

JULY 2, 2015

RULES COMMITTEE PRINT 114-22
TEXT OF H.R. 6, 21ST CENTURY CURES ACT

**[Showing text based on H.R. 6 as ordered reported by the
Committee on Energy and Commerce.]**

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.

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.
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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.
- Sec. 2102. Facilitating responsible communication of scientific and medical developments.

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.
- Sec. 2123. Encouraging the development and use of DISARM drugs.

Subtitle H—Vaccine Access, Certainty, and Innovation

- Sec. 2141. Timely review of vaccines by the Advisory Committee on Immunization Practices.
- Sec. 2142. Review of processes and consistency of ACIP recommendations.
- Sec. 2143. Meetings between CDC and vaccine developers.

Subtitle I—Orphan Product Extensions Now; Incentives for Certain Products for Limited Populations

- Sec. 2151. Extension of exclusivity periods for a drug approved for a new indication for a rare disease or condition.
- Sec. 2152. Reauthorization of rare pediatric disease priority review voucher incentive program.

Subtitle J—Domestic Manufacturing and Export Efficiencies

- Sec. 2161. Grants for studying the process of continuous drug manufacturing.
- Sec. 2162. Re-exportation among members of the European Economic Area.

Subtitle K—Enhancing Combination Products Review

- Sec. 2181. Enhancing combination products review.

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- Sec. 2201. Priority review for breakthrough devices.

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- 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.
- Sec. 2225. Easing regulatory burden with respect to certain class I and class II devices.
- Sec. 2226. Advisory committee process.
- Sec. 2227. Humanitarian device exemption application.
- Sec. 2228. CLIA waiver study design guidance for in vitro diagnostics.

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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.

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.

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.

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

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

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

10 (ii) not less than 35 percent of such
11 amounts remaining after subtracting the
12 allocation for the Accelerating Advance-
13 ment Program shall be for early stage in-
14 vestigators as defined in subsection (g);

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

22 (iv) not more than 10 percent of such
23 amounts (without subtracting the alloca-
24 tion for the Accelerating Advancement

1 Program) shall be for intramural research;
2 and

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

5 (3) INAPPLICABILITY OF CERTAIN PROVI-
6 SIONS.—Amounts in the NIH and Cures Innovation
7 Fund (including amounts made available to the Na-
8 tional Institutes of Health) shall not be subject to—

9 (A) any transfer authority of the Secretary
10 of Health and Human Services or the Director
11 of the National Institutes of Health under sec-
12 tions 241, 402A(e), or 402A(d) of the Public
13 Health Service Act (42 U.S.C. 238j, 282a(c)
14 and (d)) or any other provision of law (other
15 than this section); or

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

19 (c) AUTHORIZED USES.—

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

1 (A) Research in which—

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

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

6 (B) Research in which—

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

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

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

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

16 (E) The Accelerating Advancement Pro-
17 gram under subsection (d)(2).

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

20 (2) CURES DEVELOPMENT.—Amounts in the
21 NIH and Cures Innovation Fund that are allocated
22 pursuant to subsection (b)(2)(B) may only be used
23 for the purpose of carrying out the following provi-
24 sions:

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

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

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

11 (D) Section 2062 and the amendments
12 made by such section (relating to utilizing evi-
13 dence from clinical experience).

14 (E) Section 2161 (relating to grants for
15 studying the process of continuous drug manu-
16 facturing).

17 (F) Section 2201 and the amendments
18 made by such section (relating to priority re-
19 view for breakthrough devices).

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

23 (H) Sections 2241, 2242, and 2243 and
24 the amendments made by such sections (relat-
25 ing to health software).

1 (I) Section 513(j) of the Federal Food,
2 Drug, and Cosmetic Act, as added by section
3 2223 (relating to training and oversight in least
4 burdensome appropriate means concept).

5 (d) NIH INNOVATION FUND.—

6 (1) COORDINATION.—In conducting or sup-
7 porting biomedical research pursuant to funds allo-
8 cated pursuant to subsection (b)(2)(A), the Sec-
9 retary of Health and Human Services, acting
10 through the Director of the National Institutes of
11 Health, shall—

12 (A) ensure coordination among the na-
13 tional research institutes, the national centers,
14 and other departments, agencies, and offices of
15 the Federal Government; and

16 (B) minimize unnecessary duplication.

17 (2) ACCELERATING ADVANCEMENT PROGRAM.—

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

21 (A) the Director partners with national re-
22 search institutes and national centers to accom-
23 plish important biomedical research objectives;
24 and

1 (B) for every \$1 made available by the Di-
2 rector to a national research institute or na-
3 tional center for a research project, the insti-
4 tute or center makes \$1 available for such
5 project from funds that are not derived from
6 the NIH and Cures Innovation Fund.

7 (3) STRATEGIC PLAN.—

8 (A) IN GENERAL.—The Director of the
9 National Institutes of Health shall ensure that
10 scientifically based strategic planning is imple-
11 mented in support of research priorities, includ-
12 ing through development, use, and updating of
13 a research strategic plan that—

14 (i) is designed to increase the efficient
15 and effective focus of biomedical research
16 in a manner that leverages the best sci-
17 entific opportunities through a deliberative
18 planning process;

19 (ii) identifies areas, to be known as
20 strategic focus areas, in which the re-
21 sources of the NIH and Cures Innovation
22 Fund can contribute to the goals of ex-
23 panding knowledge to address, and find
24 more effective treatments for, unmet med-

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

3 (I) biomarkers;

4 (II) precision medicine;

5 (III) infectious diseases, includ-
6 ing pathogens listed as a qualifying
7 pathogen under section 505E(f) of the
8 Federal Food, Drug, and Cosmetic
9 Act or listed or designated as a trop-
10 ical disease under section 524 of such
11 Act; and

12 (IV) antibiotics;

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

15 (iv) ensures that basic research re-
16 mains a priority.

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

22 (e) TRANSFER AUTHORITY.—The Committee on Ap-
23 propriations of the Senate and the Committee on Appro-
24 priations of the House of Representatives may provide for

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

3 (f) SUPPLEMENT, NOT SUPPLANT; LIMITATIONS.—

4 Funds appropriated by subsection (b)—

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

8 (2) are subject to the requirements and limita-
9 tions of the most recently enacted regular or full-
10 year continuing appropriation Act or resolution (as
11 of the date of obligation) for programs of the Na-
12 tional Institutes of Health or the Food and Drug
13 Administration, as applicable; and

14 (3) notwithstanding any transfer authority in
15 any appropriation Act, shall not be used for any
16 purpose other than the purposes specified in sub-
17 section (c).

18 (g) DEFINITION.—In this subsection:

19 (1) The term “early stage investigator” means
20 an investigator who—

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

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

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

3 (C) is within 10 years of having com-
4 pleted—

5 (i) the investigator’s terminal degree;

6 or

7 (ii) a medical residency (or the equiva-
8 lent).

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

13 **TITLE I—DISCOVERY**

14 **Subtitle A—National Institutes of** 15 **Health Funding**

16 **SEC. 1001. NATIONAL INSTITUTES OF HEALTH REAUTHOR-** 17 **IZATION.**

18 Section 402A(a)(1) of the Public Health Service Act
19 (42 U.S.C. 282a(a)(1)) is amended—

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

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

24 (3) by adding at the end the following new sub-
25 paragraphs:

1 “(D) \$31,811,000,000 for fiscal year
2 2016;

3 “(E) \$33,331,000,000 for fiscal year 2017;
4 and

5 “(F) \$34,851,000,000 for fiscal year
6 2018.”.

7 **Subtitle B—National Institutes of**
8 **Health Planning and Adminis-**
9 **tration**

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

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

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

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

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

22 “(m) RESEARCH STRATEGIC PLAN.—

23 “(1) FIVE-YEAR PLANS FOR BIOMEDICAL RE-
24 SEARCH STRATEGY.—

1 “(A) IN GENERAL.—For each successive
2 five-year period beginning with the period of fis-
3 cal years 2016 through 2020, the Director of
4 NIH, in consultation with the entities described
5 in subparagraph (B), shall develop and main-
6 tain a biomedical research strategic plan that—

7 “(i) is designed to increase the effi-
8 cient and effective focus of biomedical re-
9 search in a manner that leverages the best
10 scientific opportunities through a delibera-
11 tive planning process;

12 “(ii) identifies areas, to be known as
13 strategic focus areas, in which the re-
14 sources of the National Institutes of
15 Health can best contribute to the goal of
16 expanding knowledge on human health in
17 the United States through biomedical re-
18 search; and

19 “(iii) includes objectives for each such
20 strategic focus area.

21 “(B) ENTITIES DESCRIBED.—The entities
22 described in this subparagraph are the directors
23 of the national research institutes and national
24 centers, researchers, patient advocacy groups,
25 and industry leaders.

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

4 “(A) to identify research opportunities;
5 and

6 “(B) to develop individual strategic plans
7 for the research activities of each of the na-
8 tional research institutes and national centers
9 that—

10 “(i) have a common template; and

11 “(ii) identify strategic focus areas in
12 which the resources of the national re-
13 search institutes and national centers can
14 best contribute to the goal of expanding
15 knowledge on human health in the United
16 States through biomedical research.

17 “(3) CONTENTS OF PLANS.—

18 “(A) STRATEGIC FOCUS AREAS.—The stra-
19 tegic focus areas identified pursuant to para-
20 graph (1)(A)(ii) shall—

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

22 “(I) considers the return on in-
23 vestment to the United States public
24 through the investments of the Na-

1 tional Institutes of Health in bio-
2 medical research; and

3 “(II) contributes to expanding
4 knowledge to improve the United
5 States public’s health through bio-
6 medical research; and

7 “(ii) include overarching and trans-
8 National Institutes of Health strategic
9 focus areas, to be known as Mission Pri-
10 ority Focus Areas, which best serve the
11 goals of preventing or eliminating the bur-
12 den of a disease or condition and scientif-
13 ically merit enhanced and focused research
14 over the next 5 years.

15 “(B) RARE AND PEDIATRIC DISEASES AND
16 CONDITIONS.—In developing and maintaining a
17 strategic plan under this subsection, the Direc-
18 tor of NIH shall ensure that rare and pediatric
19 diseases and conditions remain a priority.

20 “(C) WORKFORCE.—In developing and
21 maintaining a strategic plan under this sub-
22 section, the Director of NIH shall ensure that
23 maintaining the biomedical workforce of the fu-
24 ture, including the participation by scientists

1 from groups traditionally underrepresented in
2 the scientific workforce, remains a priority.

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

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

9 “(B) make such initial strategic plan pub-
10 licly available on the website of the National In-
11 stitutes of Health.

12 “(5) REVIEW; UPDATES.—

13 “(A) PROGRESS REVIEWS.—Not less than
14 annually, the Director of NIH, in consultation
15 with the directors of the national research insti-
16 tutes and national centers, shall conduct
17 progress reviews for each strategic focus area
18 identified under paragraph (1)(A)(ii).

19 “(B) UPDATES.—Not later than the end of
20 the 5-year period covered by the initial strategic
21 plan under this subsection, and every 5 years
22 thereafter, the Director of NIH, in consultation
23 with the directors of the national research insti-
24 tutes and national centers, stakeholders in the

1 scientific field, advocates, and the public at
2 large, shall—

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

6 “(ii) update such plan in accordance
7 with this section.”.

8 **SEC. 1022. INCREASING ACCOUNTABILITY AT THE NA-**
9 **TIONAL INSTITUTES OF HEALTH.**

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

14 “(a) APPOINTMENT; TERMS.—

15 “(1) APPOINTMENT.—The Director of the Na-
16 tional Cancer Institute shall be appointed by the
17 President and the directors of the other national re-
18 search institutes, as well as the directors of the na-
19 tional centers, shall be appointed by the Director of
20 NIH. The directors of the national research insti-
21 tutes, as well as national centers, shall report di-
22 rectly to the Director of NIH.

23 “(2) TERMS.—

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

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

9 “(C) REAPPOINTMENT.—At the end of the
10 term of a director of a national research insti-
11 tute or national center, the director may be re-
12 appointed. There is no limit on the number of
13 terms a director may serve.

14 “(D) VACANCIES.—If the office of a direc-
15 tor of a national research institute or national
16 center becomes vacant before the end of such
17 director’s term, the director appointed to fill the
18 vacancy shall be appointed for a 5-year term
19 starting on the date of such appointment.

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

1 (b) COMPENSATION TO CONSULTANTS OR INDI-
2 VIDUAL SCIENTISTS.—Section 202 of the Departments of
3 Labor, Health and Human Services, and Education, and
4 Related Agencies Appropriations Act, 1993 (Public Law
5 102–394; 42 U.S.C. 238f note) is amended by striking
6 “portable structures;” and all that follows and inserting
7 “portable structures.”.

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

12 “(3) Before an award is made by a national research
13 institute or by a national center for a grant for a research
14 program or project (commonly referred to as an ‘R-series
15 grant’), other than an award constituting a noncompeting
16 renewal of such grant, or a noncompeting administrative
17 supplement to such grant, the director of such national
18 research institute or national center—

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

20 “(B) shall take into consideration—

21 “(i) the mission of the national research
22 institute or national center and the scientific
23 priorities identified in the strategic plan under
24 section 402(m); and

1 “(ii) whether other agencies are funding
2 programs or projects to accomplish the same
3 goal.”.

4 (d) IOM STUDY ON DUPLICATION IN FEDERAL BIO-
5 MEDICAL RESEARCH.—The Secretary of Health and
6 Human Services shall enter into an arrangement with the
7 Institute of Medicine of the National Academies (or, if the
8 Institute declines, another appropriate entity) under which
9 the Institute (or other appropriate entity) not later than
10 2 years after the date of enactment of this Act will—

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

14 (2) submit a report to the Congress on the re-
15 sults of such study, including recommendations on
16 how to prevent such duplication.

17 **SEC. 1023. REDUCING ADMINISTRATIVE BURDENS OF RE-**
18 **SEARCHERS.**

19 (a) PLAN PREPARATION AND IMPLEMENTATION OF
20 MEASURES TO REDUCE ADMINISTRATIVE BURDENS.—
21 The Director of the National Institutes of Health shall
22 prepare a plan, including time frames, and implement
23 measures to reduce the administrative burdens of re-
24 searchers funded by the National Institutes of Health,

1 taking into account the recommendations, evaluations,
2 and plans researched by the following entities:

3 (1) The Scientific Management Review Board.

4 (2) The National Academy of Sciences.

5 (3) The 2007 and 2012 Faculty Burden Survey
6 conducted by The Federal Demonstration Partner-
7 ship.

8 (4) Relevant recommendations from the Re-
9 search Business Models Working Group.

10 (b) REPORT.—Not later than two years after the date
11 of enactment of this Act, the Director of the National In-
12 stitutes of Health shall submit to Congress a report on
13 the extent to which the Director has implemented meas-
14 ures pursuant to subsection (a).

15 **SEC. 1024. EXEMPTION FOR THE NATIONAL INSTITUTES OF**
16 **HEALTH FROM THE PAPERWORK REDUCTION**
17 **ACT REQUIREMENTS.**

18 Section 3518(c)(1) of title 44, United States Code,
19 is amended—

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

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

24 (3) by inserting at the end the following new
25 subparagraph:

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

3 **SEC. 1025. NIH TRAVEL.**

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

7 **SEC. 1026. OTHER TRANSACTIONS AUTHORITY.**

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

10 (1) in subsection (b), by striking “the appro-
11 priation of funds as described in subsection (g)” and
12 inserting “the availability of funds as described in
13 subsection (f)”;

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

16 “(C) OTHER TRANSACTIONS AUTHORITY.—
17 The Director of the Center shall have other
18 transactions authority in entering into trans-
19 actions to fund projects in accordance with the
20 terms and conditions of this section.”;

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

22 (4) by redesignating subsection (g) as sub-
23 section (f).

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

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

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

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

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

10 Part B of title IV of the Public Health Service Act
11 (42 U.S.C. 284 et seq.) is amended by adding at the end
12 the following:

13 **“SEC. 409K. HIGH-RISK, HIGH-REWARD RESEARCH PRO-**
14 **GRAM.**

15 “The director of each national research institute
16 shall, as appropriate—

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

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

1 **SEC. 1029. SENSE OF CONGRESS ON INCREASED INCLUSION**
2 **OF UNDERREPRESENTED COMMUNITIES IN**
3 **CLINICAL TRIALS.**

4 It is the sense of Congress that the National Institute
5 on Minority Health and Health Disparities (NIMHD)
6 should include within its strategic plan ways to increase
7 representation of underrepresented communities in clinical
8 trials.

9 **Subtitle C—Supporting Young**
10 **Emerging Scientists**

11 **SEC. 1041. IMPROVEMENT OF LOAN REPAYMENT PRO-**
12 **GRAMS OF THE NATIONAL INSTITUTES OF**
13 **HEALTH.**

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

16 (1) by redesignating the second section 487F
17 (42 U.S.C. 288–6; relating to pediatric research loan
18 repayment program) as section 487G; and

19 (2) by inserting after section 487G, as so reded-
20 icated, the following:

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

22 **“(a) IN GENERAL.—The Secretary shall establish a**
23 **program, based on workforce and scientific needs, of en-**
24 **tering into contracts with qualified health professionals**
25 **under which such health professionals agree to engage in**
26 **research in consideration of the Federal Government**

1 agreeing to pay, for each year of engaging in such re-
2 search, not more than \$50,000 of the principal and inter-
3 est of the educational loans of such health professionals.

4 “(b) ADJUSTMENT FOR INFLATION.—Beginning with
5 respect to fiscal year 2017, the Secretary may increase
6 the maximum amount specified in subsection (a) by an
7 amount that is determined by the Secretary, on an annual
8 basis, to reflect inflation.

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

13 “(d) APPLICABILITY OF CERTAIN PROVISIONS RE-
14 GARDING OBLIGATED SERVICE.—Except to the extent in-
15 consistent with this section, the provisions of sections
16 338B, 338C, and 338E shall apply to the program estab-
17 lished under this section to the same extent and in the
18 same manner as such provisions apply to the National
19 Health Service Corps Loan Repayment Program estab-
20 lished under section 338B.

21 “(e) AVAILABILITY OF APPROPRIATIONS.—Amounts
22 appropriated for a fiscal year for contracts under sub-
23 section (a) are authorized to remain available until the ex-
24 piration of the second fiscal year beginning after the fiscal
25 year for which the amounts were appropriated.”.

1 (b) UPDATE OF OTHER LOAN REPAYMENT PRO-
2 GRAMS.—

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

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

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

13 (2) Section 487A(a) of such Act (42 U.S.C.
14 288-1(a)) is amended—

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

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

23 (3) Section 487B(a) of such Act (42 U.S.C.
24 288-2(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 such subsection (a) of such section.”.

9 (4) Section 487C(a)(1) of such Act (42 U.S.C.
10 288–3(a)(1)) 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 paragraph in the same manner
17 as it applies to the maximum amount specified
18 in such subsection (a) of such section.”.

