approved labeling of drugs and devices.

14 (b) DEFINITION.—In this section, the terms “drug”
15 and “device” have the meaning given to such terms in sec-
16 tion 201 of the Federal Food, Drug, and Cosmetic Act
17 (21 U.S.C. 321).

18 **Subtitle G—Antibiotic Drug**
19 **Development**

20 **SEC. 2121. APPROVAL OF CERTAIN DRUGS FOR USE IN A**
21 **LIMITED POPULATION OF PATIENTS.**

22 (a) PURPOSE.—The purpose of this section is to help
23 to expedite the development and availability of treatments
24 for serious or life-threatening bacterial or fungal infections
25 in patients with unmet needs, while maintaining safety

1 and effectiveness standards for such treatments, taking
2 into account the severity of the infection and the avail-
3 ability or lack of alternative treatments.

4 (b) APPROVAL OF CERTAIN ANTIBACTERIAL AND
5 ANTIFUNGAL DRUGS.—Section 505 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 355), as amended by
7 section 2001, is further amended by adding at the end
8 the following new subsection:

9 “(z) APPROVAL OF CERTAIN ANTIBACTERIAL AND
10 ANTIFUNGAL DRUGS FOR USE IN A LIMITED POPU-
11 LATION OF PATIENTS.—

12 “(1) PROCESS.—At the request of the sponsor
13 of an antibacterial or antifungal drug that is in-
14 tended to treat a serious or life-threatening infec-
15 tion, the Secretary—

16 “(A) may execute a written agreement
17 with the sponsor on the process for developing
18 data to support an application for approval of
19 such drug, for use in a limited population of pa-
20 tients in accordance with this subsection;

21 “(B) shall proceed in accordance with this
22 subsection only if a written agreement is
23 reached under subparagraph (A);

1 “(C) shall provide the sponsor with an op-
2 portunity to request meetings under paragraph
3 (2);

4 “(D) if a written agreement is reached
5 under subparagraph (A), may approve the drug
6 under this subsection for such use—

7 “(i) in a limited population of patients
8 for which there is an unmet medical need;

9 “(ii) based on a streamlined develop-
10 ment program; and

11 “(iii) only if the standards for ap-
12 proval under subsections (c) and (d) of this
13 section or licensure under section 351 of
14 the Public Health Service Act, as applica-
15 ble, are met; and

16 “(E) in approving a drug in accordance
17 with this subsection, subject to subparagraph
18 (D)(iii), may rely upon—

19 “(i) traditional endpoints, alternate
20 endpoints, or a combination of traditional
21 and alternate endpoints, and, as appro-
22 priate, data sets of a limited size; and

23 “(ii)(I) additional data, including pre-
24 clinical, pharmacologic, or pathophysiologic
25 evidence;

1 “(II) nonclinical susceptibility and
2 pharmacokinetic data;

3 “(III) data from phase 2 clinical
4 trials; and

5 “(IV) such other confirmatory evi-
6 dence as the Secretary determines appro-
7 priate to approve the drug.

8 “(2) FORMAL MEETINGS.—

9 “(A) IN GENERAL.—To help to expedite
10 and facilitate the development and review of a
11 drug for which a sponsor intends to request ap-
12 proval in accordance with this subsection, the
13 Secretary may, at the request of the sponsor,
14 conduct meetings that provide early consulta-
15 tion, timely advice, and sufficient opportunities
16 to develop an agreement described in paragraph
17 (1)(A) and help the sponsor design and conduct
18 a drug development program as efficiently as
19 possible, including the following types of meet-
20 ings:

21 “(i) An early consultation meeting.

22 “(ii) An assessment meeting.

23 “(iii) A postapproval meeting.

24 “(B) NO ALTERING OF GOALS.—Nothing
25 in this paragraph shall be construed to alter

1 agreed-upon goals and procedures identified in
2 the letters described in section 101(b) of the
3 Prescription Drug User Fee Amendments of
4 2012.

5 “(C) BREAKTHROUGH THERAPIES.—In the
6 case of a drug designated as a breakthrough
7 therapy under section 506(a), the sponsor of
8 such drug may elect to utilize meetings pro-
9 vided under such section with respect to such
10 drug in lieu of meetings described in subpara-
11 graph (A).

12 “(3) LABELING REQUIREMENT.—The labeling
13 of an antibacterial or antifungal drug approved in
14 accordance with this subsection shall contain the
15 statement ‘Limited Population’ in a prominent man-
16 ner and adjacent to, and not more prominent than,
17 the brand name of the product. The prescribing in-
18 formation for such antibacterial or antifungal drug
19 required by section 201.57 of title 21, Code of Fed-
20 eral Regulations (or any successor regulation) shall
21 also include the following statement: ‘This drug is
22 indicated for use in a limited and specific population
23 of patients.’.

24 “(4) PROMOTIONAL MATERIALS.—The provi-
25 sions of section 506(e)(2)(B) shall apply with re-

1 spect to approval in accordance with this subsection
2 to the same extent and in the same manner as such
3 provisions apply with respect to accelerated approval
4 in accordance with section 506(c)(1).

5 “(5) TERMINATION OF REQUIREMENTS OR CON-
6 DITIONS.—If a drug is approved in accordance with
7 this subsection for an indication in a limited popu-
8 lation of patients and is subsequently approved or li-
9 censed under this section or section 351 of the Pub-
10 lic Health Service Act, other than in accordance with
11 this subsection, for—

12 “(A) the same indication and the same
13 conditions of use, the Secretary shall remove
14 any labeling requirements or postmarketing
15 conditions that were made applicable to the
16 drug under this subsection; or

17 “(B) a different indication or condition of
18 use, the Secretary shall not apply the labeling
19 requirements and postmarketing conditions that
20 were made applicable to the drug under this
21 subsection to the subsequent approval of the
22 drug for such different indication or condition
23 of use.

24 “(6) RELATION TO OTHER PROVISIONS.—Noth-
25 ing in this subsection shall be construed to prohibit

1 the approval of a drug for use in a limited popu-
2 lation of patients in accordance with this subsection,
3 in combination with—

4 “(A) an agreement on the design and size
5 of a clinical trial pursuant to subparagraphs
6 (B) and (C) of subsection (b)(5);

7 “(B) designation and treatment of the
8 drug as a breakthrough therapy under section
9 506(a);

10 “(C) designation and treatment of the
11 drug as a fast track product under section
12 506(b); or

13 “(D) accelerated approval of the drug in
14 accordance with section 506(e).

15 “(7) RULE OF CONSTRUCTION.—Nothing in
16 this subsection shall be construed—

17 “(A) to alter the standards of evidence
18 under subsection (e) or (d) (including the sub-
19 stantial evidence standard in subsection (d));

20 “(B) to waive or otherwise preclude the ap-
21 plication of requirements under subsection (o);

22 “(C) to otherwise, in any way, limit the au-
23 thority of the Secretary to approve products
24 pursuant to this Act and the Public Health

1 Service Act as authorized prior to the date of
2 enactment of this subsection; or

3 “(D) to restrict in any manner, the pre-
4 scribing of antibiotics or other products by
5 health care providers, or to otherwise limit or
6 restrict the practice of health care.

7 “(8) EFFECTIVE IMMEDIATELY.—The Sec-
8 retary shall have the authorities vested in the Sec-
9 retary by this subsection beginning on the date of
10 enactment of this subsection, irrespective of when
11 and whether the Secretary promulgates final regula-
12 tions or guidance.

13 “(9) DEFINITIONS.—In this subsection:

14 “(A) EARLY CONSULTATION MEETING.—
15 The term ‘early consultation meeting’ means a
16 pre-investigational new drug meeting or an end-
17 of-phase-1 meeting that—

18 “(i) is conducted to review and reach
19 a written agreement—

20 “(I) on the scope of the stream-
21 lined development plan for a drug for
22 which a sponsor intends to request ap-
23 proval in accordance with this sub-
24 section; and

1 “(II) which, as appropriate, may
2 include agreement on the design and
3 size of necessary preclinical and clin-
4 ical studies early in the development
5 process, including clinical trials whose
6 data are intended to form the primary
7 basis for an effectiveness claim; and

8 “(ii) provides an opportunity to dis-
9 cuss expectations of the Secretary regard-
10 ing studies or other information that the
11 Secretary deems appropriate for purposes
12 of applying paragraph (5), relating to the
13 termination of labeling requirements or
14 postmarketing conditions.

15 “(B) ASSESSMENT MEETING.—The term
16 ‘assessment meeting’ means an end-of-phase-2
17 meeting, pre-new drug application meeting, or
18 pre-biologics license application meeting con-
19 ducted to resolve questions and issues raised
20 during the course of clinical investigations, and
21 details addressed in the written agreement re-
22 garding postapproval commitments or expan-
23 sion of approved uses.

24 “(C) POSTAPPROVAL MEETING.—The term
25 ‘postapproval meeting’ means a meeting fol-

1 lowing initial approval or licensure of the drug
2 for use in a limited population, to discuss any
3 issues identified by the Secretary or the sponsor
4 regarding postapproval commitments or expan-
5 sion of approved uses.”.

6 (c) GUIDANCE.—Not later than 18 months after the
7 date of enactment of this Act, the Secretary of Health and
8 Human Services, acting through the Commissioner of
9 Food and Drugs, shall issue draft guidance describing cri-
10 teria, process, and other general considerations for dem-
11 onstrating the safety and effectiveness of antibacterial and
12 antifungal drugs to be approved for use in a limited popu-
13 lation in accordance with section 505(z) of the Federal
14 Food, Drug, and Cosmetic Act, as added by subsection
15 (b).

16 (d) CONFORMING AMENDMENTS.—

17 (1) LICENSURE OF CERTAIN BIOLOGICAL PROD-
18 UCTS.—Section 351(j) of the Public Health Service
19 Act (42 U.S.C. 262(j)) is amended—

20 (A) by striking “(j)” and inserting
21 “(j)(1)”;

22 (B) by inserting “505(z),” after “505(p),”;
23 and

24 (C) by adding at the end the following new
25 paragraph:

1 “(2) In applying section 505(z) of the Federal Food,
2 Drug, and Cosmetic Act to the licensure of biological prod-
3 ucts under this section—

4 “(A) references to an antibacterial or antifungal
5 drug that is intended to treat a serious or life-
6 threatening infection shall be construed to refer to
7 a biological product intended to treat a serious or
8 life-threatening bacterial or fungal infection; and

9 “(B) references to approval of a drug under
10 section 505(c) of such Act shall be construed to
11 refer to a licensure of a biological product under
12 subsection (a) of this section.”.

13 (2) MISBRANDING.—Section 502 of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 352) is
15 amended by adding at the end the following new
16 subsection:

17 “(dd) If it is a drug approved in accordance with sec-
18 tion 505(z) and its labeling does not meet the require-
19 ments under paragraph (3) of such subsection, subject to
20 paragraph (5) of such subsection.”.

21 (e) EVALUATION.—

22 (1) ASSESSMENT.—Not later than 48 months
23 after the date of enactment of this Act, the Sec-
24 retary of Health and Human Services shall publish
25 for public comment an assessment of the program

1 established under section 505(z) of the Federal
2 Food, Drug, and Cosmetic Act, as added by sub-
3 section (b). Such assessment shall determine if the
4 limited-use pathway established under such section
5 505(z) has improved or is likely to improve patient
6 access to novel antibacterial or antifungal treat-
7 ments and assess how the pathway could be ex-
8 panded to cover products for serious or life-threat-
9 ening diseases or conditions beyond bacterial and
10 fungal infections.

11 (2) MEETING.—Not later than 90 days after
12 the date of the publication of such assessment, the
13 Secretary, acting through the Commissioner of Food
14 and Drugs, shall hold a public meeting to discuss
15 the findings of the assessment, during which public
16 stakeholders may present their views on the success
17 of the program established under section 505(z) of
18 the Federal Food, Drug, and Cosmetic Act, as
19 added by subsection (b), and the appropriateness of
20 expanding such program.

21 (f) EXPANSION OF PROGRAM.—If the Secretary of
22 Health and Human Services determines, based on the as-
23 sessment under subsection (e)(1), evaluation of the assess-
24 ment, and any other relevant information, that the public
25 health would benefit from expansion of the limited-use

1 pathway established under section 505(z) of the Federal
2 Food, Drug, and Cosmetic Act (as added by subsection
3 (b)) beyond the drugs approved in accordance with such
4 section, the Secretary may expand such limited-use path-
5 way in accordance with such a determination. The ap-
6 proval of any drugs under any such expansion shall be
7 subject to the considerations and requirements described
8 in such section 505(z) for purposes of expansion to other
9 serious or life-threatening diseases or conditions.

10 (g) MONITORING.—The Public Health Service Act is
11 amended by inserting after section 317T (42 U.S.C.
12 247b–22) the following:

13 **“SEC. 317U. MONITORING ANTIBACTERIAL AND**
14 **ANTIFUNGAL DRUG USE AND RESISTANCE.**

15 “(a) MONITORING.—The Secretary shall use an ap-
16 propriate monitoring system to monitor—

17 “(1) the use of antibacterial and antifungal
18 drugs, including those receiving approval or licensure
19 for a limited population pursuant to section 505(z)
20 of the Federal Food, Drug, and Cosmetic Act; and

21 “(2) changes in bacterial and fungal resistance
22 to drugs.

23 “(b) PUBLIC AVAILABILITY OF DATA.—The Sec-
24 retary shall make summaries of the data derived from

1 monitoring under this section publicly available for the
2 purposes of—

3 “(1) improving the monitoring of important
4 trends in antibacterial and antifungal resistance;
5 and

6 “(2) ensuring appropriate stewardship of anti-
7 bacterial and antifungal drugs, including those re-
8 ceiving approval or licensure for a limited population
9 pursuant to section 505(z) of the Federal Food,
10 Drug, and Cosmetic Act.”.

11 **SEC. 2122. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA**
12 **FOR MICROORGANISMS.**

13 (a) IN GENERAL.—Section 511 of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 360a) is amended to
15 read as follows:

16 **“SEC. 511. IDENTIFYING AND UPDATING SUSCEPTIBILITY**
17 **TEST INTERPRETIVE CRITERIA FOR MICRO-**
18 **ORGANISMS.**

19 “(a) PURPOSE; IDENTIFICATION OF CRITERIA.—

20 “(1) PURPOSE.—The purpose of this section is
21 to provide the Secretary with an expedited, flexible
22 method for—

23 “(A) clearance or premarket approval of
24 antimicrobial susceptibility testing devices uti-
25 lizing updated, recognized susceptibility test in-

1 terpretive criteria to characterize the in vitro
2 susceptibility of particular bacteria, fungi, or
3 other microorganisms to antimicrobial drugs;
4 and

5 “(B) providing public notice of the avail-
6 ability of recognized interpretive criteria to
7 meet premarket submission requirements or
8 other requirements under this Act for anti-
9 microbial susceptibility testing devices.

10 “(2) IN GENERAL.—The Secretary shall iden-
11 tify appropriate susceptibility test interpretive cri-
12 teria with respect to antimicrobial drugs—

13 “(A) if such criteria are available on the
14 date of approval of the drug under section 505
15 of this Act or licensure of the drug under sec-
16 tion 351 of the Public Health Service Act (as
17 applicable), upon such approval or licensure; or

18 “(B) if such criteria are unavailable on
19 such date, on the date on which such criteria
20 are available for such drug.

21 “(3) BASES FOR INITIAL IDENTIFICATION.—
22 The Secretary shall identify appropriate suscepti-
23 bility test interpretive criteria under paragraph (2),
24 based on the Secretary’s review of, to the extent
25 available and relevant—

1 “(A) preclinical and clinical data, including
2 pharmacokinetic, pharmacodynamic, and epide-
3 miological data;

4 “(B) Bayesian and pharmacometric statis-
5 tical methodologies; and

6 “(C) such other evidence and information
7 as the Secretary considers appropriate.

8 “(b) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA
9 WEBSITE.—

10 “(1) IN GENERAL.—Not later than 1 year after
11 the date of the enactment of the 21st Century Cures
12 Act, the Secretary shall establish, and maintain
13 thereafter, on the website of the Food and Drug Ad-
14 ministration, a dedicated website that contains a list
15 of any appropriate new or updated susceptibility test
16 interpretive criteria standards in accordance with
17 paragraph (2) (referred to in this section as the ‘In-
18 terpretive Criteria Website’).

19 “(2) LISTING OF SUSCEPTIBILITY TEST INTER-
20 PRETIVE CRITERIA STANDARDS.—

21 “(A) IN GENERAL.—The list described in
22 paragraph (1) shall consist of any new or up-
23 dated susceptibility test interpretive criteria
24 standards that are—

1 “(i) established by a nationally or
2 internationally recognized standard devel-
3 opment organization that—

4 “(I) establishes and maintains
5 procedures to address potential con-
6 flicts of interest and ensure trans-
7 parent decisionmaking;

8 “(II) holds open meetings to en-
9 sure that there is an opportunity for
10 public input by interested parties, and
11 establishes and maintains processes to
12 ensure that such input is considered
13 in decisionmaking; and

14 “(III) permits its standards to be
15 made publicly available, through the
16 National Library of Medicine or an-
17 other similar source acceptable to the
18 Secretary; and

19 “(ii) recognized in whole, or in part,
20 by the Secretary under subsection (e).

21 “(B) OTHER LIST.—The Interpretive Cri-
22 teria Website shall, in addition to the list de-
23 scribed in subparagraph (A), include a list of
24 interpretive criteria, if any, that the Secretary
25 has determined to be appropriate with respect

1 to legally marketed antimicrobial drugs,
2 where—

3 “(i) the Secretary does not recognize,
4 in whole or in part, an interpretive criteria
5 standard described under subparagraph
6 (A) otherwise applicable to such a drug;

7 “(ii) the Secretary withdraws under
8 subsection (c)(1)(B) recognition of a
9 standard, in whole or in part, otherwise
10 applicable to such a drug;

11 “(iii) the Secretary approves an appli-
12 cation under section 505 of this Act or sec-
13 tion 351 of the Public Health Service Act,
14 as applicable, with respect to marketing of
15 such a drug for which there are no rel-
16 evant interpretive criteria included in a
17 standard recognized by the Secretary
18 under subsection (c); or

19 “(iv) because the characteristics of
20 such a drug differ from other drugs with
21 the same active ingredient, the interpretive
22 criteria with respect to such drug—

23 “(I) differ from otherwise appli-
24 cable interpretive criteria included in
25 a standard listed under subparagraph

1 (A) or interpretive criteria otherwise
2 listed under this subparagraph; and

3 “(II) are determined by the Sec-
4 retary to be appropriate for the drug.

5 “(C) REQUIRED STATEMENTS OF LIMITA-
6 TIONS OF INFORMATION.—The Interpretive Cri-
7 teria Website shall include the following:

8 “(i) A statement that—

9 “(I) the website provides infor-
10 mation about the susceptibility of bac-
11 teria, fungi, or other microorganisms
12 to a certain drug (or drugs); and

13 “(II) the safety and efficacy of
14 the drug in treating clinical infections
15 due to such bacteria, fungi, or other
16 microorganisms may not have been es-
17 tablished in adequate and well-con-
18 trolled clinical trials and the clinical
19 significance of such susceptibility in-
20 formation in such trials is unknown.

21 “(ii) A statement that directs health
22 care practitioners to consult the approved
23 product labeling for specific drugs to deter-
24 mine the uses for which the Food and

1 Drug Administration has approved the
2 product.

3 “(iii) Any other statement that the
4 Secretary determines appropriate to ade-
5 quately convey the limitations of the data
6 supporting susceptibility test interpretive
7 criteria standard listed on the website.

8 “(3) NOTICE.—Not later than the date on
9 which the Interpretive Criteria Website is estab-
10 lished, the Secretary shall publish a notice of that
11 establishment in the Federal Register.

12 “(4) INAPPLICABILITY OF MISBRANDING PROVI-
13 SION.—The inclusion in the approved labeling of an
14 antimicrobial drug of a reference or hyperlink to the
15 Interpretive Criteria Website, in and of itself, shall
16 not cause the drug to be misbranded in violation of
17 section 502, or the regulations promulgated there-
18 under.

19 “(5) TRADE SECRETS AND CONFIDENTIAL IN-
20 FORMATION.—Nothing in this section shall be con-
21 strued as authorizing the Secretary to disclose any
22 information that is a trade secret or confidential in-
23 formation subject to section 552(b)(4) of title 5,
24 United States Code.

1 “(c) RECOGNITION OF SUSCEPTIBILITY TEST INTER-
2 PRETIVE CRITERIA FROM STANDARD DEVELOPMENT OR-
3 GANIZATIONS.—

4 “(1) IN GENERAL.—Beginning on the date of
5 the establishment of the Interpretive Criteria
6 Website, and at least every 6 months thereafter, the
7 Secretary shall—

8 “(A) evaluate any appropriate new or up-
9 dated susceptibility test interpretive criteria
10 standards established by a nationally or inter-
11 nationally recognized standard development or-
12 ganization described in subsection (b)(2)(A)(i);
13 and

14 “(B) publish on the public website of the
15 Food and Drug Administration a notice—

16 “(i) withdrawing recognition of any
17 different susceptibility test interpretive cri-
18 teria standard, in whole or in part;

19 “(ii) recognizing the new or updated
20 standards;

21 “(iii) recognizing one or more parts of
22 the new or updated interpretive criteria
23 specified in such a standard and declining
24 to recognize the remainder of such stand-
25 ard; and

1 “(iv) making any necessary updates to
2 the lists under subsection (b)(2).

3 “(2) BASES FOR UPDATING INTERPRETIVE CRI-
4 TERIA STANDARDS.—In evaluating new or updated
5 susceptibility test interpretive criteria standards
6 under paragraph (1)(A), the Secretary may con-
7 sider—

8 “(A) the Secretary’s determination that
9 such a standard is not applicable to a particular
10 drug because the characteristics of the drug dif-
11 fer from other drugs with the same active in-
12 gredient;

13 “(B) information provided by interested
14 third parties, including public comment on the
15 annual compilation of notices published under
16 paragraph (3);

17 “(C) any bases used to identify suscepti-
18 bility test interpretive criteria under subsection
19 (a)(2); and

20 “(D) such other information or factors as
21 the Secretary determines appropriate.

22 “(3) ANNUAL COMPILATION OF NOTICES.—
23 Each year, the Secretary shall compile the notices
24 published under paragraph (1)(B) and publish such
25 compilation in the Federal Register and provide for

1 public comment. If the Secretary receives comments,
2 the Secretary shall review such comments and, if the
3 Secretary determines appropriate, update pursuant
4 to this subsection susceptibility test interpretive cri-
5 teria standards—

6 “(A) recognized by the Secretary under
7 this subsection; or

8 “(B) otherwise listed on the Interpretive
9 Criteria Website under subsection (b)(2).

10 “(4) RELATION TO SECTION 514(c).—Any sus-
11 ceptibility test interpretive standard recognized
12 under this subsection or any criteria otherwise listed
13 under subsection (b)(2)(B) shall be deemed to be
14 recognized as a standard by the Secretary under sec-
15 tion 514(c)(1).

16 “(5) VOLUNTARY USE OF INTERPRETIVE CRI-
17 TERIA.—Nothing in this section prohibits a person
18 from seeking approval or clearance of a drug or de-
19 vice, or changes to the drug or the device, on the
20 basis of susceptibility test interpretive criteria stand-
21 ards which differ from those recognized pursuant to
22 paragraph (1).

23 “(d) ANTIMICROBIAL DRUG LABELING.—

24 “(1) DRUGS MARKETED PRIOR TO ESTABLISH-
25 MENT OF INTERPRETIVE CRITERIA WEBSITE.—With

1 respect to an antimicrobial drug lawfully introduced
2 or delivered for introduction into interstate com-
3 merce for commercial distribution before the estab-
4 lishment of the Interpretive Criteria Website, a hold-
5 er of an approved application under section 505 of
6 this Act or section 351 of the Public Health Service
7 Act, as applicable, for each such drug—

8 “(A) not later than 1 year after establish-
9 ment of the Interpretive Criteria Website, shall
10 submit to the Secretary a supplemental applica-
11 tion for purposes of changing the drug’s label-
12 ing to substitute a reference or hyperlink to
13 such Website for any susceptibility test inter-
14 pretive criteria and related information; and

15 “(B) may begin distribution of the drug in-
16 volved upon receipt by the Secretary of the sup-
17 plemental application for such change.

18 “(2) DRUGS MARKETED SUBSEQUENT TO ES-
19 TABLISHMENT OF INTERPRETIVE CRITERIA
20 WEBSITE.—With respect to antimicrobial drugs law-
21 fully introduced or delivered for introduction into
22 interstate commerce for commercial distribution on
23 or after the date of the establishment of the Inter-
24 pretive Criteria Website, the labeling for such a drug
25 shall include, in lieu of susceptibility test interpretive

1 criteria and related information, a reference to such
2 Website.

3 “(e) SPECIAL CONDITION FOR MARKETING OF ANTI-
4 MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

5 “(1) IN GENERAL.—Notwithstanding sections
6 501, 502, 510, 513, and 515, if the conditions speci-
7 fied in paragraph (2) are met (in addition to other
8 applicable provisions under this chapter) with re-
9 spect to an antimicrobial susceptibility testing device
10 described in subsection (f)(1), the Secretary may au-
11 thorize the marketing of such device for a use de-
12 scribed in such subsection.

13 “(2) CONDITIONS APPLICABLE TO ANTI-
14 MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

15 The conditions specified in this paragraph are the
16 following:

17 “(A) The device is used to make a deter-
18 mination of susceptibility using susceptibility
19 test interpretive criteria that are—

20 “(i) included in a standard recognized
21 by the Secretary under subsection (c); or

22 “(ii) otherwise listed on the Interpre-
23 tive Criteria Website under subsection
24 (b)(2).

1 “(B) The labeling of such device promi-
2 nently and conspicuously—

3 “(i) includes a statement that—

4 “(I) the device provides informa-
5 tion about the susceptibility of bac-
6 teria and fungi to certain drugs; and

7 “(II) the safety and efficacy of
8 such drugs in treating clinical infec-
9 tions due to such bacteria or fungi
10 may not have been established in ade-
11 quate and well-controlled clinical trials
12 and the clinical significance of such
13 susceptibility information in those in-
14 stances is unknown;

15 “(ii) includes a statement directing
16 health care practitioners to consult the ap-
17 proved labeling for drugs tested using such
18 a device, to determine the uses for which
19 the Food and Drug Administration has ap-
20 proved such drugs; and

21 “(iii) includes any other statement the
22 Secretary determines appropriate to ade-
23 quately convey the limitations of the data
24 supporting the interpretive criteria de-
25 scribed in subparagraph (A).

1 “(f) DEFINITIONS.—In this section:

2 “(1) The term ‘antimicrobial susceptibility test-
3 ing device’ means a device that utilizes susceptibility
4 test interpretive criteria to determine and report the
5 in vitro susceptibility of certain microorganisms to a
6 drug (or drugs).

7 “(2) The term ‘qualified infectious disease
8 product’ means a qualified infectious disease product
9 designated under section 505E(d).

10 “(3) The term ‘susceptibility test interpretive
11 criteria’ means—

12 “(A) one or more specific numerical values
13 which characterize the susceptibility of bacteria
14 or other microorganisms to the drug tested; and

15 “(B) related categorizations of such sus-
16 ceptibility, including categorization of the drug
17 as susceptible, intermediate, resistant, or such
18 other term as the Secretary determines appro-
19 priate.

20 “(4)(A) The term ‘antimicrobial drug’ means,
21 subject to subparagraph (B), a systemic anti-
22 bacterial or antifungal drug that—

23 “(i) is intended for human use in the treat-
24 ment of a disease or condition caused by a bac-
25 terium or fungus;

1 “(ii) may include a qualified infectious dis-
2 ease product designated under section 505E(d);
3 and

4 “(iii) is subject to section 503(b)(1).

5 “(B) If provided by the Secretary through regu-
6 lations, such term may include—

7 “(i) drugs other than systemic anti-
8 bacterial and antifungal drugs; and

9 “(ii) biological products (as such term is
10 defined in section 351 of the Public Health
11 Service Act) to the extent such products exhibit
12 antimicrobial activity.

13 “(g) RULE OF CONSTRUCTION.—Nothing in this sec-
14 tion shall be construed—

15 “(1) to alter the standards of evidence—

16 “(A) under subsection (e) or (d) of section
17 505, including the substantial evidence stand-
18 ard in section 505(d), or under section 351 of
19 the Public Health Service Act (as applicable);
20 or

21 “(B) with respect to marketing authoriza-
22 tion for devices, under section 510, 513, or 515;

23 “(2) to apply with respect to any drug, device,
24 or biological product, in any context other than—

25 “(A) an antimicrobial drug; or

1 “(B) an antimicrobial susceptibility testing
2 device that uses susceptibility test interpretive
3 criteria to characterize and report the in vitro
4 susceptibility of certain bacteria, fungi, or other
5 microorganisms to antimicrobial drugs in ac-
6 cordance with this section; or

7 “(3) unless specifically stated, to have any ef-
8 fect on authorities provided under other sections of
9 this Act, including any regulations issued under such
10 sections.”.

11 (b) CONFORMING AMENDMENTS.—

12 (1) REPEAL OF RELATED AUTHORITY.—Section
13 1111 of the Food and Drug Administration Amend-
14 ments Act of 2007 (42 U.S.C. 247d–5a; relating to
15 identification of clinically susceptible concentrations
16 of antimicrobials) is repealed.

17 (2) CLERICAL AMENDMENT.—The table of con-
18 tents in section 2 of the Food and Drug Administra-
19 tion Amendments Act of 2007 is amended by strik-
20 ing the item relating to section 1111.

21 (3) MISBRANDING.—Section 502 of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 352), as
23 amended by section 2121, is further amended by
24 adding at the end the following:

1 “(ee) If it is an antimicrobial drug and its labeling
2 fails to conform with the requirements under section
3 511(d).”.

4 (4) RECOGNITION OF INTERPRETIVE CRITERIA
5 AS DEVICE STANDARD.—Section 514(e)(1)(A) of the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 360d(e)(1)(A)) is amended by inserting after “the
8 Secretary shall, by publication in the Federal Reg-
9 ister” the following: “(or, with respect to suscepti-
10 bility test interpretive criteria or standards recog-
11 nized or otherwise listed under section 511, by post-
12 ing on the Interpretive Criteria Website in accord-
13 ance with such section)”.

14 (c) REPORT TO CONGRESS.—Not later than 2 years
15 after the date of enactment of this Act, the Secretary of
16 Health and Human Services shall submit to the Com-
17 mittee on Energy and Commerce of the House of Rep-
18 resentatives and the Committee on Health, Education,
19 Labor, and Pensions of the Senate a report on the
20 progress made in implementing section 511 of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 360a), as
22 amended by this section.

23 (d) REQUESTS FOR UPDATES TO INTERPRETIVE CRI-
24 TERIA WEBSITE.—Chapter 35 of title 44, United States
25 Code, shall not apply to the collection of information from

1 interested parties regarding the updating of lists under
2 paragraph (2) of subsection (b) section 511 of the Federal
3 Food, Drug, and Cosmetic Act (as amended by subsection
4 (a)) and posted on the Interpretive Criteria Website estab-
5 lished under paragraph (1) of such subsection (b).

6 (e) NO EFFECT ON HEALTH CARE PRACTICE.—
7 Nothing in this subtitle (including the amendments made
8 by this subtitle) shall be construed to restrict, in any man-
9 ner, the prescribing or administering of antibiotics or
10 other products by health care practitioners, or to limit the
11 practice of health care.

12 **SEC. 2123. ENCOURAGING THE DEVELOPMENT AND USE OF**
13 **DISARM DRUGS.**

14 (a) ADDITIONAL PAYMENT FOR DISARM DRUGS
15 UNDER MEDICARE.—

16 (1) IN GENERAL.—Section 1886(d)(5) of the
17 Social Security Act (42 U.S.C. 1395ww(d)(5)) is
18 amended by adding at the end the following new
19 subparagraph:

20 “(M)(i) As part of the annual rulemaking conducted
21 with respect to payment for subsection (d) hospitals for
22 each fiscal year beginning with fiscal year 2018, the Sec-
23 retary shall—

24 “(I) include a list of the DISARM drugs for
25 such fiscal year; and

1 “(II) with respect to discharges by eligible hos-
2 pitals that involve a drug so listed, provide for an
3 additional payment to be made under this subsection
4 in accordance with the provisions of this subpara-
5 graph.

6 “(ii) Additional payments may not be made for a
7 drug under this subparagraph—

8 “(I) other than during the 5-fiscal-year period
9 beginning with the fiscal year for which the drug is
10 first included in the list described in clause (i)(I);
11 and

12 “(II) with respect to which payment has ever
13 been made pursuant to subparagraph (K).

14 “(iii) For purposes of this subparagraph, the term
15 ‘DISARM drug’ means a product that is approved for use,
16 or a product for which an indication is first approved for
17 use, by the Food and Drug Administration on or after
18 December 1, 2014, and that the Food and Drug Adminis-
19 tration determines is an antimicrobial product (as defined
20 in clause (iv)) and is intended to treat an infection—

21 “(I) for which there is an unmet medical need;
22 and

23 “(II) which is associated with high rates of
24 mortality or significant patient morbidity, as deter-
25 mined in consultation with the Director of the Cen-

1 ters for Disease Control and Prevention and the in-
2 fectious disease professional community.

3 “(iv) For purposes of clause (iii), the term ‘anti-
4 microbial product’ means a product that either—

5 “(I) is intended to treat an infection caused by,
6 or likely to be caused by, a qualifying pathogen (as
7 defined under section 505E(f) of the Federal Food,
8 Drug, and Cosmetic Act); or

9 “(II) meets the definition of a qualified infec-
10 tious disease product under section 505E(g) of the
11 Federal Food, Drug, and Cosmetic Act.

12 Such determination may be revoked only upon a finding
13 that the request for such determination contained an un-
14 true statement of material fact.

15 “(v) For purposes of this subparagraph, the term ‘eli-
16 gible hospital’ means a subsection (d) hospital that partici-
17 pates in the National Healthcare Safety Network of the
18 Centers for Disease Control and Prevention (or, to the ex-
19 tent a similar surveillance system that includes reporting
20 about antimicrobial drugs is determined by the Secretary
21 to be available to such hospitals, such similar surveillance
22 system as the Secretary may specify).

23 “(vi) Subject to the succeeding provisions of this sub-
24 paragraph, the additional payment under this subpara-

1 graph, with respect to a drug, shall be in the amount pro-
2 vided for such drug under section 1847A.

3 “(vii) As part of the rulemaking referred to in clause
4 (i) for each fiscal year, the Secretary shall estimate—

5 “(I) total add-on payments (as defined in sub-
6 clause (I) of clause (ix)); and

7 “(II) total hospital payments (as defined in
8 subclause (II) of such clause).

9 “(viii) If the total add-on payments estimated pursu-
10 ant to clause (vii)(I) for a fiscal year exceed 0.02 percent
11 of the total hospital payments estimated pursuant to
12 clause (vii)(II) for such fiscal year, the Secretary shall re-
13 duce in a pro rata manner the amount of each additional
14 payment under this subsection pursuant to this subpara-
15 graph for such fiscal year in order to ensure that the total
16 add-on payments estimated for such fiscal year do not ex-
17 ceed 0.02 percent of the total hospital payments estimated
18 for such fiscal year.

19 “(ix) In this subparagraph:

20 “(I) The term ‘total add-on payments’ means,
21 with respect to a fiscal year, the total amount of the
22 additional payments under this subsection pursuant
23 to this subparagraph for discharges in such fiscal
24 year without regard to the application of clause
25 (viii).

1 “(II) The term ‘total hospital payments’ means,
2 with respect to a fiscal year, the total amount of
3 payments made under this subsection for all dis-
4 charges in such fiscal year.”.

5 (2) CONFORMING AMENDMENTS.—

6 (A) NO DUPLICATIVE NTAP PAYMENTS.—

7 Section 1886(d)(5)(K)(vi) of the Social Security
8 Act (42 U.S.C. 1395ww(d)(5)(K)(vi)) is amend-
9 ed by inserting “and if additional payment has
10 never been made under this subsection pursu-
11 ant to subparagraph (M) with respect to the
12 service or technology” before the period at the
13 end.

14 (B) ACCESS TO PRICE INFORMATION.—

15 Section 1927(b)(3)(A) of the Social Security
16 Act (42 U.S.C. 1396r-8(b)(3)(A)) is amend-
17 ed—

18 (i) in clause (ii)—

19 (I) by striking “for each” and in-
20 serting “, for each”; and

21 (II) by striking “and” at the end;

22 (ii) in clause (iii)—

23 (I) in subclause (II), by inserting
24 “or under section 1886(d) pursuant to

1 paragraph (5)(M) of such section,”
2 after “1847A,”;

3 (II) in the matter following sub-
4 clause (III), by striking “or
5 1881(b)(13)(A)(ii)” and inserting “,
6 section 1881(b)(13)(A)(ii), or section
7 1886(d)(5)(M)”;

8 (III) by striking the period at the
9 end and inserting “; and”;

10 (iii) in clause (iv), by striking the
11 semicolon at the end and inserting a pe-
12 riod.

13 (b) STUDY AND REPORT ON REMOVING BARRIERS TO
14 DEVELOPMENT OF DISARM DRUGS.—

15 (1) STUDY.—The Comptroller General of the
16 United States shall, in consultation with the Direc-
17 tor of the National Institutes of Health, the Com-
18 missioner of Food and Drugs, and the Director of
19 the Centers for Disease Control and Prevention, con-
20 duct a study to—

21 (A) identify and examine the barriers that
22 prevent the development of DISARM drugs, as
23 defined in section 1886(d)(5)(M)(iii) of the So-
24 cial Security Act (42 U.S.C.

1 1395ww(d)(5)(M)(iii)), as added by subsection
2 (a)(1); and

3 (B) develop recommendations for actions
4 to be taken in order to overcome any barriers
5 identified under subparagraph (A).

6 (2) REPORT.—Not later than 1 year after the
7 date of the enactment of this Act, the Comptroller
8 General shall submit to Congress a report on the
9 study conducted under paragraph (1).

10 (c) STUDY AND REPORT ON THE IMPACT OF ADDI-
11 TIONAL MEDICARE PAYMENT FOR DISARM DRUGS ON
12 USAGE PRACTICES AND DEVELOPMENT OF RESIST-
13 ANCE.—

14 (1) STUDY.—The Director of the Centers for
15 Disease Control and Prevention shall conduct a
16 study to examine the effects of the additional pay-
17 ment for DISARM drugs under the Medicare Pro-
18 gram provided under subparagraph (M) of section
19 1886(d)(5) of the Social Security Act (42 U.S.C.
20 1395ww(d)(5)), as added by subsection (a), on—

21 (A) the usage of DISARM drugs (as de-
22 fined by clause (iii) of such subparagraph) by
23 subsection (d) hospitals (as defined in section
24 1886(d)(1)(B) of such Act); and

1 (B) the development of resistance by indi-
2 viduals to such DISARM drugs.

3 (2) REPORT.—Not later than 3 years after the
4 date of the enactment of this Act, such Director
5 shall submit to Congress a report on the study con-
6 ducted under paragraph (1).

7 **Subtitle H—Vaccine Access,**
8 **Certainty, and Innovation**

9 **SEC. 2141. TIMELY REVIEW OF VACCINES BY THE ADVISORY**
10 **COMMITTEE ON IMMUNIZATION PRACTICES.**

11 Section 2102(a) of the Public Health Service Act (42
12 U.S.C. 300aa–2(a)) is amended by adding at the end the
13 following:

14 “(10) ADVISORY COMMITTEE ON IMMUNIZATION
15 PRACTICES.—

16 “(A) STANDARD PERIODS OF TIME FOR
17 MAKING RECOMMENDATIONS.—Upon the licen-
18 sure of any vaccine or any new indication for a
19 vaccine, the Director of the Program shall di-
20 rect the Advisory Committee on Immunization
21 Practices, at its next regularly scheduled meet-
22 ing, to consider the use of the vaccine.

23 “(B) EXPEDITED REVIEW PURSUANT TO
24 REQUEST BY SPONSOR OR MANUFACTURER.—If
25 the Advisory Committee does not make rec-

1 ommendations with respect to the use of a vac-
2 cine at the Advisory Committee’s first regularly
3 scheduled meeting after the licensure of the
4 vaccine or any new indication for the vaccine,
5 the Advisory Committee, at the request of the
6 sponsor of the vaccine, shall make such rec-
7 ommendations on an expedited basis.

8 “(C) EXPEDITED REVIEW FOR BREAK-
9 THROUGH THERAPIES AND FOR USE DURING
10 PUBLIC HEALTH EMERGENCIES.—If a vaccine
11 is designated as a breakthrough therapy under
12 section 506 of the Federal Food, Drug, and
13 Cosmetic Act, and is licensed under section 351
14 of this Act, the Advisory Committee shall make
15 recommendations with respect to the use of the
16 vaccine on an expedited basis.

17 “(D) DEFINITION.—In this paragraph, the
18 terms ‘Advisory Committee on Immunization
19 Practices’ and ‘Advisory Committee’ mean the
20 advisory committee on immunization practices
21 established by the Secretary pursuant to section
22 222, acting through the Director of the Centers
23 for Disease Control and Prevention.”.

1 **SEC. 2142. REVIEW OF PROCESSES AND CONSISTENCY OF**
2 **ACIP RECOMMENDATIONS.**

3 (a) REVIEW.—The Director of the Centers for Dis-
4 ease Control and Prevention shall conduct a review of the
5 process used by the Advisory Committee on Immunization
6 Practices to evaluate consistency in formulating and
7 issuing recommendations pertaining to vaccines.

8 (b) CONSIDERATIONS.—The review under subsection
9 (a) shall include assessment of—

10 (1) the criteria used to evaluate new and exist-
11 ing vaccines;

12 (2) the Grading of Recommendations, Assess-
13 ment, Development, and Evaluation (GRADE) ap-
14 proach to the review and analysis of scientific and
15 economic data, including the scientific basis for such
16 approach; and

17 (3) the extent to which the processes used by
18 the working groups of the Advisory Committee on
19 Immunization Practices are consistent among
20 groups.

21 (c) STAKEHOLDERS.—In carrying out the review
22 under subsection (a), the Director of the Centers for Dis-
23 ease Control and Prevention shall solicit input from vac-
24 cine stakeholders.

25 (d) REPORT.—Not later than 18 months after the
26 date of enactment of this Act, the Director of the Centers

1 for Disease Control and Prevention shall submit to the
2 appropriate committees of the Congress and make publicly
3 available a report on the results of the review under sub-
4 section (a), including recommendations on improving the
5 consistency of the process described in such subsection.

6 (e) DEFINITION.—In this section, the term “Advisory
7 Committee on Immunization Practices” means the advi-
8 sory committee on immunization practices established by
9 the Secretary of Health and Human Services pursuant to
10 section 222 of the Public Health Service Act (42 U.S.C.
11 217a), acting through the Director of the Centers for Dis-
12 ease Control and Prevention.

13 **SEC. 2143. MEETINGS BETWEEN CDC AND VACCINE DEVEL-**
14 **OPERS.**

15 Section 310 of the Public Health Service Act (42
16 U.S.C. 242o) is amended by adding at the end the fol-
17 lowing:

18 “(c)(1) In this subsection, the term ‘vaccine devel-
19 oper’ means a nongovernmental entity engaged in—

20 “(A)(i) the development of a vaccine with the
21 intent to pursue licensing of the vaccine by the Food
22 and Drug Administration; or

23 “(ii) the production of a vaccine licensed by the
24 Food and Drug Administration; and

25 “(B) vaccine research.

1 “(2)(A) Upon the submission of a written request for
2 a meeting by a vaccine developer, that includes a valid jus-
3 tification for the meeting, the Secretary, acting through
4 the Director of the Centers for Disease Control and Pre-
5 vention, shall convene a meeting of representatives of the
6 vaccine developer and experts from the Centers for Dis-
7 ease Control and Prevention in immunization programs,
8 epidemiology, and other relevant areas at which the Direc-
9 tor (or the Director’s designee), for the purpose of inform-
10 ing the vaccine developer’s understanding of public health
11 needs and priorities, shall provide the perspectives of the
12 Centers for Disease Control and Prevention and other rel-
13 evant Federal agencies regarding—

14 “(i) public health needs, epidemiology, and im-
15 plementation considerations with regard to a vaccine
16 developer’s potential vaccine profile; and

17 “(ii) potential implications of such perspectives
18 for the vaccine developer’s vaccine research and de-
19 velopment planning.

20 “(B) In addition to the representatives specified in
21 subparagraph (A), the Secretary may, with the agreement
22 of the vaccine developer requesting a meeting under such
23 subparagraph, include in such meeting representatives
24 of—

25 “(i) the Food and Drug Administration; and

1 “(ii) the National Vaccine Program.

2 “(C) The Secretary shall convene a meeting re-
3 requested with a valid justification under subparagraph (A)
4 not later than 120 days after receipt of the request for
5 the meeting.

6 “(3)(A) Upon the submission of a written request by
7 a vaccine developer, the Secretary, acting through the Di-
8 rector of the Centers for Disease Control and Prevention,
9 shall provide to the vaccine developer any age-based or
10 other demographically assessed disease epidemiological
11 analyses or data that—

12 “(i) are specified in the request;

13 “(ii) have been published;

14 “(iii) have been performed by or are in the pos-
15 session of the Centers;

16 “(iv) are not a trade secret or commercial or fi-
17 nancial information that is privileged or confidential
18 and subject to section 552(b)(4) of title 5, United
19 States Code, or section 1905 of title 18, United
20 States Code; and

21 “(v) do not contain individually identifiable in-
22 formation.

23 “(B) The Secretary shall provide analyses requested
24 by a vaccine manufacturer under subparagraph (A) not

1 later than 120 calendar days after receipt of the request
2 for the analyses.

3 “(4) The Secretary shall promptly notify a vaccine
4 developer if—

5 “(A) the Secretary becomes aware of any sig-
6 nificant change to information that was—

7 “(i) shared by the Secretary with the vac-
8 cine developer during a meeting under para-
9 graph (2); or

10 “(ii) provided by the Secretary to the vac-
11 cine developer in one or more analyses under
12 paragraph (3); and

13 “(B) the change to such information may have
14 implications for the vaccine developer’s vaccine re-
15 search and development.”.

16 **Subtitle I—Orphan Product Exten-**
17 **sions Now; Incentives for Cer-**
18 **tain Products for Limited Popu-**
19 **lations**

20 **SEC. 2151. EXTENSION OF EXCLUSIVITY PERIODS FOR A**
21 **DRUG APPROVED FOR A NEW INDICATION**
22 **FOR A RARE DISEASE OR CONDITION.**

23 (a) IN GENERAL.—Chapter V of the Federal Food,
24 Drug, and Cosmetic Act, as amended by sections 2062

1 and 2063, is further amended by inserting after section
2 505H of such Act the following:

3 **“SEC. 505I. EXTENSION OF EXCLUSIVITY PERIODS FOR A**
4 **DRUG APPROVED FOR A NEW INDICATION**
5 **FOR A RARE DISEASE OR CONDITION.**

6 “(a) DESIGNATION.—

7 “(1) IN GENERAL.—The Secretary shall des-
8 ignate a drug as a drug approved for a new indica-
9 tion to prevent, diagnose, or treat a rare disease or
10 condition for purposes of granting the extensions
11 under subsection (b) if—

12 “(A) prior to approval of an application or
13 supplemental application for the new indication,
14 the drug was approved or licensed for mar-
15 keting under section 505(c) of this Act or sec-
16 tion 351(a) of the Public Health Service Act
17 but was not so approved or licensed for the new
18 indication;

19 “(B)(i) the sponsor of the approved or li-
20 censed drug files an application or a supple-
21 mental application for approval of the new indi-
22 cation for use of the drug to prevent, diagnose,
23 or treat the rare disease or condition; and

24 “(ii) the Secretary approves the application
25 or supplemental application; and

1 “(C) the application or supplemental appli-
2 cation for the new indication contains the con-
3 sent of the applicant to notice being given by
4 the Secretary under paragraph (4) respecting
5 the designation of the drug.

6 “(2) REVOCATION OF DESIGNATION.—

7 “(A) IN GENERAL.—Except as provided in
8 subparagraph (B), a designation under para-
9 graph (1) shall not be revoked for any reason.

10 “(B) EXCEPTION.—The Secretary may re-
11 voke a designation of a drug under paragraph
12 (1) if the Secretary finds that the application or
13 supplemental application resulting in such des-
14 ignation contained an untrue statement of ma-
15 terial fact.

16 “(3) NOTIFICATION PRIOR TO DISCONTINUANCE
17 OF PRODUCTION FOR SOLELY COMMERCIAL REA-
18 SONS.—A designation of a drug under paragraph (1)
19 shall be subject to the condition that the sponsor of
20 the drug will notify the Secretary of any discontinu-
21 ance of the production of the drug for solely com-
22 mercial reasons at least 1 year before such dis-
23 continuance.

1 “(4) NOTICE TO PUBLIC.—Notice respecting
2 the designation of a drug under paragraph (1) shall
3 be made available to the public.

4 “(b) EXTENSION.—If the Secretary designates a
5 drug as a drug approved for a new indication for a rare
6 disease or condition, as described in subsection (a)(1)—

7 “(1)(A) the 4-, 5-, and 7½-year periods de-
8 scribed in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii)
9 of section 505, the 3-year periods described in
10 clauses (iii) and (iv) of subsection (c)(3)(E) and
11 clauses (iii) and (iv) of subsection (j)(5)(F) of sec-
12 tion 505, and the 7-year period described in section
13 527, as applicable, shall be extended by 6 months;
14 or

15 “(B) the 4- and 12-year periods described in
16 subparagraphs (A) and (B) of section 351(k)(7) of
17 the Public Health Service Act and the 7-year period
18 described in section 527, as applicable, shall be ex-
19 tended by 6 months; and

20 “(2)(A) if the drug is the subject of a listed
21 patent for which a certification has been submitted
22 under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of
23 section 505 or a listed patent for which a certifi-
24 cation has been submitted under subsections
25 (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

1 the period during which an application may not be
2 approved under section 505(c)(3) or section
3 505(j)(5)(B) shall be extended by a period of 6
4 months after the date the patent expires (including
5 any patent extensions); or

6 “(B) if the drug is the subject of a listed patent
7 for which a certification has been submitted under
8 subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of sec-
9 tion 505, and in the patent infringement litigation
10 resulting from the certification the court determines
11 that the patent is valid and would be infringed, the
12 period during which an application may not be ap-
13 proved under section 505(c)(3) or section
14 505(j)(5)(B) shall be extended by a period of 6
15 months after the date the patent expires (including
16 any patent extensions).

17 “(c) RELATION TO PEDIATRIC AND QUALIFIED IN-
18 FECTIOUS DISEASE PRODUCT EXCLUSIVITY.—Any exten-
19 sion under subsection (b) of a period shall be in addition
20 to any extension of the periods under sections 505A and
21 505E of this Act and section 351(m) of the Public Health
22 Service Act, as applicable, with respect to the drug.

23 “(d) LIMITATIONS.—The extension described in sub-
24 section (b) shall not apply if the drug designated under

1 subsection (a)(1) has previously received an extension by
2 operation of subsection (b).

3 “(e) DEFINITION.—In this section, the term ‘rare
4 disease or condition’ has the meaning given to such term
5 in section 526(a)(2).”.

6 (b) APPLICATION.—Section 505G of the Federal
7 Food, Drug, and Cosmetic Act, as added by subsection
8 (a), applies only with respect to a drug for which an appli-
9 cation or supplemental application described in subsection
10 (a)(1)(B)(i) of such section 505G is first approved under
11 section 505(c) of such Act (21 U.S.C. 355(c)) or section
12 351(a) of the Public Health Service Act (42 U.S.C.
13 262(a)) on or after the date of the enactment of this Act.

14 (c) CONFORMING AMENDMENTS.—

15 (1) RELATION TO PEDIATRIC EXCLUSIVITY FOR
16 DRUGS.—Section 505A of the Federal Food, Drug,
17 and Cosmetic Act (21 U.S.C. 355a) is amended—

18 (A) in subsection (b), by adding at the end
19 the following:

20 “(3) RELATION TO EXCLUSIVITY FOR A DRUG
21 APPROVED FOR A NEW INDICATION FOR A RARE DIS-
22 EASE OR CONDITION.—Notwithstanding the ref-
23 erences in paragraph (1) to the lengths of the exclu-
24 sivity periods after application of pediatric exclu-
25 sivity, the 6-month extensions described in para-

1 graph (1) shall be in addition to any extensions
2 under section 505G.”; and

3 (B) in subsection (c), by adding at the end
4 the following:

5 “(3) RELATION TO EXCLUSIVITY FOR A DRUG
6 APPROVED FOR A NEW INDICATION FOR A RARE DIS-
7 EASE OR CONDITION.—Notwithstanding the ref-
8 erences in paragraph (1) to the lengths of the exclu-
9 sivity periods after application of pediatric exclu-
10 sivity, the 6-month extensions described in para-
11 graph (1) shall be in addition to any extensions
12 under section 505G.”.

13 (2) RELATION TO EXCLUSIVITY FOR NEW
14 QUALIFIED INFECTIOUS DISEASE PRODUCTS THAT
15 ARE DRUGS.—Subsection (b) of section 505E of the
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 355f) is amended—

18 (A) by amending the subsection heading to
19 read as follows: “RELATION TO PEDIATRIC EX-
20 CLUSIVITY AND EXCLUSIVITY FOR A DRUG AP-
21 PROVED FOR A NEW INDICATION FOR A RARE
22 DISEASE OR CONDITION.—”; and

23 (B) by striking “any extension of the pe-
24 riod under section 505A” and inserting “any

1 extension of the periods under sections 505A
2 and 505G, as applicable.”.

3 (3) RELATION TO PEDIATRIC EXCLUSIVITY FOR
4 BIOLOGICAL PRODUCTS.—Section 351(m) of the
5 Public Health Service Act (42 U.S.C. 262(m)) is
6 amended by adding at the end the following:

7 “(5) RELATION TO EXCLUSIVITY FOR A BIO-
8 LOGICAL PRODUCT APPROVED FOR A NEW INDICA-
9 TION FOR A RARE DISEASE OR CONDITION.—Not-
10 withstanding the references in paragraphs (2)(A),
11 (2)(B), (3)(A), and (3)(B) to the lengths of the ex-
12 clusivity periods after application of pediatric exclu-
13 sivity, the 6-month extensions described in such
14 paragraphs shall be in addition to any extensions
15 under section 505G.”.

16 **SEC. 2152. REAUTHORIZATION OF RARE PEDIATRIC DIS-**
17 **EASE PRIORITY REVIEW VOUCHER INCEN-**
18 **TIVE PROGRAM.**

19 (a) IN GENERAL.—Section 529 of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 360ff) is amended—

21 (1) in subsection (a)—

22 (A) in paragraph (3), by amending sub-
23 paragraph (A) to read as follows:

24 “(A) The disease is a serious or life-threat-
25 ening disease in which the serious or life-threat-

1 ening manifestations primarily affect individ-
2 uals aged from birth to 18 years, including age
3 groups often called neonates, infants, children,
4 and adolescents.”; and

5 (B) in paragraph (4)—

6 (i) in subparagraph (E), by striking
7 “and” at the end;

8 (ii) in subparagraph (F), by striking
9 the period at the end and inserting “;
10 and”; and

11 (iii) by adding at the end the fol-
12 lowing:

13 “(G) is for a drug or biological product for
14 which a priority review voucher has not been
15 issued under section 524 (relating to tropical
16 disease products).”; and

17 (2) in subsection (b), by striking paragraph (5)
18 and inserting the following:

19 “(5) TERMINATION OF AUTHORITY.—

20 “(A) IN GENERAL.—The Secretary may
21 not award any priority review vouchers under
22 paragraph (1) after December 31, 2018.

23 “(B) EXCEPTION.—Notwithstanding sub-
24 paragraph (A), the sponsor of a drug that is
25 designated under subsection (d) as a drug for

1 a rare pediatric disease and that is the subject
2 of a rare pediatric disease product application
3 that is submitted during the period beginning
4 on the date of enactment of the 21st Century
5 Cures Act and ending the date specified in sub-
6 paragraph (A) shall remain eligible to receive a
7 priority review voucher under paragraph (1) ir-
8 respective of whether the rare pediatric disease
9 product application with respect to such drug is
10 approved after the end of such period.”.

11 (b) GAO STUDY AND REPORT.—

12 (1) STUDY.—The Comptroller General of the
13 United States shall conduct a study on the effective-
14 ness of awarding priority review vouchers under sec-
15 tion 529 of the Federal Food, Drug, and Cosmetic
16 Act (21 U.S.C. 360ff) in providing incentives for the
17 development of drugs that treat or prevent rare pe-
18 diatric diseases (as defined in subsection (a)(3) of
19 such section) that would not otherwise have been de-
20 veloped. In conducting such study, the Comptroller
21 General shall examine the following:

22 (A) The indications for which each drug
23 for which a priority review voucher was award-
24 ed under such section 529 was approved under
25 section 505 of such Act (21 U.S.C. 355) or sec-

1 tion 351 of the Public Health Service Act (42
2 U.S.C. 262).

3 (B) Whether the priority review voucher
4 impacted a sponsor's decision to invest in devel-
5 oping a drug to treat or prevent a rare pedi-
6 atric disease.

7 (C) An analysis of the drugs that utilized
8 such priority review vouchers, which shall in-
9 clude—

10 (i) the indications for which such
11 drugs were approved under section 505 of
12 the Federal Food, Drug, and Cosmetic Act
13 (21 U.S.C. 355) or section 351 of the Pub-
14 lic Health Service Act (42 U.S.C. 262);

15 (ii) whether unmet medical needs were
16 addressed through the approval of such
17 drugs, including, for each such drug—

18 (I) if an alternative therapy was
19 previously available to treat the indi-
20 cation; and

21 (II) the benefit or advantage the
22 drug provided over another available
23 therapy;

24 (iii) the number of patients potentially
25 treated by such drugs;

1 (iv) the value of the priority review
2 voucher if transferred; and

3 (v) the length of time between the
4 date on which a priority review voucher
5 was awarded and the date on which it was
6 used.

7 (D) With respect to the priority review
8 voucher program under section 529 of the Fed-
9 eral Food, Drug, and Cosmetic Act (21 U.S.C.
10 360ff)—

11 (i) the resources used by, and burden
12 placed on, the Food and Drug Administra-
13 tion in implementing such program, includ-
14 ing the effect of such program on the Food
15 and Drug Administration's review of drugs
16 for which a priority review voucher was not
17 awarded or used;

18 (ii) the impact of the program on the
19 public health as a result of the expedited
20 review of applications for drugs that treat
21 or prevent non-serious indications that are
22 generally used by the broader public; and

23 (iii) alternative approaches to improv-
24 ing such program so that the program is
25 appropriately targeted toward providing in-

1 centives for the development of clinically
2 important drugs that—

3 (I) prevent or treat rare pediatric
4 diseases; and

5 (II) would likely not otherwise
6 have been developed to prevent or
7 treat such diseases.

8 (2) REPORT.—Not later than December 31,
9 2017, the Comptroller General of the United States
10 shall submit to the Committee on Energy and Com-
11 merce of the House of Representatives and the Com-
12 mittee on Health, Education, Labor, and Pensions
13 of the Senate a report containing the results of the
14 study of conducted under paragraph (1).

15 **Subtitle J—Domestic Manufac-**
16 **turing and Export Efficiencies**

17 **SEC. 2161. GRANTS FOR STUDYING THE PROCESS OF CON-**
18 **TINUOUS DRUG MANUFACTURING.**

19 (a) IN GENERAL.—The Commissioner of Food and
20 Drugs may award grants to institutions of higher edu-
21 cation and nonprofit organizations for the purpose of
22 studying and recommending improvements to the process
23 of continuous manufacturing of drugs and biological prod-
24 ucts and similar innovative monitoring and control tech-
25 niques.

1 (b) DEFINITIONS.—In this section:

2 (1) The term “drug” has the meaning given to
3 such term in section 201 of the Federal Food, Drug,
4 and Cosmetic Act (21 U.S.C. 321).

5 (2) The term “biological product” has the
6 meaning given to such term in section 351(i) of the
7 Public Health Service Act (42 U.S.C. 262(i)).

8 (3) The term “institution of higher education”
9 has the meaning given to such term in section 101
10 of the Higher Education Act of 1965 (20 U.S.C.
11 1001).

12 (c) AUTHORIZATION OF APPROPRIATIONS.—There is
13 authorized to be appropriated to carry out this section
14 \$5,000,000 for each of fiscal years 2016 through 2020.