19 (5) Section 487E(a)(1) of such Act (42 U.S.C.
20 288–5(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 (6) Section 487F(a) of such Act (42 U.S.C.
5 288–5a(a)), as added by section 205 of Public Law
6 106–505, is amended—

7 (A) by striking “\$35,000” and inserting
8 “\$50,000”; and

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

15 (7) Section 487G of such Act (42 U.S.C. 288–
16 6, as redesignated by subsection (a)(1)), is further
17 amended—

18 (A) in subsection (a)(1), by striking
19 “\$35,000” and inserting “\$50,000”; and

20 (B) in subsection (b), by adding at the end
21 the following new sentence: “Subsection (b) of
22 section 487H shall apply with respect to the
23 maximum amount specified in subsection (a)(1)
24 in the same manner as it applies to the max-

1 imum amount specified in such subsection (a)
2 of such section.”.

3 **SEC. 1042. REPORT.**

4 Not later than 18 months after the date of the enact-
5 ment of this Act, the Director of the National Institutes
6 of Health shall submit to Congress a report on efforts of
7 the National Institutes of Health to attract, retain, and
8 develop emerging scientists.

9 **Subtitle D—Capstone Grant**
10 **Program**

11 **SEC. 1061. CAPSTONE AWARD.**

12 Part G of title IV of the Public Health Service Act
13 (42 U.S.C. 288 et seq.) is amended by adding at the end
14 the following:

15 **“SEC. 490. CAPSTONE AWARD.**

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

20 “(b) PURPOSE.—Capstone Awards shall be made to
21 facilitate the successful transition or conclusion of re-
22 search programs, or for other purposes, as determined by
23 the Director of NIH, in consultation with the directors
24 of the national research institutes and national centers.

1 “(c) DURATION AND AMOUNT.—The duration and
2 amount of each Capstone Award shall be determined by
3 the Director of NIH in consultation with the directors of
4 the national research institutes and national centers.

5 “(d) LIMITATION.—Individuals who have received a
6 Capstone Award shall not be eligible to have principle in-
7 vestigator status on subsequent awards from the National
8 Institutes of Health.”.

9 **Subtitle E—Promoting Pediatric**
10 **Research Through the National**
11 **Institutes of Health**

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

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

15 (1) in paragraph (1)—

16 (A) by striking “in consultation with the
17 Director of the Eunice Kennedy Shriver Na-
18 tional Institute of Child Health and Human
19 Development and in collaboration with other
20 appropriate national research institutes and na-
21 tional centers that carry out activities involving
22 pediatric research” and inserting “in collabora-
23 tion with the national research institutes and
24 national centers that carry out activities involv-
25 ing pediatric research”;

1 (B) by striking subparagraph (B);

2 (C) by striking “may be comprised of, as
3 appropriate” and all that follows through “the
4 pediatric research consortia” and inserting
5 “may be comprised of, as appropriate, the pedi-
6 atric research consortia”; and

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

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

13 **SEC. 1082. GLOBAL PEDIATRIC CLINICAL STUDY NETWORK**
14 **SENSE OF CONGRESS.**

15 It is the sense of Congress that—

16 (1) the National Institutes of Health should en-
17 courage a global pediatric clinical study network
18 through the allocation of grants, contracts, or coop-
19 erative agreements to supplement the salaries of new
20 and early investigators who participate in the global
21 pediatric clinical study network;

22 (2) National Institutes of Health grants, con-
23 tracts, or cooperative agreements should be awarded,
24 solely for the purpose of supplementing the salaries
25 of new and early investigators, to entities that par-

1 participate in the global pediatric clinical study net-
2 work;

3 (3) the Food and Drug Administration should
4 engage the European Medicines Agency and other
5 foreign regulatory entities during the formation of
6 the global pediatric clinical study network to encour-
7 age their participation; and

8 (4) once a global pediatric clinical study net-
9 work is established and becomes operational, the
10 Food and Drug Administration should continue to
11 engage the European Medicines Agency and other
12 foreign regulatory entities to encourage and facili-
13 tate their participation in the network with the goal
14 of enhancing the global reach of the network.

15 **SEC. 1083. APPROPRIATE AGE GROUPINGS IN CLINICAL RE-**
16 **SEARCH.**

17 (a) INPUT FROM EXPERTS.—Not later than 180
18 days after the date of enactment of this Act, the Director
19 of the National Institutes of Health shall convene a work-
20 shop of experts on pediatrics and experts on geriatrics to
21 provide input on—

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

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

4 (b) GUIDELINES.—Not later than 180 days after the
5 conclusion of the workshop under subsection (a), the Di-
6 rector of the National Institutes of Health shall publish
7 guidelines—

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

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

13 (c) PUBLIC AVAILABILITY OF FINDINGS AND CON-
14 CLUSIONS.—The Director of the National Institutes of
15 Health shall—

16 (1) make the findings and conclusions resulting
17 from the workshop under subsection (a) available to
18 the public on the website of the National Institutes
19 of Health; and

20 (2) not less than biennially, disclose to the pub-
21 lic on such website the number of children included
22 in research that is conducted or supported by the
23 National Institutes of Health, disaggregated by de-
24 velopmentally appropriate age group, race, and gen-
25 der.

1 **Subtitle F—Advancement of the**
2 **National Institutes of Health Re-**
3 **search and Data Access**

4 **SEC. 1101. STANDARDIZATION OF DATA IN CLINICAL TRIAL**
5 **REGISTRY DATA BANK ON ELIGIBILITY FOR**
6 **CLINICAL TRIALS.**

7 (a) STANDARDIZATION.—

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

10 (A) by redesignating paragraph (7) as
11 paragraph (8); and

12 (B) by inserting after paragraph (6) the
13 following:

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

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

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

20 “(C) ensure that information required to
21 be submitted to the registry and results data
22 bank, including recruitment information under
23 paragraph (2)(A)(ii)(II), is submitted by per-
24 sons and posted by the Director of NIH in a
25 standardized format and includes at least—

1 “(i) the disease or indication being
2 studied;

3 “(ii) inclusion criteria such as age,
4 gender, diagnosis or diagnoses, laboratory
5 values, or imaging results; and

6 “(iii) exclusion criteria such as spe-
7 cific diagnosis or diagnoses, laboratory val-
8 ues, or prohibited medications; and

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

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

20 (b) CONSULTATION.—Not later than 90 days after
21 the date of enactment of this Act, the Secretary of Health
22 and Human Services shall consult with stakeholders (in-
23 cluding patients, researchers, physicians, industry rep-
24 resentatives, health information technology providers, the
25 Food and Drug Administration, and standard setting or-

1 ganizations such as CDISC that have experience working
2 with Federal agencies to standardize health data submis-
3 sions) to receive advice on enhancements to the clinical
4 trial registry data bank under section 402(j) of the Public
5 Health Service Act (42 U.S.C. 282(j)) (including enhance-
6 ments to usability, functionality, and search capability)
7 that are necessary to implement paragraph (7) of section
8 402(j) of such Act, as added by subsection (a).

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

14 **Subtitle G—Facilitating** 15 **Collaborative Research**

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

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

1 (b) APPLICATION.—Eligible entities seeking to enter
2 into a cooperative agreement, contract, or grant with the
3 Secretary under this section shall submit to the Secretary
4 an application in such time and manner, and containing
5 such information, as the Secretary may require in accord-
6 ance with this section. The Secretary shall not enter into
7 a cooperative agreement, contract, or grant under this sec-
8 tion with an eligible entity unless such entity submits an
9 application including the following:

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

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

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

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

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

21 (6) The plan of the eligible entity for securing
22 funding for the activities it would conduct under the
23 clinical trial data system agreement from govern-
24 mental sources and private foundations, entities, and
25 individuals.

1 (7) Evidence demonstrating a proven track
2 record of—

3 (A) being a neutral third party in working
4 with medical product manufacturers, academic
5 institutions, and the Food and Drug Adminis-
6 tration; and

7 (B) having the ability to protect confiden-
8 tial data.

9 (8) An agreement that the eligible entity will
10 work with the Comptroller General of the United
11 States for purposes of the study and report under
12 subsection (d).

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

20 (d) STUDY AND REPORT.—

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

1 which the pilot program is established under sub-
2 section (a).

3 (2) STUDY.—The study under paragraph (1)
4 shall—

5 (A) review the effectiveness of the pilot
6 program established under subsection (a); and

7 (B) be designed to formulate recommenda-
8 tions on improvements to the program.

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

11 (A) The new discoveries, research inquir-
12 ies, or clinical trials that have resulted from ac-
13 cessing clinical trial data under the pilot pro-
14 gram established under subsection (a).

15 (B) The number of times scientists have
16 accessed such data, disaggregated by research
17 area and clinical trial phase.

18 (C) An analysis of whether the program
19 has helped to reduce adverse events in clinical
20 trials.

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

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

3 (e) DEFINITIONS.—In this section:

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

8 (A) an institution of higher education (as
9 such term is defined in section 1001 of the
10 Higher Education Act of 1965 (20 U.S.C.
11 1001)) or a consortium of such institutions; or

12 (B) an organization described in section
13 501(c)(3) of title 26 of the Internal Revenue
14 Code of 1986 and exempt from tax under sec-
15 tion 501(a) of such title.

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

23 (3) The term “qualified clinical trial” means a
24 clinical trial sponsored solely by an agency of the

1 Department of Health and Human Services with re-
2 spect to a medical product—

3 (A) that—

4 (i) was approved or cleared under sec-
5 tion 505, 510(k), or 515, or has an exemp-
6 tion for investigational use in effect under
7 section 505 or 520(m), of the Federal
8 Food, Drug, and Cosmetic Act (42 U.S.C.
9 301 et seq.); or

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

15 (B) that is an investigational product for
16 which the original development was discon-
17 tinued and with respect to which—

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

24 (ii) the sponsor of the original inves-
25 tigational development program has pro-

1 vided its consent to the Secretary for inclu-
2 sion of data regarding such product in the
3 system established under this section.

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

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

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

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

19 **SEC. 1122. NATIONAL NEUROLOGICAL DISEASES SURVEIL-**
20 **LANCE SYSTEM.**

21 Part P of title III of the Public Health Service Act
22 (42 U.S.C. 280g et seq.) is amended by adding at the end
23 the following:

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

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

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

10 “(2) incorporate information obtained through
11 such activities into a statistically sound, scientifically
12 credible, integrated surveillance system, to be known
13 as the National Neurological Diseases Surveillance
14 System.

15 “(b) RESEARCH.—The Secretary shall ensure that
16 the National Neurological Diseases Surveillance System is
17 designed in a manner that facilitates further research on
18 neurological diseases.

19 “(c) CONTENT.—In carrying out subsection (a), the
20 Secretary—

21 “(1) shall provide for the collection and storage
22 of information on the incidence and prevalence of
23 neurological diseases in the United States;

24 “(2) to the extent practicable, shall provide for
25 the collection and storage of other available informa-

1 tion on neurological diseases, such as information
2 concerning—

3 “(A) demographics and other information
4 associated or possibly associated with neuro-
5 logical diseases, such as age, race, ethnicity,
6 sex, geographic location, and family history;

7 “(B) risk factors associated or possibly as-
8 sociated with neurological diseases, including
9 genetic and environmental risk factors; and

10 “(C) diagnosis and progression markers;

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

14 “(A) the epidemiology of the diseases;

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

16 “(C) the prevention of the diseases;

17 “(D) the detection, management, and
18 treatment approaches for the diseases; and

19 “(E) the development of outcomes meas-
20 ures; and

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

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

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

3 “(2) representatives of national voluntary
4 health associations that—

5 “(A) focus on neurological diseases, includ-
6 ing multiple sclerosis and Parkinson’s disease;
7 and

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

10 “(3) health information technology experts or
11 other information management specialists;

12 “(4) clinicians with expertise in neurological
13 diseases; and

14 “(5) research scientists with experience con-
15 ducting translational research or utilizing surveil-
16 lance systems for scientific research purposes.

17 “(e) GRANTS.—The Secretary may award grants to,
18 or enter into contracts or cooperative agreements with,
19 public or private nonprofit entities to carry out activities
20 under this section.

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

1 “(1) to Federal departments and agencies, such
2 as the National Institutes of Health, the Food and
3 Drug Administration, the Centers for Medicare &
4 Medicaid Services, the Agency for Healthcare Re-
5 search and Quality, the Department of Veterans Af-
6 fairs, and the Department of Defense; and

7 “(2) to State and local agencies.

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

12 “(h) PRIVACY.—The Secretary shall ensure that pri-
13 vacy and security protections applicable to the National
14 Neurological Diseases Surveillance System are at least as
15 stringent as the privacy and security protections under
16 HIPAA privacy and security law (as defined in section
17 3009(a)(2)).

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

23 “(1) the development and maintenance of the
24 National Neurological Diseases Surveillance System;

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

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

5 “(4) the use and coordination of databases that
6 collect or maintain information on neurological dis-
7 eases.

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

12 “(k) AUTHORIZATION OF APPROPRIATIONS.—To
13 carry out this section, there is authorized to be appro-
14 priated \$5,000,000 for each of fiscal years 2016 through
15 2020.”.

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

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

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

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

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

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

8 “(2) award grants to patient advocacy groups
9 or other organizations determined appropriate by the
10 Secretary.

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

16 “(c) ACTIVITIES OF PUBLIC-PRIVATE PARTNER-
17 SHIPS.—The activities of public-private partnerships in
18 which the Secretary may participate for purposes of this
19 section include—

20 “(1) cooperating with other entities that spon-
21 sor or maintain disease registries, including disease
22 registries and disease registry platforms for rare dis-
23 eases;

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

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

3 “(B) is easily modified as knowledge is
4 gained during such studies; and

5 “(C) is capable of handling increasing
6 amounts of data as more studies are carried
7 out; and

8 “(3) providing advice to clinical researchers, pa-
9 tient advocacy groups, and other entities with re-
10 spect to—

11 “(A) the design and conduct of disease
12 studies;

13 “(B) the modification of any such ongoing
14 studies; and

15 “(C) addressing associated patient privacy
16 issues.

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

1 “(e) CONFIDENTIALITY.—Notwithstanding sub-
2 section (d), nothing in this section authorizes the dislo-
3 sure of any information that is a trade secret or commer-
4 cial or financial information that is privileged or confiden-
5 tial and subject to section 552(b)(4) of title 5, United
6 States Code, or section 1905 of title 18, United States
7 Code.

8 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
9 is authorized to be appropriated to carry out this section
10 \$5,000,000 for each of fiscal years 2016 through 2020.”.

11 **SEC. 1124. ACCESSING, SHARING, AND USING HEALTH DATA**
12 **FOR RESEARCH PURPOSES.**

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

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

19 **“SEC. 13441. REFERENCES.**

20 “In this part:

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

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

5 **“SEC. 13442. DEFINING HEALTH DATA RESEARCH AS PART**
6 **OF HEALTH CARE OPERATIONS.**

7 “(a) IN GENERAL.—Subject to subsection (b), the
8 Secretary shall revise or clarify the Rule to allow the use
9 and disclosure of protected health information by a cov-
10 ered entity for research purposes, including studies whose
11 purpose is to obtain generalizable knowledge, to be treated
12 as the use and disclosure of such information for health
13 care operations described in subparagraph (1) of the defi-
14 nition of health care operations in section 164.501 of part
15 164.

16 “(b) MODIFICATIONS TO RULES FOR DISCLOSURES
17 FOR HEALTH CARE OPERATIONS.—In applying section
18 164.506 of part 164 to the disclosure of protected health
19 information described in subsection (a)—

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

23 “(A) another covered entity for health care
24 operations (as defined in section 164.501 of
25 part 164);

1 “(b) PERMITTED USES AND DISCLOSURES.—The
2 Secretary shall revise or clarify the Rule so that research
3 activities, including comparative research activities, re-
4 lated to the quality, safety, or effectiveness of a product
5 or activity that is regulated by the Food and Drug Admin-
6 istration are included as public health activities for pur-
7 poses of which a covered entity may disclose protected
8 health information to a person described in section
9 164.512(b)(1)(iii) of part 164.

10 **“SEC. 13444. PERMITTING REMOTE ACCESS TO PROTECTED**
11 **HEALTH INFORMATION BY RESEARCHERS.**

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

17 “(1) appropriate security and privacy safe-
18 guards are maintained by the covered entity and the
19 researcher; and

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

1 **“SEC. 13445. ALLOWING ONE-TIME AUTHORIZATION OF USE**
2 **AND DISCLOSURE OF PROTECTED HEALTH**
3 **INFORMATION FOR RESEARCH PURPOSES.**

4 “(a) IN GENERAL.—The Secretary shall revise or
5 clarify the Rule to specify that an authorization for the
6 use or disclosure of protected health information, with re-
7 spect to an individual, for future research purposes shall
8 be deemed to contain a sufficient description of the pur-
9 pose of the use or disclosure if the authorization—

10 “(1) sufficiently describes the purposes such
11 that it would be reasonable for the individual to ex-
12 pect that the protected health information could be
13 used or disclosed for such future research;

14 “(2) either—

15 “(A) states that the authorization will ex-
16 pire on a particular date or on the occurrence
17 of a particular event; or

18 “(B) states that the authorization will re-
19 main valid unless and until it is revoked by the
20 individual; and

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

23 “(b) REVOCATION OF AUTHORIZATION.—The Sec-
24 retary shall revise or clarify the Rule to specify that, if
25 an individual revokes an authorization for future research
26 purposes such as is described by subsection (a), the cov-

1 ered entity may not make any further uses or disclosures
2 based on that authorization, except, as provided in para-
3 graph (b)(5) of section 164.508 of part 164, to the extent
4 that the covered entity has taken action in reliance on the
5 authorization.”.

6 (2) The table of sections in section 13001(b) of such
7 Act is amended by adding at the end of the items relating
8 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.”.

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

15 **Subtitle H—Council for 21st**
16 **Century Cures**

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

18 Title II of the Public Health Service Act (42 U.S.C.
19 202 et seq.) is amended by adding at the end the fol-
20 lowing:

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

2 **“SEC. 281. ESTABLISHMENT.**

3 “A nonprofit corporation to be known as the Council
4 for 21st Century Cures (referred to in this part as the
5 ‘Council’) shall be established in accordance with this sec-
6 tion. The Council shall be a public-private partnership
7 headed by an Executive Director (referred to in this part
8 as the ‘Executive Director’), appointed by the members
9 of the Board of Directors. The Council shall not be an
10 agency or instrumentality of the United States Govern-
11 ment.

12 **“SEC. 281A. PURPOSE.**

13 “The purpose of the Council is to accelerate the dis-
14 covery, development, and delivery in the United States of
15 innovative cures, treatments, and preventive measures for
16 patients.

17 **“SEC. 281B. DUTIES.**

18 “For the purpose described in section 281A, the
19 Council shall—

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

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

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

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

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

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

13 “(7) facilitate the interoperability of the compo-
14 nents of the discovery, development, and delivery
15 cycle;

16 “(8) propose recommendations that will facili-
17 tate precompetitive collaboration;

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

21 “(10) identify opportunities for collaboration
22 with organizations operating outside of the United
23 States, such as the Innovative Medicines Initiative of
24 the European Union.