15 **SEC. 2162. RE-EXPORTATION AMONG MEMBERS OF THE EU-**
16 **ROPEAN ECONOMIC AREA.**

17 Section 1003 of the Controlled Substances Import
18 and Export Act (21 U.S.C. 953) is amended—

19 (1) in subsection (f)—

20 (A) in paragraph (5)—

21 (i) by striking “(5)” and inserting
22 “(5)(A)”;

23 (ii) by inserting “, except that the
24 controlled substance may be exported from
25 the second country to another country that

1 is a member of the European Economic
2 Area” before the period at the end; and

3 (iii) by adding at the end the fol-
4 lowing:

5 “(B) Subsequent to any re-exportation de-
6 scribed in subparagraph (A), a controlled substance
7 may continue to be exported from any country that
8 is a member of the European Economic Area to any
9 other such country, provided that—

10 “(i) the conditions applicable with respect
11 to the first country under paragraphs (1), (2),
12 (3), (4), (6), and (7) are met by each subse-
13 quent country from which the controlled sub-
14 stance is exported pursuant to this paragraph;
15 and

16 “(ii) the conditions applicable with respect
17 to the second country under such paragraphs
18 are met by each subsequent country to which
19 the controlled substance is exported pursuant to
20 this paragraph.”; and

21 (B) in paragraph (6)—

22 (i) by striking “(6)” and inserting
23 “(6)(A)”; and

24 (ii) by adding at the end the fol-
25 lowing:

1 “(B) In the case of re-exportation among mem-
2 bers of the European Economic Area, within 30
3 days after each re-exportation, the person who ex-
4 ported the controlled substance from the United
5 States delivers to the Attorney General—

6 “(i) documentation certifying that such re-
7 exportation has occurred; and

8 “(ii) information concerning the consignee,
9 country, and product.”; and

10 (2) by adding at the end the following:

11 “(g) LIMITATION.—Subject to paragraphs (5) and
12 (6) of subsection (f) in the case of any controlled sub-
13 stance in schedule I or II or any narcotic drug in schedule
14 III or IV, the Attorney General shall not promulgate nor
15 enforce any regulation, subregulatory guidance, or en-
16 forcement policy which impedes re-exportation of any con-
17 trolled substance among European Economic Area coun-
18 tries, including by promulgating or enforcing any require-
19 ment that—

20 “(1) re-exportation from the first country to the
21 second country or re-exportation from the second
22 country to another country occur within a specified
23 period of time; or

24 “(2) information concerning the consignee,
25 country, and product be provided prior to expor-

1 tation of the controlled substance from the United
2 States or prior to each re-exportation among mem-
3 bers of the European Economic Area.”.

4 **Subtitle K—Enhancing** 5 **Combination Products Review**

6 **SEC. 2181. ENHANCING COMBINATION PRODUCTS REVIEW.**

7 Section 503(g)(4)(C) of the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 353(g)(4)(C)) is amended by
9 adding at the end the following new clause:

10 “(iii) Not later than 18 months after the date of the
11 enactment of the 21st Century Cures Act, the Secretary
12 shall issue final guidance that describes the responsibilities
13 of each agency center regarding its review of combination
14 products. The Secretary shall, after soliciting public com-
15 ment, review and update the guidance periodically.”.

16 **Subtitle L—Priority Review for** 17 **Breakthrough Devices**

18 **SEC. 2201. PRIORITY REVIEW FOR BREAKTHROUGH DE-** 19 **VICES.**

20 (a) IN GENERAL.—Chapter V of the Federal Food,
21 Drug, and Cosmetic Act is amended—

22 (1) in section 515(d)—

23 (A) by striking paragraph (5); and

24 (B) by redesignating paragraph (6) as
25 paragraph (5); and

1 (2) by inserting after section 515A (21 U.S.C.
2 360e–1) the following:

3 **“SEC. 515B. PRIORITY REVIEW FOR BREAKTHROUGH DE-**
4 **VICES.**

5 “(a) IN GENERAL.—In order to provide for more ef-
6 fective treatment or diagnosis of life-threatening or irre-
7 versibly debilitating human diseases or conditions, the
8 Secretary shall establish a program to provide priority re-
9 view for devices—

10 “(1) representing breakthrough technologies;

11 “(2) for which no approved alternatives exist;

12 “(3) offering significant advantages over exist-
13 ing approved or cleared alternatives, including the
14 potential to, compared to existing approved or
15 cleared alternatives, reduce or eliminate the need for
16 hospitalization, improve patient quality of life, facili-
17 tate patients’ ability to manage their own care (such
18 as through self-directed personal assistance), or es-
19 tablish long-term clinical efficiencies; or

20 “(4) the availability of which is in the best in-
21 terest of patients.

22 “(b) REQUEST FOR DESIGNATION.—A sponsor of a
23 device may request that the Secretary designate the device
24 for priority review under this section. Any such request
25 for designation may be made at any time prior to the sub-

1 mission of an application under section 515(c), a petition
2 for classification under section 513(f)(2), or a notification
3 under section 510(k).

4 “(c) DESIGNATION PROCESS.—

5 “(1) IN GENERAL.—Not later than 60 calendar
6 days after the receipt of a request under subsection
7 (b), the Secretary shall determine whether the device
8 that is the subject of the request meets the criteria
9 described in subsection (a). If the Secretary deter-
10 mines that the device meets the criteria, the Sec-
11 retary shall designate the device for priority review.

12 “(2) REVIEW.—Review of a request under sub-
13 section (b) shall be undertaken by a team that is
14 composed of experienced staff and managers of the
15 Food and Drug Administration and is chaired by a
16 senior manager.

17 “(3) DESIGNATION DETERMINATION.—A deter-
18 mination approving or denying a request under sub-
19 section (b) shall be considered a significant decision
20 under section 517A and the Secretary shall provide
21 a written, substantive summary of the basis for the
22 determination in accordance with section 517A(a).

23 “(4) RECONSIDERATION.—

24 “(A) REQUEST FOR RECONSIDERATION.—

25 Any person whose request under subsection (b)

1 is denied may, within 30 days of the denial, re-
2 quest reconsideration of the denial in accord-
3 ance with section 517A(b)—

4 “(i) based upon the submission of
5 documents by such person; or

6 “(ii) based upon such documents and
7 a meeting or teleconference.

8 “(B) RESPONSE.—Reconsideration of a
9 designation determination under this paragraph
10 shall be conducted in accordance with section
11 517A(b).

12 “(5) WITHDRAWAL.—If the Secretary approves
13 a priority review designation for a device under this
14 section, the Secretary may not withdraw the des-
15 ignation based on the fact that the criteria specified
16 in subsection (a) are no longer met because of the
17 subsequent clearance or approval of another device
18 that was designated under—

19 “(A) this section; or

20 “(B) section 515(d)(5) (as in effect imme-
21 diately prior to the enactment of the 21st Cen-
22 tury Cures Act).

23 “(d) PRIORITY REVIEW.—

1 “(1) ACTIONS.—For purposes of expediting the
2 development and review of devices designated under
3 subsection (c), the Secretary shall—

4 “(A) assign a team of staff, including a
5 team leader with appropriate subject matter ex-
6 pertise and experience, for each device for
7 which a request is submitted under subsection
8 (b);

9 “(B) provide for oversight of the team by
10 senior agency personnel to facilitate the effi-
11 cient development of the device and the efficient
12 review of any submission described in sub-
13 section (b) for the device;

14 “(C) adopt an efficient process for timely
15 dispute resolution;

16 “(D) provide for interactive communication
17 with the sponsor of the device during the review
18 process;

19 “(E) expedite the Secretary’s review of
20 manufacturing and quality systems compliance,
21 as applicable;

22 “(F) disclose to the sponsor in advance the
23 topics of any consultation concerning the spon-
24 sor’s device that the Secretary intends to under-
25 take with external experts or an advisory com-

1 mittee and provide the sponsor an opportunity
2 to recommend such external experts;

3 “(G) for applications submitted under sec-
4 tion 515(c), provide for advisory committee
5 input, as the Secretary determines appropriate
6 (including in response to the request of the
7 sponsor); and

8 “(H) assign staff to be available within a
9 reasonable time to address questions posed by
10 institutional review committees concerning the
11 conditions and clinical testing requirements ap-
12 plicable to the investigational use of the device
13 pursuant to an exemption under section 520(g).

14 “(2) ADDITIONAL ACTIONS.—In addition to the
15 actions described in paragraph (1), for purposes of
16 expediting the development and review of devices
17 designated under subsection (c), the Secretary, in
18 collaboration with the device sponsor, may, as appro-
19 priate—

20 “(A) coordinate with the sponsor regarding
21 early agreement on a data development plan;

22 “(B) take steps to ensure that the design
23 of clinical trials is as efficient as practicable,
24 such as through adoption of shorter or smaller
25 clinical trials, application of surrogate

1 endpoints, and use of adaptive trial designs and
2 Bayesian statistics, to the extent scientifically
3 appropriate;

4 “(C) facilitate, to the extent scientifically
5 appropriate, expedited and efficient develop-
6 ment and review of the device through utiliza-
7 tion of timely postmarket data collection, with
8 regard to applications for approval under sec-
9 tion 515(c); and

10 “(D) agree to clinical protocols that the
11 Secretary will consider binding on the Secretary
12 and the sponsor, subject to—

13 “(i) changes agreed to by the sponsor
14 and the Secretary;

15 “(ii) changes that the Secretary deter-
16 mines are required to prevent an unreason-
17 able risk to the public health; or

18 “(iii) the identification of a substan-
19 tial scientific issue determined by the Sec-
20 retary to be essential to the safety or effec-
21 tiveness of the device involved.

22 “(e) PRIORITY REVIEW GUIDANCE.—

23 “(1) CONTENT.—The Secretary shall issue
24 guidance on the implementation of this section. Such
25 guidance shall include the following:

1 “(A) The process for a person to seek a
2 priority review designation.

3 “(B) A template for requests under sub-
4 section (b).

5 “(C) The criteria the Secretary will use in
6 evaluating a request for priority review.

7 “(D) The standards the Secretary will use
8 in assigning a team of staff, including team
9 leaders, to review devices designated for priority
10 review, including any training required for such
11 personnel on effective and efficient review.

12 “(2) PROCESS.—Prior to finalizing the guid-
13 ance under paragraph (1), the Secretary shall pro-
14 pose such guidance for public comment.

15 “(f) CONSTRUCTION.—

16 “(1) PURPOSE.—This section is intended to en-
17 courage the Secretary and provide the Secretary suf-
18 ficient authorities to apply efficient and flexible ap-
19 proaches to expedite the development of, and
20 prioritize the agency’s review of, devices that rep-
21 resent breakthrough technologies.

22 “(2) CONSTRUCTION.—Nothing in this section
23 shall be construed to alter the criteria and standards
24 for evaluating an application pursuant to section
25 515(c), a report and request for classification under

1 section 513(f)(2), or a report under section 510(k),
2 including the recognition of valid scientific evidence
3 as described in section 513(a)(3)(B), and consider-
4 ation of the least burdensome means of evaluating
5 device effectiveness or demonstrating substantial
6 equivalence between devices with differing techno-
7 logical characteristics, as applicable. Nothing in this
8 section alters the authority of the Secretary to act
9 on an application pursuant to section 515(d) before
10 completion of an establishment inspection, as the
11 Secretary deems appropriate.”.

12 (b) CONFORMING AMENDMENT RELATED TO DES-
13 IGNATION DETERMINATIONS.—Section 517A(a)(1) of the
14 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–
15 1(a)(1)) is amended by inserting “a request for designa-
16 tion under section 515B,” after “an application under sec-
17 tion 515,”.

18 **Subtitle M—Medical Device**
19 **Regulatory Process Improvements**

20 **SEC. 2221. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

21 (a) ESTABLISHMENT OF THIRD-PARTY QUALITY
22 SYSTEM ASSESSMENT PROGRAM.—Chapter V of the Fed-
23 eral Food, Drug, and Cosmetic Act is amended by insert-
24 ing after section 524A (21 U.S.C. 360n–1) the following
25 new section:

1 **“SEC. 524B. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

2 “(a) ACCREDITATION AND ASSESSMENT.—

3 “(1) IN GENERAL; CERTIFICATION OF DEVICE
4 QUALITY SYSTEM.—The Secretary shall, in accord-
5 ance with this section, establish a third-party quality
6 system assessment program—

7 “(A) to accredit persons to assess whether
8 a requestor’s quality system, including its de-
9 sign controls, can reasonably assure the safety
10 and effectiveness of in-scope devices subject to
11 device-related changes;

12 “(B) under which accredited persons shall
13 (as applicable) certify that a requestor’s quality
14 system meets the criteria included in the guid-
15 ance issued under paragraph (5) with respect to
16 the in-scope devices at issue; and

17 “(C) under which the Secretary shall rely
18 on such certifications for purposes of deter-
19 mining the safety and effectiveness (or as appli-
20 cable, substantial equivalence) of in-scope de-
21 vices subject to the device-related changes in-
22 volved, in lieu of compliance with the following
23 submission requirements:

24 “(i) A premarket notification.

25 “(ii) A 30-day notice.

26 “(iii) A Special PMA supplement.

1 “(2) DEFINITIONS.—For purposes of this sec-
2 tion—

3 “(A) the term ‘device-related changes’
4 means changes made by a requestor with re-
5 spect to in-scope devices, which are—

6 “(i) changes to a device found to be
7 substantially equivalent under sections
8 513(i) and 510(k) to a predicate device,
9 that—

10 “(I) would otherwise be subject
11 to a premarket notification; and

12 “(II) do not alter—

13 “(aa) the intended use of
14 the changed device; or

15 “(bb) the fundamental sci-
16 entific technology of such device;

17 “(ii) manufacturing changes subject
18 to a 30-day notice;

19 “(iii) changes that qualify for a Spe-
20 cial PMA Supplement; and

21 “(iv) such other changes relating to
22 the devices or the device manufacturing
23 process as the Secretary determines appro-
24 priate;

1 “(B) the term ‘in-scope device’ means a
2 device within the scope of devices agreed to by
3 the requestor and the accredited person for pur-
4 poses of a request for certification under this
5 section;

6 “(C) the term ‘premarket notification’
7 means a premarket notification under section
8 510(k);

9 “(D) the term ‘quality system’ means the
10 methods used in, and the facilities and controls
11 used for, the design, manufacture, packaging,
12 labeling, storage, installation, and servicing of
13 devices, as described in section 520(f);

14 “(E) the term ‘requestor’ means a device
15 manufacturer that is seeking certification under
16 this section of a quality system used by such
17 manufacturer;

18 “(F) the term ‘Special PMA’ means a Spe-
19 cial PMA supplement under section 814.39(d)
20 of title 21, Code of Federal Regulations (or any
21 successor regulations); and

22 “(G) the term ‘30-day notice’ means a no-
23 tice described in section 515(d)(6).

24 “(3) ACCREDITATION PROCESS; ACCREDITATION
25 RENEWAL.—Except as inconsistent with this section,

1 the process and qualifications for accreditation of
2 persons and renewal of such accreditation under sec-
3 tion 704(g) shall apply with respect to accreditation
4 of persons and renewal of such accreditation under
5 this section.

6 “(4) USE OF ACCREDITED PARTIES TO CON-
7 DUCT ASSESSMENTS.—

8 “(A) INITIATION OF ASSESSMENT SERV-
9 ICES.—

10 “(i) DATE ASSESSMENTS AUTHOR-
11 IZED.—Beginning after the date on which
12 the final guidance is issued under para-
13 graph (5), an accredited person may con-
14 duct an assessment under this section.

15 “(ii) INITIATION OF ASSESSMENTS.—
16 Use of one or more accredited persons to
17 assess a requestor’s quality system under
18 this section with respect to in-scope devices
19 shall be at the initiation of the person who
20 registers and lists the devices at issue
21 under section 510.

22 “(B) COMPENSATION.—Compensation for
23 such accredited persons shall—

24 “(i) be determined by agreement be-
25 tween the accredited person and the person

1 who engages the services of the accredited
2 person; and

3 “(ii) be paid by the person who en-
4 gages such services.

5 “(C) ACCREDITED PERSON SELECTION.—
6 Each person who chooses to use an accredited
7 person to assess a requestor’s quality system,
8 as described in this section, shall select the ac-
9 credited person from a list of such persons pub-
10 lished by the Secretary in accordance with sec-
11 tion 704(g)(4).

12 “(5) GUIDANCE; CRITERIA FOR CERTIFI-
13 CATION.—

14 “(A) IN GENERAL.—The criteria for cer-
15 tification of a quality system under this section
16 shall be as specified by the Secretary in guid-
17 ance issued under this paragraph.

18 “(B) CONTENTS; CRITERIA.—The guidance
19 under this paragraph shall include specification
20 of—

21 “(i) evaluative criteria to be used by
22 an accredited person to assess and, as ap-
23 plicable, certify a requestor’s quality sys-
24 tem under this section with respect to in-
25 scope devices; and

1 “(ii) criteria for accredited persons to
2 apply for a waiver of, and exemptions
3 from, the criteria under clause (i).

4 “(C) TIMEFRAME FOR ISSUING GUID-
5 ANCE.—The Secretary shall issue under this
6 paragraph—

7 “(i) draft guidance not later than 12
8 months after the enactment of the 21st
9 Century Cures Act; and

10 “(ii) final guidance not later than 12
11 months after issuance of the draft guid-
12 ance under clause (i).

13 “(b) USE OF THIRD-PARTY ASSESSMENT.—

14 “(1) ASSESSMENT SUMMARY; CERTIFI-
15 CATION.—

16 “(A) SUBMISSION OF ASSESSMENT TO SEC-
17 RETARY.—An accredited person who assesses a
18 requestor’s quality system under subsection (a)
19 shall submit to the Secretary a summary of the
20 assessment—

21 “(i) within 30 days of the assessment;
22 and

23 “(ii) which shall include (as applica-
24 ble)—

1 “(I) the accredited person’s cer-
2 tification that the requestor has satis-
3 fied the criteria specified in the guid-
4 ance issued under subsection (a)(5)
5 for quality system certification with
6 respect to the in-scope devices at
7 issue; and

8 “(II) any waivers or exemptions
9 from such criteria applied by the ac-
10 credited person.

11 “(B) TREATMENT OF ASSESSMENTS.—

12 Subject to action by the Secretary under sub-
13 paragraph (C), with respect to assessments
14 which include a certification under this sec-
15 tion—

16 “(i) the Secretary’s review of the as-
17 sessment summary shall be deemed com-
18 plete on the day that is 30 days after the
19 date on which the Secretary receives the
20 summary under subparagraph (A); and

21 “(ii) the assessment summary and
22 certification of the quality system of a re-
23 questor shall be deemed accepted by the
24 Secretary on such 30th day.

25 “(C) ACTIONS BY SECRETARY.—

1 “(i) IN GENERAL.—Within 30 days of
2 receiving an assessment summary and cer-
3 tification under subparagraph (A), the Sec-
4 retary may, by written notice to the ac-
5 credited person submitting such assess-
6 ment certification, deem any such certifi-
7 cation to be provisional beyond such 30-
8 day period, suspended pending further re-
9 view by the Secretary, or otherwise quali-
10 fied or cancelled, based on the Secretary’s
11 determination that (as applicable)—

12 “(I) additional information is
13 needed to support such certification;

14 “(II) such assessment or certifi-
15 cation is unwarranted; or

16 “(III) such action with regard to
17 the certification is otherwise justified
18 according to such factors and criteria
19 as the Secretary finds appropriate.

20 “(ii) ACCEPTANCE OF CERTIFI-
21 CATION.—If following action by the Sec-
22 retary under clause (i) with respect to a
23 certification, the Secretary determines that
24 such certification is acceptable, the Sec-
25 retary shall issue written notice to the ap-

1 plicable accredited person indicating such
2 acceptance.

3 “(2) NOTIFICATIONS TO SECRETARY BY CER-
4 TIFIED REQUESTORS OR ACCREDITED PERSONS FOR
5 PROGRAM EVALUATION PURPOSES.—

6 “(A) ANNUAL SUMMARY REPORT FOR DE-
7 VICE-RELATED CHANGES OTHERWISE SUBJECT
8 TO PREMARKET NOTIFICATION.—A requestor
9 whose quality system is certified under this sec-
10 tion that effectuates device-related changes with
11 respect to in-scope devices, without prior sub-
12 mission of a premarket notification, shall en-
13 sure that an annual summary report is sub-
14 mitted to the Secretary by the accredited per-
15 son which—

16 “(i) describes the changes made to the
17 in-scope device; and

18 “(ii) indicates the effective dates of
19 such changes.

20 “(B) PERIODIC NOTIFICATION FOR MANU-
21 FACTURING CHANGES OTHERWISE SUBJECT TO
22 30-DAY NOTICE.—A requestor whose quality
23 system is certified under this section that effec-
24 tuates device-related changes with respect to in-
25 scope devices, without prior submission of a 30-

1 day notice, shall provide notification to the Sec-
2 retary of such changes in the requestor's next
3 periodic report under section 814.84(b) of title
4 21, Code of Federal Regulations (or any suc-
5 cessor regulation). Such notification shall—

6 “(i) describe the changes made; and

7 “(ii) indicate the effective dates of
8 such changes.

9 “(C) PERIODIC NOTIFICATION FOR DE-
10 VICE-RELATED CHANGES OTHERWISE SUBJECT
11 TO SPECIAL PMA SUPPLEMENT.—A requestor
12 whose quality system is certified under this sec-
13 tion that effectuates device-related changes with
14 respect to in-scope devices, without prior sub-
15 mission of a Special PMA Supplement, shall
16 provide notification to the Secretary of such
17 changes in the requestor's next periodic report
18 under section 814.84(b) of title 21, Code of
19 Federal Regulations (or any successor regula-
20 tion). Such notification shall—

21 “(i) describe the changes made, in-
22 cluding a full explanation of the basis for
23 the changes; and

24 “(ii) indicate the effective dates of
25 such changes.

1 “(D) USE OF NOTIFICATIONS FOR PRO-
2 GRAM EVALUATION PURPOSES.—Information
3 submitted to the Secretary under subpara-
4 graphs (A) through (C) shall be used by the
5 Secretary for purposes of the program evalua-
6 tion under subsection (d).

7 “(c) DURATION AND EFFECT OF CERTIFICATION.—
8 A certification under this section—

9 “(1) shall remain in effect for a period of 2
10 years from the date such certification is accepted by
11 the Secretary, subject to paragraph (6);

12 “(2) may be renewed through the process de-
13 scribed in subsection (a)(3);

14 “(3) shall continue to apply with respect to de-
15 vice-related changes made during such 2-year period,
16 provided the certification remains in effect, irrespec-
17 tive of whether such certification is renewed after
18 such 2-year period;

19 “(4) shall have no effect on the need to comply
20 with applicable submission requirements specified in
21 subsection (a)(1)(C) with respect to any change per-
22 taining to in-scope devices which is not a device-re-
23 lated change under subsection (a)(2);

24 “(5) shall have no effect on the authority of the
25 Secretary to conduct an inspection or otherwise de-

1 termine whether the requestor has complied with the
2 applicable requirements of this Act; and

3 “(6) may be revoked by the Secretary upon a
4 determination that the requestor’s quality system no
5 longer meets the criteria specified in the guidance
6 issued under subsection (a)(5) with respect to the
7 in-scope devices at issue.

8 “(d) NOTICE OF REVOCATION.—The Secretary shall
9 provide written notification to the requestor of a revoca-
10 tion pursuant to subsection (c)(6) not later than 10 busi-
11 ness days after the determination described in such sub-
12 section. Upon receipt of the written notification, the re-
13 questor shall satisfy the applicable submission require-
14 ments specified in subsection (a)(1)(C) for any device-re-
15 lated changes effectuated after the date of such deter-
16 mination. After such revocation, such requestor is eligible
17 to seek re-certification under this section of its quality sys-
18 tem.

19 “(e) PROGRAM EVALUATION; SUNSET.—

20 “(1) PROGRAM EVALUATION AND REPORT.—

21 “(A) EVALUATION.—The Secretary shall
22 complete an evaluation of the third-party qual-
23 ity system assessment program under this sec-
24 tion no later than January 31, 2021, based
25 on—

1 “(i) analysis of information from a
2 representative group of device manufactur-
3 ers obtained from notifications provided by
4 certified requestors or accredited persons
5 under subsection (b)(2); and

6 “(ii) such other available information
7 and data as the Secretary determines ap-
8 propriate.

9 “(B) REPORT.—No later than 1 year after
10 completing the evaluation under subparagraph
11 (A), the Secretary shall issue a report of the
12 evaluation’s findings on the website of the Food
13 and Drug Administration, which shall include
14 the Secretary’s recommendations with respect
15 to continuation and as applicable expansion of
16 the program under this section to encompass—

17 “(i) device submissions beyond those
18 identified in subsection (a)(1)(C); and

19 “(ii) device changes beyond those de-
20 scribed in subsection (a)(2)(A).

21 “(2) SUNSET.—This section shall cease to be
22 effective October 1, 2022.

23 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-
24 tion shall be construed to limit the authority of the Sec-
25 retary to request and review the complete assessment of

1 a certified requestor under this section on a for-cause
2 basis.”.

3 (b) CONFORMING AMENDMENTS.—

4 (1) REQUIREMENTS FOR PREMARKET AP-
5 PROVAL SUPPLEMENTS.—Section 515(d)(5)(A)(i) of
6 the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 360e(d)(5)(A)(i)), as redesignated by section
8 2201, is further amended by inserting “, subject to
9 section 524B” after “that affects safety or effective-
10 ness”.

11 (2) REQUIREMENTS FOR 30-DAY NOTICE.—Sec-
12 tion 515(d)(5)(A)(ii) of the Federal Food, Drug,
13 and Cosmetic Act (21 U.S.C. 360e(d)(5)(A)(ii)), as
14 redesignated by section 2201, is further amended by
15 inserting “, subject to section 524B” after “the date
16 on which the Secretary receives the notice”.

17 (3) REQUIREMENTS FOR PREMARKET NOTIFI-
18 CATION; TECHNICAL CORRECTION TO REFERENCE
19 TO SECTION 510(K).—Section 510(l) of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is
21 amended by striking “of this subsection under sub-
22 section (m)” and inserting “of subsection (k) under
23 subsection (m) or section 524B”.

24 (4) MISBRANDED DEVICES.—Section 502(t) of
25 the Federal Food, Drug, and Cosmetic Act (21

1 U.S.C. 352(t)) is amended by inserting “or 524B”
2 after “section 519”.

3 **SEC. 2222. VALID SCIENTIFIC EVIDENCE.**

4 Section 513(a)(3)(B) of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 360c(a)(3)(B)) is amended—

6 (1) by redesignating clauses (i) and (ii) as sub-
7 clauses (I) and (II), respectively;

8 (2) by striking “(B) If the Secretary” and in-
9 serting “(B)(i) If the Secretary”; and

10 (3) by adding at the end the following:

11 “(ii) For purposes of clause (i), valid scientific evi-
12 dence may include—

13 “(I) evidence described in well-documented case
14 histories, including registry data, that are collected
15 and monitored under a protocol determined to be ac-
16 ceptable by the Secretary;

17 “(II) studies published in peer-reviewed jour-
18 nals; and

19 “(III) data collected in countries other than the
20 United States so long as such data otherwise meet
21 the criteria specified in this subparagraph.

22 “(iii) In the case of a study published in a peer-re-
23 viewed journal that is offered as valid scientific evidence
24 for purposes of clause (i), the Secretary may request data
25 underlying the study if—

1 “(I) the Secretary, in making such request,
2 complies with the requirement of subparagraph
3 (D)(ii) to consider the least burdensome appropriate
4 means of evaluating device effectiveness or sub-
5 section (i)(1)(D) to consider the least burdensome
6 means of determining substantial equivalence, as ap-
7 plicable;

8 “(II) the Secretary furnishes a written rationale
9 for so requesting the underlying data together with
10 such request; and

11 “(III) if the requested underlying data for such
12 a study are unavailable, the Secretary shall consider
13 such study to be part of the totality of the evidence
14 with respect to the device, as the Secretary deter-
15 mines appropriate.”.

16 **SEC. 2223. TRAINING AND OVERSIGHT IN LEAST BURDEN-**
17 **SOME APPROPRIATE MEANS CONCEPT.**

18 (a) IN GENERAL.—Section 513 of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by
20 adding at the end the following:

21 “(j) TRAINING AND OVERSIGHT IN LEAST BURDEN-
22 SOME APPROPRIATE MEANS CONCEPT.—

23 “(1) TRAINING.—Each employee of the Food
24 and Drug Administration who is involved in the re-
25 view of premarket submissions under section 515 or

1 section 510(k), including supervisors, shall receive
2 training regarding the meaning and implementation
3 of the least burdensome appropriate means concept
4 in the context of the use of that term in subsections
5 (a)(3)(D) and (i)(1)(D) of this section and in section
6 515(c)(5).

7 “(2) GUIDANCE DOCUMENTS.—

8 “(A) DRAFT UPDATED GUIDANCE.—Not
9 later than 12 months after the date of enact-
10 ment of the 21st Century Cures Act, the Sec-
11 retary shall issue a draft guidance document
12 updating the October 4, 2002, guidance docu-
13 ment entitled ‘The Least Burdensome Provision
14 of the FDA Modernization Act of 1997: Con-
15 cept and Principles; Final Guidance for FDA
16 and Industry’.

17 “(B) MEETING OF STAKEHOLDERS.—In
18 developing such draft guidance document, the
19 Secretary shall convene a meeting of stake-
20 holders to ensure a full record to support the
21 publication of such document.

22 “(3) OMBUDSMAN AUDIT.—Not later than 18
23 months after the date of issuance of final version of
24 the draft guidance under paragraph (2), the om-
25 budsman for the organizational unit of the Food and

1 Drug Administration responsible for the premarket
2 review of devices shall—

3 “(A) conduct, or have conducted, an audit
4 of the training described in paragraph (1); and

5 “(B) include in such audit interviews with
6 a representative sample of persons from indus-
7 try regarding their experience in the device pre-
8 market review process.”.

9 (b) ADDITIONAL INFORMATION REGARDING PRE-
10 MARKET APPLICATIONS.—Subsection (c) of section 515 of
11 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 360e) is amended by adding at the end the following:

13 “(5)(A) Whenever the Secretary requests additional
14 information from an applicant regarding an application
15 under paragraph (1), the Secretary shall consider the least
16 burdensome appropriate means necessary to demonstrate
17 device safety and effectiveness, and request information
18 accordingly.

19 “(B) For purposes of subparagraph (A), the term
20 ‘necessary’ means the minimum required information that
21 would support a determination by the Secretary that an
22 application provides a reasonable assurance of the safety
23 and effectiveness of the device.

24 “(C) Nothing in this paragraph alters the standards
25 for premarket approval of a device.”.

1 **SEC. 2224. RECOGNITION OF STANDARDS.**

2 Section 514(c) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 360d(c)) is amended—

4 (1) in paragraph (1), by inserting after sub-
5 paragraph (B) the following new subparagraphs:

6 “(C)(i) Any person may submit a request for recogni-
7 tion under subparagraph (A) of all or part of an appro-
8 priate standard established by a nationally or internation-
9 ally recognized standard organization.

10 “(ii) Not later than 60 days after the Secretary re-
11 ceives such a request, the Secretary shall—

12 “(I) make a determination to recognize all,
13 part, or none of the standard that is the subject of
14 the request; and

15 “(II) issue to the person who submitted such
16 request a response in writing that states the Sec-
17 retary’s rationale for that determination, including
18 the scientific, technical, regulatory, or other basis for
19 such determination.

20 “(iii) The Secretary shall make a response issued
21 under clause (ii)(II) publicly available, in such manner as
22 the Secretary determines appropriate.

23 “(iv) The Secretary shall take such actions as may
24 be necessary to implement all or part of a standard recog-
25 nized under clause (i)(I), in accordance with subparagraph
26 (A).

1 “(D) The Secretary shall make publicly available, in
2 such manner as the Secretary determines appropriate, the
3 rationale for recognition under subparagraph (A) of part
4 of a standard, including the scientific, technical, regu-
5 latory, or other basis for such recognition.”; and

6 (2) by adding at the end the following new
7 paragraphs:

8 “(4) TRAINING ON USE OF STANDARDS.—The
9 Secretary shall provide to all employees of the Food
10 and Drug Administration who review premarket sub-
11 missions for devices periodic training on the concept
12 and use of recognized standards for purposes of
13 meeting a premarket submission requirement or
14 other applicable requirement under this Act, includ-
15 ing standards relevant to an employee’s area of de-
16 vice review.