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

2 “(a) BOARD OF DIRECTORS.—

3 “(1) ESTABLISHMENT.—

4 “(A) IN GENERAL.—The Council shall
5 have a Board of Directors (in this part referred
6 to as the ‘Board of Directors’), which shall be
7 composed of the ex officio members under sub-
8 paragraph (B) and the appointed members
9 under subparagraph (C). All members of the
10 Board shall be voting members.

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

14 “(i) The Director of the National In-
15 stitutes of Health.

16 “(ii) The Commissioner of Food and
17 Drugs.

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

20 “(iv) The heads of five other Federal
21 agencies deemed by the Secretary to be en-
22 gaged in biomedical research and develop-
23 ment.

24 “(C) APPOINTED MEMBERS.—The ap-
25 pointed members of the Board shall consist of
26 17 individuals, of whom—

1 “(i) 8 shall be appointed by the
2 Comptroller General of the United States
3 from a list of nominations submitted by
4 leading trade associations—

5 “(I) 4 of whom shall be rep-
6 resentatives of the biopharmaceutical
7 industry;

8 “(II) 2 of whom shall be rep-
9 resentatives of the medical device in-
10 dustry; and

11 “(III) 2 of whom shall be rep-
12 resentatives of the information and
13 digital technology industry; and

14 “(ii) 9 shall be appointed by the
15 Comptroller General of the United States,
16 after soliciting nominations—

17 “(I) 2 of whom shall be rep-
18 resentatives of academic researchers;

19 “(II) 3 of whom shall be rep-
20 resentatives of patients;

21 “(III) 2 of whom shall be rep-
22 resentatives of health care providers;
23 and

1 “(IV) 2 of whom shall be rep-
2 representatives of health care plans and
3 insurers.

4 “(D) CHAIR.—The Chair of the Board
5 shall be selected by the members of the Board
6 by majority vote from among the members of
7 the Board.

8 “(2) TERMS AND VACANCIES.—

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

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

14 “(i) shall not affect the power of the
15 remaining members to execute the duties
16 of the Board; and

17 “(ii) shall be filled by appointment by
18 the appointed members described in para-
19 graph (1)(C) by majority vote.

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

1 mainder of the term of the predecessor of the
2 individual.

3 “(3) RESPONSIBILITIES.—Not later than 90
4 days after the date on which the Council is incor-
5 porated and its Board of Directors is fully con-
6 stituted, the Board of Directors shall establish by-
7 laws and policies for the Council that—

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

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

12 “(i) the officers, employees, agents,
13 and contractors of the Council; and

14 “(ii) the members of any committees
15 of the Council;

16 “(C) establish policies, including ethical
17 standards, for the conduct of programs and
18 other activities under section 281D; and

19 “(D) establish specific duties of the Execu-
20 tive Director.

21 “(4) MEETINGS.—

22 “(A) IN GENERAL.—The Board of Direc-
23 tors shall—

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

1 “(ii) submit to Congress, and make
2 publicly available, the minutes of such
3 meetings.

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

7 “(i) issue an agenda (in this part re-
8 ferred to as the ‘agenda’) outlining how
9 the Council will achieve the purpose de-
10 scribed in section 281A; and

11 “(ii) annually thereafter, in consulta-
12 tion with the Executive Director, review
13 and update such agenda.

14 “(b) APPOINTMENT AND INCORPORATION.—Not
15 later than 6 months after the date of enactment of the
16 21st Century Cures Act—

17 “(1) the Comptroller General of the United
18 States shall appoint the appointed members of the
19 Board of Directors under subsection (a)(1)(C); and

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

24 “(c) NONPROFIT STATUS.—In carrying out this part,
25 the Board of Directors shall establish such policies and

1 bylaws, and the Executive Director shall carry out such
2 activities, as may be necessary to ensure that the Council
3 maintains status as an organization that—

4 “(1) is described in subsection (c)(3) of section
5 501 of the Internal Revenue Code of 1986; and

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

8 “(d) EXECUTIVE DIRECTOR.—The Executive Direc-
9 tor shall—

10 “(1) be the chief executive officer of the Coun-
11 cil; and

12 “(2) subject to the oversight of the Board of
13 Directors, be responsible for the day-to-day manage-
14 ment of the Council.

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

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

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

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

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

1 “(b) REPORT.—Not later than one year after the
2 date on which the Council is established and each year
3 thereafter, the Executive Director shall submit to the ap-
4 propriate congressional committees a report on the per-
5 formance of the Council. In preparing such report, the
6 Council shall consult with a nongovernmental consultant
7 with appropriate expertise.

8 **“SEC. 281F. FUNDING.**

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

13 **TITLE II—DEVELOPMENT**
14 **Subtitle A—Patient-Focused Drug**
15 **Development**

16 **SEC. 2001. DEVELOPMENT AND USE OF PATIENT EXPERI-**
17 **ENCE DATA TO ENHANCE STRUCTURED RISK-**
18 **BENEFIT ASSESSMENT FRAMEWORK.**

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

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

24 (2) by adding at the end the following new sub-
25 sections:

1 “(x) STRUCTURED RISK-BENEFIT ASSESSMENT
2 FRAMEWORK.—

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

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

8 “(B) to develop and implement a con-
9 sistent and systematic approach to the discus-
10 sion of, regulatory decisionmaking with respect
11 to, and the communication of, the benefits and
12 risks of new drugs.

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

16 “(y) DEVELOPMENT AND USE OF PATIENT EXPERI-
17 ENCE DATA TO ENHANCE STRUCTURED RISK-BENEFIT
18 ASSESSMENT FRAMEWORK.—

19 “(1) IN GENERAL.—Not later than two years
20 after the date of the enactment of this subsection,
21 the Secretary shall establish and implement proc-
22 esses under which—

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

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

3 “(ii) with respect to patient experience
4 data collected by the entity, draft guidance
5 documents, completed data, and sum-
6 maries and analyses of such data;

7 “(B) the Secretary may request such an
8 entity to submit such documents, data, and
9 summaries and analyses; and

10 “(C) patient experience data may be devel-
11 oped and used to enhance the structured risk-
12 benefit assessment framework under subsection
13 (x).

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

24 (b) GUIDANCE.—

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

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

11 (i) specifying the timelines for the re-
12 view of such documents, data, or sum-
13 maries and analyses by the Secretary; and

14 (ii) on how the Secretary will use such
15 documents, data, or summaries and anal-
16 yses to update any guidance documents
17 published under this subsection or publish
18 new guidance;

19 (B) with respect to the collection and anal-
20 ysis of patient experience data (as defined in
21 paragraph (2) of such subsection (y)), guidance
22 on—

23 (i) methodological considerations for
24 the collection of patient experience data,

1 which may include structured approaches
2 to gathering information on—

3 (I) the experience of a patient liv-
4 ing with a particular disease;

5 (II) the burden of living with or
6 managing the disease;

7 (III) the impact of the disease on
8 daily life and long-term functioning;
9 and

10 (IV) the effect of current thera-
11 peutic options on different aspects of
12 the disease; and

13 (ii) the establishment and mainte-
14 nance of registries designed to increase un-
15 derstanding of the natural history of a dis-
16 ease;

17 (C) methodological approaches that may be
18 used to assess patients' beliefs with respect to
19 the benefits and risks in the management of the
20 patient's disease; and

21 (D) methodologies, standards, and poten-
22 tial experimental designs for patient-reported
23 outcomes.

24 (2) TIMING.—Not later than 3 years after the
25 date of the enactment of this Act, the Secretary of

1 Health and Human Services shall issue draft guid-
2 ance on the implementation of subsection (y) of sec-
3 tion 505 of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 355), as added by subsection (a).
5 The Secretary shall issue final guidance on the im-
6 plementation of such subsection not later than one
7 year after the date on which the comment period for
8 the draft guidance closes.

9 (3) WORKSHOPS.—

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

19 (B) ATTENDEES.—A workshop convened
20 under this paragraph shall include—

21 (i) patients;

22 (ii) representatives from patient advo-
23 cacy organizations, biopharmaceutical com-
24 panies, and disease research foundations;

1 (iii) representatives of the reviewing
2 divisions of the Food and Drug Adminis-
3 tration; and

4 (iv) methodological experts with sig-
5 nificant expertise in patient experience
6 data.

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

12 **Subtitle B—Qualification and Use** 13 **of Drug Development Tools**

14 **SEC. 2021. QUALIFICATION OF DRUG DEVELOPMENT** 15 **TOOLS.**

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

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

19 (2) Development of drug development tools can
20 benefit the availability of new medical therapies by
21 helping to translate scientific discoveries into clinical
22 applications.

23 (3) Biomedical research consortia (as defined in
24 section 507(f) of the Federal Food, Drug, and Cos-
25 metic Act, as added by subsection (c)) can play a

1 valuable role in helping to develop and qualify drug
2 development tools.

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

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

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

13 (B) to coordinate efforts toward developing
14 and qualifying drug development tools in key
15 therapeutic areas; and

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

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

1 (c) QUALIFICATION OF DRUG DEVELOPMENT
2 TOOLS.—Chapter V of the Federal Food, Drug, and Cos-
3 metic Act is amended by inserting after section 506F the
4 following new section:

5 **“SEC. 507. QUALIFICATION OF DRUG DEVELOPMENT**
6 **TOOLS.**

7 “(a) PROCESS FOR QUALIFICATION.—

8 “(1) IN GENERAL.—The Secretary shall estab-
9 lish a process for the qualification of drug develop-
10 ment tools for a proposed context of use under
11 which—

12 “(A)(i) a requestor initiates such process
13 by submitting a letter of intent to the Sec-
14 retary; and

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

17 “(B)(i) if the Secretary accepts the letter
18 of intent, a requestor submits a qualification
19 plan to the Secretary; and

20 “(ii) the Secretary accepts or declines to
21 accept the qualification plan; and

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

1 “(ii) the Secretary determines whether to
2 accept such qualification package for review;
3 and

4 “(iii) if the Secretary accepts such quali-
5 fication package for review, the Secretary con-
6 ducts such review in accordance with this sec-
7 tion.

8 “(2) ACCEPTANCE AND REVIEW OF SUBMIS-
9 SIONS.—

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

16 “(B) ACCEPTANCE FACTORS; NONACCEPT-
17 ANCE.—The Secretary shall determine whether
18 to accept a qualification submission based on
19 factors which may include the scientific merit of
20 the submission and the available resources of
21 the Food and Drug Administration to review
22 the qualification submission. A determination
23 not to accept a submission under paragraph (1)
24 shall not be construed as a final determination
25 by the Secretary under this section regarding

1 the qualification of a drug development tool for
2 its proposed context of use.

3 “(C) PRIORITIZATION OF QUALIFICATION
4 REVIEW.—The Secretary may prioritize the re-
5 view of a full qualification package submitted
6 under paragraph (1) with respect to a drug de-
7 velopment tool, based on factors determined ap-
8 propriate by the Secretary, including—

9 “(i) as applicable, the severity, rarity,
10 or prevalence of the disease or condition
11 targeted by the drug development tool and
12 the availability or lack of alternative treat-
13 ments for such disease or condition; and

14 “(ii) the identification, by the Sec-
15 retary or by biomedical research consortia
16 and other expert stakeholders, of such a
17 drug development tool and its proposed
18 context of use as a public health priority.

19 “(D) ENGAGEMENT OF EXTERNAL EX-
20 PERTS.—The Secretary may, for purposes of
21 the review of qualification submissions, through
22 the use of cooperative agreements, grants, or
23 other appropriate mechanisms, consult with bio-
24 medical research consortia and may consider
25 the recommendations of such consortia with re-

1 spect to the review of any qualification plan
2 submitted under paragraph (1) or the review of
3 any full qualification package under paragraph
4 (3).

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

7 “(A) conduct a comprehensive review of a
8 full qualification package accepted under para-
9 graph (1)(C); and

10 “(B) determine whether the drug develop-
11 ment tool at issue is qualified for its proposed
12 context of use.

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

18 “(b) EFFECT OF QUALIFICATION.—

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

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

4 “(A) supporting or obtaining approval or
5 licensure (as applicable) of a drug or biological
6 product (including in accordance with section
7 506(c)) under section 505 of this Act or section
8 351 of the Public Health Service Act; or

9 “(B) supporting the investigational use of
10 a drug or biological product under section
11 505(i) of this Act or section 351(a)(3) of the
12 Public Health Service Act.

13 “(3) RESCISSION OR MODIFICATION.—

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

23 “(B) MEETING FOR REVIEW.—If the Sec-
24 retary rescinds or modifies under subparagraph
25 (A) a determination to qualify a drug develop-

1 ment tool, the requestor involved shall, on re-
2 quest, be granted a meeting with the Secretary
3 to discuss the basis of the Secretary’s decision
4 to rescind or modify the determination before
5 the effective date of the rescission or modifica-
6 tion.

7 “(c) TRANSPARENCY.—

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

13 “(A) Information with respect to each
14 qualification submission under the qualification
15 process under subsection (a), including—

16 “(i) the stage of the review process
17 applicable to the submission;

18 “(ii) the date of the most recent
19 change in stage status;

20 “(iii) whether the external scientific
21 experts were utilized in the development of
22 a qualification plan or the review of a full
23 qualification package; and

24 “(iv) submissions from requestors
25 under the qualification process under sub-

1 section (a), including any data and evi-
2 dence contained in such submissions, and
3 any updates to such submissions.

4 “(B) The Secretary’s formal written deter-
5 minations in response to such qualification sub-
6 missions.

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

10 “(D) Summary reviews that document con-
11 clusions and recommendations for determina-
12 tions to qualify drug development tools under
13 subsection (a).

14 “(E) A comprehensive list of—

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

17 “(ii) all surrogate endpoints which
18 were the basis of approval or licensure (as
19 applicable) of a drug or biological product
20 (including in accordance with section
21 506(e)) under section 505 of this Act or
22 section 351 of the Public Health Service
23 Act.

24 “(2) RELATION TO TRADE SECRETS ACT.—In-
25 formation made publicly available by the Secretary

1 under paragraph (1) shall be considered a disclosure
2 authorized by law for purposes of section 1905 of
3 title 18, United States Code.

4 “(3) APPLICABILITY.—Nothing in this section
5 shall be construed as authorizing the Secretary to
6 disclose any information contained in an application
7 submitted under section 505 of this Act or section
8 351 of the Public Health Service Act that is con-
9 fidential commercial or trade secret information sub-
10 ject to section 552(b)(4) of title 5, United States
11 Code, or section 1905 of title 18, United States
12 Code.

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

15 “(1) to alter the standards of evidence under
16 subsection (c) or (d) of section 505, including the
17 substantial evidence standard in such subsection (d),
18 or under section 351 of the Public Health Service
19 Act (as applicable); or

20 “(2) to limit the authority of the Secretary to
21 approve or license products under this Act or the
22 Public Health Service Act, as applicable (as in effect
23 before the date of the enactment of the 21st Century
24 Cures Act).

25 “(e) DEFINITIONS.—In this section:

1 “(1) BIOMARKER.—(A) The term ‘biomarker’
2 means a characteristic (such as a physiologic,
3 pathologic, or anatomic characteristic or measure-
4 ment) that is objectively measured and evaluated as
5 an indicator of normal biologic processes, pathologic
6 processes, or biological responses to a therapeutic
7 intervention; and

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

9 “(2) BIOMEDICAL RESEARCH CONSORTIA.—The
10 term ‘biomedical research consortia’ means collabo-
11 rative groups that may take the form of public-pri-
12 vate partnerships and may include government agen-
13 cies, institutions of higher education (as defined in
14 section 101(a) of the Higher Education Act of 1965,
15 patient advocacy groups, industry representatives,
16 clinical and scientific experts, and other relevant en-
17 tities and individuals.

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

23 “(B) such term includes a patient-reported out-
24 come.

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

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

8 “(A) a biomarker;

9 “(B) a clinical outcome assessment; and

10 “(C) any other method, material, or meas-
11 ure that the Secretary determines aids drug de-
12 velopment and regulatory review for purposes of
13 this section.

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

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

1 “(8) REQUESTOR.—The term ‘requestor’ means
2 an entity or entities, including a drug sponsor or a
3 biomedical research consortia, seeking to qualify a
4 drug development tool for a proposed context of use
5 under this section.

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

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

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

18 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
19 are authorized to be appropriated to carry out this section,
20 \$10,000,000 for each of fiscal years 2016 through 2020.”.

21 (d) GUIDANCE.—

22 (1) IN GENERAL.—The Secretary of Health and
23 Human Services shall, in consultation with bio-
24 medical research consortia (as defined in subsection
25 (f) of section 507 the Federal Food, Drug, and Cos-

1 metic Act (as added by subsection (c))) and other
2 interested parties through a collaborative public
3 process, issue guidance to implement such section
4 507 that—

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

10 (B) makes recommendations for dem-
11 onstrating that a surrogate endpoint is reason-
12 ably likely to predict clinical benefit for the pur-
13 pose of supporting the accelerated approval of
14 a drug under section 506(c) of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C.
16 356(c));

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

19 (i) describes the requirements that en-
20 tities seeking to qualify a drug develop-
21 ment tool under such section shall observe
22 when engaging in such process;

23 (ii) outlines reasonable timeframes for
24 the Secretary’s review of letters, qualifica-

1 tion plans, or full qualification packages
2 submitted under such process; and

3 (iii) establishes a process by which
4 such entities or the Secretary may consult
5 with biomedical research consortia and
6 other individuals and entities with expert
7 knowledge and insights that may assist the
8 Secretary in the review of qualification
9 plans and full qualification submissions
10 under such section; and

11 (D) includes such other information as the
12 Secretary determines appropriate.

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

23 (3) TAXONOMY.—

24 (A) IN GENERAL.—For purposes of in-
25 forming guidance under this subsection, the

1 Secretary of Health and Human Services shall,
2 in consultation with biomedical research con-
3 sortia and other interested parties through a
4 collaborative public process, establish a tax-
5 onomy for the classification of biomarkers (and
6 related scientific concepts) for use in drug de-
7 velopment.

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

16 (e) MEETING AND REPORT.—

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

24 (2) REPORT.—Not later than 5 years after the
25 date of the enactment of this Act, the Secretary

1 shall make publicly available on the Internet website
2 of the Food and Drug Administration a report. Such
3 report shall include, with respect to the qualification
4 process under section 507 of the Federal Food,
5 Drug, and Cosmetic Act, as added by subsection (c),
6 information on—

7 (A) the number of requests submitted, as
8 a letter of intent, for qualification of a drug de-
9 velopment tool (as defined in subsection (f) of
10 such section);

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

16 (C) the number of such requests for which
17 external scientific experts were utilized in the
18 development of a qualification plan or review of
19 a full qualification package; and

20 (D) the number of qualification plans and
21 full qualification packages, respectively, sub-
22 mitted to the Secretary; and

23 (3) the drug development tools qualified
24 through such qualification process, specified by type
25 of tool, such as a biomarker or clinical outcome as-

1 sessment (as such terms are defined in subsection
2 (f) of such section 507).

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

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

7 “(g) ACCELERATED APPROVAL DEVELOPMENT
8 PLAN.—

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

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

22 “(A) the surrogate endpoint to be assessed
23 under such plan;

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

1 “(C) the magnitude of the effect of the
2 drug on the surrogate endpoint that is the sub-
3 ject of the agreement that would be sufficient
4 to form the primary basis of a claim that the
5 drug is effective.

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

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

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

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

23 “(5) DEFINITION.—In this section, the term
24 ‘accelerated approval development plan’ means a de-
25 velopment plan agreed upon by the Secretary and

1 the sponsor submitting the plan that contains study
2 parameters for the use of a surrogate endpoint
3 that—

4 “(A) is reasonably likely to predict clinical
5 benefit; and

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

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

12 (1) by striking “(f) AWARENESS EFFORTS” and
13 inserting “(e) AWARENESS EFFORTS”; and

14 (2) by striking “(e) CONSTRUCTION” and in-
15 serting “(f) CONSTRUCTION”.

16 **Subtitle C—FDA Advancement of** 17 **Precision Medicine**

18 **SEC. 2041. PRECISION MEDICINE GUIDANCE AND OTHER** 19 **PROGRAMS OF FOOD AND DRUG ADMINIS-** 20 **TRATION.**

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

1 **“Subchapter J—Precision Medicine**

2 **“SEC. 591. GENERAL AGENCY GUIDANCE ON PRECISION**
3 **MEDICINE.**

4 “(a) IN GENERAL.—The Secretary shall issue and
5 periodically update guidance to assist sponsors in the de-
6 velopment of a precision drug or biological product. Such
7 guidance shall—

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

10 “(2) address the topics described in subsection
11 (b).

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

14 “(1) the evidence needed to support the use of
15 biomarkers (as defined in section 507(e)) that iden-
16 tify subsets of patients as likely responders to thera-
17 pies in order to streamline the conduct of clinical
18 trials;

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

22 “(3) the manner and extent to which a benefit-
23 risk assessment may be affected when clinical trials
24 are limited to patient population subsets that are
25 identified using biomarkers;

1 ological product, or another sponsor, provided that
2 the sponsor of the precision drug or biological prod-
3 uct has obtained a contractual right of reference to
4 such other sponsor’s data and information, in an ap-
5 plication approved under section 505(c) or licensed
6 under section 351(a) of the Public Health Service
7 Act, as applicable—

8 “(A) for a different drug or biological
9 product; or

10 “(B) for a different indication for such
11 precision drug or biological product,

12 in order to expedite clinical development for a preci-
13 sion drug or biological product that is using the
14 same or similar approach as that used to support
15 approval of the prior approved application or license,
16 as appropriate; and

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

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

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

5 “(2) confer any new rights, beyond those au-
6 thorized under this Act prior to enactment of this
7 section, with respect to a sponsor’s ability to ref-
8 erence information contained in another application
9 submitted under section 505(b)(1) of this Act or sec-
10 tion 351(a) of the Public Health Service Act.”.

11 **Subtitle D—Modern Trial Design**
12 **and Evidence Development**

13 **SEC. 2061. BROADER APPLICATION OF BAYESIAN STATIS-**
14 **TICS AND ADAPTIVE TRIAL DESIGNS.**

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

1 (b) GUIDANCE ADDRESSING USE OF ADAPTIVE
2 TRIAL DESIGNS AND BAYESIAN METHODS.—

3 (1) IN GENERAL.—The Secretary of Health and
4 Human Services, acting through the Commissioner
5 of Food and Drugs (in this subsection referred to as
6 the “Secretary”), shall—

7 (A) update and finalize the draft guidance
8 addressing the use of adaptive trial design for
9 drugs and biological products; and

10 (B) issue draft guidance on the use of
11 Bayesian methods in the development and regu-
12 latory review and approval or licensure of drugs
13 and biological products.

14 (2) CONTENTS.—The guidances under para-
15 graph (1) shall address—

16 (A) the use of adaptive trial designs and
17 Bayesian methods in clinical trials, including
18 clinical trials proposed or submitted to help to
19 satisfy the substantial evidence standard under
20 section 505(d) of the Federal Food, Drug, and
21 Cosmetic Act (21 U.S.C. 355(d));

22 (B) how sponsors may obtain feedback
23 from the Secretary on technical issues related
24 to modeling and simulations prior to—

1 (i) completion of such modeling or
2 simulations; or

3 (ii) the submission of resulting infor-
4 mation to the Secretary;

5 (C) the types of quantitative and quali-
6 tative information that should be submitted for
7 review; and

8 (D) recommended analysis methodologies.

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

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

18 (A) the final guidance required by para-
19 graph (1)(A) not later than 18 months after the
20 date of the public meeting required by para-
21 graph (3); and

22 (B) the guidance required by paragraph
23 (1)(B) not later than 48 months after the date
24 of the public meeting required by paragraph
25 (3).

1 **SEC. 2062. UTILIZING EVIDENCE FROM CLINICAL EXPERI-**
2 **ENCE.**

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

6 **“SEC. 505F. UTILIZING EVIDENCE FROM CLINICAL EXPERI-**
7 **ENCE.**

8 “(a) IN GENERAL.—The Secretary shall establish a
9 program to evaluate the potential use of evidence from
10 clinical experience—

11 “(1) to help to support the approval of a new
12 indication for a drug approved under section 505(b);
13 and

14 “(2) to help to support or satisfy postapproval
15 study requirements.

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

22 “(c) PROGRAM FRAMEWORK.—

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

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

3 “(A) the current sources of data developed
4 through clinical experience, including ongoing
5 safety surveillance, registry, claims, and pa-
6 tient-centered outcomes research activities;

7 “(B) the gaps in current data collection ac-
8 tivities;

9 “(C) the current standards and methodolo-
10 gies for collection and analysis of data gen-
11 erated through clinical experience; and

12 “(D) the priority areas, remaining chal-
13 lenges, and potential pilot opportunities that
14 the program established under this section will
15 address.

16 “(3) CONSULTATION.—

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

1 “(B) PROCESS.—The consultation under
2 subparagraph (A) may be carried out through
3 approaches such as—

4 “(i) a public-private partnership with
5 the entities described in such subparagraph
6 in which the Secretary may participate; or

7 “(ii) a contract, grant, or other ar-
8 rangement, as determined appropriate by
9 the Secretary with such a partnership or
10 an independent research organization.

11 “(d) PROGRAM IMPLEMENTATION.—The Secretary
12 shall, not later than 24 months after the date of enact-
13 ment of this section and in accordance with the framework
14 established under subsection (c), implement the program
15 to evaluate the potential use of evidence from clinical expe-
16 rience.

17 “(e) GUIDANCE FOR INDUSTRY.—The Secretary
18 shall—

19 “(1) utilize the program established under sub-
20 section (a), its activities, and any subsequent pilots
21 or written reports, to inform a guidance for industry
22 on—

23 “(A) the circumstances under which spon-
24 sors of drugs and the Secretary may rely on
25 evidence from clinical experience for the pur-

1 poses described in subsection (a)(1) or (a)(2);
2 and

3 “(B) the appropriate standards and meth-
4 odologies for collection and analysis of evidence
5 from clinical experience submitted for such pur-
6 poses;

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

10 “(3) not later than 48 months after the date of
11 enactment of this section, after providing an oppor-
12 tunity for public comment on the draft guidance,
13 issue final guidance.

14 “(f) RULE OF CONSTRUCTION.—

15 “(1) Subject to paragraph (2), nothing in this
16 section prohibits the Secretary from using evidence
17 from clinical experience for purposes not specified in
18 this section, provided the Secretary determines that
19 sufficient basis exists for any such nonspecified use.

20 “(2) This section shall not be construed to
21 alter—

22 “(A) the standards of evidence under—

23 “(i) subsection (c) or (d) of section
24 505, including the substantial evidence
25 standard in such subsection (d); or

1 “(ii) section 351(a) of the Public
2 Health Service Act; or

3 “(B) the Secretary’s authority to require
4 postapproval studies or clinical trials, or the
5 standards of evidence under which studies or
6 trials are evaluated.

7 **“SEC. 505G. COLLECTING EVIDENCE FROM CLINICAL EXPE-**
8 **RIENCE THROUGH TARGETED EXTENSIONS**
9 **OF THE SENTINEL SYSTEM.**

10 “(a) IN GENERAL.—The Secretary shall, in parallel
11 to implementing the program established under section
12 505F and in order to build capacity for utilizing the evi-
13 dence from clinical experience described in that section,
14 identify and execute pilot demonstrations to extend exist-
15 ing use of the Sentinel System surveillance infrastructure
16 authorized under section 505(k).

17 “(b) PILOT DEMONSTRATIONS.—

18 “(1) IN GENERAL.—The Secretary—

19 “(A) shall design and implement pilot dem-
20 onstrations to utilize data captured through the
21 Sentinel System surveillance infrastructure au-
22 thorized under section 505(k) for purposes of,
23 as appropriate—

24 “(i) generating evidence from clinical
25 experience to improve characterization or

1 assessment of risks or benefits of a drug
2 approved under section 505(c);

3 “(ii) protecting the public health; or

4 “(iii) advancing patient-centered care;

5 and

6 “(B) may make strategic linkages with
7 sources of complementary public health data
8 and infrastructure the Secretary determines ap-
9 propriate and necessary.

10 “(2) CONSULTATION.—In developing the pilot
11 demonstrations under this subsection, the Secretary
12 shall—

13 “(A) consult with regulated industry, aca-
14 demia, medical professional organizations, rep-
15 resentatives of patient advocacy organizations,
16 disease research foundations, and other inter-
17 ested parties through a public process; and

18 “(B) develop a framework to promote ap-
19 propriate transparency and dialogue about re-
20 search conducted under these pilot demonstra-
21 tions, including by—

22 “(i) providing adequate notice to a
23 sponsor of a drug approved under section
24 505 or section 351 of the Public Health
25 Service Act of the Secretary’s intent to

1 conduct analyses of such sponsor’s drug or
2 drugs under these pilot demonstrations;

3 “(ii) providing adequate notice of the
4 findings related to analyses described in
5 clause (i) and an opportunity for the spon-
6 sor of such drug or drugs to comment on
7 such findings; and

8 “(iii) ensuring the protection from
9 public disclosure of any information that is
10 a trade secret or confidential information
11 subject to section 552(b)(4) of title 5,
12 United States Code, or section 1905 of
13 title 18, United States Code.

14 “(3) HIPAA PRIVACY RULE; HUMAN SUBJECT
15 RESEARCH REGULATION.—The Secretary may deem
16 such pilot demonstrations—

17 “(A) public health activities, for purposes
18 of which a use or disclosure of protected health
19 information would be permitted as described in
20 section 164.512(b)(1) of title 45, Code of Fed-
21 eral Regulations (or any successor regulation);
22 and

23 “(B) outside the scope of ‘research’ as de-
24 fined in section 46.102(d) of title 45, Code of

1 Federal Regulations (or any successor regula-
2 tion).

3 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
4 are authorized to be appropriated to carry out this section
5 \$3,000,000 for each of fiscal years 2016 through 2020.”.

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

7 (a) IN GENERAL.—Chapter V of the Federal Food,
8 Drug, and Cosmetic Act, as amended by section 2062, is
9 further amended by inserting after section 505G of such
10 Act the following:

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

12 “(a) IN GENERAL.—The Secretary shall establish a
13 streamlined data review program under which a holder of
14 an approved application submitted under section
15 505(b)(1) or under section 351(a) of the Public Health
16 Service Act may, to support the approval or licensure (as
17 applicable) of the use of the drug that is the subject of
18 such approved application for a new qualified indication,
19 submit qualified data summaries.

20 “(b) ELIGIBILITY.—In carrying out the streamlined
21 data review program under subsection (a), the Secretary
22 may authorize the holder of the approved application to
23 include one or more qualified data summaries described
24 in subsection (a) in a supplemental application if—

1 “(1) the drug has been approved under section
2 505(c) of this Act or licensed under section 351(a)
3 of the Public Health Service Act for one or more in-
4 dications, and such approval or licensure remains in
5 effect;

6 “(2) the supplemental application is for ap-
7 proval or licensure (as applicable) under such section
8 505(c) or 351(a) of the use of the drug for a new
9 qualified indication under such section 505(c) or
10 351(a);

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

16 “(4) the supplemental application incorporates
17 or supplements the data submitted in the application
18 for approval or licensure referred to in paragraph
19 (1); and

20 “(5) the full data sets used to develop the quali-
21 fied data summaries are submitted, unless the Sec-
22 retary determines that the full data sets are not re-
23 quired.

24 “(c) PUBLIC AVAILABILITY OF INFORMATION ON
25 PROGRAM.—The Secretary shall post on the public website

1 of the Food and Drug Administration and update annu-
2 ally—

3 “(1) the number of applications reviewed under
4 the streamlined data review program;

5 “(2) the average time for completion of review
6 under the streamlined data review program versus
7 other review of applications for new indications; and

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

12 “(d) DEFINITIONS.—In this section:

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

14 “(A) an indication for the treatment of
15 cancer, as determined appropriate by the Sec-
16 retary; or

17 “(B) such other types of indications as the
18 Secretary determines to be subject to the
19 streamlined data review program under this
20 section.

21 “(2) The term ‘qualified data summary’ means
22 a summary of clinical data intended to demonstrate
23 safety and effectiveness with respect to a qualified
24 indication for use of a drug.”.

1 (b) SENSE OF CONGRESS.—It is the sense of Con-
2 gress that the streamlined data review program under sec-
3 tion 505H of the Federal Food, Drug, and Cosmetic Act,
4 as added by subsection (a), should enable the Food and
5 Drug Administration to make approval decisions for cer-
6 tain supplemental applications based on qualified data
7 summaries (as defined in such section 505H).

8 (c) GUIDANCE; REGULATIONS.—The Commissioner
9 of Food and Drugs—

10 (1) shall—

11 (A) issue final guidance for implementation
12 of the streamlined data review program estab-
13 lished under section 505H of the Federal Food,
14 Drug, and Cosmetic Act, as added by sub-
15 section (a), not later than 24 months after the
16 date of enactment of this Act; and

17 (B) include in such guidance the process
18 for expanding the types of indications to be
19 subject to the streamlined data review program,
20 as authorized by section 505H(c)(1)(B) of such
21 Act; and

22 (2) in addition to issuing guidance under para-
23 graph (1), may issue such regulations as may be
24 necessary for implementation of the program.

1 **Subtitle E—Expediting Patient**
2 **Access**

3 **SEC. 2081. SENSE OF CONGRESS.**

4 It is the sense of Congress that the Food and Drug
5 Administration should continue to expedite the approval
6 of drugs designated as breakthrough therapies pursuant
7 to section 506(a) of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 356(a)) by approving drugs so des-
9 ignated as early as possible in the clinical development
10 process, regardless of the phase of development, provided
11 that the Secretary of Health and Human Services deter-
12 mines that an application for such a drug meets the stand-
13 ards of evidence of safety and effectiveness under section
14 505 of such Act (21 U.S.C. 355), including the substantial
15 evidence standard under subsection (d) of such section or
16 under section 351(a) of the Public Health Service Act (42
17 U.S.C. 262(a)).

18 **SEC. 2082. EXPANDED ACCESS POLICY.**

19 Chapter V of the Federal Food, Drug, and Cosmetic
20 Act is amended by inserting after section 561 (21 U.S.C.
21 360bbb) the following:

22 **“SEC. 561A. EXPANDED ACCESS POLICY REQUIRED FOR IN-**
23 **VESTIGATIONAL DRUGS.**

24 “(a) IN GENERAL.—The manufacturer or distributor
25 of one or more investigational drugs for the diagnosis,

1 monitoring, or treatment of one or more serious diseases
2 or conditions shall make publicly available the policy of
3 the manufacturer or distributor on evaluating and re-
4 sponding to requests submitted under section 561(b) for
5 provision of such a drug. A manufacturer or distributor
6 may satisfy the requirement of the preceding sentence by
7 posting such policy as generally applicable to all of such
8 manufacturer's or distributor's investigational drugs.

9 “(b) CONTENT OF POLICY.—A policy described in
10 subsection (a) shall include making publicly available—

11 “(1) contact information for the manufacturer
12 or distributor to facilitate communication about re-
13 quests described in subsection (a);

14 “(2) procedures for making such requests;

15 “(3) the general criteria the manufacturer or
16 distributor will consider or use to approve such re-
17 quests; and

18 “(4) the length of time the manufacturer or dis-
19 tributor anticipates will be necessary to acknowledge
20 receipt of such requests.

21 “(c) NO GUARANTEE OF ACCESS.—The posting of
22 policies by manufacturers and distributors under sub-
23 section (a) shall not serve as a guarantee of access to any
24 specific investigational drug by any individual patient.

1 “(d) REVISED POLICY.—A manufacturer or dis-
2 tributor that has made a policy publicly available as re-
3 quired by this section may revise the policy at any time.

4 “(e) APPLICATION.—This section shall apply to a
5 manufacturer or distributor with respect to an investiga-
6 tional drug beginning on the later of—

7 “(1) the date that is 60 days after the date of
8 enactment of the 21st Century Cures Act; or

9 “(2) the first initiation of a phase 2 or phase
10 3 study (as such terms are defined in section
11 312.21(b) and (c) of title 21, Code of Federal Regu-
12 lations (or any successor regulations)) with respect
13 to such investigational new drug.”.

14 **SEC. 2083. FINALIZING DRAFT GUIDANCE ON EXPANDED**
15 **ACCESS.**

16 (a) IN GENERAL.—Not later than 12 months after
17 the date of enactment of this Act, the Secretary of Health
18 and Human Services shall finalize the draft guidance enti-
19 tled “Expanded Access to Investigational Drugs for Treat-
20 ment Use—Qs & As” and dated May 2013.

21 (b) CONTENTS.—The final guidance referred to in
22 subsection (a) shall clearly define how the Secretary of
23 Health and Human Services interprets and uses adverse
24 drug event data reported by investigators in the case of
25 data reported from use under a request submitted under

1 section 561(b) of the Federal Food, Drug, and Cosmetic
2 Act (21 U.S.C. 360bbb(b)).