17 “(5) GUIDANCE.—

18 “(A) DRAFT GUIDANCE.—The Secretary
19 shall publish guidance identifying the principles
20 for recognizing standards under this section. In
21 publishing such guidance, the Secretary shall
22 consider—

23 “(i) the experience with, and reliance
24 on, a standard by other Federal regulatory
25 authorities and the device industry; and

1 “(ii) whether recognition of a stand-
2 ard will promote harmonization among reg-
3 ulatory authorities in the regulation of de-
4 vices.

5 “(B) TIMING.—The Secretary shall pub-
6 lish—

7 “(i) draft guidance under subpara-
8 graph (A) not later than 12 months after
9 the date of the enactment of the 21st Cen-
10 tury Cures Act; and

11 “(ii) final guidance not later than 12
12 months after the close of the public com-
13 ment period for the draft guidance under
14 clause (i).”.

15 **SEC. 2225. EASING REGULATORY BURDEN WITH RESPECT**
16 **TO CERTAIN CLASS I AND CLASS II DEVICES.**

17 (a) CLASS I DEVICES.—Section 510(l) of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is
19 amended—

20 (1) by striking “A report under subsection (k)”
21 and inserting “(1) A report under subsection (k)”;
22 and

23 (2) by adding at the end the following new
24 paragraph:

1 “(2) Not later than 120 days after the date of the
2 enactment of the 21st Century Cures Act, the Secretary
3 shall identify, through publication in the Federal Register,
4 any type of class I device that the Secretary determines
5 no longer requires a report under subsection (k) to provide
6 reasonable assurance of safety and effectiveness. Upon
7 such publication—

8 “(A) each type of class I device so identified
9 shall be exempt from the requirement for a report
10 under subsection (k); and

11 “(B) the classification regulation applicable to
12 each such type of device shall be deemed amended
13 to incorporate such exemption.”.

14 (b) CLASS II DEVICES.—Section 510(m) of the Fed-
15 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360(m))
16 is amended—

17 (1) by striking paragraph (1) and inserting the
18 following new paragraph: “(1) The Secretary shall—

19 “(A) not later than 60 days after the date of
20 the enactment of the 21st Century Cures Act—

21 “(i) publish in the Federal Register a no-
22 tice that contains a list of each type of class II
23 device that the Secretary determines no longer
24 requires a report under subsection (k) to pro-

1 vide reasonable assurance of safety and effec-
2 tiveness; and

3 “(ii) provide for a period of not less than
4 60 days for public comment beginning on the
5 date of the publication of such notice; and

6 “(B) not later than 180 days after the date of
7 the enactment of 21st Century Cures Act, publish in
8 the Federal Register a list representing the Sec-
9 retary’s final determination with respect to the de-
10 vices included in the list published under subpara-
11 graph (A).”;

12 (2) in paragraph (2)—

13 (A) by striking “1 day after the date of the
14 publication of a list under this subsection,” and
15 inserting “1 day after the date of publication of
16 the final list under paragraph (1)(B),”; and

17 (B) by striking “30-day period” and in-
18 serting “60-day period”; and

19 (3) by adding at the end the following new
20 paragraph:

21 “(3) Upon the publication of the final list under para-
22 graph (1)(B)—

23 “(A) each type of class II device so listed shall
24 be exempt from the requirement for a report under
25 subsection (k); and

1 “(B) the classification regulation applicable to
2 each such type of device shall be deemed amended
3 to incorporate such exemption.”.

4 **SEC. 2226. ADVISORY COMMITTEE PROCESS.**

5 (a) CLASSIFICATION PANELS.—Paragraph (5) of sec-
6 tion 513(b) of the Federal Food, Drug, and Cosmetic Act
7 (21 U.S.C. 360c(b)) is amended—

8 (1) by striking “(5)” and inserting “(5)(A)”;
9 and

10 (2) by adding at the end the following:

11 “(B) When a device is specifically the subject of re-
12 view by a classification panel, the Secretary shall—

13 “(i) ensure that adequate expertise is rep-
14 resented on the classification panel to assess—

15 “(I) the disease or condition which the de-
16 vice is intended to cure, treat, mitigate, prevent,
17 or diagnose; and

18 “(II) the technology of the device; and

19 “(ii) as part of the process to ensure adequate
20 expertise under clause (i), give due consideration to
21 the recommendations of the person whose premarket
22 submission is subject to panel review on the exper-
23 tise needed among the voting members of the panel.

24 “(C) For purposes of subparagraph (B)(ii), the term
25 ‘adequate expertise’ means, with respect to the member-

1 ship of the classification panel reviewing a premarket sub-
2 mission, that such membership includes—

3 “(i) two or more voting members, with a spe-
4 cialty or other expertise clinically relevant to the de-
5 vice under review; and

6 “(ii) at least one voting member who is knowl-
7 edgeable about the technology of the device.”.

8 (b) PANEL REVIEW PROCESS.—Section 513(b)(6) of
9 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 360c(b)(6)) is amended—

11 (1) in subparagraph (A)(iii), by inserting before
12 the period at the end “, including by designating a
13 representative who will be provided a time during
14 the panel meeting to address the panel individually
15 (or accompanied by experts selected by such rep-
16 resentative) for the purpose of correcting
17 misstatements of fact or providing clarifying infor-
18 mation, subject to the discretion of the panel chair-
19 person”; and

20 (2) by striking subparagraph (B) and inserting
21 the following new subparagraph:

22 “(B)(i) Any meeting of a classification panel for a
23 device that is specifically the subject of review shall—

24 “(I) provide adequate time for initial presen-
25 tations by the person whose device is specifically the

1 subject of a classification panel review and by the
2 Secretary; and

3 “(II) encourage free and open participation by
4 all interested persons.

5 “(ii) Following the initial presentations described in
6 clause (i), the panel may—

7 “(I) pose questions to a designated representa-
8 tive described in subparagraph (A)(iii); and

9 “(II) consider the responses to such questions
10 in the panel’s review of the device that is specifically
11 the subject of review by the panel.”.

12 **SEC. 2227. HUMANITARIAN DEVICE EXEMPTION APPLICA-**
13 **TION.**

14 (a) IN GENERAL.—Section 520(m) of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amend-
16 ed—

17 (1) in paragraph (1) by striking “fewer than
18 4,000” and inserting “not more than 8,000”;

19 (2) in paragraph (2)(A) by striking “fewer than
20 4,000” and inserting “not more than 8,000”; and

21 (3) in paragraph (6)(A)(ii), by striking “4,000”
22 and inserting “8,000”.

23 (b) GUIDANCE DOCUMENT ON PROBABLE BEN-
24 EFIT.—Not later than 18 months after the date of enact-
25 ment of this Act, the Secretary of Health and Human

1 Services, acting through the Commissioner of Food and
2 Drugs, shall publish a draft guidance document that de-
3 fines the criteria for establishing “probable benefit” as
4 that term is used in section 520(m)(2)(C) of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)(C)).

6 **SEC. 2228. CLIA WAIVER STUDY DESIGN GUIDANCE FOR IN**
7 **VITRO DIAGNOSTICS.**

8 (a) DRAFT REVISED GUIDANCE.—Not later than 12
9 months after the date of the enactment of this Act, the
10 Secretary of Health and Human Services shall publish a
11 draft guidance that—

12 (1) revises “Section V. Demonstrating Insignifi-
13 cant Risk of an Erroneous Result—‘Accuracy’” of
14 the guidance entitled “Recommendations for Clinical
15 Laboratory Improvement Amendments of 1988
16 (CLIA) Waiver Applications for Manufacturers of In
17 Vitro Diagnostic Devices” and dated January 30,
18 2008; and

19 (2) includes guidance on the appropriate use of
20 comparable performance between a waived user and
21 a moderately complex laboratory user to dem-
22 onstrate accuracy.

23 (b) FINAL REVISED GUIDANCE.—The Secretary of
24 Health and Human Services shall finalize the draft guid-
25 ance published under subsection (a) not later than 12

1 months after the comment period for such draft guidance
2 closes.

3 **Subtitle N—Sensible Oversight for**
4 **Technology Which Advances**
5 **Regulatory Efficiency**

6 **SEC. 2241. HEALTH SOFTWARE.**

7 Section 201 of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 321) is amended by adding at the end the
9 following:

10 “(ss)(1) The term ‘health software’ means software
11 that does not, through use of an in vitro diagnostic device
12 or signal acquisition system, acquire, process, or analyze
13 an image or physiological signal, is not an accessory, is
14 not an integral part of a device necessary to support the
15 use of the device, is not used in the manufacture and
16 transfusion of blood and blood components to assist in the
17 prevention of disease in humans, and—

18 “(A) is intended for use for administrative or
19 operational support or the processing and mainte-
20 nance of financial records;

21 “(B) is intended for use in clinical, laboratory,
22 or administrative workflow and related record-
23 keeping;

24 “(C)(i) is intended for use solely in the trans-
25 fer, aggregation, conversion (in accordance with a

1 present specification), storage, management, re-
2 trieval, or transmission of data or information;

3 “(ii) utilizes a connectivity software platform,
4 electronic or electrical hardware, or a physical com-
5 munications infrastructure; and

6 “(iii) is not intended for use—

7 “(I) in active patient monitoring; or

8 “(II) in controlling or altering the func-
9 tions or parameters of a device that is con-
10 nected to such software;

11 “(D) is intended for use to organize and
12 present information for health or wellness education
13 or for use in maintaining a healthy lifestyle, includ-
14 ing medication adherence and health management
15 tools;

16 “(E) is intended for use to analyze information
17 to provide general health information that does not
18 include patient-specific recommended options to con-
19 sider in the prevention, diagnosis, treatment, cure,
20 or mitigation of a particular disease or condition; or

21 “(F) is intended for use to analyze information
22 to provide patient-specific recommended options to
23 consider in the prevention, diagnosis, treatment,
24 cure, or mitigation of a particular disease or condi-
25 tion.

1 “(2) The term ‘accessory’ means a product that—

2 “(A) is intended for use with one or more par-
3 ent devices;

4 “(B) is intended to support, supplement, or
5 augment the performance of one or more parent de-
6 vices; and

7 “(C) shall be classified by the Secretary—

8 “(i) according to its intended use; and

9 “(ii) independently of any classification of
10 any parent device with which it is used.”.

11 **SEC. 2242. APPLICABILITY AND INAPPLICABILITY OF REGU-**
12 **LATION.**

13 Subchapter A of chapter V of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), as
15 amended by section 2221(a), is further amended by add-
16 ing at the end the following:

17 **“SEC. 524C. HEALTH SOFTWARE.**

18 “(a) INAPPLICABILITY OF REGULATION TO HEALTH
19 SOFTWARE.—Except as provided in subsection (b), health
20 software shall not be subject to regulation under this Act.

21 “(b) EXCEPTION.—

22 “(1) IN GENERAL.—Subsection (a) shall not
23 apply with respect to a software product—

24 “(A) of a type described in subparagraph
25 (F) of section 201(ss)(1); and

1 “(B) that the Secretary determines poses a
2 significant risk to patient safety.

3 “(2) CONSIDERATIONS.—In making a deter-
4 mination under subparagraph (B) of paragraph (1)
5 with respect to a product to which such paragraph
6 applies, the Secretary shall consider the following:

7 “(A) The likelihood and severity of patient
8 harm if the product were to not perform as in-
9 tended.

10 “(B) The extent to which the product is
11 intended to support the clinical judgment of a
12 medical professional.

13 “(C) Whether there is a reasonable oppor-
14 tunity for a medical professional to review the
15 basis of the information or treatment rec-
16 ommendation provided by the product.

17 “(D) The intended user and user environ-
18 ment, such as whether a medical professional
19 will use a software product of a type described
20 in subparagraph (F) of section 201(ss)(1).

21 “(c) DELEGATION.—The Secretary shall delegate pri-
22 mary jurisdiction for regulating a software product deter-
23 mined under subsection (b) to be subject to regulation
24 under this Act to the center at the Food and Drug Admin-
25 istration charged with regulating devices.

1 “(d) REGULATION OF SOFTWARE.—

2 “(1) IN GENERAL.—The Secretary shall review
3 existing regulations and guidance regarding the reg-
4 ulation of software under this Act. The Secretary
5 may implement a new framework for the regulation
6 of software and shall, as appropriate, modify such
7 regulations and guidance or issue new regulations or
8 guidance.

9 “(2) ISSUANCE BY ORDER.—Notwithstanding
10 subchapter II of chapter 5 of title 5, United States
11 Code, the Secretary may modify or issue regulations
12 for the regulation of software under this Act by ad-
13 ministrative order published in the Federal Register
14 following the publication of a proposed order.

15 “(3) AREAS UNDER REVIEW.—The review of ex-
16 isting regulations and guidance under paragraph (1)
17 may include review of the following areas:

18 “(A) Classification of software.

19 “(B) Standards for development of soft-
20 ware.

21 “(C) Standards for validation and
22 verification of software.

23 “(D) Review of software.

24 “(E) Modifications to software.

25 “(F) Manufacturing of software.

1 “(G) Quality systems for software.

2 “(H) Labeling requirements for software.

3 “(I) Postmarketing requirements for re-
4 porting of adverse events.

5 “(4) PROCESS FOR ISSUING PROPOSED REGU-
6 LATIONS, ADMINISTRATIVE ORDER, AND GUID-
7 ANCE.—Not later than 18 months after the date of
8 enactment of this section, the Secretary shall consult
9 with external stakeholders (including patients, indus-
10 try, health care providers, academia, and govern-
11 ment) to gather input before issuing regulations, an
12 administrative order, and guidance under this sub-
13 section.

14 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-
15 tion shall be construed as providing the Secretary with the
16 authority to regulate under this Act any health software
17 product of the type described in subparagraph (F) of sec-
18 tion 201(ss)(1) unless and until the Secretary has made
19 a determination described in subsection (b)(1)(B) with re-
20 spect to such product.”.

21 **SEC. 2243. EXCLUSION FROM DEFINITION OF DEVICE.**

22 Section 201(h) of the Federal Food, Drug, and Cos-
23 metic Act (21 U.S.C. 321) is amended—

24 (1) in subparagraph (2), by striking “or” after
25 “or other animals,”;

1 (2) in subparagraph (3), by striking “and” and
2 inserting “or”; and

3 (3) by inserting after subparagraph (3) the fol-
4 lowing:

5 “(4) not health software (other than software
6 determined to be a risk to patient safety under sec-
7 tion 524B(b)), and”.

8 **Subtitle O—Streamlining Clinical** 9 **Trials**

10 **SEC. 2261. PROTECTION OF HUMAN SUBJECTS IN RE-** 11 **SEARCH; APPLICABILITY OF RULES.**

12 (a) IN GENERAL.—In order to simplify and facilitate
13 compliance by researchers with applicable regulations for
14 the protection of human subjects in research, the Sec-
15 retary of Health and Human Services shall, to the extent
16 possible and consistent with other statutory provisions,
17 harmonize differences between the HHS Human Subject
18 Regulations and the FDA Human Subject Regulations in
19 accordance with subsection (b).

20 (b) AVOIDING REGULATORY DUPLICATION AND UN-
21 NECESSARY DELAYS.—

22 (1) IN GENERAL.—The Secretary shall—

23 (A) make such modifications to the provi-
24 sions of the HHS Human Subject Regulations,
25 the FDA Human Subject Regulations, and the

1 vulnerable-populations rules as may be nec-
2 essary—

3 (i) to reduce regulatory duplication
4 and unnecessary delays;

5 (ii) to modernize such provisions in
6 the context of multisite and cooperative re-
7 search projects; and

8 (iii) to incorporate local consider-
9 ations, community values, and mechanisms
10 to protect vulnerable populations; and

11 (B) ensure that human subject research
12 that is subject to the HHS Human Subject
13 Regulations or to the FDA Human Subject
14 Regulations may—

15 (i) use joint or shared review;

16 (ii) rely upon the review of—

17 (I) an independent institutional
18 review board; or

19 (II) an institutional review board
20 of an entity other than the sponsor of
21 the research; or

22 (iii) use similar arrangements to avoid
23 duplication of effort.

24 (2) REGULATIONS AND GUIDANCE.—Not later
25 than 36 months after the date of enactment of this

1 Act, the Secretary, acting through the relevant agen-
2 cies and offices of the Department of Health and
3 Human Services, including the Office for Human
4 Research Protections and relevant agencies and of-
5 fices of the Food and Drug Administration, shall
6 issue such regulations and guidance and take such
7 other actions as may be necessary to implement this
8 section and help to facilitate the broader use of sin-
9 gle, central, or lead institutional review boards. Such
10 regulations and guidance shall clarify the require-
11 ments and policies relating to the following:

12 (A) Arrangements to avoid duplication de-
13 scribed in paragraph (1)(A)(i), including—

14 (i) delineating the roles of institu-
15 tional review boards in multisite or cooper-
16 ative, multisite studies where one or more
17 local institutional review boards are relied
18 upon, or similar arrangements are used;

19 (ii) the risks and benefits to human
20 subjects;

21 (iii) standardizing the informed con-
22 sent and other processes and legal docu-
23 ments; and

24 (iv) incorporating community values
25 through the use of local institutional re-

1 view boards while continuing to use central
2 or lead institutional review boards.

3 (B) Concerns about regulatory and legal li-
4 ability contributing to decisions by the sponsors
5 of research to rely on local institutional review
6 boards for multisite research.

7 (3) CONSULTATION.—In issuing regulations or
8 guidance under paragraph (2), the Secretary shall
9 consult with stakeholders (including researchers,
10 academic organizations, hospitals, institutional re-
11 search boards, pharmaceutical, biotechnology and
12 medical device developers, clinical research organiza-
13 tions, patient groups, and others).

14 (c) TIMING.—The Secretary shall complete the har-
15 monization described in subsection (a) not later than 36
16 months after the date of enactment of this Act.

17 (d) PROGRESS REPORT.—Not later than 24 months
18 after the date of enactment of this Act, the Secretary shall
19 submit to Congress a report on the progress made toward
20 completing such harmonization.

21 (e) DRAFT NIH POLICY.—Not later than 12 months
22 after the date of enactment of this Act, the Secretary, act-
23 ing through the Director of the National Institutes of
24 Health, shall finalize the draft policy entitled “Draft NIH

1 Policy on Use of a Single Institutional Review Board for
2 Multi-Site Research”.

3 (f) DEFINITIONS.—

4 (1) HUMAN SUBJECT REGULATIONS.—In this
5 section:

6 (A) FDA HUMAN SUBJECT REGULA-
7 TIONS.—The term “FDA Human Subject Reg-
8 ulations” means the provisions of parts 50, 56,
9 312, and 812 of title 21, Code of Federal Regu-
10 lations (or any successor regulations).

11 (B) HHS HUMAN SUBJECT REGULA-
12 TIONS.—The term “HHS Human Subject Reg-
13 ulations” means the provisions of subpart A of
14 part 46 of title 45, Code of Federal Regulations
15 (or any successor regulations).

16 (C) VULNERABLE-POPULATIONS RULES.—
17 The term “vulnerable-populations rules”—

18 (i) subject to clause (ii), means the
19 provisions of subparts B through D of
20 such part 46 (or any successor regula-
21 tions); or

22 (ii) as applicable to research that is
23 subject to the FDA Human Subject Regu-
24 lations, means the provisions applicable to
25 vulnerable populations under part 56 of

1 such title 21 (or any successor regulations)
2 and subpart D of part 50 of such title 21
3 (or any successor regulations).

4 (2) OTHER DEFINITIONS.—In this section:

5 (A) INSTITUTIONAL REVIEW BOARD.—The
6 term “institutional review board” has the mean-
7 ing that applies to the term “institutional re-
8 view board” under the HHS Human Subject
9 Regulations.

10 (B) LEAD INSTITUTIONAL REVIEW
11 BOARD.—The term “lead institutional review
12 board” means an institutional review board that
13 otherwise meets the requirements of the HHS
14 Human Subject Regulations and enters into a
15 written agreement with an institution, another
16 institutional review board, a sponsor, or a prin-
17 cipal investigator to approve and oversee human
18 subject research that is conducted at multiple
19 locations. References to an institutional review
20 board include an institutional review board that
21 serves a single institution as well as a lead in-
22 stitutional review board.

1 **SEC. 2262. USE OF NON-LOCAL INSTITUTIONAL REVIEW**
2 **BOARDS FOR REVIEW OF INVESTIGATIONAL**
3 **DEVICE EXEMPTIONS AND HUMAN DEVICE**
4 **EXEMPTIONS.**

5 (a) IN GENERAL.—Section 520 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 360(j)) is amended—

7 (1) in subsection (g)(3)—

8 (A) by striking “local” each place it ap-
9 pears; and

10 (B) in subparagraph (A)(i), by striking
11 “which has been”; and

12 (2) in subsection (m)(4)—

13 (A) by striking “local” each place it ap-
14 pears; and

15 (B) by striking subparagraph (A) and in-
16 serting the following new subparagraph:

17 “(A) in facilities in which clinical testing of de-
18 vices is supervised by an institutional review com-
19 mittee established in accordance with the regulations
20 of the Secretary, and”.

21 (b) REGULATIONS.—Not later than 12 months after
22 the date of the enactment of this Act, the Secretary of
23 Health and Human Services shall revise or issue such reg-
24 ulations or guidance as may be necessary to carry out the
25 amendments made by subsection (a).

1 **SEC. 2263. ALTERATION OR WAIVER OF INFORMED CON-**
2 **SENT FOR CLINICAL INVESTIGATIONS.**

3 (a) DEVICES.—Section 520(g)(3) of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(3)) is
5 amended—

6 (1) in subparagraph (D), by striking “except
7 where subject to such conditions as the Secretary
8 may prescribe, the investigator” and inserting the
9 following: “except where, subject to such conditions
10 as the Secretary may prescribe—

11 “(i) the proposed clinical testing poses no
12 more than minimal risk to the human subject
13 and includes appropriate safeguards to protect
14 the rights, safety, and welfare of the human
15 subject; or

16 “(ii) the investigator”; and

17 (2) in the matter following subparagraph (D),
18 by striking “subparagraph (D)” and inserting “sub-
19 paragraph (D)(ii)”.

20 (b) DRUGS.—Section 505(i)(4) of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) is amended
22 by striking “except where it is not feasible or it is contrary
23 to the best interests of such human beings” and inserting
24 “except where it is not feasible, it is contrary to the best
25 interests of such human beings, or the proposed clinical
26 testing poses no more than minimal risk to such human

1 beings and includes appropriate safeguards as prescribed
2 to protect the rights, safety, and welfare of such human
3 beings”.

4 **Subtitle P—Improving Scientific** 5 **Expertise and Outreach at FDA**

6 **SEC. 2281. SILVIO O. CONTE SENIOR BIOMEDICAL RE-** 7 **SEARCH SERVICE.**

8 (a) HIRING AND RETENTION AUTHORITY.—Section
9 228 of the Public Health Service Act (42 U.S.C. 237) is
10 amended—

11 (1) in the section heading, by inserting “AND
12 BIOMEDICAL PRODUCT ASSESSMENT” after “RE-
13 SEARCH”;

14 (2) in subsection (a)(1), by striking “Silvio O.
15 Conte Senior Biomedical Research Service, not to
16 exceed 500 members” and inserting “Silvio O. Conte
17 Senior Biomedical Research and Biomedical Product
18 Assessment Service (in this section referred to as the
19 ‘Service’), the purpose of which is to recruit and re-
20 tain competitive and qualified scientific and tech-
21 nical experts outstanding in the field of biomedical
22 research, clinical research evaluation, and biomedical
23 product assessment”;

24 (3) by amending subsection (a)(2) to read as
25 follows:

1 “(2) The authority established in paragraph (1) may
2 not be construed to require the Secretary to reduce the
3 number of employees serving under any other employment
4 system in order to offset the number of members serving
5 in the Service.”;

6 (4) in subsection (b)—

7 (A) in the matter preceding paragraph (1),
8 by striking “or clinical research evaluation” and
9 inserting “, clinical research evaluation or bio-
10 medical product assessment”; and

11 (B) in paragraph (1), by inserting “or a
12 master’s level degree in engineering,
13 bioinformatics, or a related or emerging field,”
14 after the comma;

15 (5) in subsection (d)(2), by striking “and shall
16 not exceed the rate payable for level I of the Execu-
17 tive Schedule unless approved by the President
18 under section 5377(d)(2) of title 5, United States
19 Code” and inserting “and shall not exceed the rate
20 payable for the President”;

21 (6) by striking subsection (e); and

22 (7) by redesignating subsections (f) and (g) as
23 subsections (e) and (f), respectively.

24 (b) REPORT.—Not later than 3 years after the date
25 of the enactment of this Act, the Secretary of Health and

1 Human Services shall submit, and publish on the website
2 of the Department of Health and Human Services a report
3 on the implementation of the amendments made by sub-
4 section (a), including whether the amendments have im-
5 proved the ability of the Food and Drug Administration
6 to hire and retain qualified experts to fulfill obligations
7 specified under user fee agreements.

8 **SEC. 2282. ENABLING FDA SCIENTIFIC ENGAGEMENT.**

9 It is the sense of Congress that the participation in,
10 or sponsorship of, scientific conferences and meetings is
11 essential to the mission of the Food and Drug Administra-
12 tion.

13 **SEC. 2283. REAGAN-UDALL FOUNDATION FOR THE FOOD**
14 **AND DRUG ADMINISTRATION.**

15 (a) BOARD OF DIRECTORS.—

16 (1) COMPOSITION AND SIZE.—Section
17 770(d)(1)(C) of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 379dd(d)(1)(C)) is amended—

19 (A) by redesignating clause (ii) as clause
20 (iii);

21 (B) by inserting after clause (i) the fol-
22 lowing:

23 “(ii) ADDITIONAL MEMBERS.—The
24 Board, through amendments to the bylaws
25 of the Foundation, may provide that the

1 number of voting members of the Board
2 shall be a number (to be specified in such
3 amendment) greater than 14. Any Board
4 positions that are established by any such
5 amendment shall be appointed (by majority
6 vote) by the individuals who, as of the date
7 of such amendment, are voting members of
8 the Board and persons so appointed may
9 represent any of the categories specified in
10 subclauses (I) through (V) of clause (i), so
11 long as no more than 30 percent of the
12 total voting members of the Board (includ-
13 ing members whose positions are estab-
14 lished by such amendment) are representa-
15 tives of the general pharmaceutical, device,
16 food, cosmetic, and biotechnology indus-
17 tries.”; and

18 (C) in clause (iii)(I), as redesignated by
19 subparagraph (A), by striking “The ex officio
20 members shall ensure” and inserting “The ex
21 officio members, acting pursuant to clause (i),
22 and the Board, acting pursuant to clause (ii),
23 shall ensure”.

24 (2) FEDERAL EMPLOYEES ALLOWED TO SERVE
25 ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C)

1 of the Federal Food, Drug, and Cosmetic Act (21
2 U.S.C. 379dd(d)(1)(C)), as redesignated by para-
3 graph (1)(A), is amended by adding at the end the
4 following: “For purposes of this section, the term
5 ‘employee of the Federal Government’ does not in-
6 clude a ‘special Government employee’, as that term
7 is defined in section 202(a) of title 18, United
8 States Code.”.

9 (3) STAGGERED TERMS.—Subparagraph (A) of
10 section 770(d)(3) of the Federal Food, Drug, and
11 Cosmetic Act (21 U.S.C. 379dd(d)(3)) is amended
12 to read as follows:

13 “(A) TERM.—The term of office of each
14 member of the Board appointed under para-
15 graph (1)(C)(i), and the term of office of any
16 member of the Board whose position is estab-
17 lished pursuant to paragraph (1)(C)(ii), shall be
18 4 years, except that—

19 “(i) the terms of offices for the mem-
20 bers of the Board initially appointed under
21 paragraph (1)(C)(i) shall expire on a stag-
22 gered basis as determined by the ex officio
23 members; and

24 “(ii) the terms of office for the per-
25 sons initially appointed to positions estab-

1 lished pursuant to paragraph (1)(C)(ii)
2 may be made to expire on a staggered
3 basis, as determined by the individuals
4 who, as of the date of the amendment es-
5 tablishing such positions, are members of
6 the Board.”.

7 (b) EXECUTIVE DIRECTOR COMPENSATION.—Section
8 770(g)(2) of the Federal Food, Drug, and Cosmetic Act
9 (21 U.S.C. 379dd(g)(2)) is amended by striking “but shall
10 not be greater than the compensation of the Commis-
11 sioner”.

12 (c) SEPARATION OF FUNDS.—Section 770(m) of the
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 379dd(m)) is amended by striking “are held in separate
15 accounts from funds received from entities under sub-
16 section (i)” and inserting “are managed as individual pro-
17 grammatic funds under subsection (i), according to best
18 accounting practices”.

19 **SEC. 2284. COLLECTION OF CERTAIN VOLUNTARY INFOR-**
20 **MATION EXEMPTED FROM PAPERWORK RE-**
21 **DUCTION ACT.**

22 Chapter VII of the Federal Food, Drug, and Cos-
23 metic Act is amended by inserting after section 708 of
24 such Act (21 U.S.C. 379) the following:

1 **“SEC. 708A. COLLECTION OF CERTAIN VOLUNTARY INFOR-**
2 **MATION EXEMPTED FROM PAPERWORK RE-**
3 **DUCTION ACT.**

4 “Chapter 35 of title 44, United States Code, shall
5 not apply to the collection from patients, industry, aca-
6 demia, and other stakeholders, of voluntary information
7 such as through voluntary surveys or questionnaires, initi-
8 ated by the Secretary.”.

9 **SEC. 2285. HIRING AUTHORITY FOR SCIENTIFIC, TECH-**
10 **NICAL, AND PROFESSIONAL PERSONNEL.**

11 (a) IN GENERAL.—The Federal Food, Drug, and
12 Cosmetic Act is amended by inserting after section 714
13 (21 U.S.C. 379d–3) the following:

14 **“SEC. 714A. ADDITIONAL HIRING AUTHORITY.**

15 “(a) IN GENERAL.—The Secretary may, without re-
16 gard to the provisions of title 5, United States Code, gov-
17 erning appointments in the competitive service, appoint
18 qualified candidates to scientific, technical, or professional
19 positions within the following centers of the Food and
20 Drug Administration:

21 “(1) The Center for Drug Evaluation and Re-
22 search.

23 “(2) The Center for Biologics Evaluation and
24 Research.

25 “(3) The Center for Devices and Radiological
26 Health.

1 Such positions shall be within the competitive service.

2 “(b) COMPENSATION.—

3 “(1) IN GENERAL.—Notwithstanding any other
4 provision of law, including any requirement with re-
5 spect to General Schedule pay rates under sub-
6 chapter III of chapter 53 of title 5, United States
7 Code, and consistent with the requirements of para-
8 graph (2), the Secretary may determine and fix—

9 “(A) the annual rate of pay of any indi-
10 vidual appointed under subsection (a); and

11 “(B) for purposes of retaining qualified
12 employees, the annual rate of pay for any high-
13 ly qualified scientific, technical, or professional
14 personnel appointed to a position at any of the
15 centers listed under subsection (a) before the
16 date of enactment of this section.