3 **Subtitle F—Facilitating Respon-**
4 **sible Manufacturer Communica-**
5 **tions**

6 **SEC. 2101. FACILITATING DISSEMINATION OF HEALTH**
7 **CARE ECONOMIC INFORMATION.**

8 Section 502(a) of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 352(a)) is amended—

10 (1) by striking “(a) If its” and inserting
11 “(a)(1) If its”;

12 (2) by striking “a formulary committee, or
13 other similar entity, in the course of the committee
14 or the entity carrying out its responsibilities for the
15 selection of drugs for managed care or other similar
16 organizations” and inserting “a payor, formulary
17 committee, or other similar entity with knowledge
18 and expertise in the area of health care economic
19 analysis, carrying out its responsibilities for the se-
20 lection of drugs for coverage or reimbursement”;

21 (3) by striking “directly relates” and inserting
22 “relates”;

23 (4) by striking “and is based on competent and
24 reliable scientific evidence. The requirements set
25 forth in section 505(a) or in section 351(a) of the

1 Public Health Service Act shall not apply to health
2 care economic information provided to such a com-
3 mittee or entity in accordance with this paragraph”
4 and inserting “, is based on competent and reliable
5 scientific evidence, and includes, where applicable, a
6 conspicuous and prominent statement describing any
7 material differences between the health care eco-
8 nomic information and the labeling approved for the
9 drug under section 505 or under section 351 of the
10 Public Health Service Act. The requirements set
11 forth in section 505(a) or in subsections (a) and (k)
12 of section 351 of the Public Health Service Act shall
13 not apply to health care economic information pro-
14 vided to such a payor, committee, or entity in ac-
15 cordance with this paragraph”; and

16 (5) by striking “In this paragraph, the term”
17 and all that follows and inserting the following:

18 “(2)(A) For purposes of this paragraph, the term
19 ‘health care economic information’ means any analysis (in-
20 cluding the clinical data, inputs, clinical or other assump-
21 tions, methods, results, and other components underlying
22 or comprising the analysis) that identifies, measures, or
23 describes the economic consequences, which may be based
24 on the separate or aggregated clinical consequences of the
25 represented health outcomes, of the use of a drug. Such

1 analysis may be comparative to the use of another drug,
2 to another health care intervention, or to no intervention.

3 “(B) Such term does not include any analysis that
4 relates only to an indication that is not approved under
5 section 505 or under section 351 of the Public Health
6 Service Act for such drug.”.

7 **SEC. 2102. FACILITATING RESPONSIBLE COMMUNICATION**
8 **OF SCIENTIFIC AND MEDICAL DEVELOP-**
9 **MENTS.**

10 (a) GUIDANCE.—Not later than 18 months after the
11 date of enactment of this Act, the Secretary of Health and
12 Human Services shall issue draft guidance on facilitating
13 the responsible dissemination of truthful and nonmis-
14 leading scientific and medical information not included in
15 the approved labeling of drugs and devices.

16 (b) DEFINITION.—In this section, the terms “drug”
17 and “device” have the meaning given to such terms in sec-
18 tion 201 of the Federal Food, Drug, and Cosmetic Act
19 (21 U.S.C. 321).

20 **Subtitle G—Antibiotic Drug**
21 **Development**

22 **SEC. 2121. APPROVAL OF CERTAIN DRUGS FOR USE IN A**
23 **LIMITED POPULATION OF PATIENTS.**

24 (a) PURPOSE.—The purpose of this section is to help
25 to expedite the development and availability of treatments

1 for serious or life-threatening bacterial or fungal infections
2 in patients with unmet needs, while maintaining safety
3 and effectiveness standards for such treatments, taking
4 into account the severity of the infection and the avail-
5 ability or lack of alternative treatments.

6 (b) APPROVAL OF CERTAIN ANTIBACTERIAL AND
7 ANTIFUNGAL DRUGS.—Section 505 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 355), as amended by
9 section 2001, is further amended by adding at the end
10 the following new subsection:

11 “(z) APPROVAL OF CERTAIN ANTIBACTERIAL AND
12 ANTIFUNGAL DRUGS FOR USE IN A LIMITED POPU-
13 LATION OF PATIENTS.—

14 “(1) PROCESS.—At the request of the sponsor
15 of an antibacterial or antifungal drug that is in-
16 tended to treat a serious or life-threatening infec-
17 tion, the Secretary—

18 “(A) may execute a written agreement
19 with the sponsor on the process for developing
20 data to support an application for approval of
21 such drug, for use in a limited population of pa-
22 tients in accordance with this subsection;

23 “(B) shall proceed in accordance with this
24 subsection only if a written agreement is
25 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 (c) 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 two
15 years after the date of enactment of this Act, the Sec-
16 retary of Health and Human Services shall submit to the
17 Committee on Energy and Commerce of the House of
18 Representatives and the Committee on Health, Education,
19 Labor and Pensions of the Senate a report on the progress
20 made in implementing section 511 of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 360a), as amended
22 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 **Subtitle H—Vaccine Access,**
11 **Certainty, and Innovation**

12 **SEC. 2141. TIMELY REVIEW OF VACCINES BY THE ADVISORY**
13 **COMMITTEE ON IMMUNIZATION PRACTICES.**

14 Section 2102(a) of the Public Health Service Act (42
15 U.S.C. 300aa–2(a)) is amended by adding at the end the
16 following:

17 “(10) ADVISORY COMMITTEE ON IMMUNIZATION
18 PRACTICES.—

19 “(A) STANDARD PERIODS OF TIME FOR
20 MAKING RECOMMENDATIONS.—Upon the licen-
21 sure of any vaccine or any new indication for a
22 vaccine, the Director of the Program shall di-
23 rect the Advisory Committee on Immunization
24 Practices, at its next regularly scheduled meet-
25 ing, to consider the use of the vaccine.

1 “(B) EXPEDITED REVIEW PURSUANT TO
2 REQUEST BY SPONSOR OR MANUFACTURER.—If
3 the Advisory Committee does not make rec-
4 ommendations with respect to the use of a vac-
5 cine at the Advisory Committee’s first regularly
6 scheduled meeting after the licensure of the
7 vaccine or any new indication for the vaccine,
8 the Advisory Committee, at the request of the
9 sponsor of the vaccine, shall make such rec-
10 ommendations on an expedited basis.

11 “(C) EXPEDITED REVIEW FOR BREAK-
12 THROUGH THERAPIES AND FOR USE DURING
13 PUBLIC HEALTH EMERGENCIES.—If a vaccine
14 is designated as a breakthrough therapy under
15 section 506 of the Federal Food, Drug, and
16 Cosmetic Act and is licensed under section 351
17 of this Act, the Advisory Committee shall make
18 recommendations with respect to the use of the
19 vaccine on an expedited basis.

20 “(D) DEFINITION.—In this paragraph, the
21 terms ‘Advisory Committee on Immunization
22 Practices’ and ‘Advisory Committee’ mean the
23 advisory committee on immunization practices
24 established by the Secretary pursuant to section

1 222, acting through the Director of the Centers
2 for Disease Control and Prevention.”.

3 **SEC. 2142. REVIEW OF PROCESSES AND CONSISTENCY OF**
4 **ACIP RECOMMENDATIONS.**

5 (a) REVIEW.—The Director of the Centers for Dis-
6 ease Control and Prevention shall conduct a review of the
7 process used by the Advisory Committee on Immunization
8 Practices to evaluate consistency in formulating and
9 issuing recommendations pertaining to vaccines.

10 (b) CONSIDERATIONS.—The review under subsection
11 (a) shall include assessment of—

12 (1) the criteria used to evaluate new and exist-
13 ing vaccines;

14 (2) the Grading of Recommendations, Assess-
15 ment, Development, and Evaluation (GRADE) ap-
16 proach to the review and analysis of scientific and
17 economic data, including the scientific basis for such
18 approach; and

19 (3) the extent to which the processes used by
20 the working groups of the Advisory Committee on
21 Immunization Practices are consistent among
22 groups.

23 (c) STAKEHOLDERS.—In carrying out the review
24 under subsection (a), the Director of the Centers for Dis-

1 ease Control and Prevention shall solicit input from vac-
2 cine stakeholders.

3 (d) REPORT.—Not later than 18 months after the
4 date of enactment of this Act, the Director of the Centers
5 for Disease Control and Prevention shall submit to the
6 appropriate committees of the Congress and make publicly
7 available a report on the results of the review under sub-
8 section (a), including recommendations on improving the
9 consistency of the process described in such subsection.

10 (e) DEFINITION.—In this section, the term “Advisory
11 Committee on Immunization Practices” means the advi-
12 sory committee on immunization practices established by
13 the Secretary of Health and Human Services pursuant to
14 section 222 of the Public Health Service Act (42 U.S.C.
15 217a), acting through the Director of the Centers for Dis-
16 ease Control and Prevention.

17 **SEC. 2143. MEETINGS BETWEEN CDC AND VACCINE DEVEL-**
18 **OPERS.**

19 Section 310 of the Public Health Service Act (42
20 U.S.C. 242o) is amended by adding at the end the fol-
21 lowing:

22 “(c)(1) In this subsection, the term ‘vaccine devel-
23 oper’ means a nongovernmental entity engaged in—

1 “(A)(i) the development of a vaccine with the
2 intent to pursue licensing of the vaccine by the Food
3 and Drug Administration; or

4 “(ii) the production of a vaccine licensed by the
5 Food and Drug Administration; and

6 “(B) vaccine research.

7 “(2)(A) Upon the submission of a written request for
8 a meeting by a vaccine developer, that includes a valid jus-
9 tification for the meeting, the Secretary, acting through
10 the Director of the Centers for Disease Control and Pre-
11 vention, shall convene a meeting of representatives of the
12 vaccine developer and experts from the Centers for Dis-
13 ease Control and Prevention in immunization programs,
14 epidemiology, and other relevant areas at which the Direc-
15 tor (or the Director’s designee), for the purpose of inform-
16 ing the vaccine developer’s understanding of public health
17 needs and priorities, shall provide the perspectives of the
18 Centers for Disease Control and Prevention and other rel-
19 evant Federal agencies regarding—

20 “(i) public health needs, epidemiology, and im-
21 plementation considerations with regard to a vaccine
22 developer’s potential vaccine profile; and

23 “(ii) potential implications of such perspectives
24 for the vaccine developer’s vaccine research and de-
25 velopment planning.

1 “(B) In addition to the representatives specified in
2 subparagraph (A), the Secretary may, with the agreement
3 of the vaccine developer requesting a meeting under such
4 subparagraph, include in such meeting representatives
5 of—

6 “(i) the Food and Drug Administration; and

7 “(ii) the National Vaccine Program.

8 “(C) The Secretary shall convene a meeting re-
9 quested with a valid justification under subparagraph (A)
10 not later than 120 days after receipt of the request for
11 the meeting.

12 “(3)(A) Upon the submission of a written request by
13 a vaccine developer, the Secretary, acting through the Di-
14 rector of the Centers for Disease Control and Prevention,
15 shall provide to the vaccine developer any age-based or
16 other demographically assessed disease epidemiological
17 analyses or data that—

18 “(i) are specified in the request;

19 “(ii) have been published;

20 “(iii) have been performed by or are in the pos-
21 session of the Centers;

22 “(iv) are not a trade secret or commercial or fi-
23 nancial information that is privileged or confidential
24 and subject to section 552(b)(4) of title 5, United

1 States Code, or section 1905 of title 18, United
2 States Code; and

3 “(v) do not contain individually identifiable in-
4 formation.

5 “(B) The Secretary shall provide analyses requested
6 by a vaccine manufacturer under subparagraph (A) not
7 later than 120 calendar days after receipt of the request
8 for the analyses.

9 “(4) The Secretary shall promptly notify a vaccine
10 developer if—

11 “(A) the Secretary becomes aware of any sig-
12 nificant change to information that was—

13 “(i) shared by the Secretary with the vac-
14 cine developer during a meeting under para-
15 graph (2); or

16 “(ii) provided by the Secretary to the vac-
17 cine developer in one or more analyses under
18 paragraph (3); and

19 “(B) the change to such information may have
20 implications for the vaccine developer’s vaccine re-
21 search and development.”.

1 **Subtitle I—Orphan Product Exten-**
2 **sions Now; Incentives for Cer-**
3 **tain Products for Limited Popu-**
4 **lations**

5 **SEC. 2151. EXTENSION OF EXCLUSIVITY PERIODS FOR A**
6 **DRUG APPROVED FOR A NEW INDICATION**
7 **FOR A RARE DISEASE OR CONDITION.**

8 (a) IN GENERAL.—Chapter V of the Federal Food,
9 Drug, and Cosmetic Act, as amended by sections 2062
10 and 2063, is further amended by inserting after section
11 505H of such Act the following:

12 **“SEC. 505I. EXTENSION OF EXCLUSIVITY PERIODS FOR A**
13 **DRUG APPROVED FOR A NEW INDICATION**
14 **FOR A RARE DISEASE OR CONDITION.**

15 “(a) DESIGNATION.—

16 “(1) IN GENERAL.—The Secretary shall des-
17 ignate a drug as a drug approved for a new indica-
18 tion to prevent, diagnose, or treat a rare disease or
19 condition for purposes of granting the extensions
20 under subsection (b) if—

21 “(A) prior to approval of an application or
22 supplemental application for the new indication,
23 the drug was approved or licensed for mar-
24 keting under section 505(c) of this Act or sec-
25 tion 351(a) of the Public Health Service Act

1 but was not so approved or licensed for the new
2 indication;

3 “(B)(i) the sponsor of the approved or li-
4 censed drug files an application or a supple-
5 mental application for approval of the new indi-
6 cation for use of the drug to prevent, diagnose,
7 or treat the rare disease or condition; and

8 “(ii) the Secretary approves the application
9 or supplemental application; and

10 “(C) the application or supplemental appli-
11 cation for the new indication contains the con-
12 sent of the applicant to notice being given by
13 the Secretary under paragraph (4) respecting
14 the designation of the drug.

15 “(2) REVOCATION OF DESIGNATION.—

16 “(A) IN GENERAL.—Except as provided in
17 subparagraph (B), a designation under para-
18 graph (1) shall not be revoked for any reason.

19 “(B) EXCEPTION.—The Secretary may re-
20 voke a designation of a drug under paragraph
21 (1) if the Secretary finds that the application or
22 supplemental application resulting in such des-
23 ignation contained an untrue statement of ma-
24 terial fact.

1 “(3) NOTIFICATION PRIOR TO DISCONTINUANCE
2 OF PRODUCTION FOR SOLELY COMMERCIAL REA-
3 SONS.—A designation of a drug under paragraph (1)
4 shall be subject to the condition that the sponsor of
5 the drug will notify the Secretary of any discontinu-
6 ance of the production of the drug for solely com-
7 mercial reasons at least one year before such dis-
8 continuance.

9 “(4) NOTICE TO PUBLIC.—Notice respecting
10 the designation of a drug under paragraph (1) shall
11 be made available to the public.

12 “(b) EXTENSION.—If the Secretary designates a
13 drug as a drug approved for a new indication for a rare
14 disease or condition, as described in subsection (a)(1)—

15 “(1)(A) the 4-, 5-, and 7½-year periods de-
16 scribed in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii)
17 of section 505, the 3-year periods described in
18 clauses (iii) and (iv) of subsection (c)(3)(E) and
19 clauses (iii) and (iv) of subsection (j)(5)(F) of sec-
20 tion 505, and the 7-year period described in section
21 527, as applicable, shall be extended by 6 months;
22 or

23 “(B) the 4- and 12-year periods described in
24 subparagraphs (A) and (B) of section 351(k)(7) of
25 the Public Health Service Act and the 7-year period

1 described in section 527, as applicable, shall be ex-
2 tended by 6 months; and

3 “(2)(A) if the drug is the subject of a listed
4 patent for which a certification has been submitted
5 under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of
6 section 505 or a listed patent for which a certifi-
7 cation has been submitted under subsections
8 (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,
9 the period during which an application may not be
10 approved under section 505(c)(3) or section
11 505(j)(5)(B) shall be extended by a period of 6
12 months after the date the patent expires (including
13 any patent extensions); or

14 “(B) if the drug is the subject of a listed patent
15 for which a certification has been submitted under
16 subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of sec-
17 tion 505, and in the patent infringement litigation
18 resulting from the certification the court determines
19 that the patent is valid and would be infringed, the
20 period during which an application may not be ap-
21 proved under section 505(c)(3) or section
22 505(j)(5)(B) shall be extended by a period of 6
23 months after the date the patent expires (including
24 any patent extensions).

1 “(c) RELATION TO PEDIATRIC AND QUALIFIED IN-
2 FECTIOUS DISEASE PRODUCT EXCLUSIVITY.—Any exten-
3 sion under subsection (b) of a period shall be in addition
4 to any extension of the periods under sections 505A and
5 505E of this Act and section 351(m) of the Public Health
6 Service Act, as applicable, with respect to the drug.

7 “(d) LIMITATIONS.—The extension described in sub-
8 section (b) shall not apply if the drug designated under
9 subsection (a)(1) has previously received an extension by
10 operation of subsection (b).

11 “(e) DEFINITION.—In this section, the term ‘rare
12 disease or condition’ has the meaning given to such term
13 in section 526(a)(2).”.

14 (b) APPLICATION.—Section 505G of the Federal
15 Food, Drug, and Cosmetic Act, as added by subsection
16 (a), applies only with respect to a drug for which an appli-
17 cation or supplemental application described in subsection
18 (a)(1)(B)(i) of such section 505G is first approved under
19 section 505(c) of such Act (21 U.S.C. 355(c)) or section
20 351(a) of the Public Health Service Act (42 U.S.C.
21 262(a)) on or after the date of the enactment of this Act.

22 (c) CONFORMING AMENDMENTS.—

23 (1) RELATION TO PEDIATRIC EXCLUSIVITY FOR
24 DRUGS.—Section 505A of the Federal Food, Drug,
25 and Cosmetic Act (21 U.S.C. 355a) is amended—

1 (A) in subsection (b), by adding at the end
2 the following:

3 “(3) RELATION TO EXCLUSIVITY FOR A DRUG
4 APPROVED FOR A NEW INDICATION FOR A RARE DIS-
5 EASE OR CONDITION.—Notwithstanding the ref-
6 erences in paragraph (1) to the lengths of the exclu-
7 sivity periods after application of pediatric exclu-
8 sivity, the 6-month extensions described in para-
9 graph (1) shall be in addition to any extensions
10 under section 505G.”; and

11 (B) in subsection (c), by adding at the end
12 the following:

13 “(3) RELATION TO EXCLUSIVITY FOR A DRUG
14 APPROVED FOR A NEW INDICATION FOR A RARE DIS-
15 EASE OR CONDITION.—Notwithstanding the ref-
16 erences in paragraph (1) to the lengths of the exclu-
17 sivity periods after application of pediatric exclu-
18 sivity, the 6-month extensions described in para-
19 graph (1) shall be in addition to any extensions
20 under section 505G.”.

21 (2) RELATION TO EXCLUSIVITY FOR NEW
22 QUALIFIED INFECTIOUS DISEASE PRODUCTS THAT
23 ARE DRUGS.—Subsection (b) of section 505E of the
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 355f) is amended—

1 (A) by amending the subsection heading to
2 read as follows: “RELATION TO PEDIATRIC EX-
3 CLUSIVITY AND EXCLUSIVITY FOR A DRUG AP-
4 PROVED FOR A NEW INDICATION FOR A RARE
5 DISEASE OR CONDITION.—”; and

6 (B) by striking “any extension of the pe-
7 riod under section 505A” and inserting “any
8 extension of the periods under sections 505A
9 and 505G, as applicable.”.

10 (3) RELATION TO PEDIATRIC EXCLUSIVITY FOR
11 BIOLOGICAL PRODUCTS.—Section 351(m) of the
12 Public Health Service Act (42 U.S.C. 262(m)) is
13 amended by adding at the end the following:

14 “(5) RELATION TO EXCLUSIVITY FOR A BIO-
15 LOGICAL PRODUCT APPROVED FOR A NEW INDICA-
16 TION FOR A RARE DISEASE OR CONDITION.—Not-
17 withstanding the references in paragraphs (2)(A),
18 (2)(B), (3)(A), and (3)(B) to the lengths of the ex-
19 clusivity periods after application of pediatric exclu-
20 sivity, the 6-month extensions described in such
21 paragraphs shall be in addition to any extensions
22 under section 505G.”.

1 **SEC. 2152. REAUTHORIZATION OF RARE PEDIATRIC DIS-**
2 **EASE PRIORITY REVIEW VOUCHER INCEN-**
3 **TIVE PROGRAM.**

4 (a) IN GENERAL.—Section 529 of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 360ff) is amended—

6 (1) in subsection (a)—

7 (A) in paragraph (3), by amending sub-
8 paragraph (A) to read as follows:

9 “(A) The disease is a serious or life-threat-
10 ening disease in which the serious or life-threat-
11 ening manifestations primarily affect individ-
12 uals aged from birth to 18 years, including age
13 groups often called neonates, infants, children,
14 and adolescents.”; and

15 (B) in paragraph (4)—

16 (i) in subparagraph (E), by striking
17 “and” at the end;

18 (ii) in subparagraph (F), by striking
19 the period at the end and inserting “;
20 and”; and

21 (iii) by adding at the end the fol-
22 lowing:

23 “(G) is for a drug or biological product for
24 which a priority review voucher has not been
25 issued under section 524 (relating to tropical
26 disease products).”; and

1 (2) in subsection (b), by striking paragraph (5)
2 and inserting the following:

3 “(5) TERMINATION OF AUTHORITY.—

4 “(A) IN GENERAL.—The Secretary may
5 not award any priority review vouchers under
6 paragraph (1) after December 31, 2018.

7 “(B) EXCEPTION.—Notwithstanding sub-
8 paragraph (A), the sponsor of a drug that is
9 designated under subsection (d) as a drug for
10 a rare pediatric disease and that is the subject
11 of a rare pediatric disease product application
12 that is submitted during the period beginning
13 on the date of enactment of the 21st Century
14 Cures Act and ending the date specified in sub-
15 paragraph (A) shall remain eligible to receive a
16 priority review voucher under paragraph (1) ir-
17 respective of whether the rare pediatric disease
18 product application with respect to such drug is
19 approved after the end of such period.”.

20 (b) GAO STUDY AND REPORT.—

21 (1) STUDY.—The Comptroller General of the
22 United States shall conduct a study on the effective-
23 ness of awarding priority review vouchers under sec-
24 tion 529 of the Federal Food, Drug, and Cosmetic
25 Act (21 U.S.C. 360ff) in providing incentives for the

1 development of drugs that treat or prevent rare pe-
2 diatric diseases (as defined in subsection (a)(3) of
3 such section) that would not otherwise have been de-
4 veloped. In conducting such study, the Comptroller
5 General shall examine the following:

6 (A) The indications for which each drug
7 for which a priority review voucher was award-
8 ed under such section 529 was approved under
9 section 505 of such Act (21 U.S.C. 355) or sec-
10 tion 351 of the Public Health Service Act (42
11 U.S.C. 262).

12 (B) Whether the priority review voucher
13 impacted a sponsor's decision to invest in devel-
14 oping a drug to treat or prevent a rare pedi-
15 atric disease.

16 (C) An analysis of the drugs that utilized
17 such priority review vouchers, which shall in-
18 clude—

19 (i) the indications for which such
20 drugs were approved under section 505 of
21 the Federal Food, Drug, and Cosmetic Act
22 (21 U.S.C. 355) or section 351 of the Pub-
23 lic Health Service Act (42 U.S.C. 262);

1 (ii) whether unmet medical needs were
2 addressed through the approval of such
3 drugs, including, for each such drug—

4 (I) if an alternative therapy was
5 previously available to treat the indi-
6 cation; and

7 (II) the benefit or advantage the
8 drug provided over another available
9 therapy;

10 (iii) the number of patients potentially
11 treated by such drugs;

12 (iv) the value of the priority review
13 voucher if transferred; and

14 (v) the length of time between the
15 date on which a priority review voucher
16 was awarded and the date on which it was
17 used.

18 (D) With respect to the priority review
19 voucher program under section 529 of the Fed-
20 eral Food, Drug, and Cosmetic Act (21 U.S.C.
21 360ff)—

22 (i) the resources used by, and burden
23 placed on, the Food and Drug Administra-
24 tion in implementing such program, includ-
25 ing the effect of such program on the Food

1 and Drug Administration's review of drugs
2 for which a priority review voucher was not
3 awarded or used;

4 (ii) the impact of the program on the
5 public health as a result of the expedited
6 review of applications for drugs that treat
7 or prevent non-serious indications that are
8 generally used by the broader public; and
9 (iii) alternative approaches to improv-
10 ing such program so that the program is
11 appropriately targeted toward providing in-
12 centives for the development of clinically
13 important drugs that—

14 (I) prevent or treat rare pediatric
15 diseases; and

16 (II) would likely not otherwise
17 have been developed to prevent or
18 treat such diseases.

19 (2) REPORT.—Not later than December 31,
20 2017, the Comptroller General of the United States
21 shall submit to the Committee on Energy and Com-
22 merce of the House of Representatives and the Com-
23 mittee on Health, Education, Labor and Pensions of
24 the Senate a report containing the results of the
25 study of conducted under paragraph (1).

1 **Subtitle J—Domestic Manufac-**
2 **turing and Export Efficiencies**

3 **SEC. 2161. GRANTS FOR STUDYING THE PROCESS OF CON-**
4 **TINUOUS DRUG MANUFACTURING.**

5 (a) IN GENERAL.—The Commissioner of Food and
6 Drugs may award grants to institutions of higher edu-
7 cation and nonprofit organizations for the purpose of
8 studying and recommending improvements to the process
9 of continuous manufacturing of drugs and biological prod-
10 ucts and similar innovative monitoring and control tech-
11 niques.

12 (b) DEFINITIONS.—In this section:

13 (1) The term “drug” has the meaning given to
14 such term in section 201 of the Federal Food, Drug,
15 and Cosmetic Act (21 U.S.C. 321).

16 (2) The term “biological product” has the
17 meaning given to such term in section 351(i) of the
18 Public Health Service Act (42 U.S.C. 262(i)).

19 (3) The term “institution of higher education”
20 has the meaning given to such term in section 101
21 of the Higher Education Act of 1965 (20 U.S.C.
22 1001).

23 (c) AUTHORIZATION OF APPROPRIATIONS.—There is
24 authorized to be appropriated to carry out this section
25 \$5,000,000 for each of fiscal years 2016 through 2020.

1 **SEC. 2162. RE-EXPORTATION AMONG MEMBERS OF THE EU-**
2 **ROPEAN ECONOMIC AREA.**

3 Section 1003 of the Controlled Substances Import
4 and Export Act (21 U.S.C. 953) is amended—

5 (1) in subsection (f)—

6 (A) in paragraph (5)—

7 (i) by striking “(5)” and inserting
8 “(5)(A)”;

9 (ii) by inserting “, except that the
10 controlled substance may be exported from
11 the second country to another country that
12 is a member of the European Economic
13 Area” before the period at the end; and

14 (iii) by adding at the end the fol-
15 lowing:

16 “(B) Subsequent to any re-exportation de-
17 scribed in subparagraph (A), a controlled substance
18 may continue to be exported from any country that
19 is a member of the European Economic Area to any
20 other such country, provided that—

21 “(i) the conditions applicable with respect
22 to the first country under paragraphs (1), (2),
23 (3), (4), (6), and (7) are met by each subse-
24 quent country from which the controlled sub-
25 stance is exported pursuant to this paragraph;
26 and

1 “(ii) the conditions applicable with respect
2 to the second country under such paragraphs
3 are met by each subsequent country to which
4 the controlled substance is exported pursuant to
5 this paragraph.”; and

6 (B) in paragraph (6)—

7 (i) by striking “(6)” and inserting
8 “(6)(A)”; and

9 (ii) by adding at the end the fol-
10 lowing:

11 “(B) In the case of re-exportation among mem-
12 bers of the European Economic Area, within 30
13 days after each re-exportation, the person who ex-
14 ported the controlled substance from the United
15 States delivers to the Attorney General—

16 “(i) documentation certifying that such re-
17 exportation has occurred; and

18 “(ii) information concerning the consignee,
19 country, and product.”; and

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

21 “(g) LIMITATION.—Subject to paragraphs (5) and
22 (6) of subsection (f) in the case of any controlled sub-
23 stance in schedule I or II or any narcotic drug in schedule
24 III or IV, the Attorney General shall not promulgate nor
25 enforce any regulation, subregulatory guidance, or en-

1 enforcement policy which impedes re-exportation of any con-
2 trolled substance among European Economic Area coun-
3 tries, including by promulgating or enforcing any require-
4 ment that—

5 “(1) re-exportation from the first country to the
6 second country or re-exportation from the second
7 country to another country occur within a specified
8 period of time; or

9 “(2) information concerning the consignee,
10 country, and product be provided prior to expor-
11 tation of the controlled substance from the United
12 States or prior to each re-exportation among mem-
13 bers of the European Economic Area.”.

14 **Subtitle K—Enhancing**
15 **Combination Products Review**

16 **SEC. 2181. ENHANCING COMBINATION PRODUCTS REVIEW.**

17 Section 503(g)(4)(C) of the Federal Food, Drug, and
18 Cosmetic Act (21 U.S.C. 353(g)(4)(C)) is amended by
19 adding at the end the following new clause:

20 “(iii) Not later than 18 months after the date of the
21 enactment of the 21st Century Cures Act, the Secretary
22 shall issue final guidance that describes the responsibilities
23 of each agency center regarding its review of combination
24 products. The Secretary shall, after soliciting public com-
25 ment, review and update the guidance periodically.”.

1 **Subtitle L—Priority Review for**
2 **Breakthrough Devices**

3 **SEC. 2201. PRIORITY REVIEW FOR BREAKTHROUGH DE-**
4 **VICES.**

5 (a) IN GENERAL.—Chapter V of the Federal Food,
6 Drug, and Cosmetic Act is amended—

7 (1) in section 515(d)—

8 (A) by striking paragraph (5); and

9 (B) by redesignating paragraph (6) as
10 paragraph (5); and

11 (2) by inserting after section 515A (21 U.S.C.
12 360e–1) the following:

13 **“SEC. 515B. PRIORITY REVIEW FOR BREAKTHROUGH DE-**
14 **VICES.**

15 “(a) IN GENERAL.—In order to provide for more ef-
16 fective treatment or diagnosis of life-threatening or irre-
17 versibly debilitating human diseases or conditions, the
18 Secretary shall establish a program to provide priority re-
19 view for devices—

20 “(1) representing breakthrough technologies;

21 “(2) for which no approved alternatives exist;

22 “(3) offering significant advantages over exist-
23 ing approved or cleared alternatives, including the
24 potential to, compared to existing approved or
25 cleared alternatives, reduce or eliminate the need for

1 hospitalization, improve patient quality of life, facili-
2 tate patients' ability to manage their own care (such
3 as through self-directed personal assistance), or es-
4 tablish long-term clinical efficiencies; or

5 “(4) the availability of which is in the best in-
6 terest of patients.

7 “(b) REQUEST FOR DESIGNATION.—A sponsor of a
8 device may request that the Secretary designate the device
9 for priority review under this section. Any such request
10 for designation may be made at any time prior to the sub-
11 mission of an application under section 515(c), a petition
12 for classification under section 513(f)(2), or a notification
13 under section 510(k).

14 “(c) DESIGNATION PROCESS.—

15 “(1) IN GENERAL.—Not later than 60 calendar
16 days after the receipt of a request under subsection
17 (b), the Secretary shall determine whether the device
18 that is the subject of the request meets the criteria
19 described in subsection (a). If the Secretary deter-
20 mines that the device meets the criteria, the Sec-
21 retary shall designate the device for priority review.

22 “(2) REVIEW.—Review of a request under sub-
23 section (b) shall be undertaken by a team that is
24 composed of experienced staff and managers of the

1 Food and Drug Administration and is chaired by a
2 senior manager.

3 “(3) DESIGNATION DETERMINATION.—A deter-
4 mination approving or denying a request under sub-
5 section (b) shall be considered a significant decision
6 under section 517A and the Secretary shall provide
7 a written, substantive summary of the basis for the
8 determination in accordance with section 517A(a).

9 “(4) RECONSIDERATION.—

10 “(A) REQUEST FOR RECONSIDERATION.—
11 Any person whose request under subsection (b)
12 is denied may, within 30 days of the denial, re-
13 quest reconsideration of the denial in accord-
14 ance with section 517A(b)—

15 “(i) based upon the submission of
16 documents by such person; or

17 “(ii) based upon such documents and
18 a meeting or teleconference.

19 “(B) RESPONSE.—Reconsideration of a
20 designation determination under this paragraph
21 shall be conducted in accordance with section
22 517A(b).

23 “(5) WITHDRAWAL.—If the Secretary approves
24 a priority review designation for a device under this
25 section, the Secretary may not withdraw the des-

1 ignation based on the fact that the criteria specified
2 in subsection (a) are no longer met because of the
3 subsequent clearance or approval of another device
4 that was designated under—

5 “(A) this section; or

6 “(B) section 515(d)(5) (as in effect imme-
7 diately prior to the enactment of the 21st Cen-
8 tury Cures Act).

9 “(d) PRIORITY REVIEW.—

10 “(1) ACTIONS.—For purposes of expediting the
11 development and review of devices designated under
12 subsection (c), the Secretary shall—

13 “(A) assign a team of staff, including a
14 team leader with appropriate subject matter ex-
15 pertise and experience, for each device for
16 which a request is submitted under subsection
17 (b);

18 “(B) provide for oversight of the team by
19 senior agency personnel to facilitate the effi-
20 cient development of the device and the efficient
21 review of any submission described in sub-
22 section (b) for the device;

23 “(C) adopt an efficient process for timely
24 dispute resolution;

1 “(D) provide for interactive communication
2 with the sponsor of the device during the review
3 process;

4 “(E) expedite the Secretary’s review of
5 manufacturing and quality systems compliance,
6 as applicable;

7 “(F) disclose to the sponsor in advance the
8 topics of any consultation concerning the spon-
9 sor’s device that the Secretary intends to under-
10 take with external experts or an advisory com-
11 mittee and provide the sponsor an opportunity
12 to recommend such external experts;

13 “(G) for applications submitted under sec-
14 tion 515(c), provide for advisory committee
15 input, as the Secretary determines appropriate
16 (including in response to the request of the
17 sponsor); and

18 “(H) assign staff to be available within a
19 reasonable time to address questions posed by
20 institutional review committees concerning the
21 conditions and clinical testing requirements ap-
22 plicable to the investigational use of the device
23 pursuant to an exemption under section 520(g).

24 “(2) ADDITIONAL ACTIONS.—In addition to the
25 actions described in paragraph (1), for purposes of

1 expediting the development and review of devices
2 designated under subsection (c), the Secretary, in
3 collaboration with the device sponsor, may, as appro-
4 priate—

5 “(A) coordinate with the sponsor regarding
6 early agreement on a data development plan;

7 “(B) take steps to ensure that the design
8 of clinical trials is as efficient as practicable,
9 such as through adoption of shorter or smaller
10 clinical trials, application of surrogate
11 endpoints, and use of adaptive trial designs and
12 Bayesian statistics, to the extent scientifically
13 appropriate;

14 “(C) facilitate, to the extent scientifically
15 appropriate, expedited and efficient develop-
16 ment and review of the device through utiliza-
17 tion of timely postmarket data collection, with
18 regard to applications for approval under sec-
19 tion 515(c); and

20 “(D) agree to clinical protocols that the
21 Secretary will consider binding on the Secretary
22 and the sponsor, subject to—

23 “(i) changes agreed to by the sponsor
24 and the Secretary;

1 “(ii) changes that the Secretary deter-
2 mines are required to prevent an unreason-
3 able risk to the public health; or

4 “(iii) the identification of a substan-
5 tial scientific issue determined by the Sec-
6 retary to be essential to the safety or effec-
7 tiveness of the device involved.

8 “(e) PRIORITY REVIEW GUIDANCE.—

9 “(1) CONTENT.—The Secretary shall issue
10 guidance on the implementation of this section. Such
11 guidance shall include the following:

12 “(A) The process for a person to seek a
13 priority review designation.

14 “(B) A template for requests under sub-
15 section (b).

16 “(C) The criteria the Secretary will use in
17 evaluating a request for priority review.

18 “(D) The standards the Secretary will use
19 in assigning a team of staff, including team
20 leaders, to review devices designated for priority
21 review, including any training required for such
22 personnel on effective and efficient review.

23 “(2) PROCESS.—Prior to finalizing the guid-
24 ance under paragraph (1), the Secretary shall pro-
25 pose such guidance for public comment.

1 “(f) CONSTRUCTION.—

2 “(1) PURPOSE.—This section is intended to en-
3 courage the Secretary and provide the Secretary suf-
4 ficient authorities to apply efficient and flexible ap-
5 proaches to expedite the development of, and
6 prioritize the agency’s review of, devices that rep-
7 resent breakthrough technologies.

8 “(2) CONSTRUCTION.—Nothing in this section
9 shall be construed to alter the criteria and standards
10 for evaluating an application pursuant to section
11 515(c), a report and request for classification under
12 section 513(f)(2), or a report under section 510(k),
13 including the recognition of valid scientific evidence
14 as described in section 513(a)(3)(B), and consider-
15 ation of the least burdensome means of evaluating
16 device effectiveness or demonstrating substantial
17 equivalence between devices with differing techno-
18 logical characteristics, as applicable. Nothing in this
19 section alters the authority of the Secretary to act
20 on an application pursuant to section 515(d) before
21 completion of an establishment inspection, as the
22 Secretary deems appropriate.”.

23 (b) CONFORMING AMENDMENT RELATED TO DES-
24 IGNATION DETERMINATIONS.—Section 517A(a)(1) of the
25 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–

1 1(a)(1)) is amended by inserting “a request for designa-
2 tion under section 515B,” after “an application under sec-
3 tion 515,”.