17 “(2) LIMITATION.—The annual rate of pay es-
18 tablished pursuant to paragraph (1) may not exceed
19 the annual rate of pay of the President.

20 “(c) REPORT.—

21 “(1) IN GENERAL.—Not later than September
22 30, 2021, the Secretary shall submit a report to
23 Congress that examines the extent to which the au-
24 thority to appoint and retain personnel under this
25 section enhanced the Food and Drug Administra-

1 tion’s ability to meet the agency’s critical need for
2 highly qualified individuals for scientific, technical,
3 or professional positions.

4 “(2) RECOMMENDATIONS.—The report under
5 paragraph (1) shall include the recommendations of
6 the Secretary on—

7 “(A) whether the authority to appoint per-
8 sonnel under this section should be reauthor-
9 ized; and

10 “(B) other personnel authorities that
11 would help the Food and Drug Administration
12 to better recruit and retain highly qualified in-
13 dividuals for scientific, technical, or professional
14 positions in the agency’s medical product cen-
15 ters.”.

16 (b) RULE OF CONSTRUCTION.—The authority pro-
17 vided by section 714A of the Federal Food, Drug, and
18 Cosmetic Act (as added by subsection (a)) shall not be
19 construed to affect the authority provided under section
20 714 of such Act.

1 **Subtitle Q—Exempting From**
2 **Sequestration Certain User Fees**

3 **SEC. 2301. EXEMPTING FROM SEQUESTRATION CERTAIN**
4 **USER FEES OF FOOD AND DRUG ADMINIS-**
5 **TRATION.**

6 The Balanced Budget and Emergency Deficit Control
7 Act of 1985 is amended—

8 (1) in section 255(g)(1)(A) (2 U.S.C.
9 905(g)(1)(A)), by inserting after the item relating to
10 “Financial Agent Services” the following new item:

11 “Food and Drug Administration, Salaries
12 and Expenses, but only the portion of appro-
13 priations under such account corresponding to
14 fees collected under sections 736, 738, 740,
15 741, 744B, and 744H of the Federal Food,
16 Drug, and Cosmetic Act (75–9911–0–1–554).”;

17 and

18 (2) in section 256(h) (2 U.S.C. 906(h)), by
19 adding at the end the following new paragraph:

20 “(5) Notwithstanding any other provision of
21 law, this subsection shall not apply with respect to
22 the portion of administrative expenses incurred by
23 the Food and Drug Administration that are funded
24 through fees collected under sections 736, 738, 740,

1 741, 744B, and 744H of the Federal Food, Drug,
2 and Cosmetic Act.”.

3 **Subtitle R—Other Provisions**

4 **SEC. 2321. SENSE OF CONGRESS.**

5 It is the sense of the Congress that recording unique
6 device identifiers at the point-of-care in electronic health
7 record systems could significantly enhance the availability
8 of medical device data for postmarket surveillance pur-
9 poses.

10 **TITLE III—DELIVERY**

11 **Subtitle A—Interoperability**

12 **SEC. 3001. ENSURING INTEROPERABILITY OF HEALTH IN-** 13 **FORMATION TECHNOLOGY.**

14 (a) INTEROPERABILITY STANDARDS.—

15 (1) IN GENERAL.—Subtitle A of title XXX of
16 the Public Health Service Act (42 U.S.C. 300jj–11
17 et seq.) is amended by adding at the end the fol-
18 lowing new section:

19 **“SEC. 3010. ENSURING INTEROPERABILITY OF HEALTH IN-** 20 **FORMATION TECHNOLOGY.**

21 “(a) INTEROPERABILITY.—In order for health infor-
22 mation technology to be considered interoperable, such
23 technology must satisfy the following criteria:

24 “(1) SECURE TRANSFER.—The technology al-
25 lows the secure transfer of all electronically acces-

1 sible health information to and from any and all
2 health information technology for authorized use
3 under applicable State or Federal law.

4 “(2) COMPLETE ACCESS TO HEALTH INFORMA-
5 TION.—The technology allows for complete access,
6 exchange, and use of all electronically accessible
7 health information for authorized use under applica-
8 ble State or Federal law without special effort by the
9 requestor of such health information.

10 “(3) NO INFORMATION BLOCKING.—The tech-
11 nology is not configured, set up, or implemented to
12 information block, as defined in section 3010A(d).

13 “(b) CATEGORIES FOR INTEROPERABILITY STAND-
14 ARDS.—The categories described in this subsection, with
15 respect to standards and the corresponding implementa-
16 tion specifications for determining if health information
17 technology is interoperable, consistent with the criteria de-
18 scribed in subsection (a), include at least categories of
19 standards and implementation specifications with respect
20 to the following:

21 “(1) Vocabulary and terminology.

22 “(2) Content and structure.

23 “(3) Transport.

24 “(4) Security.

25 “(5) Services.

1 “(6) Querying and requesting health informa-
2 tion for access, exchange, and use.

3 “(c) ALLOWING FOR FLEXIBILITY.—A standard and
4 implementation specification, with respect to such stand-
5 ard, that is determined under section 3001(e)(5)(D) to be
6 compatible with baseline standards and implementation
7 specifications (as defined in clause (ii) of such section)
8 shall be treated as in compliance with this section.”.

9 (2) GUIDANCE.—Not later than January 1,
10 2017, the Secretary of Health and Human Services,
11 in consultation with the National Coordinator of the
12 Office of the National Coordinator for Health Infor-
13 mation Technology, shall issue guidance with respect
14 to the implementation of section 3010 of the Public
15 Health Service Act, as added by paragraph (1), in-
16 cluding with respect to defining and providing exam-
17 ples of authorized use under applicable State or
18 Federal law of health information.

19 (b) IMPROVEMENTS TO RECOMMENDATION PROC-
20 ESS.—

21 (1) HIT POLICY COMMITTEE TO INCORPORATE
22 POLICIES FOR UPDATES TO INTEROPERABILITY
23 STANDARDS.—Section 3002 of the Public Health
24 Service Act (42 U.S.C. 300jj–12) is amended—

25 (A) in subsection (a)—

1 (i) by striking “National Coordinator”
2 and inserting “Secretary, in consultation
3 with the National Coordinator,”; and

4 (ii) by adding at the end the following
5 new sentence: “The HIT Policy Committee
6 is authorized only to provide policy and
7 priority recommendations to the Secretary
8 and not authorized to otherwise affect the
9 development or modification of any stand-
10 ard, implementation specification, or cer-
11 tification criterion under this title.”; and

12 (B) in subsection (b)(2)—

13 (i) in subparagraph (A), in the first
14 sentence—

15 (I) by striking “The HIT Policy
16 Committee” and inserting “Subject to
17 subparagraph (D), the HIT Policy
18 Committee”; and

19 (II) by inserting “(including the
20 areas in which modifications and addi-
21 tions to interoperability standards and
22 implementation specifications, with re-
23 spect to such interoperability stand-
24 ards, under section 3010 are needed
25 for the electronic access, exchange,

1 and use of health information for pur-
2 poses of adoption of such modifica-
3 tions and additions under section
4 3004)” after “section 3004”.

5 (ii) by adding at the end the following
6 new subparagraph:

7 “(D) SPECIAL RULE RELATED TO INTER-
8 OPERABILITY.—Any recommendation made by
9 the HIT Policy Committee on or after the date
10 of the enactment of this subparagraph with re-
11 spect to interoperability of health information
12 technology shall be consistent with the criteria
13 described in subsection (a) of section 3010.”.

14 (2) SUNSET OF HIT STANDARDS COMMITTEE.—
15 Section 3003 of the Public Health Service Act (42
16 U.S.C. 300jj–13) is amended by adding at the end
17 the following new subsection:

18 “(f) TERMINATION.—The HIT Standards Committee
19 shall terminate on the date that is 90 days after the date
20 of the enactment of this subsection.”.

21 (3) STANDARDS DEVELOPMENT ORGANIZA-
22 TIONS.—Title XXX of the Public Health Service Act
23 is amended by inserting after section 3003 the fol-
24 lowing new section:

1 **“SEC. 3003A. RECOMMENDATIONS FOR STANDARDS**
2 **THROUGH CONTRACTS WITH STANDARDS DE-**
3 **VELOPMENT ORGANIZATIONS.**

4 “(a) CONTRACTS.—

5 “(1) IN GENERAL.—For purposes of activities
6 conducted under this title, the Secretary shall enter
7 into one or more contracts with health care stand-
8 ards development organizations accredited by the
9 American National Standards Institute (or with the
10 American National Standards Institute) to carry
11 out, directly or through contracts with subcontract-
12 tors, the duties described in subsection (b), as appli-
13 cable.

14 “(2) TIMING FOR FIRST CONTRACT.—As soon
15 as practicable after the date of the enactment of this
16 section, the Secretary shall enter into the first con-
17 tracts under paragraph (1).

18 “(3) PERIOD OF CONTRACT.—Each contract
19 under paragraph (1) shall be for a period deter-
20 mined necessary by the Secretary, in consultation
21 with the National Coordinator, to carry out the ap-
22 plicable duties described in subsection (b).

23 “(4) APPROPRIATE ENTITIES.—The Secretary
24 shall ensure the most appropriate entities described
25 in paragraph (1) are selected for each contract
26 under such paragraph.

1 “(b) DUTIES.—

2 “(1) INITIAL CONTRACT.—The Secretary shall
3 initially enter into one or more contracts under sub-
4 section (a)(1) with entities described in such sub-
5 section, under which the entities—

6 “(A) shall recommend to the Secretary—

7 “(i) for adoption under section 3004,
8 an initial set of interoperability standards
9 and implementation specifications, with re-
10 spect to such standards, identified or, as
11 appropriate, developed by such entities
12 that are consistent with the criteria de-
13 scribed in subsection (a) of section 3010,
14 and with respect to the categories de-
15 scribed in subsection (b) of such section;
16 and

17 “(ii) as applicable, for purposes of
18 section 3001(c)(5)(D), methods to test if
19 health information technology is compat-
20 ible with health information technology
21 that applies baseline standards and imple-
22 mentation specifications (as defined in
23 clause (ii) of such section); and

24 “(B) may provide to the Secretary rec-
25 ommendations described in paragraph (2).

1 “(2) SUBSEQUENT CONTRACTS.—Under each
2 subsequent contract entered into under this section
3 with entities described in subsection (a)(1) pursuant
4 to subsection (c), the entities shall recommend to the
5 Secretary—

6 “(A) for adoption under section 3004 any
7 standards (including interoperability stand-
8 ards), implementation specifications, and, to the
9 extent necessary, certification criteria (and
10 modifications, including additions, to such
11 standards, specifications, and, to the extent
12 necessary, criteria), which are in accordance
13 with the criteria described in section 3010; and

14 “(B) as applicable, for purposes of section
15 3001(c)(5)(D), methods to test if health infor-
16 mation technology is compatible with baseline
17 standards and implementation specifications (as
18 defined in clause (ii) of such section).

19 “(3) SUBMISSION TO NIST.—Under each con-
20 tract with an entity under this section, the entity
21 shall submit to the Director of the National Institute
22 of Standards and Technology each recommendation
23 submitted to the Secretary by such entity under this
24 section.

1 “(4) CONSULTATION.—For the purposes of de-
2 veloping methods to test interoperability standards
3 and implementation specifications with respect to
4 such standards, the entities with a contract under
5 this section may consult with the Director of the Na-
6 tional Institute of Standards and Technology.

7 “(c) MODIFICATIONS AND SUBSEQUENT CON-
8 TRACTS.—

9 “(1) IN GENERAL.—The Secretary, in consulta-
10 tion with the National Coordinator, shall periodically
11 conduct hearings to evaluate and review the stand-
12 ards, implementation specifications, and certification
13 criteria adopted under section 3004 for purposes of
14 determining if modifications, including any addi-
15 tions, are needed with respect to such standards,
16 specifications, and criteria.

17 “(2) CONTRACT TRIGGER.—Based on the needs
18 for standards, implementation specifications, and
19 certification criteria (and modifications, including
20 additions, to such standards, specifications, and cri-
21 teria) under this title, as determined by the Sec-
22 retary, with due consideration to section 3010(b)
23 and in consultation with the National Coordinator,
24 the Secretary shall, as needed, enter into contracts
25 under subsection (a) to carry out the duties de-

1 scribed in subsection (b)(2) in addition to any con-
2 tract entered into to carry out the duties described
3 in subsection (b)(1).

4 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
5 is authorized to be appropriated \$10,000,000 for contracts
6 under subsection (a), to remain available until expended.”.

7 (4) MODIFICATIONS TO ROLE OF THE NA-
8 TIONAL COORDINATOR.—Section 3001(c)(1)(A) of
9 the Public Health Service Act (42 U.S.C. 300jj–
10 11(c)(1)(A)) is amended by inserting “for rec-
11 ommendations made before the date of the enact-
12 ment of the 21st Century Cures Act,” before “review
13 and determine”.

14 (c) ADOPTION.—Section 3004 of the Public Health
15 Service Act (42 U.S.C. 300jj–14) is amended—

16 (1) in subsection (a)—

17 (A) in paragraph (1), by inserting after
18 “section 3001(c)” the following: “(or, subject to
19 subsection (c), in the case of a standard, imple-
20 mentation specification, or criterion rec-
21 ommended on or after the date of the enact-
22 ment of the 21st Century Cures Act, after the
23 date of submission of the recommendation to
24 the Secretary under section 3003A)”; and

1 (B) in paragraph (2)(B), by striking “and
2 the HIT Standards Committee”;

3 (2) in subsection (b)—

4 (A) in paragraph (3), by striking “with the
5 schedule published under section 3003(b)(2)”
6 and inserting “with subsection (d)”; and

7 (B) by adding at the end the following new
8 paragraph:

9 “(4) LIMITATION.—The Secretary may not
10 adopt any policies, priorities, standards, implementa-
11 tion specifications, or certification criteria under this
12 subsection or subsection (a) that are inconsistent
13 with or duplicative of an interoperability standard or
14 implementation specification with respect to such
15 standard adopted under this section, in accordance
16 with subsections (c) and (d). In the case of a stand-
17 ard, specification, or criterion that has been adopted
18 under this section and is inconsistent or duplicative
19 of such an interoperability standard or specification
20 that is subsequently adopted under this section, such
21 interoperability standard or specification shall
22 supercede such other standard, specification, or cri-
23 terion and such other standard, specification, or cri-
24 terion shall no longer be considered adopted under
25 this section beginning on the date that such inter-

1 operability standard or specification becomes effective.”; and
2

3 (3) by adding at the end the following new sub-
4 sections:

5 “(c) ADOPTION OF INITIAL INTEROPERABILITY
6 STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—
7 Notwithstanding the previous subsections of this section,
8 the following shall apply in the case of the initial set of
9 interoperability standards and implementation specifica-
10 tions with respect to such standards recommended under
11 section 3003A:

12 “(1) REVIEW OF STANDARDS.—Not later than
13 90 days after the date of receipt of recommendations
14 for such interoperability standards and implementa-
15 tion specifications, the Secretary, in consultation
16 with the National Coordinator and representatives of
17 other relevant Federal agencies, such as the Na-
18 tional Institute of Standards and Technology, shall
19 jointly review such standards and implementation
20 specifications and shall determine whether or not to
21 propose adoption of such standards and implementa-
22 tion specifications.

23 “(2) DETERMINATION TO ADOPT.—If, subject
24 to subsection (d)(3), the Secretary determines—

1 “(A) to propose adoption of such standards
2 and implementation specifications, the Sec-
3 retary shall, by regulation under section 553 of
4 title 5, United States Code, determine whether
5 or not to adopt such standards and implemen-
6 tation specifications; or

7 “(B) not to propose adoption of such
8 standards and implementation specifications,
9 the Secretary shall notify the applicable entity
10 with a contract under section 3003A in writing
11 of such determination and the reasons for not
12 proposing the adoption of the recommendation
13 for such standards and implementation speci-
14 fications.

15 “(3) PUBLICATION.—The Secretary shall pro-
16 vide for publication in the Federal Register of all de-
17 terminations made by the Secretary under para-
18 graph (1).

19 “(d) RULES FOR ADOPTION.—In the case of a stand-
20 ard (including interoperability standard), implementation
21 specification, or certification criterion adopted under this
22 section on or after the date of the enactment of the 21st
23 Century Cures Act, the following shall apply:

24 “(1) IN GENERAL.—Except as provided in para-
25 graphs (2) and (3), any such standard (including

1 interoperability standard), implementation specifica-
2 tion, or certification criterion shall be a standard,
3 specification, or criterion that has been rec-
4 ommended by the entities with which the Secretary
5 has entered into a contract under section 3003A.

6 “(2) SPECIAL RULE IF NO STANDARD, SPECI-
7 FICATION, OR CRITERION RECOMMENDED.—If no
8 standard, implementation specification, or, to the ex-
9 tent necessary, certification criterion is rec-
10 ommended under paragraph (1)—

11 “(A) in the case of interoperability stand-
12 ards and implementation specifications with re-
13 spect to such standards, relating to a category
14 described in section 3010(b)—

15 “(i) paragraph (1) shall not apply;

16 and

17 “(ii) paragraph (4) shall apply; or

18 “(B) in the case of any other standard, im-
19 plementation specification, or, to the extent nec-
20 essary, certification criterion, relating to a pol-
21 icy or priority to carry out this title, as deter-
22 mined by the Secretary, in consultation with the
23 National Coordinator—

24 “(i) paragraph (1) shall not apply;

25 and

1 “(ii) paragraph (4) shall apply.

2 “(3) AUTHORITY TO MODIFY IMPLEMENTATION
3 SPECIFICATIONS.—If, following public comment pur-
4 suant to subsection (c), the Secretary would propose
5 adoption of interoperability standards recommended
6 under section 3003A but for the implementation
7 specifications, with respect to such standards, so
8 recommended, the Secretary may modify such imple-
9 mentation specifications and adopt such standards
10 and specifications in accordance with subsection
11 (c)(2).

12 “(4) EFFECTIVE DATE.—In the case of a
13 standard, implementation specification, or certifi-
14 cation criterion for which there is a determination to
15 adopt such standard, implementation specification,
16 or certification criterion, such standard, implementa-
17 tion specification, or certification criterion shall be
18 considered adopted under this section and shall be
19 effective beginning on the date that is 12 months
20 after the date of publication of the final rule to
21 adopt such standard, implementation specification,
22 or certification criterion.

23 “(5) ASSISTANCE TO THE SECRETARY.—In
24 complying with the requirements of this subsection,
25 the Secretary shall give due consideration to any rec-

1 ommendations of the National Committee on Vital
2 and Health Statistics established under section
3 306(k), and shall consult with appropriate Federal
4 and State agencies and private organizations. The
5 Secretary shall publish in the Federal Register any
6 recommendation of the National Committee on Vital
7 and Health Statistics regarding the adoption of a
8 standard, implementation specification, or certifi-
9 cation criterion under this section. Any standard,
10 implementation specification, or certification cri-
11 terion adopted pursuant to this paragraph shall be
12 promulgated in accordance with the rulemaking pro-
13 cedures of subchapter III of chapter 5 of title 5,
14 United States Code.

15 “(e) ALLOWING FOR FLEXIBILITY THROUGH COM-
16 PATIBILITY WITH BASELINE STANDARDS AND IMPLE-
17 MENTATION SPECIFICATIONS.—For purposes of this title,
18 title XVIII of the Social Security Act, title XIX of such
19 Act, and any other provision of law, a standard and imple-
20 mentation specification, with respect to such standard,
21 that is determined under section 3001(c)(5)(D) to be com-
22 patible with baseline standards and implementation speci-
23 fications (as defined in clause (ii) of such section) shall
24 be treated as if such standard and specification were an
25 interoperability standard and implementation specifica-

1 tion, with respect to such interoperability standard, adopt-
2 ed under this section.”.

3 (d) REPORTS AND NOTIFICATIONS.—Section 3010 of
4 the Public Health Service Act, as added by subsection (a),
5 is amended by adding at the end the following new sub-
6 section:

7 “(c) DISSEMINATION OF INFORMATION.—

8 “(1) INITIAL SUMMARY REPORT.—Not later
9 than July 1, 2017, the Secretary, after consultation
10 with relevant stakeholders, shall submit to Congress
11 and provide for publication in the Federal Register
12 and the posting on the Internet website of the Office
13 of the National Coordinator for Health Information
14 Technology a report on the following:

15 “(A) The initial set of interoperability
16 standards and implementation specifications
17 adopted under section 3004(c).

18 “(B) The strategies for achieving wide-
19 spread interoperability.

20 “(C) Any barriers that are preventing
21 widespread interoperability.

22 “(D) The plan and milestones, including
23 specific steps, to achieve widespread interoper-
24 ability.

1 “(2) ONGOING PUBLICATION OF RECOMMENDA-
2 TIONS.—The Secretary shall provide for publication
3 in the Federal Register, and the posting on the
4 Internet website of the Office of the National Coor-
5 dinator for Health Information Technology, of all
6 recommendations made under this section.”.

7 (e) CERTIFICATION AND OTHER ENFORCEMENT
8 PROVISIONS.—

9 (1) CERTIFICATION OF QUALIFIED ELECTRONIC
10 HEALTH RECORDS.—

11 (A) IN GENERAL.—Section 3007(b) of the
12 Public Health Service Act (42 U.S.C. 300jj–
13 17(b)) is amended by striking “under section
14 3001(c)(3) to be in compliance with” and all
15 that follows through the period at the end and
16 inserting “under section 3001(c)(3)—

17 “(1) for certifications made before January 1,
18 2018, to be in compliance with applicable standards
19 adopted under subsections (a) and (b) of section
20 3004; and

21 “(2) for certifications made on or after January
22 1, 2018, to be in compliance with applicable stand-
23 ards adopted under subsections (a) and (b) of sec-
24 tion 3004 and to be interoperable in accordance with

1 section 3010 and in compliance with interoperability
2 standards adopted under section 3004.”.

3 (B) REQUIREMENTS OF SECRETARY.—Sec-
4 tion 3001(c)(5) of the Public Health Service
5 Act (42 U.S.C. 300jj–11(c)(5)) is amended—

6 (i) in subparagraph (B), by inserting
7 before the period at the end the following:
8 “and, for certifications made on or after
9 January 1, 2018, with respect to health in-
10 formation technology, additional criteria to
11 establish that the technology is interoper-
12 able, in accordance with section 3010, and
13 in compliance with interoperability stand-
14 ards and implementation specifications,
15 with respect to such standards, adopted
16 under section 3004”; and

17 (ii) by adding at the end the following
18 new subparagraphs:

19 “(C) ENFORCEMENT;
20 DECERTIFICATIONS.—

21 “(i) REQUIREMENTS.—Under any
22 program kept or recognized under subpara-
23 graph (A), the Secretary shall ensure that
24 any vendor of or other entity offering to
25 health care providers (as defined in section

1 3010A(g)) qualified electronic health
2 records seeking a certification of such
3 records under such program on or after
4 January 1, 2018, shall, as a condition of
5 certification (and maintenance of certifi-
6 cation) of such a record under such pro-
7 gram—

8 “(I) provide to the Secretary an
9 attestation—

10 “(aa) the entity has imple-
11 mented interoperability standards
12 and implementation specifica-
13 tions, with respect to such stand-
14 ards, adopted under section 3004
15 (including through application of
16 subsection (e) of such section);

17 “(bb) that the entity, unless
18 for a legitimate purpose specified
19 by the Secretary, has not taken
20 and will not take any action that
21 constitutes information blocking
22 (as defined in section 3010A(d)),
23 with respect to such qualified
24 electronic health records;

1 “(cc) that includes the pric-
2 ing information described in
3 clause (iii) for purposes of inclu-
4 sion under subsection (f) of such
5 information on the Internet
6 website of the Department of
7 Health and Human Services; that
8 such information will be available
9 on a public Internet website of
10 such entity; and that the entity
11 will voluntarily provide such in-
12 formation to customers prior to
13 offering any qualified electronic
14 health records or related product
15 or service (including subsequent
16 updates, add-ons, or additional
17 products or services to be pro-
18 vided during the course of an on-
19 going contract), prospective cus-
20 tomers (such as persons who re-
21 quest or receive a quotation or
22 estimate), and other persons who
23 request such information;

24 “(dd) that the technology
25 with respect to such records has

1 published application program-
2 ming interfaces, with respect to
3 health information within such
4 records, for search and indexing,
5 semantic harmonization and vo-
6 cabulary translation, and user
7 interface applications;

8 “(ee) that the entity has
9 successfully and rigorously tested
10 the real world use of the record
11 in the type of setting in which it
12 would be marketed; and

13 “(ff) that the entity has in
14 place data sharing programs or
15 capabilities based on common
16 data elements through such
17 mechanisms as application pro-
18 gramming interfaces without the
19 requirement for vendor-specific
20 interfaces;

21 “(II) publish application pro-
22 gramming interfaces and associated
23 documentation, with respect to health
24 information within such records, for
25 search and indexing, semantic harmo-

1 nization and vocabulary translation,
2 and user interface applications; and

3 “(III) demonstrate to the satis-
4 faction of the Secretary that health
5 information from such records are
6 able to be exchanged, accessed, and
7 used through the use of application
8 programming interfaces without spe-
9 cial effort, as authorized under appli-
10 cable law.

11 “(ii) DECERTIFICATION.—Under any
12 program kept or recognized under subpara-
13 graph (A), the Secretary shall ensure that
14 beginning January 1, 2019, any qualified
15 electronic health records that do not sat-
16 isfy the certification criteria described in
17 subparagraph (B) or with respect to which
18 the vendor or other entity described in
19 clause (i) does not satisfy the requirements
20 under such clause (or is determined to be
21 in violation of the terms of the attestation
22 or other requirements under such clause)
23 shall no longer be considered as certified
24 under such program.

1 “(iii) PRICING INFORMATION.—For
2 purposes of clause (i)(I)(cc), the pricing in-
3 formation described in this clause, with re-
4 spect to a vendor of or other entity offer-
5 ing a qualified electronic health record, is
6 the following:

7 “(I) Additional types of costs or
8 fees (whether fixed, recurring, trans-
9 action based, or otherwise) imposed by
10 the entity (or any third-party from
11 whom the entity purchases, licenses,
12 or obtains any technology, products,
13 or services in connection with the
14 qualified electronic health record) to
15 purchase, license, implement, main-
16 tain, upgrade, use, or otherwise enable
17 and support the use of capabilities to
18 which such record is to be certified
19 under this section; or in connection
20 with any health information generated
21 in the course of using any capability
22 to which the record is to be so cer-
23 tified.

24 “(II) Limitations, whether by
25 contract or otherwise, on the use of

1 any capability to which the record is
2 to be certified under this section for
3 any purpose within the scope of the
4 record's certification; or in connection
5 with any health information generated
6 in the course of using any capability
7 to which the record is to be certified
8 under this section.

9 “(III) Limitations, including
10 technical or practical limitations of
11 technology or its capabilities, that
12 could prevent or impair the successful
13 implementation, configuration,
14 customization, maintenance, support,
15 or use of any capabilities to which the
16 record is to be certified under this
17 section; or that could prevent or limit
18 the access, use, exchange, or port-
19 ability of any health information gen-
20 erated in the course of using any ca-
21 pability to which the record is to be so
22 certified.

23 “(D) FLEXIBILITY THROUGH COMPAT-
24 IBILITY.—

1 “(i) IN GENERAL.—Under any pro-
2 gram kept or recognized under subpara-
3 graph (A), the Secretary shall provide for
4 a method and process by which a vendor of
5 or other entity offering to health care pro-
6 viders (as defined in section 3010A(g))
7 qualified electronic health records seeking
8 a certification of such records under such
9 program on or after January 1, 2018, may
10 demonstrate, using such mechanisms as a
11 reference implementation model or other
12 means, that the standards and implemen-
13 tation specifications applied by such entity
14 with respect to such records are compatible
15 with baseline standards and implementa-
16 tion specifications, including by dem-
17 onstrating such records are able to trans-
18 mit information that is compatible with
19 qualified electronic health records that
20 would receive such information and that
21 apply the baseline standards and imple-
22 mentation specifications. Such a method
23 and process shall ensure that any such en-
24 tity using a standard or implementation
25 specification other than a baseline stand-

1 ard or implementation specification dem-
2 onstrates, through testing, compatibility
3 with the baseline standard and implemen-
4 tation specification with respect to receiv-
5 ing information.

6 “(ii) BASELINE STANDARDS AND IM-
7 PLEMENTATION SPECIFICATIONS.—For
8 purposes of clause (i), the term ‘baseline
9 standards and implementation specifica-
10 tions’ means the interoperability standards
11 and implementation specifications, with re-
12 spect to such standards, adopted under
13 section 3004 (without application of sub-
14 section (e) of such section).”.

15 (2) ADDITIONAL ENFORCEMENT PROVISIONS
16 UNDER THE PUBLIC HEALTH SERVICE ACT.—Sub-
17 title A of title XXX of the Public Health Service Act
18 (42 U.S.C. 300jj–11 et seq.), as amended by sub-
19 sections (a)(1) and (d), is further amended by add-
20 ing at the end the following new section:

21 **“SEC. 3010A. ENFORCEMENT MECHANISMS.**

22 “(a) INSPECTOR GENERAL AUTHORITY.—The In-
23 spector General of the Department of Health and Human
24 Services shall have the authority to investigate claims of—

1 “(1)(A) vendors of, or other entities offering to
2 health care providers (as defined in subsection (g)),
3 qualified electronic health records (as defined in sec-
4 tion 3000(13)) being in violation of an attestation
5 (whether providing false information at the time of
6 such attestation or by act or practice conducted
7 after such attestation) made under section
8 3001(e)(5)(C)(i)(I), with respect to the use of such
9 records by a health care provider with respect to
10 items and services furnished under the Medicare
11 Program under title XVIII of the Social Security
12 Act or Medicaid program under title XIX of such
13 Act; and

14 “(B) vendors of, or other entities offering to
15 health care providers (as defined in subsection (g)),
16 health information technology having engaged in in-
17 formation blocking (as defined in subsection (d)),
18 unless for a legitimate purpose specified by the Sec-
19 retary, with respect to the use of such technology by
20 a health care provider with respect to items and
21 services furnished under such a program;

22 “(2) health care providers having engaged in in-
23 formation blocking (as so defined), with respect to
24 the use of health information technology with re-
25 spect to items and services furnished under such a

1 program, unless for a legitimate purpose specified by
2 the Secretary; and

3 “(3) health information system providers (such
4 as operators of health information exchanges, clin-
5 ical data registries, and other systems that facilitate
6 the exchange of information) having engaged in in-
7 formation blocking (as so defined), unless for a le-
8 gitimate purpose specified by the Secretary, with re-
9 spect to the use of health information technology
10 with respect to items and services furnished under
11 such a program.

12 “(b) INFORMATION SHARING PROVISIONS.—

13 “(1) IN GENERAL.—The National Coordinator
14 may serve as a technical consultant to the Inspector
15 General of the Department of Health and Human
16 Services and the Federal Trade Commission for pur-
17 poses of carrying out this section. As such technical
18 consultant, the National Coordinator may, notwith-
19 standing any other provision of law, share informa-
20 tion related to claims or investigations under sub-
21 section (a) with the Federal Trade Commission for
22 purposes of such investigations and shall share in-
23 formation with the Inspector General, as required by
24 law.

1 “(2) PROTECTION FROM DISCLOSURE OF IN-
2 FORMATION.—Any information that is received by
3 the National Coordinator in connection with a claim
4 or suggestion of possible information blocking and
5 that could reasonably be expected to facilitate identi-
6 fication of the source of the information—

7 “(A) shall not be disclosed by the National
8 Coordinator except as may be necessary to
9 carry out the purpose of this section; and

10 “(B) shall be exempt from mandatory dis-
11 closure under section 552 of title 5, United
12 States Code, as provided by subsection (b)(3) of
13 such section.

14 Such information may be used by the Inspector Gen-
15 eral of the Department of Health and Human Serv-
16 ices or Federal Trade Commission for reporting pur-
17 poses to the extent that such information could not
18 reasonably be expected to facilitate identification of
19 the source of such information.

20 “(3) NON-APPLICATION OF PAPERWORK REDUC-
21 TION ACT.—Chapter 35 of title 44, United States
22 Code (commonly referred to as the Paperwork Re-
23 duction Act of 1995) shall not apply to the National
24 Coordinator or to the Office of the National Coordi-
25 nator for Health Information Technology with re-

1 spect to the collection of complaints relating to
2 claims described in subsection (a).

3 “(4) STANDARDIZED PROCESS.—The National
4 Coordinator shall implement a standardized process
5 for the public to submit reports on claims of—

6 “(A) health information technology prod-
7 ucts of vendors (or other entities offering such
8 products to health care providers (as defined in
9 subsection (g))) not being interoperable or re-
10 sulting in information blocking; or

11 “(B) actions by such entities, health care
12 providers, or health information system pro-
13 viders that result in such technology not being
14 interoperable or in information blocking with
15 respect to such technology; and

16 “(C) any other act described in subsection
17 (a).

18 The standardized process shall provide for the collec-
19 tion of such information as the originating institu-
20 tion, location, type of transaction, system and
21 version, timestamp, terminating institution, loca-
22 tions, system and version, failure notice, and other
23 related information.

24 “(c) PENALTY.—

1 “(1) IN GENERAL.—Any person or entity de-
2 scribed in paragraph (1), (2), or (3) of subsection
3 (a) determined to have committed on or after Janu-
4 ary 1, 2018, an act described in such respective
5 paragraph with respect to the use of a qualified elec-
6 tronic health record or health information tech-
7 nology, as applicable under such respective para-
8 graph, with respect to items and services furnished
9 under the Medicare Program under title XVIII of
10 the Social Security Act or the Medicaid program
11 under title XIX of such Act, shall be subject to a
12 civil monetary penalty in such amount as determined
13 appropriate by the Secretary through rulemaking.

14 “(2) APPLICATION.—Subject to paragraph (3),
15 the provisions of section 1128A (other than sub-
16 sections (a) and (b)) of such Act (42 U.S.C. 1320a-
17 7a) shall apply to a civil money penalty applied
18 under this subsection in the same manner as they
19 apply to a civil money penalty or proceeding under
20 subsection (a) of such section 1128A.

21 “(3) RECOVERY OF FUNDS.—Notwithstanding
22 section 3302 of title 31, United States Code, or any
23 other provision of law affecting the crediting of col-
24 lections, the Inspector General of the Department of
25 Health and Human Services may receive and retain

1 for current use any amounts recovered under this
2 subsection. In addition to amounts otherwise avail-
3 able to the Inspector General, funds received by the
4 Inspector General under this paragraph shall be de-
5 posited, as an offsetting collection, to the credit of
6 any appropriation available for purposes of carrying
7 out this subsection and subsection (a) and shall be
8 available without fiscal year limitation and without
9 further appropriation.

10 “(d) INFORMATION BLOCKING.—

11 “(1) IN GENERAL.—For purposes of this sec-
12 tion and section 3010, subject to paragraph (3), the
13 term ‘information blocking’ means, with respect to
14 the access, use, and exchange of qualified electronic
15 health records and other health information tech-
16 nology, business, technical, and organizational prac-
17 tices, including practices described in paragraph (2),
18 that—

19 “(A) prevent or materially discourage the
20 access, exchange, or use of electronic health in-
21 formation; and

22 “(B) the actor knows or should know (as
23 defined in section 1128A(i)(7) of the Social Se-
24 curity Act) are likely to interfere with the ac-

1 cess, exchange, or use of electronic health infor-
2 mation.

3 “(2) PRACTICES DESCRIBED.—For purposes of
4 paragraph (1), the practices described in this para-
5 graph shall include the following:

6 “(A) Contract terms, policies, or business
7 or organizational practices that restrict author-
8 ized use under applicable State or Federal law
9 of electronic health information or restrict the
10 authorized exchange under applicable State or
11 Federal law of such information for treatment
12 and other permitted purposes under such appli-
13 cable law, including transitions between cer-
14 tified EHR technologies.

15 “(B) Charging unreasonable prices or fees
16 (such as for health information exchange, port-
17 ability, interfaces, and full export of health in-
18 formation) that make accessing, exchanging, or
19 using electronic health information cost prohibi-
20 tive.

21 “(C) Developing or implementing health
22 information technology in nonstandard ways
23 that are likely to substantially increase the
24 costs, complexity, or burden of sharing elec-
25 tronic health information, especially in cases in

1 which relevant interoperability standards or
2 methods to measure interoperability have been
3 adopted by the Secretary.

4 “(D) Developing or implementing health
5 information technology in ways that are likely
6 to lock in users or electronic health information,
7 such as not allowing for the full export of
8 health information; lead to fraud, waste, or
9 abuse; or impede innovations and advancements
10 in health information access, exchange, and use,
11 including health information technology-enabled
12 care delivery.

13 “(3) EXCEPTIONS.—

14 “(A) IN GENERAL.—The term ‘information
15 blocking’ shall not include practices that—

16 “(i) are required by applicable law; or

17 “(ii) that the Secretary, through regu-
18 lation, identifies as necessary to protect
19 patient safety, to maintain the privacy or
20 security of individuals’ health information,
21 or to promote competition and consumer
22 welfare.

23 “(B) PROCESS.—For purposes of subpara-
24 graph (A)(ii), not later than 12 months after
25 the date of the enactment of this section, the

1 Secretary shall issue regulations following the
2 notice and comment procedures of section 553
3 of title 5, United States Code, except that the
4 Secretary may issue the first such regulation as
5 an interim final regulation.

6 “(C) NO ENFORCEMENT BEFORE EXCEP-
7 TIONS IDENTIFIED.—The term ‘information
8 blocking’ shall not include any practice or con-
9 duct occurring before the date that is 30 days
10 after the date on which the first regulation (as
11 described in subparagraph (B)) is issued under
12 such subparagraph.

13 “(D) CONSULTATION.—To the extent that
14 regulations issued under this paragraph define
15 practices that are necessary to promote com-
16 petition and consumer welfare, the Secretary
17 may consult with the Federal Trade Commis-
18 sion in issuing such regulations.

19 “(E) APPLICATION.—The term ‘informa-
20 tion blocking’, with respect to an individual or
21 entity, shall not include an act or practice other
22 than an act or practice committed by such indi-
23 vidual or entity.

1 “(e) TREATMENT OF VENDORS WITH RESPECT TO
2 PATIENT SAFETY ORGANIZATIONS.—In applying part C
3 of title IX—

4 “(1) vendors shall be treated as a provider (as
5 defined in section 921) for purposes of reporting re-
6 quirements under such part, to the extent that such
7 reports are related to attestation requirements under
8 section 3001(c)(5)(C)(i)(I);

9 “(2) claims of information blocking described in
10 subsection (a) shall be treated as a patient safety ac-
11 tivity under such part for purposes of reporting re-
12 quirements under such part; and

13 “(3) health care providers that are not mem-
14 bers of patient safety organizations shall be treated
15 in the same manner as health care providers that
16 are such members for purposes of such reporting re-
17 quirements with respect to claims of information
18 blocking described in subsection (a).

19 “(f) RULEMAKING AND GUIDANCE.—

20 “(1) IN GENERAL.—Not later than 12 months
21 after the date of the enactment of this section, the
22 Secretary, in consultation with the National Coordi-
23 nator and the Inspector General of the Department
24 of Health and Human Services, shall, through rule-
25 making, implement the provisions of section 3001 of

1 the 21st Century Cures Act, including amendments
2 made by such section, relating to information block-
3 ing.

4 “(2) NON-DUPLICATION OF PENALTY STRUC-
5 TURES.—In carrying out paragraph (1), in deter-
6 mining the scope of penalties, assessments, or exclu-
7 sions under such section 3001, including amend-
8 ments made by such section, relating to information
9 blocking, the Secretary shall ensure to the extent
10 possible that such penalties, assessments, and exclu-
11 sions do not duplicate penalty, assessment, and ex-
12 clusion structures that would otherwise apply with
13 respect to information blocking and the type of indi-
14 vidual or entity involved as of the day before the
15 date of the enactment of this section.

16 “(3) CLARIFICATION.—In carrying out para-
17 graph (1), the Secretary shall ensure that health
18 care providers are not penalized for actions of ven-
19 dor of, and other entities offering to such providers,
20 health information technology for the failure of such
21 technology to meet requirements for such technology
22 to be certified under this title.

23 “(4) GUIDANCE RELATING TO HIPAA.—Not
24 later than January 1, 2017, the National Coordi-
25 nator shall publish guidance to clarify the relation-

1 ship of the provisions of the HIPAA privacy and se-
2 curity law, as defined in section 3009(a)(2) to infor-
3 mation blocking, including—

4 “(A) examples of how such provisions may
5 result in information blocking; and

6 “(B) clarifying that a health care provider
7 (as defined in subsection (g)) who discloses
8 health information as allowed under applicable
9 State and Federal law is not liable for unlawful
10 actions, including breaches that occur in the
11 custody of the recipient unless the disclosure
12 proximately cause the breach.

13 “(g) HEALTH CARE PROVIDER DEFINED.—For pur-
14 poses of this section, the term ‘health care provider’ means
15 a provider of services under subsection (u) of section 1861
16 of the Social Security Act and a supplier under subsection
17 (d) of such section.

18 “(h) AUTHORIZATION OF APPROPRIATIONS.—In ad-
19 dition to amounts made available under subsection (c)(3),
20 there is authorized to be appropriated \$10,000,000 for fis-
21 cal year 2017 to carry out subsection (a), to remain avail-
22 able until expended.”.

23 (3) POSTINGS RELATING TO ENFORCEMENT ON
24 HHS INTERNET WEBSITE.—Section 3001 of the
25 Public Health Service Act (42 U.S.C. 300jj–11) is

1 amended by adding at the end the following new
2 subsection:

3 “(f) ENFORCEMENT INFORMATION POSTED ON HHS
4 INTERNET WEBSITE.—

5 “(1) PRICING INFORMATION.—Not later than
6 January 1, 2019, the National Coordinator shall
7 post the information described in subsection
8 (c)(5)(C)(I)(i)(cc) on the public Internet website of
9 the Office of the National Coordinator for Health
10 Information Technology in a manner that allows for
11 comparison of functionality, price information, and
12 other features among health information technology
13 products that aids in making informed decisions for
14 purchasing such a product.

15 “(2) ANNUAL POSTING.—For 2019 and each
16 subsequent year, the Secretary shall post on the
17 public Internet website of the Department of Health
18 and Human Services a list of any qualified electronic
19 health records with respect to which certification has
20 been withdrawn under subsection (c)(5)(C)(ii) dur-
21 ing such year and the vendor of or other entity of-
22 fering to health care providers (as defined in section
23 3010A(g)) such qualified electronic health records.

24 “(3) PERIODIC REVIEW.—The Secretary shall
25 periodically review and confirm that vendors of and

1 other entities offering to health care providers (as
2 defined in section 3010A(g)) qualified electronic
3 health records have publicly published application
4 programming interfaces and associated documenta-
5 tion as required by subsection (c)(5)(C)(i)(II) for
6 purposes of certification and maintaining certifi-
7 cation under any program kept or recognized under
8 subsection (c)(5)(A).”.

9 (4) DEMONSTRATION REQUIRED FOR MEANING-
10 FUL EHR USE UNDER MEDICARE.—

11 (A) ELIGIBLE PROFESSIONALS.—

12 (i) IN GENERAL.—Section
13 1848(o)(2)(A) of the Social Security Act
14 (42 U.S.C. 1395w-4(o)(2)(A)) is amended
15 by inserting after clause (iii) the following
16 new clause:

17 “(iv) INTEROPERABILITY.—With re-
18 spect to EHR reporting periods for pay-
19 ment years beginning with 2020, the eligi-
20 ble professional demonstrates to the satis-
21 faction of the Secretary, in accordance
22 with subparagraph (C)(i), that during such
23 period the professional has not taken any
24 action described in subsection (a)(2) of
25 section 3010A of the Public Health Service

1 Act, with respect to the use of any certified
2 EHR technology.”.

3 (ii) HARDSHIP EXEMPTION IN CASE
4 OF DECERTIFIED EHR.—Subparagraph (B)
5 of section 1848(a)(7) of the Social Security
6 Act (42 U.S.C. 1395w-4(a)(7)) is amend-
7 ed to read as follows:

8 “(B) SIGNIFICANT HARDSHIP EXCEP-
9 TION.—

10 “(i) IN GENERAL.—The Secretary
11 may, on a case-by-case basis, exempt an el-
12 igible professional from the application of
13 the payment adjustment under subpara-
14 graph (A) if the Secretary determines, sub-
15 ject to annual renewal, that compliance
16 with the requirement for being a meaning-
17 ful EHR user would result in a significant
18 hardship, such as in the case of an eligible
19 professional who practices in a rural area
20 without sufficient Internet access.

21 “(ii) DECERTIFICATION.—The Sec-
22 retary shall exempt an eligible professional
23 from the application of the payment ad-
24 justment under subparagraph (A) if the
25 Secretary determines that such profes-

1 sional was determined to not be a mean-
2 ingful EHR user because the certified
3 EHR technology used by such professional
4 is decertified under section 3001(c)(5)(C)
5 of the Public Health Service Act. An ex-
6 emption under the previous sentence may
7 be applied to an eligible professional only,
8 subject to clause (iii), during the first pay-
9 ment year with respect to the first EHR
10 reporting period to which such decertifica-
11 tion applies.

12 “(iii) DURATION OF DECERTIFICA-
13 TION.—

14 “(I) IN GENERAL.—Notwith-
15 standing clause (iv)(I), in no case
16 shall an exemption by reason of clause
17 (ii) be for a period of less than 12
18 months.

19 “(II) EXTENSION.—An exemp-
20 tion under clause (ii) may be ex-
21 tended, on a case-by-case basis, for a
22 period of an additional 12 months
23 subject to the limitation described in
24 clause (iv)(I).

25 “(iv) LIMITATION.—

1 “(I) IN GENERAL.—Subject to
2 subclause (II), in no case may an eli-
3 gible professional be granted an ex-
4 emption under this subparagraph for
5 more than 5 years.

6 “(II) EXCEPTION.—Subclause (I)
7 shall not apply to an exemption by
8 reason of clause (ii) to the extent nec-
9 essary to satisfy clause (iii)(I).”.

10 (iii) FURTHER APPLICATION.—Section
11 1848(o)(2) of the Social Security Act (42
12 U.S.C. 1395w-4(o)(2)) is amended by add-
13 ing at the end the following new subpara-
14 graph:

15 “(E) HARDSHIP EXEMPTION IN CASE OF
16 DECERTIFIED EHR.—In the case of certified
17 EHR technology used by an eligible profes-
18 sional that is decertified under section
19 3001(c)(5)(C), during the first payment year
20 with respect to the first EHR reporting period
21 to which such decertification applies, the Sec-
22 retary shall not treat the professional as not
23 being a meaningful EHR user solely because
24 the technology used by such professional was so
25 decertified. The treatment of a professional

1 under the previous sentence shall be for a pe-
2 riod of at least 12 months and may, on a case-
3 by-case basis, be for a period of an additional
4 12 months.”.

5 (B) ELIGIBLE HOSPITALS.—

6 (i) IN GENERAL.—Section
7 1886(n)(3)(A) of the Social Security Act
8 (42 U.S.C. 1395ww(n)(3)(A)) is amended
9 by inserting after clause (iii) the following
10 new clause:

11 “(iv) INTEROPERABILITY.—With re-
12 spect to EHR reporting periods for pay-
13 ment years beginning with 2020, the hos-
14 pital demonstrates to the satisfaction of
15 the Secretary, in accordance with subpara-
16 graph (C)(i), that during such period the
17 hospital has not taken any action described
18 in subsection (a)(2) of section 3010A of
19 the Public Health Service Act, with respect
20 to the use of any certified EHR tech-
21 nology.”.

22 (ii) HARDSHIP EXEMPTION IN CASE
23 OF DECERTIFIED EHR.—Subclause (II) of
24 section 1886(b)(3)(B)(ix) of the Social Se-
25 curity Act (42 U.S.C.

1 1395ww(b)(3)(B)(ix)) is amended to read
2 as follows:

3 “(II)(aa) The Secretary may, on a
4 case-by-case basis, exempt a subsection (d)
5 hospital from the application of subclause
6 (I) with respect to a fiscal year if the Sec-
7 retary determines, subject to annual re-
8 newal, that requiring such hospital to be a
9 meaningful EHR user during such fiscal
10 year would result in a significant hardship,
11 such as in the case of a hospital in a rural
12 area without sufficient Internet access.

13 “(bb) The Secretary shall exempt a
14 subsection (d) hospital from the applica-
15 tion of subclause (I) with respect to a fis-
16 cal year if the Secretary determines that
17 such hospital was determined to not be a
18 meaningful EHR user because the certified
19 EHR technology used by such hospital is
20 decertified under section 3001(c)(5)(C) of
21 the Public Health Service Act. An exemp-
22 tion under the previous sentence may be
23 applied to a subsection (d) hospital only,
24 subject to items (cc) and (dd), during the
25 first payment year with respect to the first

1 EHR reporting period to which such decer-
2 tification applies.

3 “(cc) Notwithstanding item (ee), in no
4 case shall an exemption by reason of item
5 (bb) be for a period of less than 12
6 months.

7 “(dd) An exemption under item (bb)
8 may, on a case-by-case basis, be extended
9 for a period of an additional 12 months
10 subject to the limitation described in item
11 (ee).

12 “(ee) Subject to item (ff), in no case
13 may a hospital be granted an exemption
14 under this subclause for more than 5
15 years.

16 “(ff) Item (ee) shall not apply to an
17 exemption by reason of item (bb) to the ex-
18 tent necessary to satisfy item (cc).”.

19 (C) DEMONSTRATION REQUIRED FOR
20 MEANINGFUL EHR USE UNDER MEDICAID.—
21 Section 1903(t)(2) of the Social Security Act
22 (42 U.S.C. 1396b(t)(2)) is amended by adding
23 at the end the following: “An eligible profes-
24 sional shall not qualify as a Medicaid provider
25 under this subsection, with respect to a year be-

1 ginning with 2020, unless such provider dem-
2 onstrates to the Secretary, through means such
3 as an attestation, that the provider has not
4 taken any action described in subsection (a)(2)
5 of section 3010A of the Public Health Service
6 Act, with respect to the use of any certified
7 EHR technology.”.

8 (5) GUIDANCE.—Not later than January 1,
9 2018, the Secretary of Health and Human Services
10 shall issue guidance to further the voluntary transi-
11 tion of health care providers between different cer-
12 tified EHR technology (as defined in section
13 3000(1) of the Public Health Service Act (42 U.S.C.
14 300jj(1)) by removing disincentives to such transi-
15 tion, which may include applying to instances of
16 such a transition the hardship exemption authority
17 under section 1848(a)(7) of the Social Security Act
18 (42 U.S.C. 1395w-4(a)(7)), section
19 1886(b)(3)(B)(ix) of such Act (42 U.S.C.
20 1395ww(b)(3)(B)(ix)), and other provisions of law in
21 existence as of the date of the enactment of this Act.
22 In developing such guidance, the Secretary may con-
23 sult with the relevant Federal agencies.

24 (f) DEFINITIONS.—

1 (1) CERTIFIED EHR TECHNOLOGY.—Paragraph
2 (1) of section 3000 of the Public Health Service Act
3 (42 U.S.C. 300jj) is amended to read as follows:

4 “(1) CERTIFIED EHR TECHNOLOGY.—The term
5 ‘certified EHR technology’ means a qualified elec-
6 tronic health record that is certified pursuant to sec-
7 tion 3001(c)(5) as meeting the certification criteria
8 defined in subparagraph (B) of such section that are
9 applicable to the type of record involved (as deter-
10 mined by the Secretary, such as an ambulatory elec-
11 tronic health record for office-based physicians or an
12 inpatient hospital electronic health record for hos-
13 pitals) including, beginning January 1, 2018, with
14 respect to which the vendor or other entity offering
15 such technology is in compliance with the require-
16 ments under section 3001(c)(5)(C)(i).”.

17 (2) WIDESPREAD INTEROPERABILITY.—Section
18 3000 of the Public Health Service Act (42 U.S.C.
19 300jj) is amended by adding at the end the following
20 new paragraph:

21 “(15) WIDESPREAD INTEROPERABILITY.—The
22 term ‘widespread interoperability’ means that, on a
23 nationwide basis—

1 “(A) health information technology is
2 interoperable, in accordance with section 3010;
3 and

4 “(B) such technology is employed by mean-
5 ingful EHR users under the Medicare Program
6 under title XVIII of the Social Security Act and
7 the Medicaid program under title XIX of such
8 Act and by other clinicians and health care pro-
9 viders.”.

10 (g) CONFORMING AMENDMENTS.—

11 (1) VOLUNTARY USE OF STANDARDS.—Section
12 3006 of the Public Health Service Act (42 U.S.C.
13 300jj–16) is amended—

14 (A) in subsection (a)(1), by inserting “, in-
15 cluding an interoperability standard or imple-
16 mentation specification, with respect to such
17 interoperability standard, adopted under such
18 section” after “section 3004”.

19 (B) in subsection (b), by inserting “, in-
20 cluding the interoperability standards and im-
21 plementation specifications, with respect to such
22 interoperability standards, adopted under such
23 section” after “section 3004”.

24 (2) HIPAA PRIVACY AND SECURITY LAW DEFINI-
25 TION CORRECTION.—Section 3009(a)(2)(A) of the

1 Public Health Service Act (42 U.S.C. 300jj–
2 19(a)(2)(A)) is amended by striking “title IV” and
3 inserting “title XIII”.

4 (3) COORDINATION OF FEDERAL ACTIVITIES.—
5 Section 13111 of the HITECH Act is amended—

6 (A) in subsection (a), by inserting before
7 the period at the end the following: “(and, be-
8 ginning on January 1, 2018, that are also
9 interoperable under section 3010 of such Act
10 and in compliance with interoperability stand-
11 ards and implementation specifications, with re-
12 spect to such interoperability standards, adopt-
13 ed under section 3004 of such Act)”; and

14 (B) in subsection (b), by inserting “(and,
15 beginning on January 1, 2018, including an
16 interoperability standard or implementation
17 specification, with respect to such interoper-
18 ability standard, adopted under section 3004 of
19 such Act)” before “the President”.

20 (4) APPLICATION TO PRIVATE ENTITIES.—Sec-
21 tion 13112 of the HITECH Act is amended by in-
22 serting before the period at the end the following:
23 “(and, beginning on January 1, 2018, that are also
24 interoperable under section 3010 of such Act and in
25 compliance with interoperability standards and im-

1 plementation specifications, with respect to such
2 interoperability standards, adopted under section
3 3004 of such Act)”.
4

5 (5) NIST TESTING.—Section 13201 of the
6 HITECH Act (42 U.S.C. 17911) is amended—

7 (A) in subsection (a), by inserting “(or, be-
8 ginning January 1, 2018, in coordination with
9 the entities with contracts under section 3003A,
10 with respect to standards, and implementation
11 specifications under section 3004)” before “,
12 the Director”;

13 (B) in subsection (b), by inserting “(or, be-
14 ginning January 1, 2018, in coordination with
15 the entities with contracts under section 3003A,
16 with respect to standards and implementation
17 specifications under section 3004)” before “,
18 the Director”; and

19 (C) by adding at the end the following new
20 subsection:

21 “(c) FUNDING.—For purposes of carrying out this
22 section, in addition to any other funds made available to
23 carry out this section, there is authorized to be appro-
24 priated \$15,000,000, to remain available until expended.”.

25 (6) COORDINATION WITH RECOMMENDATIONS
 FOR ACHIEVING WIDESPREAD EHR INTEROPER-

1 ABILITY.—Section 106 of the Medicare Access and
2 CHIP Reauthorization Act of 2015 (Public Law
3 114–10) is amended by striking subsection (b).”.

4 (h) PATIENT ENGAGEMENT AND EMPOWERMENT.—
5 It is the sense of Congress that—

6 (1) if the strategic goals that Congress set forth
7 in the HITECH Act are to be achieved, interoper-
8 ability is best achieved with individuals and author-
9 ized representatives having equal access to the
10 health information of such individuals in electronic
11 format;

12 (2) patients have the right to the entirety of the
13 health information of such individuals, including
14 such information contained in an electronic health
15 record of such individuals;

16 (3) such right extends to both structured and
17 unstructured data;

18 (4) such right extends to authorized representa-
19 tives of the individual involved, such as caretakers of
20 such individual, family members of such individual,
21 and guardians of such individual; and

22 (5) to further facilitate access of an individual
23 to health information of such individual—

24 (A) health care providers should not have
25 the ability to deny a request of the individual

1 for access to the entirety of such health infor-
2 mation of such individual;

3 (B) health care providers do not need the
4 consent of individuals to share personal health
5 information of such individuals with other cov-
6 ered entities, in compliance with the HIPAA
7 privacy regulations promulgated pursuant to
8 section 264(c) of the Health Insurance Port-
9 ability and Accountability Act of 1996 for the
10 purposes of supporting patient care, except in
11 situations where consent is specifically required
12 under such regulations, such as in cases related
13 to the psychiatric records of the individual in-
14 volved;

15 (C) mechanisms should be utilized that
16 allow for the bidirectional exchange of informa-
17 tion through such mechanisms as web portals,
18 appointments, and prescription refills, for the
19 purpose of patients partnering with providers to
20 assist in managing health and care;

21 (D) mechanisms described in subparagraph
22 (C) should allow for connecting individuals
23 across the continuum of care;

1 (E) an individual has the right to access
2 the health information of the individual without
3 cost to the individual;

4 (F) mechanisms described in subparagraph
5 (C) should allow for data of an individual gen-
6 erated by the individual to be integrated into
7 such platforms as electronic health records;

8 (G) such access should be timely, in ac-
9 cordance with the HIPAA privacy regulations
10 described in subparagraph (B), and take into
11 account communications preferences of the indi-
12 vidual involved;

13 (H) an individual should have the right to
14 be confident that the data in the electronic
15 health record of the individual pertains to such
16 individual; and

17 (I) the right described in subparagraph
18 (H) will promote safety and care coordination
19 for individuals.

20 **Subtitle B—Telehealth**

21 **SEC. 3021. TELEHEALTH SERVICES UNDER THE MEDICARE** 22 **PROGRAM.**

23 (a) PROVISION OF INFORMATION BY CENTERS FOR
24 MEDICARE & MEDICAID SERVICES.—Not later than 1
25 year after the date of the enactment of this Act, the Ad-

1 administrator of the Centers for Medicare & Medicaid Serv-
2 ices shall provide to the committees of jurisdiction of the
3 House of Representatives and the Senate information on
4 the following:

5 (1) The populations of Medicare beneficiaries,
6 such as those who are dually eligible for the Medi-
7 care Program under title XVIII of the Social Secu-
8 rity Act (42 U.S.C. 1395 et seq.) and the Medicaid
9 program under title XIX of such Act (42 U.S.C.
10 1396 et seq.) and those with chronic conditions,
11 whose care may be improved most in terms of qual-
12 ity and efficiency by the expansion, in a manner that
13 meets or exceeds the existing in-person standard of
14 care under the Medicare Program under title XVIII
15 of such Act, of telehealth services under section
16 1834(m)(4) of such Act (42 U.S.C. 1395m(m)(4)).

17 (2) Activities by the Center for Medicare and
18 Medicaid Innovation which examine the use of tele-
19 health services in models, projects, or initiatives
20 funded through section 1115A of the Social Security
21 Act (42 U.S.C. 1315a).

22 (3) The types of high-volume services (and re-
23 lated diagnoses) under such title XVIII which might
24 be suitable to the furnishing of services via tele-
25 health.

1 (4) Barriers that might prevent the expansion
2 of telehealth services under section 1834(m)(4) of
3 the Social Security Act (42 U.S.C. 1395m(m)(4))
4 beyond such services that are in effect as of the date
5 of the enactment of this Act.

6 (b) PROVISION OF INFORMATION BY MEDPAC.—Not
7 later than March 15, 2017, the Medicare Payment Advi-
8 sory Commission established under section 1805 of the So-
9 cial Security Act (42 U.S.C. 1395b–6) shall, using quan-
10 titative and qualitative research methods, provide informa-
11 tion to the committees of jurisdiction of the House of Rep-
12 resentatives and the Senate that identifies—

13 (1) the telehealth services for which payment
14 can be made, as of the date of the enactment of this
15 Act, under the fee-for-service program under parts A
16 and B of title XVIII of such Act;

17 (2) the telehealth services for which payment
18 can be made, as of such date, under private health
19 insurance plans;

20 (3) with respect to services identified under
21 paragraph (2) but not under paragraph (1), ways in
22 which payment for such services might be incor-
23 porated into such fee-for-service program (including
24 any recommendations for ways to accomplish this in-
25 corporation).

1 (c) SENSE OF CONGRESS.—It is the sense of Con-
2 gress that—

3 (1) eligible originating sites should be expanded
4 beyond those originating sites described in section
5 1834(m)(4)(C) of the Social Security Act (42 U.S.C.
6 1395m(m)(4)(C)); and

7 (2) any expansion of telehealth services under
8 the Medicare Program should—

9 (A) recognize that telemedicine is the deliv-
10 ery of safe, effective, quality health care serv-
11 ices, by a health care provider, using technology
12 as the mode of care delivery;

13 (B) meet or exceed the conditions of cov-
14 erage and payment with respect to the Medicare
15 Program under title XVIII unless specifically
16 address in subsequent statute, of such Act if
17 the service were furnished in person, including
18 standards of care; and

19 (C) involve clinically appropriate means to
20 furnish such services.