4 **Subtitle M—Medical Device**
5 **Regulatory Process Improvements**

6 **SEC. 2221. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

7 (a) ESTABLISHMENT OF THIRD-PARTY QUALITY
8 SYSTEM ASSESSMENT PROGRAM.—Chapter V of the Fed-
9 eral Food, Drug, and Cosmetic Act is amended by insert-
10 ing after section 524A (21 U.S.C. 360n–1) the following
11 new section:

12 **“SEC. 524B. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

13 **“(a) ACCREDITATION AND ASSESSMENT.—**

14 **“(1) IN GENERAL; CERTIFICATION OF DEVICE**
15 **QUALITY SYSTEM.—**The Secretary shall, in accord-
16 ance with this section, establish a third-party quality
17 system assessment program—

18 **“(A) to accredit persons to assess whether**
19 **a requestor’s quality system, including its de-**
20 **sign controls, can reasonably assure the safety**
21 **and effectiveness of in-scope devices subject to**
22 **device-related changes;**

23 **“(B) under which accredited persons shall**
24 **(as applicable) certify that a requestor’s quality**
25 **system meets the criteria included in the guid-**

1 ance issued under paragraph (5) with respect to
2 the in-scope devices at issue; and

3 “(C) under which the Secretary shall rely
4 on such certifications for purposes of deter-
5 mining the safety and effectiveness (or as appli-
6 cable, substantial equivalence) of in-scope de-
7 vices subject to the device-related changes in-
8 volved, in lieu of compliance with the following
9 submission requirements:

10 “(i) A premarket notification.

11 “(ii) A thirty-day notice.

12 “(iii) A Special PMA supplement.

13 “(2) DEFINITIONS.—For purposes of this sec-
14 tion—

15 “(A) the term ‘device-related changes’
16 means changes made by a requestor with re-
17 spect to in-scope devices, which are—

18 “(i) changes to a device found to be
19 substantially equivalent under sections
20 513(i) and 510(k) to a predicate device,
21 that—

22 “(I) would otherwise be subject
23 to a premarket notification; and

24 “(II) do not alter—

1 “(aa) the intended use of
2 the changed device; or

3 “(bb) the fundamental sci-
4 entific technology of such device;

5 “(ii) manufacturing changes subject
6 to a 30-day notice;

7 “(iii) changes that qualify for a Spe-
8 cial PMA Supplement; and

9 “(iv) such other changes relating to
10 the devices or the device manufacturing
11 process as the Secretary determines appro-
12 priate;

13 “(B) the term ‘in-scope device’ means a
14 device within the scope of devices agreed to by
15 the requestor and the accredited person for pur-
16 poses of a request for certification under this
17 section;

18 “(C) the term ‘premarket notification’
19 means a premarket notification under section
20 510(k);

21 “(D) the term ‘quality system’ means the
22 methods used in, and the facilities and controls
23 used for, the design, manufacture, packaging,
24 labeling, storage, installation, and servicing of
25 devices, as described in section 520(f);

1 “(E) the term ‘requestor’ means a device
2 manufacturer that is seeking certification under
3 this section of a quality system used by such
4 manufacturer;

5 “(F) the term ‘Special PMA’ means a Spe-
6 cial PMA supplement under section 814.39(d)
7 of title 21, Code of Federal Regulations (or any
8 successor regulations); and

9 “(G) the term ‘thirty-day notice’ means a
10 notice described in section 515(d)(6).

11 “(3) ACCREDITATION PROCESS; ACCREDITATION
12 RENEWAL.—Except as inconsistent with this section,
13 the process and qualifications for accreditation of
14 persons and renewal of such accreditation under sec-
15 tion 704(g) shall apply with respect to accreditation
16 of persons and renewal of such accreditation under
17 this section.

18 “(4) USE OF ACCREDITED PARTIES TO CON-
19 DUCT ASSESSMENTS.—

20 “(A) INITIATION OF ASSESSMENT SERV-
21 ICES.—

22 “(i) DATE ASSESSMENTS AUTHOR-
23 IZED.—Beginning after the date on which
24 the final guidance is issued under para-

1 graph (5), an accredited person may con-
2 duct an assessment under this section.

3 “(ii) INITIATION OF ASSESSMENTS.—
4 Use of one or more accredited persons to
5 assess a requestor’s quality system under
6 this section with respect to in-scope devices
7 shall be at the initiation of the person who
8 registers and lists the devices at issue
9 under section 510.

10 “(B) COMPENSATION.—Compensation for
11 such accredited persons shall—

12 “(i) be determined by agreement be-
13 tween the accredited person and the person
14 who engages the services of the accredited
15 person; and

16 “(ii) be paid by the person who en-
17 gages such services.

18 “(C) ACCREDITED PERSON SELECTION.—
19 Each person who chooses to use an accredited
20 person to assess a requestor’s quality system,
21 as described in this section, shall select the ac-
22 credited person from a list of such persons pub-
23 lished by the Secretary in accordance with sec-
24 tion 704(g)(4).

1 “(5) GUIDANCE; CRITERIA FOR CERTIFI-
2 CATION.—

3 “(A) IN GENERAL.—The criteria for cer-
4 tification of a quality system under this section
5 shall be as specified by the Secretary in guid-
6 ance issued under this paragraph.

7 “(B) CONTENTS; CRITERIA.—The guidance
8 under this paragraph shall include specification
9 of—

10 “(i) evaluative criteria to be used by
11 an accredited person to assess and, as ap-
12 plicable, certify a requestor’s quality sys-
13 tem under this section with respect to in-
14 scope devices; and

15 “(ii) criteria for accredited persons to
16 apply for a waiver of, and exemptions
17 from, the criteria under clause (i).

18 “(C) TIMEFRAME FOR ISSUING GUID-
19 ANCE.—The Secretary shall issue under this
20 paragraph—

21 “(i) draft guidance not later than 12
22 months after the enactment of the 21st
23 Century Cures Act; and

1 “(ii) final guidance not later than 12
2 months after issuance of the draft guid-
3 ance under clause (i).

4 “(b) USE OF THIRD-PARTY ASSESSMENT.—

5 “(1) ASSESSMENT SUMMARY; CERTIFI-
6 CATION.—

7 “(A) SUBMISSION OF ASSESSMENT TO SEC-
8 RETARY.—An accredited person who assesses a
9 requestor’s quality system under subsection (a)
10 shall submit to the Secretary a summary of the
11 assessment—

12 “(i) within 30 days of the assessment;
13 and

14 “(ii) which shall include (as applica-
15 ble)—

16 “(I) the accredited person’s cer-
17 tification that the requestor has satis-
18 fied the criteria specified in the guid-
19 ance issued under subsection (a)(5)
20 for quality system certification with
21 respect to the in-scope devices at
22 issue; and

23 “(II) any waivers or exemptions
24 from such criteria applied by the ac-
25 credited person.

1 “(B) TREATMENT OF ASSESSMENTS.—
2 Subject to action by the Secretary under sub-
3 paragraph (C), with respect to assessments
4 which include a certification under this sec-
5 tion—

6 “(i) the Secretary’s review of the as-
7 sessment summary shall be deemed com-
8 plete on the day that is 30 days after the
9 date on which the Secretary receives the
10 summary under subparagraph (A); and

11 “(ii) the assessment summary and
12 certification of the quality system of a re-
13 questor shall be deemed accepted by the
14 Secretary on such 30th day.

15 “(C) ACTIONS BY SECRETARY.—

16 “(i) IN GENERAL.—Within 30 days of
17 receiving an assessment summary and cer-
18 tification under subparagraph (A), the Sec-
19 retary may, by written notice to the ac-
20 credited person submitting such assess-
21 ment certification, deem any such certifi-
22 cation to be provisional beyond such 30-
23 day period, suspended pending further re-
24 view by the Secretary, or otherwise quali-

1 fied or cancelled, based on the Secretary’s
2 determination that (as applicable)—

3 “(I) additional information is
4 needed to support such certification;

5 “(II) such assessment or certifi-
6 cation is unwarranted; or

7 “(III) such action with regard to
8 the certification is otherwise justified
9 according to such factors and criteria
10 as the Secretary finds appropriate.

11 “(ii) ACCEPTANCE OF CERTIFI-
12 CATION.—If following action by the Sec-
13 retary under clause (i) with respect to a
14 certification, the Secretary determines that
15 such certification is acceptable, the Sec-
16 retary shall issue written notice to the ap-
17 plicable accredited person indicating such
18 acceptance.

19 “(2) NOTIFICATIONS TO SECRETARY BY CER-
20 TIFIED REQUESTORS OR ACCREDITED PERSONS FOR
21 PROGRAM EVALUATION PURPOSES.—

22 “(A) ANNUAL SUMMARY REPORT FOR DE-
23 VICE-RELATED CHANGES OTHERWISE SUBJECT
24 TO PREMARKET NOTIFICATION.—A requestor
25 whose quality system is certified under this sec-

1 tion that effectuates device-related changes with
2 respect to in-scope devices, without prior sub-
3 mission of a premarket notification, shall en-
4 sure that an annual summary report is sub-
5 mitted to the Secretary by the accredited per-
6 son which—

7 “(i) describes the changes made to the
8 in-scope device; and

9 “(ii) indicates the effective dates of
10 such changes.

11 “(B) PERIODIC NOTIFICATION FOR MANU-
12 FACTURING CHANGES OTHERWISE SUBJECT TO
13 THIRTY-DAY NOTICE.—A requestor whose qual-
14 ity system is certified under this section that ef-
15 fectuates device-related changes with respect to
16 in-scope devices, without prior submission of a
17 thirty-day notice, shall provide notification to
18 the Secretary of such changes in the requestor’s
19 next periodic report under section 814.84(b) of
20 title 21, Code of Federal Regulations (or any
21 successor regulation). Such notification shall—

22 “(i) describe the changes made; and

23 “(ii) indicate the effective dates of
24 such changes.

1 “(C) PERIODIC NOTIFICATION FOR DE-
2 VICE-RELATED CHANGES OTHERWISE SUBJECT
3 TO SPECIAL PMA SUPPLEMENT.—A requestor
4 whose quality system is certified under this sec-
5 tion that effectuates device-related changes with
6 respect to in-scope devices, without prior sub-
7 mission of a Special PMA Supplement, shall
8 provide notification to the Secretary of such
9 changes in the requestor’s next periodic report
10 under section 814.84(b) of title 21, Code of
11 Federal Regulations (or any successor regula-
12 tion). Such notification shall—

13 “(i) describe the changes made, in-
14 cluding a full explanation of the basis for
15 the changes; and

16 “(ii) indicate the effective dates of
17 such changes.

18 “(D) USE OF NOTIFICATIONS FOR PRO-
19 GRAM EVALUATION PURPOSES.—Information
20 submitted to the Secretary under subpara-
21 graphs (A) through (C) shall be used by the
22 Secretary for purposes of the program evalua-
23 tion under subsection (d).

24 “(e) DURATION AND EFFECT OF CERTIFICATION.—

25 A certification under this section—

1 “(1) shall remain in effect for a period of 2
2 years from the date such certification is accepted by
3 the Secretary, subject to paragraph (6);

4 “(2) may be renewed through the process de-
5 scribed in subsection (a)(3);

6 “(3) shall continue to apply with respect to de-
7 vice-related changes made during such 2-year period,
8 provided the certification remains in effect, irrespec-
9 tive of whether such certification is renewed after
10 such 2-year period;

11 “(4) shall have no effect on the need to comply
12 with applicable submission requirements specified in
13 subsection (a)(1)(C) with respect to any change per-
14 taining to in-scope devices which is not a device-re-
15 lated change under subsection (a)(2);

16 “(5) shall have no effect on the authority of the
17 Secretary to conduct an inspection or otherwise de-
18 termine whether the requestor has complied with the
19 applicable requirements of this Act; and

20 “(6) may be revoked by the Secretary upon a
21 determination that the requestor’s quality system no
22 longer meets the criteria specified in the guidance
23 issued under subsection (a)(5) with respect to the
24 in-scope devices at issue.

1 “(d) NOTICE OF REVOCATION.—The Secretary shall
2 provide written notification to the requestor of a revoca-
3 tion pursuant to subsection (c)(6) not later than 10 busi-
4 ness days after the determination described in such sub-
5 section. Upon receipt of the written notification, the re-
6 questor shall satisfy the applicable submission require-
7 ments specified in subsection (a)(1)(C) for any device-re-
8 lated changes effectuated after the date of such deter-
9 mination. After such revocation, such requestor is eligible
10 to seek re-certification under this section of its quality sys-
11 tem.

12 “(e) PROGRAM EVALUATION; SUNSET.—

13 “(1) PROGRAM EVALUATION AND REPORT.—

14 “(A) EVALUATION.—The Secretary shall
15 complete an evaluation of the third-party qual-
16 ity system assessment program under this sec-
17 tion no later than January 31, 2021, based
18 on—

19 “(i) analysis of information from a
20 representative group of device manufactur-
21 ers obtained from notifications provided by
22 certified requestors or accredited persons
23 under subsection (b)(2); and

1 “(ii) such other available information
2 and data as the Secretary determines ap-
3 propriate.

4 “(B) REPORT.—No later than 1 year after
5 completing the evaluation under subparagraph
6 (A), the Secretary shall issue a report of the
7 evaluation’s findings on the website of the Food
8 and Drug Administration, which shall include
9 the Secretary’s recommendations with respect
10 to continuation and as applicable expansion of
11 the program under this section to encompass—

12 “(i) device submissions beyond those
13 identified in subsection (a)(1)(C); and

14 “(ii) device changes beyond those de-
15 scribed in subsection (a)(2)(A).

16 “(2) SUNSET.—This section shall cease to be
17 effective October 1, 2022.

18 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-
19 tion shall be construed to limit the authority of the Sec-
20 retary to request and review the complete assessment of
21 a certified requestor under this section on a for-cause
22 basis.”.

23 (b) CONFORMING AMENDMENTS.—

24 (1) REQUIREMENTS FOR PREMARKET AP-
25 PROVAL SUPPLEMENTS.—Section 515(d)(5)(A)(i) of

1 the Federal Food, Drug, and Cosmetic Act (21
2 U.S.C. 360e(d)(5)(A)(i)), as redesignated by section
3 2201, is further amended by inserting “, subject to
4 section 524B” after “that affects safety or effective-
5 ness”.

6 (2) REQUIREMENTS FOR THIRTY-DAY NO-
7 TICE.—Section 515(d)(5)(A)(ii) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C.
9 360e(d)(5)(A)(ii)), as redesignated by section 2201,
10 is further amended by inserting “, subject to section
11 524B” after “the date on which the Secretary re-
12 ceives the notice”.

13 (3) REQUIREMENTS FOR PREMARKET NOTIFI-
14 CATION; TECHNICAL CORRECTION TO REFERENCE
15 TO SECTION 510(K).—Section 510(l) of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is
17 amended by striking “of this subsection under sub-
18 section (m)” and inserting “of subsection (k) under
19 subsection (m) or section 524B”.

20 (4) MISBRANDED DEVICES.—Section 502(t) of
21 the Federal Food, Drug, and Cosmetic Act (21
22 U.S.C. 352(t)) is amended by inserting “or 524B”
23 after “section 519”.

1 **SEC. 2222. VALID SCIENTIFIC EVIDENCE.**

2 Section 513(a)(3)(B) of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 360c(a)(3)(B)) is amended—

4 (1) by redesignating clauses (i) and (ii) as sub-
5 clauses (I) and (II), respectively;

6 (2) by striking “(B) If the Secretary” and in-
7 serting “(B)(i) If the Secretary”; and

8 (3) by adding at the end the following:

9 “(ii) For purposes of clause (i), valid scientific evi-
10 dence may include—

11 “(I) evidence described in well-documented case
12 histories, including registry data, that are collected
13 and monitored under a protocol determined to be ac-
14 ceptable by the Secretary;

15 “(II) studies published in peer-reviewed jour-
16 nals; and

17 “(III) data collected in countries other than the
18 United States so long as such data otherwise meet
19 the criteria specified in this subparagraph.

20 “(iii) In the case of a study published in a peer-re-
21 viewed journal that is offered as valid scientific evidence
22 for purposes of clause (i), the Secretary may request data
23 underlying the study if—

24 “(I) the Secretary, in making such request,
25 complies with the requirement of subparagraph
26 (D)(ii) to consider the least burdensome appropriate

1 means of evaluating device effectiveness or sub-
2 section (i)(1)(D) to consider the least burdensome
3 means of determining substantial equivalence, as ap-
4 plicable;

5 “(II) the Secretary furnishes a written rationale
6 for so requesting the underlying data together with
7 such request; and

8 “(III) if the requested underlying data for such
9 a study are unavailable, the Secretary shall consider
10 such study to be part of the totality of the evidence
11 with respect to the device, as the Secretary deter-
12 mines appropriate.”.

13 **SEC. 2223. TRAINING AND OVERSIGHT IN LEAST BURDEN-**
14 **SOME APPROPRIATE MEANS CONCEPT.**

15 (a) IN GENERAL.—Section 513 of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by
17 adding at the end the following:

18 “(j) TRAINING AND OVERSIGHT IN LEAST BURDEN-
19 SOME APPROPRIATE MEANS CONCEPT.—

20 “(1) TRAINING.—Each employee of the Food
21 and Drug Administration who is involved in the re-
22 view of premarket submissions under section 515 or
23 section 510(k), including supervisors, shall receive
24 training regarding the meaning and implementation
25 of the least burdensome appropriate means concept

1 in the context of the use of that term in subsections
2 (a)(3)(D) and (i)(1)(D) of this section and in section
3 515(c)(5).

4 “(2) GUIDANCE DOCUMENTS.—

5 “(A) DRAFT UPDATED GUIDANCE.—Not
6 later than 12 months after the date of enact-
7 ment of the 21st Century Cures Act, the Sec-
8 retary shall issue a draft guidance document
9 updating the October 4, 2002, guidance docu-
10 ment entitled ‘The Least Burdensome Provision
11 of the FDA Modernization Act of 1997: Con-
12 cept and Principles; Final Guidance for FDA
13 and Industry’.

14 “(B) MEETING OF STAKEHOLDERS.—In
15 developing such draft guidance document, the
16 Secretary shall convene a meeting of stake-
17 holders to ensure a full record to support the
18 publication of such document.

19 “(3) OMBUDSMAN AUDIT.—Not later than 18
20 months after the date of issuance of final version of
21 the draft guidance under paragraph (2), the om-
22 budsman for the organizational unit of the Food and
23 Drug Administration responsible for the premarket
24 review of devices shall—

1 “(A) conduct, or have conducted, an audit
2 of the training described in paragraph (1); and

3 “(B) include in such audit interviews with
4 a representative sample of persons from indus-
5 try regarding their experience in the device pre-
6 market review process.”.

7 (b) **ADDITIONAL INFORMATION REGARDING PRE-**
8 **MARKET APPLICATIONS.**—Subsection (c) of section 515 of
9 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 360e) is amended by adding at the end the following:

11 “(5)(A) Whenever the Secretary requests additional
12 information from an applicant regarding an application
13 under paragraph (1), the Secretary shall consider the least
14 burdensome appropriate means necessary to demonstrate
15 device safety and effectiveness, and request information
16 accordingly.