1 **Subtitle C—Encouraging Con-**
2 **tinuing Medical Education for**
3 **Physicians**

4 **SEC. 3041. EXEMPTING FROM MANUFACTURER TRANS-**
5 **PARENCY REPORTING CERTAIN TRANSFERS**
6 **USED FOR EDUCATIONAL PURPOSES.**

7 (a) IN GENERAL.—Section 1128G(e)(10)(B) of the
8 Social Security Act (42 U.S.C. 1320a–7h(e)(10)(B)) is
9 amended—

10 (1) in clause (iii), by inserting “, including
11 peer-reviewed journals, journal reprints, journal sup-
12 plements, medical conference reports, and medical
13 textbooks” after “patient use”; and

14 (2) by adding at the end the following new
15 clause:

16 “(xiii) In the case of a covered recipi-
17 ent who is a physician, an indirect pay-
18 ment or transfer of value to the covered re-
19 cipient—

20 “(I) for speaking at, or preparing
21 educational materials for, an edu-
22 cational event for physicians or other
23 health care professionals that does not
24 commercially promote a covered drug,

1 device, biological, or medical supply;
2 or

3 “(II) that serves the sole purpose
4 of providing the covered recipient with
5 medical education, such as by pro-
6 viding the covered recipient with the
7 tuition required to attend an edu-
8 cational event or with materials pro-
9 vided to physicians at an educational
10 event.”.

11 (b) EFFECTIVE DATE.—The amendments made by
12 this section shall apply with respect to transfers of value
13 made on or after the date of the enactment of this Act.

14 **Subtitle D—Disposable Medical**
15 **Technologies**

16 **SEC. 3061. TREATMENT OF CERTAIN ITEMS AND DEVICES.**

17 (a) IN GENERAL.—Section 1834 of the Social Secu-
18 rity Act (42 U.S.C. 1395m) is amended by adding at the
19 end the following new subsection:

20 “(r) PAYMENT FOR CERTAIN DISPOSABLE DE-
21 VICES.—

22 “(1) IN GENERAL.—The Secretary shall make
23 separate payment in the amount established under
24 paragraph (3) to a home health agency for a device
25 described in paragraph (2) when furnished to an in-

1 dividual who receives home health services for which
2 payment is made under section 1895(b).

3 “(2) DEVICE DESCRIBED.—For purposes of
4 paragraph (1), a device described in this paragraph
5 is a disposable device for which, as of January 1,
6 2015, there is—

7 “(A) a Level I Healthcare Common Proce-
8 dure Coding System (HCPCS) code for which
9 the description for a professional service in-
10 cludes the furnishing of such device; and

11 “(B) a separate Level I HCPCS code for
12 a professional service that uses durable medical
13 equipment instead of such device.

14 “(3) PAYMENT AMOUNT.—The Secretary shall
15 establish the separate payment amount for such a
16 device such that such amount does not exceed the
17 payment that would be made for the HCPCS code
18 described in paragraph (2)(A) under section 1833(t)
19 (relating to payment for covered OPD services).”.

20 (b) CONFORMING AMENDMENT.—Section
21 1861(m)(5) of the Social Security Act (42 U.S.C.
22 1395x(m)(5)) is amended by inserting “and devices de-
23 scribed in section 1834(r)(2)” after “durable medical
24 equipment”.

1 (c) EFFECTIVE DATE.—The amendments made by
2 this section shall apply to devices furnished on or after
3 January 1, 2017.

4 **Subtitle E—Local Coverage**
5 **Decision Reforms**

6 **SEC. 3081. IMPROVEMENTS IN THE MEDICARE LOCAL COV-**
7 **ERAGE DETERMINATION (LCD) PROCESS.**

8 (a) IN GENERAL.—Section 1862(l)(5) of the Social
9 Security Act (42 U.S.C. 1395y(l)(5)) is amended by add-
10 ing at the end the following new subparagraph:

11 “(D) LOCAL COVERAGE DETERMINA-
12 TIONS.—The Secretary shall require each Medi-
13 care administrative contractor that develops a
14 local coverage determination to make available
15 on the website of such contractor and on the
16 Medicare website, at least 45 days before the
17 effective date of such determination, the fol-
18 lowing information:

19 “(i) Such determination in its en-
20 tirety.

21 “(ii) Where and when the proposed
22 determination was first made public.

23 “(iii) Hyperlinks to the proposed de-
24 termination and a response to comments

1 submitted to the contractor with respect to
2 such proposed determination.

3 “(iv) A summary of evidence that was
4 considered by the contractor during the de-
5 velopment of such determination and a list
6 of the sources of such evidence.

7 “(v) An explanation of the rationale
8 that supports such determination.”.

9 (b) EFFECTIVE DATE.—The amendment made by
10 subsection (a) shall apply with respect to local coverage
11 determinations that are proposed or revised on or after
12 the date that is 180 days after the date of the enactment
13 of this Act.

14 **Subtitle F—Medicare Pharma-**
15 **ceutical and Technology Om-**
16 **budsman**

17 **SEC. 3101. MEDICARE PHARMACEUTICAL AND TECH-**
18 **NOLOGY OMBUDSMAN.**

19 Section 1808(c) of the Social Security Act (42 U.S.C.
20 1395b–9(c)) is amended by adding at the end the fol-
21 lowing new paragraph:

22 “(4) PHARMACEUTICAL AND TECHNOLOGY OM-
23 BUDSMAN.—Not later than 12 months after the date
24 of the enactment of this paragraph, the Secretary
25 shall provide for a pharmaceutical and technology

1 ombudsman within the Centers for Medicare & Med-
2 icaid Services who shall receive and respond to com-
3 plaints, grievances, and requests that—

4 “(A) are from entities that manufacture
5 pharmaceutical, biotechnology, medical device,
6 or diagnostic products that are covered or for
7 which coverage is being sought under this title;
8 and

9 “(B) are with respect to coverage, coding,
10 or payment under this title for such products.

11 The second sentence of paragraph (2) shall apply to
12 this paragraph in the same manner as such sentence
13 applies to paragraph (2).”.

14 **Subtitle G—Medicare Site-of-**
15 **Service Price Transparency**

16 **SEC. 3121. MEDICARE SITE-OF-SERVICE PRICE TRANS-**
17 **PARENCY.**

18 Section 1834 of the Social Security Act (42 U.S.C.
19 1395m), as amended by section 3061, is further amended
20 by adding at the end the following new subsection:

21 “(s) SITE-OF-SERVICE PRICE TRANSPARENCY.—

22 “(1) IN GENERAL.—In order to facilitate price
23 transparency with respect to items and services for
24 which payment may be made either to a hospital
25 outpatient department or to an ambulatory surgical

1 center under this title, the Secretary shall, for 2017
2 and each year thereafter, make available to the pub-
3 lic via a searchable website, with respect to an ap-
4 propriate number of such items and services—

5 “(A) the estimated payment amount for
6 the item or service under the outpatient depart-
7 ment fee schedule under subsection (t) of sec-
8 tion 1833 and the ambulatory surgical center
9 payment system under subsection (i) of such
10 section; and

11 “(B) the estimated amount of beneficiary
12 liability applicable to the item or service.

13 “(2) CALCULATION OF ESTIMATED BENE-
14 FICIARY LIABILITY.—For purposes of paragraph
15 (1)(B), the estimated amount of beneficiary liability,
16 with respect to an item or service, is the amount for
17 such item or service for which an individual who
18 does not have coverage under a Medicare supple-
19 mental policy certified under section 1882 or any
20 other supplemental insurance coverage is respon-
21 sible.

22 “(3) IMPLEMENTATION.—In carrying out this
23 subsection, the Secretary—

24 “(A) shall include in the notice described
25 in section 1804(a) a notification of the avail-

1 ability of the estimated amounts made available
2 under paragraph (1); and

3 “(B) may utilize mechanisms in existence
4 on the date of the enactment of this subsection,
5 such as the portion of the website of the Cen-
6 ters for Medicare & Medicaid Services on which
7 information comparing physician performance is
8 posted (commonly referred to as the Physician
9 Compare website), to make available such esti-
10 mated amounts under such paragraph.

11 “(4) FUNDING.—For purposes of implementing
12 this subsection, the Secretary shall provide for the
13 transfer, from the Supplemental Medical Insurance
14 Trust Fund under section 1841 to the Centers for
15 Medicare & Medicaid Services Program Management
16 Account, of \$6,000,000 for fiscal year 2015, to re-
17 main available until expended.”.

18 **Subtitle H—Medicare Part D Pa-**
19 **tient Safety and Drug Abuse**
20 **Prevention**

21 **SEC. 3141. PROGRAMS TO PREVENT PRESCRIPTION DRUG**

22 **ABUSE UNDER MEDICARE PARTS C AND D.**

23 (a) DRUG MANAGEMENT PROGRAM FOR AT-RISK
24 BENEFICIARIES.—

1 (1) IN GENERAL.—Section 1860D–4(c) of the
2 Social Security Act (42 U.S.C. 1395w–10(c)) is
3 amended by adding at the end the following:

4 “(5) DRUG MANAGEMENT PROGRAM FOR AT-
5 RISK BENEFICIARIES.—

6 “(A) AUTHORITY TO ESTABLISH.—A PDP
7 sponsor may establish a drug management pro-
8 gram for at-risk beneficiaries under which, sub-
9 ject to subparagraph (B), the PDP sponsor
10 may, in the case of an at-risk beneficiary for
11 prescription drug abuse who is an enrollee in a
12 prescription drug plan of such PDP sponsor,
13 limit such beneficiary’s access to coverage for
14 frequently abused drugs under such plan to fre-
15 quently abused drugs that are prescribed for
16 such beneficiary by one or more prescribers se-
17 lected under subparagraph (D), and dispensed
18 for such beneficiary by one or more pharmacies
19 selected under such subparagraph.

20 “(B) REQUIREMENT FOR NOTICES.—

21 “(i) IN GENERAL.—A PDP sponsor
22 may not limit the access of an at-risk ben-
23 eficiary for prescription drug abuse to cov-
24 erage for frequently abused drugs under a

1 prescription drug plan until such spon-
2 sor—

3 “(I) provides to the beneficiary
4 an initial notice described in clause
5 (ii) and a second notice described in
6 clause (iii); and

7 “(II) verifies with the providers
8 of the beneficiary that the beneficiary
9 is an at-risk beneficiary for prescrip-
10 tion drug abuse.

11 “(ii) INITIAL NOTICE.—An initial no-
12 tice described in this clause is a notice that
13 provides to the beneficiary—

14 “(I) notice that the PDP sponsor
15 has identified the beneficiary as po-
16 tentially being an at-risk beneficiary
17 for prescription drug abuse;

18 “(II) information describing all
19 State and Federal public health re-
20 sources that are designed to address
21 prescription drug abuse to which the
22 beneficiary has access, including men-
23 tal health services and other coun-
24 seling services;

1 “(III) notice of, and information
2 about, the right of the beneficiary to
3 appeal such identification under sub-
4 section (h) and the option of an auto-
5 matic escalation to external review;

6 “(IV) a request for the bene-
7 ficiary to submit to the PDP sponsor
8 preferences for which prescribers and
9 pharmacies the beneficiary would pre-
10 fer the PDP sponsor to select under
11 subparagraph (D) in the case that the
12 beneficiary is identified as an at-risk
13 beneficiary for prescription drug
14 abuse as described in clause (iii)(I);

15 “(V) an explanation of the mean-
16 ing and consequences of the identi-
17 fication of the beneficiary as poten-
18 tially being an at-risk beneficiary for
19 prescription drug abuse, including an
20 explanation of the drug management
21 program established by the PDP
22 sponsor pursuant to subparagraph
23 (A);

24 “(VI) clear instructions that ex-
25 plain how the beneficiary can contact

1 the PDP sponsor in order to submit
2 to the PDP sponsor the preferences
3 described in subclause (IV) and any
4 other communications relating to the
5 drug management program for at-risk
6 beneficiaries established by the PDP
7 sponsor; and

8 “(VII) contact information for
9 other organizations that can provide
10 the beneficiary with assistance regard-
11 ing such drug management program
12 (similar to the information provided
13 by the Secretary in other standardized
14 notices provided to part D eligible in-
15 dividuals enrolled in prescription drug
16 plans under this part).

17 “(iii) SECOND NOTICE.—A second no-
18 tice described in this clause is a notice that
19 provides to the beneficiary notice—

20 “(I) that the PDP sponsor has
21 identified the beneficiary as an at-risk
22 beneficiary for prescription drug
23 abuse;

24 “(II) that such beneficiary is
25 subject to the requirements of the

1 drug management program for at-risk
2 beneficiaries established by such PDP
3 sponsor for such plan;

4 “(III) of the prescriber (or pre-
5 scribers) and pharmacy (or phar-
6 macies) selected for such individual
7 under subparagraph (D);

8 “(IV) of, and information about,
9 the beneficiary’s right to appeal such
10 identification under subsection (h)
11 and the option of an automatic esca-
12 lation to external review;

13 “(V) that the beneficiary can, in
14 the case that the beneficiary has not
15 previously submitted to the PDP
16 sponsor preferences for which pre-
17 scribers and pharmacies the bene-
18 ficiary would prefer the PDP sponsor
19 select under subparagraph (D), sub-
20 mit such preferences to the PDP
21 sponsor; and

22 “(VI) that includes clear instruc-
23 tions that explain how the beneficiary
24 can contact the PDP sponsor.

25 “(iv) TIMING OF NOTICES.—

1 “(I) IN GENERAL.—Subject to
2 subclause (II), a second notice de-
3 scribed in clause (iii) shall be provided
4 to the beneficiary on a date that is
5 not less than 60 days after an initial
6 notice described in clause (ii) is pro-
7 vided to the beneficiary.

8 “(II) EXCEPTION.—In the case
9 that the PDP sponsor, in conjunction
10 with the Secretary, determines that
11 concerns identified through rule-
12 making by the Secretary regarding
13 the health or safety of the beneficiary
14 or regarding significant drug diversion
15 activities require the PDP sponsor to
16 provide a second notice described in
17 clause (iii) to the beneficiary on a
18 date that is earlier than the date de-
19 scribed in subclause (I), the PDP
20 sponsor may provide such second no-
21 tice on such earlier date.

22 “(C) AT-RISK BENEFICIARY FOR PRE-
23 SCRIPTION DRUG ABUSE.—

24 “(i) IN GENERAL.—For purposes of
25 this paragraph, the term ‘at-risk bene-

1 beneficiary for prescription drug abuse’ means
2 a part D eligible individual who is not an
3 exempted individual described in clause (ii)
4 and—

5 “(I) who is identified as such an
6 at-risk beneficiary through the use of
7 clinical guidelines developed by the
8 Secretary in consultation with PDP
9 sponsors and other stakeholders de-
10 scribed in section 3141(f)(2)(A) of the
11 21st Century Cures Act; or

12 “(II) with respect to whom the
13 PDP sponsor of a prescription drug
14 plan, upon enrolling such individual in
15 such plan, received notice from the
16 Secretary that such individual was
17 identified under this paragraph to be
18 an at-risk beneficiary for prescription
19 drug abuse under the prescription
20 drug plan in which such individual
21 was most recently previously enrolled
22 and such identification has not been
23 terminated under subparagraph (F).

24 “(ii) EXEMPTED INDIVIDUAL DE-
25 SCRIBED.—An exempted individual de-

1 scribed in this clause is an individual
2 who—

3 “(I) receives hospice care under
4 this title;

5 “(II) is a resident of a long-term
6 care facility, of an intermediate care
7 facility for the mentally retarded, or
8 of another facility for which fre-
9 quently abused drugs are dispensed
10 for residents through a contract with
11 a single pharmacy; or

12 “(III) the Secretary elects to
13 treat as an exempted individual for
14 purposes of clause (i).

15 “(D) SELECTION OF PRESCRIBERS AND
16 PHARMACIES.—

17 “(i) IN GENERAL.—With respect to
18 each at-risk beneficiary for prescription
19 drug abuse enrolled in a prescription drug
20 plan offered by such sponsor, a PDP spon-
21 sor shall, based on the preferences sub-
22 mitted to the PDP sponsor by the bene-
23 ficiary pursuant to clauses (ii)(IV) and
24 (iii)(V) of subparagraph (B) (except as

1 otherwise provided in this subparagraph),
2 select—

3 “(I) one or more individuals who
4 are authorized to prescribe frequently
5 abused drugs (referred to in this
6 paragraph as ‘prescribers’) who may
7 write prescriptions for such drugs for
8 such beneficiary; and

9 “(II) one or more pharmacies
10 that may dispense such drugs to such
11 beneficiary.

12 “(ii) REASONABLE ACCESS.—In mak-
13 ing the selections under this subpara-
14 graph—

15 “(I) a PDP sponsor shall ensure
16 that the beneficiary continues to have
17 reasonable access to frequently abused
18 drugs (as defined in subparagraph
19 (G)), taking into account geographic
20 location, beneficiary preference, im-
21 pact on costsharing, and reasonable
22 travel time; and

23 “(II) a PDP sponsor shall ensure
24 such access (including access to pre-
25 scribers and pharmacies with respect

1 to frequently abused drugs) in the
2 case of individuals with multiple resi-
3 dences and in the case of natural dis-
4 asters and similar emergency situa-
5 tions.

6 “(iii) BENEFICIARY PREFERENCES.—

7 If an at-risk beneficiary for prescription
8 drug abuse submits preferences for which
9 in-network prescribers and pharmacies the
10 beneficiary would prefer the PDP sponsor
11 select in response to a notice under sub-
12 paragraph (B), the PDP sponsor shall—

13 “(I) review such preferences;

14 “(II) select or change the selec-
15 tion of prescribers and pharmacies for
16 the beneficiary based on such pref-
17 erences; and

18 “(III) inform the beneficiary of
19 such selection or change of selection.

20 “(iv) EXCEPTION REGARDING BENE-
21 FICIARY PREFERENCES.—In the case that
22 the PDP sponsor determines that a change
23 to the selection of prescriber or pharmacy
24 under clause (iii)(II) by the PDP sponsor
25 is contributing or would contribute to pre-

1 scripture drug abuse or drug diversion by
2 the beneficiary, the PDP sponsor may
3 change the selection of prescriber or phar-
4 macy for the beneficiary without regard to
5 the preferences of the beneficiary described
6 in clause (iii).

7 “(v) CONFIRMATION.—Before select-
8 ing a prescriber (or prescribers) or phar-
9 macy (or pharmacies) under this subpara-
10 graph, a PDP sponsor must request and
11 receive confirmation from such a prescriber
12 or pharmacy acknowledging and accepting
13 that the beneficiary involved is in the drug
14 management program for at-risk bene-
15 ficiaries.

16 “(E) TERMINATIONS AND APPEALS.—The
17 identification of an individual as an at-risk ben-
18 eficiary for prescription drug abuse under this
19 paragraph, a coverage determination made
20 under a drug management program for at-risk
21 beneficiaries, and the selection of prescriber or
22 pharmacy under subparagraph (D) with respect
23 to such individual shall be subject to reconsider-
24 ation and appeal under subsection (h) and the

1 option of an automatic escalation to external re-
2 view to the extent provided by the Secretary.

3 “(F) TERMINATION OF IDENTIFICATION.—

4 “(i) IN GENERAL.—The Secretary
5 shall develop standards for the termination
6 of identification of an individual as an at-
7 risk beneficiary for prescription drug abuse
8 under this paragraph. Under such stand-
9 ards such identification shall terminate as
10 of the earlier of—

11 “(I) the date the individual dem-
12 onstrates that the individual is no
13 longer likely, in the absence of the re-
14 strictions under this paragraph, to be
15 an at-risk beneficiary for prescription
16 drug abuse described in subparagraph
17 (C)(i); and

18 “(II) the end of such maximum
19 period of identification as the Sec-
20 retary may specify.

21 “(ii) RULE OF CONSTRUCTION.—

22 Nothing in clause (i) shall be construed as
23 preventing a plan from identifying an indi-
24 vidual as an at-risk beneficiary for pre-
25 scription drug abuse under subparagraph

1 (C)(i) after such termination on the basis
2 of additional information on drug use oc-
3 ccurring after the date of notice of such ter-
4 mination.

5 “(G) FREQUENTLY ABUSED DRUG.—For
6 purposes of this subsection, the term ‘frequently
7 abused drug’ means a drug that is a controlled
8 substance that the Secretary determines to be
9 frequently abused or diverted.

10 “(H) DATA DISCLOSURE.—In the case of
11 an at-risk beneficiary for prescription drug
12 abuse whose access to coverage for frequently
13 abused drugs under a prescription drug plan
14 has been limited by a PDP sponsor under this
15 paragraph, such PDP sponsor shall disclose
16 data, including any necessary individually iden-
17 tifiable health information, in a form and man-
18 ner specified by the Secretary, about the deci-
19 sion to impose such limitations and the limita-
20 tions imposed by the sponsor under this part to
21 other PDP sponsors that request such data.

22 “(I) EDUCATION.—The Secretary shall
23 provide education to enrollees in prescription
24 drug plans of PDP sponsors and providers re-
25 garding the drug management program for at-

1 risk beneficiaries described in this paragraph,
2 including education—

3 “(i) provided by Medicare administra-
4 tive contractors through the improper pay-
5 ment outreach and education program de-
6 scribed in section 1874A(h); and

7 “(ii) through current education efforts
8 (such as State health insurance assistance
9 programs described in subsection (a)(1)(A)
10 of section 119 of the Medicare Improve-
11 ments for Patients and Providers Act of
12 2008 (42 U.S.C. 1395b–3 note)) and ma-
13 terials directed toward such enrollees.

14 “(J) APPLICATION UNDER MA–PD
15 PLANS.—Pursuant to section 1860D–21(c)(1),
16 the provisions of this paragraph apply under
17 part D to MA organizations offering MA–PD
18 plans to MA eligible individuals in the same
19 manner as such provisions apply under this
20 part to a PDP sponsor offering a prescription
21 drug plan to a part D eligible individual.”.

22 (2) INFORMATION FOR CONSUMERS.—Section
23 1860D–4(a)(1)(B) of the Social Security Act (42
24 U.S.C. 1395w–104(a)(1)(B)) is amended by adding
25 at the end the following:

1 “(v) The drug management program
2 for at-risk beneficiaries under subsection
3 (c)(5).”.

4 (b) UTILIZATION MANAGEMENT PROGRAMS.—Sec-
5 tion 1860D–4(c) of the Social Security Act (42 U.S.C.
6 1395w–104(c)), as amended by subsection (a)(1), is fur-
7 ther amended—

8 (1) in paragraph (1), by inserting after sub-
9 paragraph (D) the following new subparagraph:

10 “(E) A utilization management tool to pre-
11 vent drug abuse (as described in paragraph
12 (6)(A)).”; and

13 (2) by adding at the end the following new
14 paragraph:

15 “(6) UTILIZATION MANAGEMENT TOOL TO PRE-
16 VENT DRUG ABUSE.—

17 “(A) IN GENERAL.—A tool described in
18 this paragraph is any of the following:

19 “(i) A utilization tool designed to pre-
20 vent the abuse of frequently abused drugs
21 by individuals and to prevent the diversion
22 of such drugs at pharmacies.

23 “(ii) Retrospective utilization review
24 to identify—

1 “(I) individuals that receive fre-
2 quently abused drugs at a frequency
3 or in amounts that are not clinically
4 appropriate; and

5 “(II) providers of services or sup-
6 pliers that may facilitate the abuse or
7 diversion of frequently abused drugs
8 by beneficiaries.

9 “(iii) Consultation with the contractor
10 described in subparagraph (B) to verify if
11 an individual enrolling in a prescription
12 drug plan offered by a PDP sponsor has
13 been previously identified by another PDP
14 sponsor as an individual described in
15 clause (ii)(I).

16 “(B) REPORTING.—A PDP sponsor offer-
17 ing a prescription drug plan (and an MA orga-
18 nization offering an MA–PD plan) in a State
19 shall submit to the Secretary and the Medicare
20 drug integrity contractor with which the Sec-
21 retary has entered into a contract under section
22 1893 with respect to such State a report, on a
23 monthly basis, containing information on—

24 “(i) any provider of services or sup-
25 plier described in subparagraph (A)(ii)(II)

1 that is identified by such plan sponsor (or
2 organization) during the 30-day period be-
3 fore such report is submitted; and

4 “(ii) the name and prescription
5 records of individuals described in para-
6 graph (5)(C).”.

7 (c) EXPANDING ACTIVITIES OF MEDICARE DRUG IN-
8 TEGRITY CONTRACTORS (MEDICS).—

9 (1) IN GENERAL.—Section 1893 of the Social
10 Security Act (42 U.S.C. 1395ddd) is amended by
11 adding at the end the following new subsection:

12 “(j) EXPANDING ACTIVITIES OF MEDICARE DRUG
13 INTEGRITY CONTRACTORS (MEDICS).—

14 “(1) ACCESS TO INFORMATION.—Under con-
15 tracts entered into under this section with Medicare
16 drug integrity contractors (including any successor
17 entity to a Medicare drug integrity contractor), the
18 Secretary shall authorize such contractors to directly
19 accept prescription and necessary medical records
20 from entities such as pharmacies, prescription drug
21 plans, MA–PD plans, and physicians with respect to
22 an individual in order for such contractors to pro-
23 vide information relevant to the determination of
24 whether such individual is an at-risk beneficiary for

1 prescription drug abuse, as defined in section
2 1860D–4(c)(5)(C).

3 “(2) REQUIREMENT FOR ACKNOWLEDGMENT
4 OF REFERRALS.—If a PDP sponsor or MA organiza-
5 tion refers information to a contractor described in
6 paragraph (1) in order for such contractor to assist
7 in the determination described in such paragraph,
8 the contractor shall—

9 “(A) acknowledge to the sponsor or organi-
10 zation receipt of the referral; and

11 “(B) in the case that any PDP sponsor or
12 MA organization contacts the contractor re-
13 questing to know the determination by the con-
14 tractor of whether or not an individual has been
15 determined to be an individual described such
16 paragraph, shall inform such sponsor or organi-
17 zation of such determination on a date that is
18 not later than 15 days after the date on which
19 the sponsor or organization contacts the con-
20 tractor.

21 “(3) MAKING DATA AVAILABLE TO OTHER EN-
22 TITIES.—

23 “(A) IN GENERAL.—For purposes of car-
24 rying out this subsection, subject to subpara-
25 graph (B), the Secretary shall authorize MED-

1 ICs to respond to requests for information from
2 PDP sponsors and MA organizations, State
3 prescription drug monitoring programs, and
4 other entities delegated by such sponsors or or-
5 ganizations using available programs and sys-
6 tems in the effort to prevent fraud, waste, and
7 abuse.

8 “(B) HIPAA COMPLIANT INFORMATION
9 ONLY.—Information may only be disclosed by a
10 MEDIC under subparagraph (A) if the disclo-
11 sure of such information is permitted under the
12 Federal regulations (concerning the privacy of
13 individually identifiable health information) pro-
14 mulgated under section 264(c) of the Health
15 Insurance Portability and Accountability Act of
16 1996 (42 U.S.C. 1320d–2 note).”.

17 (2) OIG STUDY AND REPORT ON EFFECTIVE-
18 NESS OF MEDICS.—

19 (A) STUDY.—The Inspector General of the
20 Department of Health and Human Services
21 shall conduct a study on the effectiveness of
22 Medicare drug integrity contractors with which
23 the Secretary of Health and Human Services
24 has entered into a contract under section 1893
25 of the Social Security Act (42 U.S.C. 1395ddd)

1 in identifying, combating, and preventing fraud
2 under the Medicare Program, including under
3 the authority provided under section 1893(j) of
4 the Social Security Act, added by paragraph
5 (1).

6 (B) REPORT.—Not later than 1 year after
7 the date of the enactment of this Act, the In-
8 spector General shall submit to Congress a re-
9 port on the study conducted under subpara-
10 graph (A). Such report shall include such rec-
11 ommendations for improvements in the effec-
12 tiveness of such contractors as the Inspector
13 General determines appropriate.

14 (d) TREATMENT OF CERTAIN COMPLAINTS FOR PUR-
15 POSSES OF QUALITY OR PERFORMANCE ASSESSMENT.—
16 Section 1860D–42 of the Social Security Act (42 U.S.C.
17 1395w–152) is amended by adding at the end the fol-
18 lowing new subsection:

19 “(d) TREATMENT OF CERTAIN COMPLAINTS FOR
20 PURPOSES OF QUALITY OR PERFORMANCE ASSESS-
21 MENT.—In conducting a quality or performance assess-
22 ment of a PDP sponsor, the Secretary shall develop or
23 utilize existing screening methods for reviewing and con-
24 sidering complaints that are received from enrollees in a
25 prescription drug plan offered by such PDP sponsor and

1 that are complaints regarding the lack of access by the
2 individual to prescription drugs due to a drug manage-
3 ment program for at-risk beneficiaries.”.

4 (e) SENSE OF CONGRESS REGARDING USE OF TECH-
5 NOLOGY TOOLS TO COMBAT FRAUD.—It is the sense of
6 Congress that MA organizations and PDP sponsors
7 should consider using e-prescribing and other health infor-
8 mation technology tools to support combating fraud under
9 MA–PD plans and prescription drug plans under parts C
10 and D of the Medicare Program.

11 (f) EFFECTIVE DATE.—

12 (1) IN GENERAL.—The amendments made by
13 this section shall apply to prescription drug plans
14 (and MA–PD plans) for plan years beginning more
15 than 1 year after the date of the enactment of this
16 Act.

17 (2) STAKEHOLDER MEETINGS PRIOR TO EFFEC-
18 TIVE DATE.—

19 (A) IN GENERAL.—Not later than January
20 1, 2016, the Secretary of Health and Human
21 Services shall convene stakeholders, including
22 individuals entitled to benefits under part A of
23 title XVIII of the Social Security Act or en-
24 rolled under part B of such title of such Act,
25 advocacy groups representing such individuals,

1 physicians, pharmacists, and other clinicians,
2 retail pharmacies, plan sponsors, entities dele-
3 gated by plan sponsors, and biopharmaceutical
4 manufacturers for input regarding the topics
5 described in subparagraph (B).

6 (B) TOPICS DESCRIBED.—The topics de-
7 scribed in this subparagraph are the topics of—

8 (i) the anticipated impact of drug
9 management programs for at-risk bene-
10 ficiaries under paragraph (5) of section
11 1860D–4(c) of the Social Security Act (42
12 U.S.C. 1395w–104(c)) on cost-sharing and
13 ensuring accessibility to prescription drugs
14 for enrollees in prescription drug plans of
15 PDP sponsors, and enrollees in MA–PD
16 plans, who are at-risk beneficiaries for pre-
17 scription drug abuse (as defined in sub-
18 paragraph (C) of such paragraph);

19 (ii) the use of an expedited appeals
20 process under which such an enrollee may
21 appeal an identification of such enrollee as
22 an at-risk beneficiary for prescription drug
23 abuse under such paragraph (similar to the
24 processes established under the Medicare
25 Advantage program under part C of title

1 XVIII of the Social Security Act that allow
2 an automatic escalation to external review
3 of claims submitted under such part);

4 (iii) the types of enrollees that should
5 be treated as exempted individuals, as de-
6 scribed in subparagraph (C)(ii) of such
7 paragraph;

8 (iv) the manner in which terms and
9 definitions in such paragraph should be ap-
10 plied, such as the use of clinical appro-
11 priateness in determining whether an en-
12 rollee is an at-risk beneficiary for prescrip-
13 tion drug abuse as defined in subpara-
14 graph (C) of such paragraph;

15 (v) the information to be included in
16 the notices described in subparagraph (B)
17 of such paragraph and the standardization
18 of such notices; and

19 (vi) with respect to a PDP sponsor
20 (or Medicare Advantage organization) that
21 establishes a drug management program
22 for at-risk beneficiaries under such para-
23 graph, the responsibilities of such PDP
24 sponsor (or organization) with respect to
25 the implementation of such program.

1 (g) RULEMAKING.—The Secretary of Health and
2 Human Services shall promulgate regulations based on the
3 input gathered pursuant to subsection (f)(2)(A).

4 **TITLE IV—MEDICAID, MEDI-**
5 **CARE, AND OTHER REFORMS**
6 **Subtitle A—Medicaid and Medicare**
7 **Reforms**

8 **SEC. 4001. LIMITING FEDERAL MEDICAID REIMBURSEMENT**
9 **TO STATES FOR DURABLE MEDICAL EQUIP-**
10 **MENT (DME) TO MEDICARE PAYMENT RATES.**

11 (a) MEDICAID REIMBURSEMENT.—

12 (1) IN GENERAL.—Section 1903(i) of the Social
13 Security Act (42 U.S.C. 1396b(i)) is amended—

14 (A) in paragraph (25), by striking “or” at
15 the end;

16 (B) in paragraph (26), by striking the pe-
17 riod at the end and inserting “; or”; and

18 (C) by inserting after paragraph (26) the
19 following new paragraph:

20 “(27) with respect to any amounts expended by
21 the State on the basis of a fee schedule for items de-
22 scribed in section 1861(n), as determined in the ag-
23 gregate with respect to each class of such items as
24 defined by the Secretary, in excess of the aggregate
25 amount, if any, that would be paid for such items

1 within such class on a fee-for-service basis under the
2 program under part B of title XVIII, including, as
3 applicable, under a competitive acquisition program
4 under section 1847 in an area of the State.”.

5 (2) EFFECTIVE DATE.—The amendments made
6 by this subsection shall be effective with respect to
7 payments for items furnished on or after January 1,
8 2020.

9 (b) MEDICARE OMBUDSMAN.—Section 1808(c) of the
10 Social Security Act (42 U.S.C. 1395b(c)), as amended by
11 section 3101, is further amended by adding at the end
12 the following new paragraph:

13 “(5) MONITORING DME REIMBURSEMENT
14 UNDER MEDICAID.—The ombudsmen under each of
15 paragraphs (1) and (4) shall evaluate the impact of
16 the competitive acquisition program under section
17 1847, including as applied under section
18 1903(i)(27), on beneficiary health status and health
19 outcomes.”.

20 **SEC. 4002. EXCLUDING AUTHORIZED GENERICS FROM CAL-**
21 **CULATION OF AVERAGE MANUFACTURER**
22 **PRICE.**

23 (a) IN GENERAL.—Subparagraph (C) of section
24 1927(k)(1) of the Social Security Act (42 U.S.C. 1396r-
25 8(k)(1)) is amended—

1 (1) in the subparagraph heading, by striking
2 “INCLUSION” and inserting “EXCLUSION”;

3 (2) by striking “a new drug application” and
4 inserting “the manufacturer’s new drug applica-
5 tion”; and

6 (3) by striking “inclusive” and inserting “exclu-
7 sive”.

8 (b) EFFECTIVE DATE.—The amendments made by
9 this section take effect on October 1, 2015.

10 **SEC. 4003. MEDICARE PAYMENT INCENTIVE FOR THE TRAN-**
11 **SITION FROM TRADITIONAL X-RAY IMAGING**
12 **TO DIGITAL RADIOGRAPHY AND OTHER**
13 **MEDICARE IMAGING PAYMENT PROVISION.**

14 (a) PHYSICIAN FEE SCHEDULE.—

15 (1) PAYMENT INCENTIVE FOR TRANSITION.—

16 (A) IN GENERAL.—Section 1848(b) of the
17 Social Security Act (42 U.S.C. 1395w–4(b)) is
18 amended by adding at the end the following
19 new paragraph:

20 “(9) SPECIAL RULE TO INCENTIVIZE TRANSI-
21 TION FROM TRADITIONAL X-RAY IMAGING TO DIG-
22 ITAL RADIOGRAPHY.—

23 “(A) LIMITATION ON PAYMENT FOR FILM
24 X-RAY IMAGING SERVICES.—In the case of an
25 imaging service (including the imaging portion

1 of a service) that is an X-ray taken using film
2 and that is furnished during 2017 or a subse-
3 quent year, the payment amount for the tech-
4 nical component (including the technical compo-
5 nent portion of a global service) of such service
6 that would otherwise be determined under this
7 section (without application of this paragraph
8 and before application of any other adjustment
9 under this section) for such year shall be re-
10 duced by 20 percent.

11 “(B) PHASED-IN LIMITATION ON PAYMENT
12 FOR COMPUTED RADIOGRAPHY IMAGING SERV-
13 ICES.—In the case of an imaging service (in-
14 cluding the imaging portion of a service) that is
15 an X-ray taken using computed radiography
16 technology—

17 “(i) in the case of such a service fur-
18 nished during 2018, 2019, 2020, 2021, or
19 2022, the payment amount for the tech-
20 nical component (including the technical
21 component portion of a global service) of
22 such service that would otherwise be deter-
23 mined under this section (without applica-
24 tion of this paragraph and before applica-
25 tion of any other adjustment under this

1 section) for such year shall be reduced by
2 7 percent; and

3 “(ii) in the case of such a service fur-
4 nished during 2023 or a subsequent year,
5 the payment amount for the technical com-
6 ponent (including the technical component
7 portion of a global service) of such service
8 that would otherwise be determined under
9 this section (without application of this
10 paragraph and before application of any
11 other adjustment under this section) for
12 such year shall be reduced by 10 percent.

13 “(C) COMPUTED RADIOGRAPHY TECH-
14 NOLOGY DEFINED.—For purposes of this para-
15 graph, the term ‘computed radiography tech-
16 nology’ means cassette-based imaging which
17 utilizes an imaging plate to create the image in-
18 volved.

19 “(D) IMPLEMENTATION.—In order to im-
20 plement this paragraph, the Secretary shall
21 adopt appropriate mechanisms which may in-
22 clude use of modifiers.”.

23 (B) EXEMPTION FROM BUDGET NEU-
24 TRALITY.—Section 1848(c)(2)(B)(v) of the So-
25 cial Security Act (42 U.S.C. 1395w-

1 4(c)(2)(B)(v)) is amended by adding at the end
2 the following new subclause:

3 “(X) REDUCED EXPENDITURES
4 ATTRIBUTABLE TO INCENTIVES TO
5 TRANSITION TO DIGITAL RADIOG-
6 RAPHY.—Effective for fee schedules
7 established beginning with 2017, re-
8 duced expenditures attributable to
9 subparagraph (A) of subsection (b)(9)
10 and effective for fee schedules estab-
11 lished beginning with 2018, reduced
12 expenditures attributable to subpara-
13 graph (B) of such subsection.”.

14 (2) ELIMINATION OF APPLICATION OF MUL-
15 TIPLE PROCEDURE PAYMENT REDUCTION.—

16 (A) IN GENERAL.—Section 1848(b)(4) of
17 the Social Security Act (42 U.S.C. 1395w-
18 4(b)(4)) is amended by adding at the end the
19 following new subparagraph:

20 “(E) ELIMINATION OF APPLICATION OF
21 MULTIPLE PROCEDURE PAYMENT REDUC-
22 TION.—

23 “(i) IN GENERAL.—For services fur-
24 nished on or after January 1, 2017, the
25 Secretary shall not apply a multiple proce-

1 dure payment reduction to the professional
2 component of imaging services unless the
3 Secretary has published as part of a Medi-
4 care Physician Fee Schedule Proposed
5 Rule the empirical analysis described in
6 clause (ii) with tables made available on
7 the website of the Centers for Medicare &
8 Medicaid Services.

9 “(ii) EMPIRICAL ANALYSIS DE-
10 SCRIBED.—The empirical analysis de-
11 scribed in this clause is an analysis of the
12 Resource-Based Relative Value Scale Data
13 Manager information or other information
14 that is used to determine what, if any, effi-
15 ciencies exist within the professional com-
16 ponent of imaging services when two or
17 more studies are furnished to the same in-
18 dividual on the same day. Such empirical
19 analysis shall include—

20 “(I) information detailing which
21 physician work activities overlap and
22 the reductions applicable to such over-
23 lap;

24 “(II) a discussion of the clinical
25 aspects that informed the assignment

1 of the reduction percentages described
2 in subclause (I);

3 “(III) to the extent that such re-
4 ductions are used for proposed pay-
5 ment reductions, an explanation of
6 how the percentage reductions for pre-
7 service, intra-service, and post-service
8 work were determined and calculated;

9 “(IV) other data used to deter-
10 mine a reduction; and

11 “(V) a demonstration that the
12 Secretary has consulted with prac-
13 ticing radiologists to gain knowledge
14 of how radiologists interpret studies of
15 multiple body parts on the same indi-
16 vidual on the same day.”.

17 (B) CONFORMING AMENDMENT.—Section
18 220(i) of the Protecting Access to Medicare Act
19 of 2014 (42 U.S.C. 1395w–4 note) is repealed.

20 (b) PAYMENT INCENTIVE FOR TRANSITION UNDER
21 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYS-
22 TEM.—Section 1833(t)(16) of the Social Security Act (42
23 U.S.C. 1395(t)(16)) is amended by adding at the end the
24 following new subparagraph:

1 “(F) PAYMENT INCENTIVE FOR THE TRAN-
2 SITION FROM TRADITIONAL X-RAY IMAGING TO
3 DIGITAL RADIOGRAPHY.—Notwithstanding the
4 previous provisions of this subsection:

5 “(i) LIMITATION ON PAYMENT FOR
6 FILM X-RAY IMAGING SERVICES.—In the
7 case of an imaging service that is an X-ray
8 taken using film and that is furnished dur-
9 ing 2017 or a subsequent year, the pay-
10 ment amount for such service (including
11 the X-ray component of a packaged serv-
12 ice) that would otherwise be determined
13 under this section (without application of
14 this paragraph and before application of
15 any other adjustment under this sub-
16 section) for such year shall be reduced by
17 20 percent.

18 “(ii) PHASED-IN LIMITATION ON PAY-
19 MENT FOR COMPUTED RADIOGRAPHY IM-
20 AGING SERVICES.—In the case of an imag-
21 ing service that is an X-ray taken using
22 computed radiography technology (as de-
23 fined in section 1848(b)(9)(C))—

24 “(I) in the case of such a service
25 furnished during 2018, 2019, 2020,

1 2021, or 2022, the payment amount
2 for such service (including the X-ray
3 component of a packaged service) that
4 would otherwise be determined under
5 this section (without application of
6 this paragraph and before application
7 of any other adjustment under this
8 subsection) for such year shall be re-
9 duced by 7 percent; and

10 “(II) in the case of such a service
11 furnished during 2023 or a subse-
12 quent year, the payment amount for
13 such service (including the X-ray com-
14 ponent of a packaged service) that
15 would otherwise be determined under
16 this section (without application of
17 this paragraph and before application
18 of any other adjustment under this
19 subsection) for such year shall be re-
20 duced by 10 percent.

21 “(iii) APPLICATION WITHOUT REGARD
22 TO BUDGET NEUTRALITY.—The reductions
23 made under this paragraph—

1 “(I) shall not be considered an
2 adjustment under paragraph (2)(E);
3 and

4 “(II) shall not be implemented in
5 a budget neutral manner.

6 “(iv) IMPLEMENTATION.—In order to
7 implement this subparagraph, the Sec-
8 retary shall adopt appropriate mechanisms
9 which may include use of modifiers.”.

10 **SEC. 4004. TREATMENT OF INFUSION DRUGS FURNISHED**
11 **THROUGH DURABLE MEDICAL EQUIPMENT.**

12 Section 1842(o)(1) of the Social Security Act (42
13 U.S.C. 1395u(o)(1)) is amended—

14 (1) in subparagraph (C), by inserting “(and in-
15 cluding a drug or biological described in subpara-
16 graph (D)(i) furnished on or after January 1,
17 2017)” after “2005”; and

18 (2) in subparagraph (D)—

19 (A) by striking “infusion drugs” and in-
20 serting “infusion drugs or biologicals” each
21 place it appears; and

22 (B) in clause (i)—

23 (i) by striking “2004” and inserting
24 “2004, and before January 1, 2017”; and

25 (ii) by striking “for such drug”.

1 **SEC. 4005. EXTENSION AND EXPANSION OF PRIOR AUTHOR-**
2 **IZATION FOR POWER MOBILITY DEVICES**
3 **(PMDS) AND ACCESSORIES AND PRIOR AU-**
4 **THORIZATION AUDIT LIMITATIONS.**

5 Section 1834(a) of the Social Security Act (42 U.S.C.
6 1395m(a)) is amended—

7 (1) in paragraph (15), by adding at the end the
8 following new subparagraph:

9 “(D) LIMITATION ON AUDITS AFTER AD-
10 VANCE DETERMINATION.—A claim for an item
11 that has received a provisional affirmation
12 under an advance determination under this
13 paragraph or a prior authorization under para-
14 graph (23) shall not be subject to review under
15 section 1893(h) but may be subject to audits
16 for potential fraud, inappropriate utilization,
17 changes in billing patterns, or information that
18 could not have been considered during the ad-
19 vance determination (such as proof of item de-
20 livery).”; and

21 (2) by adding at the end the following new
22 paragraph:

23 “(23) PRIOR AUTHORIZATION FOR POWER MO-
24 BILITY DEVICES (PMDS) AND ACCESSORIES.—Not
25 later than 90 days after the date of the enactment
26 of this paragraph, the Secretary shall, using funds

1 provided under paragraph (2) of section 402(a) of
2 the Social Security Amendments of 1967 and other
3 funds available to the Secretary—

4 “(A) extend at least through August 31,
5 2018, the PMD Prior Authorization Dem-
6 onstration (being conducted under paragraph
7 (1)(J) of such section);

8 “(B) begin to expand, as appropriate, such
9 demonstration to include additional power mo-
10 bility devices and accessories as part of initial
11 claims for payment under this part for such de-
12 vices; and

13 “(C) begin to expand such demonstration
14 to such additional States or geographic areas as
15 may be appropriate.”.

16 **SEC. 4006. CIVIL MONETARY PENALTIES FOR VIOLATIONS**
17 **RELATED TO GRANTS, CONTRACTS, AND**
18 **OTHER AGREEMENTS.**

19 (a) IN GENERAL.—Section 1128A of the Social Secu-
20 rity Act (42 U.S.C. 1320a–7a) is amended by adding at
21 the end the following new subsection:

22 “(o) Any person (including an organization, agency,
23 or other entity, but excluding a program beneficiary, as
24 defined in subsection (r)(4)) that, with respect to a grant,

1 contract, or other agreement for which the Secretary of
2 Health and Human Services provides funding—

3 “(1) knowingly presents or causes to be pre-
4 sented a specified claim (as defined in subsection
5 (r)(6)) under such grant, contract, or other agree-
6 ment that the person knows or should know is false
7 or fraudulent;

8 “(2) knowingly makes, uses, or causes to be
9 made or used any false statement, omission, or mis-
10 representation of a material fact in any application,
11 proposal, bid, progress report, or other document
12 that is required to be submitted in order to directly
13 or indirectly receive or retain funds provided in
14 whole or in part by such Secretary pursuant to such
15 grant, contract, or other agreement;

16 “(3) knowingly makes, uses, or causes to be
17 made or used, a false record or statement material
18 to a false or fraudulent specified claim under such
19 grant, contract, or other agreement;

20 “(4) knowingly makes, uses, or causes to be
21 made or used, a false record or statement material
22 to an obligation to pay or transmit funds or property
23 to such Secretary with respect to such grant, con-
24 tract, or other agreement, or knowingly conceals or
25 knowingly and improperly avoids or decreases an ob-

1 ligation to pay or transmit funds or property to such
2 Secretary with respect to such grant, contract, or
3 other agreement; or

4 “(5) fails to grant timely access, upon reason-
5 able request (as defined by such Secretary in regula-
6 tions), to the Inspector General of the Department,
7 for the purpose of audits, investigations, evaluations,
8 or other statutory functions of such Inspector Gen-
9 eral in matters involving such grants, contracts, or
10 other agreements;

11 shall be subject, in addition to any other penalties that
12 may be prescribed by law, to a civil money penalty in cases
13 under paragraph (1), of not more than \$10,000 for each
14 specified claim; in cases under paragraph (2), not more
15 than \$50,000 for each false statement, omission, or mis-
16 representation of a material fact; in cases under para-
17 graph (3), not more than \$50,000 for each false record
18 or statement; in cases under paragraph (4), not more than
19 \$50,000 for each false record or statement or \$10,000 for
20 each day that the person knowingly conceals or knowingly
21 and improperly avoids or decreases an obligation to pay;
22 or in cases under paragraph (5), not more than \$15,000
23 for each day of the failure described in such paragraph.
24 In addition, in cases under paragraphs (1) and (3), such
25 a person shall be subject to an assessment of not more

1 than 3 times the amount claimed in the specified claim
2 described in such paragraph in lieu of damages sustained
3 by the United States or a specified State agency because
4 of such specified claim, and in cases under paragraphs (2)
5 and (4), such a person shall be subject to an assessment
6 of not more than 3 times the total amount of the funds
7 described in paragraph (2) or (4), respectively (or, in the
8 case of an obligation to transmit property to the Secretary
9 Health and Human Services described in paragraph (4),
10 of the value of the property described in such paragraph)
11 in lieu of damages sustained by the United States or a
12 specified State agency because of such case. In addition,
13 the Secretary of Health and Human Services may make
14 a determination in the same proceeding to exclude the per-
15 son from participation in the Federal health care pro-
16 grams (as defined in section 1128B(f)(1)) and to direct
17 the appropriate State agency to exclude the person from
18 participation in any State health care program.

19 “(p) The provisions of subsections (c), (d), and (g)
20 shall apply to a civil money penalty or assessment under
21 subsection (o) in the same manner as such provisions
22 apply to a penalty, assessment, or proceeding under sub-
23 section (a).

24 “(q) With respect to a penalty or assessment under
25 subsection (o), the Inspector General of the Department

1 is authorized to receive, and to retain for current use, such
2 amounts of such penalty or assessment as are necessary
3 to provide reimbursement for the costs of conducting in-
4 vestigations and audits with respect to such subsection
5 and for monitoring compliance plans with respect to such
6 subsection when such penalty or assessment is ordered by
7 a court, voluntarily agreed to by the payor, or otherwise.
8 Funds received by such Inspector General as reimburse-
9 ment under the preceding sentence shall be deposited to
10 the credit of the appropriations from which initially paid,
11 or to appropriations for similar purposes currently avail-
12 able at the time of deposit, and shall remain available for
13 obligation for 1 year from the date of the deposit of such
14 funds.

15 “(r) For purposes of this subsection and subsections
16 (o), (p), and (q):

17 “(1) The term ‘Department’ means the Depart-
18 ment of Health and Human Services.

19 “(2) The term ‘material’ means having a nat-
20 ural tendency to influence, or be capable of influ-
21 encing, the payment or receipt of money or property.

22 “(3) The term ‘other agreement’ includes a co-
23 operative agreement, scholarship, fellowship, loan,
24 subsidy, payment for a specified use, donation agree-
25 ment, award, or sub-award (regardless of whether

1 one or more of the persons entering into the agree-
2 ment is a contractor or sub-contractor).

3 “(4) The term ‘program beneficiary’ means, in
4 the case of a grant, contract, or other agreement de-
5 signed to accomplish the objective of awarding or
6 otherwise furnishing benefits or assistance to indi-
7 viduals and for which the Secretary of Health and
8 Human Services provides funding, an individual who
9 applies for, or who receives, such benefits or assist-
10 ance from such grant, contract, or other agreement.
11 Such term does not include, with respect to such
12 grant, contract, or other agreement, an officer, em-
13 ployee, or agent of a person or entity that receives
14 such grant or that enters into such contract or other
15 agreement.

16 “(5) The term ‘recipient’ includes a sub-recipient
17 or subcontractor.

18 “(6) The term ‘specified claim’ means any ap-
19 plication, request, or demand under a grant, con-
20 tract, or other agreement for money or property,
21 whether or not the United States or a specified
22 State agency has title to the money or property, that
23 is not a claim (as defined in subsection (i)(2)) and
24 that—

1 “(A) is presented or caused to be pre-
2 sented to an officer, employee, or agent of the
3 Department or agency thereof, or of any speci-
4 fied State agency; or

5 “(B) is made to a contractor, grantee, or
6 any other recipient if the money or property is
7 to be spent or used on the Department’s behalf
8 or to advance a Department program or inter-
9 est, and if the Department—

10 “(i) provides or has provided any por-
11 tion of the money or property requested or
12 demanded; or

13 “(ii) will reimburse such contractor,
14 grantee or other recipient for any portion
15 of the money or property which is re-
16 quested or demanded.

17 “(7) The term ‘specified State agency’ means
18 an agency of a State government established or des-
19 ignated to administer or supervise the administra-
20 tion of a grant, contract, or other agreement funded
21 in whole or in part by the Secretary of Health and
22 Human Services.

23 “(s) For purposes of subsection (o), the term ‘obliga-
24 tion’ means an established duty, whether or not fixed, aris-
25 ing from an express or implied contractual, grantor-grant-

1 ee, or licensor-licensee relationship, for a fee-based or
2 similar relationship, from statute or regulation, or from
3 the retention of any overpayment.”.

4 (b) CONFORMING AMENDMENTS.—Section 1128A of
5 the Social Security Act (42 U.S.C. 1320a–7a) is amend-
6 ed—

7 (1) in subsection (d)—

8 (A) in paragraph (1), by inserting “or
9 specified claims” after “claims”; and

10 (B) in paragraph (2), by inserting “or
11 specified claims” after “claims”;

12 (2) in subsection (e), by inserting “or specified
13 claim” after “claim”; and

14 (3) in subsection (f)—

15 (A) by inserting “or specified claim (as de-
16 fined in subsection (r)(6))” after “district
17 where the claim”;

18 (B) by inserting “(or, with respect to a
19 person described in subsection (o), the person)”
20 after “claimant”;

21 (C) by inserting “that are not received by
22 the Inspector General of the Department of
23 Health and Human Services under subsection
24 (q) as reimbursement” after “amounts recov-
25 ered”; and

1 (D) by inserting “(or, in the case of a pen-
2 alty or assessment under subsection (o), by a
3 specified State agency (as defined in subsection
4 (r)(7))” after “or a State agency”.

5 **Subtitle B—Other Reforms**

6 **SEC. 4041. SPR DRAWDOWN.**

7 (a) DRAWDOWN AND SALE.—Notwithstanding sec-
8 tion 161 of the Energy Policy and Conservation Act (42
9 U.S.C. 6241), except as provided in subsection (b) the
10 Secretary of Energy shall draw down and sell—

11 (1) 4 million barrels of crude oil from the Stra-
12 tegic Petroleum Reserve during fiscal year 2018;

13 (2) 5 million barrels of crude oil from the Stra-
14 tegic Petroleum Reserve during fiscal year 2019;

15 (3) 8 million barrels of crude oil from the Stra-
16 tegic Petroleum Reserve during fiscal year 2020;

17 (4) 8 million barrels of crude oil from the Stra-
18 tegic Petroleum Reserve during fiscal year 2021;

19 (5) 10 million barrels of crude oil from the
20 Strategic Petroleum Reserve during fiscal year
21 2022;

22 (6) 15 million barrels of crude oil from the
23 Strategic Petroleum Reserve during fiscal year
24 2023;

1 (7) 15 million barrels of crude oil from the
2 Strategic Petroleum Reserve during fiscal year
3 2024; and

4 (8) 15 million barrels of crude oil from the
5 Strategic Petroleum Reserve during fiscal year
6 2025.

7 Amounts received for a sale under this subsection shall
8 be deposited in the General Fund of the Treasury during
9 the fiscal year in which the sale occurs.

10 (b) EMERGENCY PROTECTION.—The Secretary shall
11 not draw down and sell crude oil under this section in
12 amounts that would result in a Strategic Petroleum Re-
13 serve that contains an inventory of petroleum products
14 representing less than 90 days of emergency reserves,
15 based on the average daily level of net imports of crude
16 oil and petroleum products in the previous calendar year.

17 (c) PROCEEDS.—Proceeds from a sale under this sec-
18 tion shall be deposited into the general fund of the Treas-
19 ury of the United States.

20 **Subtitle C—Miscellaneous**

21 **SEC. 4061. LYME DISEASE AND OTHER TICK-BORNE DIS-** 22 **EASES.**

23 (a) IN GENERAL.—Title III of the Public Health
24 Service Act (42 U.S.C. 241 et seq.) is amended by adding
25 at the end the following new part:

1 “(1) not later than 24 months after the date of
2 enactment of this part, and every 24 months there-
3 after, develop or update a summary of—

4 “(A) ongoing Lyme disease and other tick-
5 borne disease research related to causes, pre-
6 vention, treatment, surveillance, diagnosis,
7 diagnostics, duration of illness, intervention,
8 and access to services and supports for individ-
9 uals with Lyme disease or other tick-borne dis-
10 eases;

11 “(B) advances made pursuant to such re-
12 search;

13 “(C) the engagement of the Department of
14 Health and Human Services with persons that
15 participate at the public meetings required by
16 paragraph (5); and

17 “(D) the comments received by the Work-
18 ing Group at such public meetings and the Sec-
19 retary’s response to such comments;

20 “(2) ensure that a broad spectrum of scientific
21 viewpoints is represented in each such summary;

22 “(3) monitor Federal activities with respect to
23 Lyme disease and other tick-borne diseases;

1 “(4) make recommendations to the Secretary
2 regarding any appropriate changes to such activities;
3 and

4 “(5) ensure public input by holding annual pub-
5 lic meetings that address scientific advances, re-
6 search questions, surveillance activities, and emerg-
7 ing strains in species of pathogenic organisms.

8 “(c) MEMBERSHIP.—

9 “(1) IN GENERAL.—The Working Group shall
10 be composed of a total of 14 members as follows:

11 “(A) FEDERAL MEMBERS.—Seven Federal
12 members, consisting of one or more representa-
13 tives of each of—

14 “(i) the Office of the Assistant Sec-
15 retary for Health;

16 “(ii) the Food and Drug Administra-
17 tion;

18 “(iii) the Centers for Disease Control
19 and Prevention;

20 “(iv) the National Institutes of
21 Health; and

22 “(v) such other agencies and offices of
23 the Department of Health and Human
24 Services as the Secretary determines ap-
25 propriate.

1 “(B) NON-FEDERAL PUBLIC MEMBERS.—
2 Seven non-Federal public members, consisting
3 of representatives of the following categories:

4 “(i) Physicians and other medical pro-
5 viders with experience in diagnosing and
6 treating Lyme disease and other tick-borne
7 diseases.

8 “(ii) Scientists or researchers with ex-
9 pertise.

10 “(iii) Patients and their family mem-
11 bers.

12 “(iv) Nonprofit organizations that ad-
13 vocate for patients with respect to Lyme
14 disease and other tick-borne diseases.

15 “(v) Other individuals whose expertise
16 is determined by the Secretary to be bene-
17 ficial to the functioning of the Working
18 Group.

19 “(2) APPOINTMENT.—The members of the
20 Working Group shall be appointed by the Secretary,
21 except that of the non-Federal public members
22 under paragraph (1)(B)—

23 “(A) one shall be appointed by the Speaker
24 of the House of Representatives; and

1 “(B) one shall be appointed by the major-
2 ity leader of the Senate.

3 “(3) DIVERSITY OF SCIENTIFIC PERSPEC-
4 TIVES.—In making appointments under paragraph
5 (2), the Secretary, the Speaker of the House of Rep-
6 resentatives, and the majority leader of the Senate
7 shall ensure that the non-Federal public members of
8 the Working Group represent a diversity of scientific
9 perspectives.

10 “(4) TERMS.—The non-Federal public members
11 of the Working Group shall each be appointed to
12 serve a 4-year term and may be reappointed at the
13 end of such term.

14 “(d) MEETINGS.—The Working Group shall meet as
15 often as necessary, as determined by the Secretary, but
16 not less than twice each year.

17 “(e) APPLICABILITY OF FACCA.—The Working Group
18 shall be treated as an advisory committee subject to the
19 Federal Advisory Committee Act.

20 “(f) REPORTING.—Not later than 24 months after
21 the date of enactment of this part, and every 24 months
22 thereafter, the Working Group—

23 “(1) shall submit a report on its activities, in-
24 cluding an up-to-date summary under subsection
25 (b)(1) and any recommendations under subsection

1 (b)(4), to the Secretary, the Committee on Energy
2 and Commerce of the House of Representatives, and
3 the Committee on Health, Education, Labor, and
4 Pensions of the Senate;

5 “(2) shall make each such report publicly avail-
6 able on the website of the Department of Health and
7 Human Services; and

8 “(3) shall allow any member of the Working
9 Group to include in any such report minority views.

10 **“SEC. 39900-2. STRATEGIC PLAN.**

11 “Not later than 3 years after the date of enactment
12 of this section, and every 5 years thereafter, the Secretary
13 shall submit to the Congress a strategic plan, informed
14 by the most recent summary under section 39900-
15 1(b)(1), for the conduct and support of Lyme disease and
16 tick-borne disease research, including—

17 “(1) proposed budgetary requirements;

18 “(2) a plan for improving outcomes of Lyme
19 disease and other tick-borne diseases, including
20 progress related to chronic or persistent symptoms
21 and chronic or persistent infection and co-infections;

22 “(3) a plan for improving diagnosis, treatment,
23 and prevention;

1 “(4) appropriate benchmarks to measure
2 progress on achieving the improvements described in
3 paragraphs (2) and (3); and

4 “(5) a plan to disseminate each summary under
5 section 39900–1(b)(1) and other relevant informa-
6 tion developed by the Working Group to the public,
7 including health care providers, public health depart-
8 ments, and other relevant medical groups.”.

9 (b) **NO ADDITIONAL AUTHORIZATION OF APPRO-**
10 **PRIATIONS.**—No additional funds are authorized to be ap-
11 propriated for the purpose of carrying out this section and
12 the amendment made by this section, and this section and
13 such amendment shall be carried out using amounts other-
14 wise available for such purpose.

15 **SEC. 4062. OUTREACH TO HISTORICALLY BLACK COLLEGES**
16 **AND UNIVERSITIES.**

17 The Secretary of Health and Human Services shall
18 conduct outreach to historically Black colleges and univer-
19 sities, Hispanic-serving institutions, Native American col-
20 leges, and rural colleges to ensure that health profes-

- 1 sionals from underrepresented populations are aware of
- 2 research opportunities under this Act.

Passed the House of Representatives July 10, 2015.

Attest:

Clerk.

114TH CONGRESS
1ST SESSION

H. R. 6

AN ACT

To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.