17 “(B) For purposes of subparagraph (A), the term
18 ‘necessary’ means the minimum required information that
19 would support a determination by the Secretary that an
20 application provides a reasonable assurance of the safety
21 and effectiveness of the device.

22 “(C) Nothing in this paragraph alters the standards
23 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 **TITLE III—DELIVERY**

4 **Subtitle A—Interoperability**

5 **SEC. 3001. ENSURING INTEROPERABILITY OF HEALTH IN-**
6 **FORMATION TECHNOLOGY.**

7 (a) INTEROPERABILITY STANDARDS.—

8 (1) IN GENERAL.—Subtitle A of title XXX of
9 the Public Health Service Act (42 U.S.C. 300jj–11
10 et seq.) is amended by adding at the end the fol-
11 lowing new section:

12 **“SEC. 3010. ENSURING INTEROPERABILITY OF HEALTH IN-**
13 **FORMATION TECHNOLOGY.**

14 “(a) INTEROPERABILITY.—In order for health infor-
15 mation technology to be considered interoperable, such
16 technology must satisfy the following criteria:

17 “(1) SECURE TRANSFER.—The technology al-
18 lows the secure transfer of all electronically acces-
19 sible health information to and from any and all
20 health information technology for authorized use
21 under applicable State or Federal law.

22 “(2) COMPLETE ACCESS TO HEALTH INFORMA-
23 TION.—The technology allows for complete access,
24 exchange, and use of all electronically accessible
25 health information for authorized use under applica-

1 ble State or Federal law without special effort by the
2 requestor of such health information.

3 “(3) NO INFORMATION BLOCKING.—The tech-
4 nology is not configured, set up, or implemented to
5 information block, as defined in section 3010A(d).

6 “(b) CATEGORIES FOR INTEROPERABILITY STAND-
7 ARDS.—The categories described in this subsection, with
8 respect to standards and the corresponding implementa-
9 tion specifications for determining if health information
10 technology is interoperable, consistent with the criteria de-
11 scribed in subsection (a), include at least categories of
12 standards and implementation specifications with respect
13 to the following:

14 “(1) Vocabulary and terminology.

15 “(2) Content and structure.

16 “(3) Transport.

17 “(4) Security.

18 “(5) Services.

19 “(6) Querying and requesting health informa-
20 tion for access, exchange, and use.

21 “(c) ALLOWING FOR FLEXIBILITY.—A standard and
22 implementation specification, with respect to such stand-
23 ard, that is determined under section 3001(e)(5)(D) to be
24 compatible with baseline standards and implementation

1 specifications (as defined in clause (ii) of such section)
2 shall be treated as in compliance with this section.”.

3 (2) GUIDANCE.—Not later than January 1,
4 2017, the Secretary of Health and Human Services,
5 in consultation with the National Coordinator of the
6 Office of the National Coordinator for Health Infor-
7 mation Technology, shall issue guidance with respect
8 to the implementation of section 3010 of the Public
9 Health Service Act, as added by paragraph (1), in-
10 cluding with respect to defining and providing exam-
11 ples of authorized use under applicable State or
12 Federal law of health information.

13 (b) IMPROVEMENTS TO RECOMMENDATION PROC-
14 ESS.—

15 (1) HIT POLICY COMMITTEE TO INCORPORATE
16 POLICIES FOR UPDATES TO INTEROPERABILITY
17 STANDARDS.—Section 3002 of the Public Health
18 Service Act (42 U.S.C. 300jj–12) is amended—

19 (A) in subsection (a)—

20 (i) by striking “National Coordinator”
21 and inserting “Secretary, in consultation
22 with the National Coordinator,”; and

23 (ii) by adding at the end the following
24 new sentence: “The HIT Policy Committee
25 is authorized only to provide policy and

1 priority recommendations to the Secretary
2 and not authorized to otherwise affect the
3 development or modification of any stand-
4 ard, implementation specification, or cer-
5 tification criterion under this title.”; and

6 (B) in subsection (b)(2)—

7 (i) in subparagraph (A), in the first
8 sentence—

9 (I) by striking “The HIT Policy
10 Committee” and inserting “Subject to
11 subparagraph (D), the HIT Policy
12 Committee”; and

13 (II) by inserting “(including the
14 areas in which modifications and addi-
15 tions to interoperability standards and
16 implementation specifications, with re-
17 spect to such interoperability stand-
18 ards, under section 3010 are needed
19 for the electronic access, exchange,
20 and use of health information for pur-
21 poses of adoption of such modifica-
22 tions and additions under section
23 3004)” after “section 3004”.

24 (ii) by adding at the end the following
25 new subparagraph:

1 ards development organizations accredited by the
2 American National Standards Institute (or with the
3 American National Standards Institute) to carry
4 out, directly or through contracts with subcontractors,
5 the duties described in subsection (b), as applicable.
6 cable.

7 “(2) TIMING FOR FIRST CONTRACT.—As soon
8 as practicable after the date of the enactment of this
9 section, the Secretary shall enter into the first contracts
10 under paragraph (1).

11 “(3) PERIOD OF CONTRACT.—Each contract
12 under paragraph (1) shall be for a period determined
13 necessary by the Secretary, in consultation with the
14 National Coordinator, to carry out the applicable duties
15 described in subsection (b).

16 “(4) APPROPRIATE ENTITIES.—The Secretary
17 shall ensure the most appropriate entities described
18 in paragraph (1) are selected for each contract
19 under such paragraph.

20 “(b) DUTIES.—

21 “(1) INITIAL CONTRACT.—The Secretary shall
22 initially enter into one or more contracts under subsection
23 (a)(1) with entities described in such subsection,
24 under which the entities—

25 “(A) shall recommend to the Secretary—

1 “(i) for adoption under section 3004,
2 an initial set of interoperability standards
3 and implementation specifications, with re-
4 spect to such standards, identified or, as
5 appropriate, developed by such entities
6 that are consistent with the criteria de-
7 scribed in subsection (a) of section 3010,
8 and with respect to the categories de-
9 scribed in subsection (b) of such section;
10 and

11 “(ii) as applicable, for purposes of
12 section 3001(c)(5)(D), methods to test if
13 health information technology is compat-
14 ible with health information technology
15 that applies baseline standards and imple-
16 mentation specifications (as defined in
17 clause (ii) of such section); and

18 “(B) may provide to the Secretary rec-
19 ommendations described in paragraph (2).

20 “(2) SUBSEQUENT CONTRACTS.—Under each
21 subsequent contract entered into under this section
22 with entities described in subsection (a)(1) pursuant
23 to subsection (c), the entities shall recommend to the
24 Secretary—

1 “(A) for adoption under section 3004 any
2 standards (including interoperability stand-
3 ards), implementation specifications, and, to the
4 extent necessary, certification criteria (and
5 modifications, including additions, to such
6 standards, specifications, and, to the extent
7 necessary, criteria), which are in accordance
8 with the criteria described in section 3010; and

9 “(B) as applicable, for purposes of section
10 3001(c)(5)(D), methods to test if health infor-
11 mation technology is compatible with baseline
12 standards and implementation specifications (as
13 defined in clause (ii) of such section).

14 “(3) SUBMISSION TO NIST.—Under each con-
15 tract with an entity under this section, the entity
16 shall submit to the Director of the National Institute
17 of Standards and Technology each recommendation
18 submitted to the Secretary by such entity under this
19 section.

20 “(4) CONSULTATION.—For the purposes of de-
21 veloping methods to test interoperability standards
22 and implementation specifications with respect to
23 such standards, the entities with a contract under
24 this section may consult with the Director of the Na-
25 tional Institute of Standards and Technology.

1 “(c) MODIFICATIONS AND SUBSEQUENT CON-
2 TRACTS.—

3 “(1) IN GENERAL.—The Secretary, in consulta-
4 tion with the National Coordinator, shall periodically
5 conduct hearings to evaluate and review the stand-
6 ards, implementation specifications, and certification
7 criteria adopted under section 3004 for purposes of
8 determining if modifications, including any addi-
9 tions, are needed with respect to such standards,
10 specifications, and criteria.

11 “(2) CONTRACT TRIGGER.—Based on the needs
12 for standards, implementation specifications, and
13 certification criteria (and modifications, including
14 additions, to such standards, specifications, and cri-
15 teria) under this title, as determined by the Sec-
16 retary, with due consideration to section 3010(b)
17 and in consultation with the National Coordinator,
18 the Secretary shall, as needed, enter into contracts
19 under subsection (a) to carry out the duties de-
20 scribed in subsection (b)(2) in addition to any con-
21 tract entered into to carry out the duties described
22 in subsection (b)(1).

23 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
24 is authorized to be appropriated \$10,000,000 for contracts
25 under subsection (a), to remain available until expended.”.

1 (4) MODIFICATIONS TO ROLE OF THE NA-
2 TIONAL COORDINATOR.—Section 3001(c)(1)(A) of
3 the Public Health Service Act (42 U.S.C. 300jj–
4 11(c)(1)(A)) is amended by inserting “for rec-
5 ommendations made before the date of the enact-
6 ment of the 21st Century Cures Act,” before “review
7 and determine”.

8 (c) ADOPTION.—Section 3004 of the Public Health
9 Service Act (42 U.S.C. 300jj–14) is amended—

10 (1) in subsection (a)—

11 (A) in paragraph (1), by inserting after
12 “section 3001(c)” the following: “(or, subject to
13 subsection (c), in the case of a standard, imple-
14 mentation specification, or criterion rec-
15 ommended on or after the date of the enact-
16 ment of the 21st Century Cures Act, after the
17 date of submission of the recommendation to
18 the Secretary under section 3003A)”; and

19 (B) in paragraph (2)(B), by striking “and
20 the HIT Standards Committee”;

21 (2) in subsection (b)—

22 (A) in paragraph (3), by striking “with the
23 schedule published under section 3003(b)(2)”
24 and inserting “with subsection (d)”; and

1 (B) by adding at the end the following new
2 paragraph:

3 “(4) LIMITATION.—The Secretary may not
4 adopt any policies, priorities, standards, implementa-
5 tion specifications, or certification criteria under this
6 subsection or subsection (a) that are inconsistent
7 with or duplicative of an interoperability standard or
8 implementation specification with respect to such
9 standard adopted under this section, in accordance
10 with subsections (c) and (d). In the case of a stand-
11 ard, specification, or criterion that has been adopted
12 under this section and is inconsistent or duplicative
13 of such an interoperability standard or specification
14 that is subsequently adopted under this section, such
15 interoperability standard or specification shall
16 supercede such other standard, specification, or cri-
17 terion and such other standard, specification, or cri-
18 terion shall no longer be considered adopted under
19 this section beginning on the date that such inter-
20 operability standard or specification becomes effec-
21 tive.”; and

22 (3) by adding at the end the following new sub-
23 sections:

24 “(c) ADOPTION OF INITIAL INTEROPERABILITY
25 STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—

1 Notwithstanding the previous subsections of this section,
2 the following shall apply in the case of the initial set of
3 interoperability standards and implementation specifica-
4 tions with respect to such standards recommended under
5 section 3003A:

6 “(1) REVIEW OF STANDARDS.—Not later than
7 90 days after the date of receipt of recommendations
8 for such interoperability standards and implementa-
9 tion specifications, the Secretary, in consultation
10 with the National Coordinator and representatives of
11 other relevant Federal agencies, such as the Na-
12 tional Institute of Standards and Technology, shall
13 jointly review such standards and implementation
14 specifications and shall determine whether or not to
15 propose adoption of such standards and implementa-
16 tion specifications.

17 “(2) DETERMINATION TO ADOPT.—If, subject
18 to subsection (d)(3), the Secretary determines—

19 “(A) to propose adoption of such standards
20 and implementation specifications, the Sec-
21 retary shall, by regulation under section 553 of
22 title 5, United States Code, determine whether
23 or not to adopt such standards and implemen-
24 tation specifications; or

1 “(B) not to propose adoption of such
2 standards and implementation specifications,
3 the Secretary shall notify the applicable entity
4 with a contract under section 3003A in writing
5 of such determination and the reasons for not
6 proposing the adoption of the recommendation
7 for such standards and implementation speci-
8 fications.

9 “(3) PUBLICATION.—The Secretary shall pro-
10 vide for publication in the Federal Register of all de-
11 terminations made by the Secretary under para-
12 graph (1).

13 “(d) RULES FOR ADOPTION.—In the case of a stand-
14 ard (including interoperability standard), implementation
15 specification, or certification criterion adopted under this
16 section on or after the date of the enactment of the 21st
17 Century Cures Act, the following shall apply:

18 “(1) IN GENERAL.—Except as provided in para-
19 graphs (2) and (3), any such standard (including
20 interoperability standard), implementation specifica-
21 tion, or certification criterion shall be a standard,
22 specification, or criterion that has been rec-
23 ommended by the entities with which the Secretary
24 has entered into a contract under section 3003A.

1 “(2) SPECIAL RULE IF NO STANDARD, SPECI-
2 FICATION, OR CRITERION RECOMMENDED.—If no
3 standard, implementation specification, or, to the ex-
4 tent necessary, certification criterion is rec-
5 ommended under paragraph (1)—

6 “(A) in the case of interoperability stand-
7 ards and implementation specifications with re-
8 spect to such standards, relating to a category
9 described in section 3010(b)—

10 “(i) paragraph (1) shall not apply;

11 and

12 “(ii) paragraph (4) shall apply; or

13 “(B) in the case of any other standard, im-
14 plementation specification, or, to the extent nec-
15 essary, certification criterion, relating to a pol-
16 icy or priority to carry out this title, as deter-
17 mined by the Secretary, in consultation with the
18 National Coordinator—

19 “(i) paragraph (1) shall not apply;

20 and

21 “(ii) paragraph (4) shall apply.

22 “(3) AUTHORITY TO MODIFY IMPLEMENTATION
23 SPECIFICATIONS.—If, following public comment pur-
24 suant to subsection (c), the Secretary would propose
25 adoption of interoperability standards recommended

1 under section 3003A but for the implementation
2 specifications, with respect to such standards, so
3 recommended, the Secretary may modify such imple-
4 mentation specifications and adopt such standards
5 and specifications in accordance with subsection
6 (c)(2).

7 “(4) EFFECTIVE DATE.—In the case of a
8 standard, implementation specification, or certifi-
9 cation criterion for which there is a determination to
10 adopt such standard, implementation specification,
11 or certification criterion, such standard, implementa-
12 tion specification, or certification criterion shall be
13 considered adopted under this section and shall be
14 effective beginning on the date that is 12 months
15 after the date of publication of the final rule to
16 adopt such standard, implementation specification,
17 or certification criterion.

18 “(5) ASSISTANCE TO THE SECRETARY.—In
19 complying with the requirements of this subsection,
20 the Secretary shall give due consideration to any rec-
21 ommendations of the National Committee on Vital
22 and Health Statistics established under section
23 306(k), and shall consult with appropriate Federal
24 and State agencies and private organizations. The
25 Secretary shall publish in the Federal Register any

1 recommendation of the National Committee on Vital
2 and Health Statistics regarding the adoption of a
3 standard, implementation specification, or certifi-
4 cation criterion under this section. Any standard,
5 implementation specification, or certification cri-
6 terion adopted pursuant to this paragraph shall be
7 promulgated in accordance with the rulemaking pro-
8 cedures of subchapter III of chapter 5 of title 5,
9 United States Code.

10 “(e) ALLOWING FOR FLEXIBILITY THROUGH COM-
11 PATIBILITY WITH BASELINE STANDARDS AND IMPLE-
12 MENTATION SPECIFICATIONS.—For purposes of this title,
13 title XVIII of the Social Security Act, title XIX of such
14 Act, and any other provision of law, a standard and imple-
15 mentation specification, with respect to such standard,
16 that is determined under section 3001(e)(5)(D) to be com-
17 patible with baseline standards and implementation speci-
18 fications (as defined in clause (ii) of such section) shall
19 be treated as if such standard and specification were an
20 interoperability standard and implementation specifica-
21 tion, with respect to such interoperability standard, adopt-
22 ed under this section.”

23 (d) REPORTS AND NOTIFICATIONS.—Section 3010 of
24 the Public Health Service Act, as added by subsection (a),

1 is amended by adding at the end the following new sub-
2 section:

3 “(c) DISSEMINATION OF INFORMATION.—

4 “(1) INITIAL SUMMARY REPORT.—Not later
5 than July 1, 2017, the Secretary, after consultation
6 with relevant stakeholders, shall submit to Congress
7 and provide for publication in the Federal Register
8 and the posting on the Internet website of the Office
9 of the National Coordinator for Health Information
10 Technology a report on the following:

11 “(A) The initial set of interoperability
12 standards and implementation specifications
13 adopted under section 3004(c).

14 “(B) The strategies for achieving wide-
15 spread interoperability.

16 “(C) Any barriers that are preventing
17 widespread interoperability.

18 “(D) The plan and milestones, including
19 specific steps, to achieve widespread interoper-
20 ability.

21 “(2) ONGOING PUBLICATION OF RECOMMENDA-
22 TIONS.—The Secretary shall provide for publication
23 in the Federal Register, and the posting on the
24 Internet website of the Office of the National Coor-

1 dinator for Health Information Technology, of all
2 recommendations made under this section.”.

3 (e) CERTIFICATION AND OTHER ENFORCEMENT
4 PROVISIONS.—

5 (1) CERTIFICATION OF QUALIFIED ELECTRONIC
6 HEALTH RECORDS.—

7 (A) IN GENERAL.—Section 3007(b) of the
8 Public Health Service Act (42 U.S.C. 300jj–
9 17(b)) is amended by striking “under section
10 3001(c)(3) to be in compliance with” and all
11 that follows through the period at the end and
12 inserting “under section 3001(c)(3)—

13 “(1) for certifications made before January 1,
14 2018, to be in compliance with applicable standards
15 adopted under subsections (a) and (b) of section
16 3004; and

17 “(2) for certifications made on or after January
18 1, 2018, to be in compliance with applicable stand-
19 ards adopted under subsections (a) and (b) of sec-
20 tion 3004 and to be interoperable in accordance with
21 section 3010 and in compliance with interoperability
22 standards adopted under section 3004.”.

23 (B) REQUIREMENTS OF SECRETARY.—Sec-
24 tion 3001(c)(5) of the Public Health Service
25 Act (42 U.S.C. 300jj–11(c)(5)) is amended—

1 (i) in subparagraph (B), by inserting
2 before the period at the end the following:
3 “and, for certifications made on or after
4 January 1, 2018, with respect to health in-
5 formation technology, additional criteria to
6 establish that the technology is interoper-
7 able, in accordance with section 3010, and
8 in compliance with interoperability stand-
9 ards and implementation specifications,
10 with respect to such standards, adopted
11 under section 3004”; and

12 (ii) by adding at the end the following
13 new subparagraphs:

14 “(C) ENFORCEMENT;
15 DECERTIFICATIONS.—

16 “(i) REQUIREMENTS.—Under any
17 program kept or recognized under subpara-
18 graph (A), the Secretary shall ensure that
19 any vendor of or other entity offering to
20 health care providers (as defined in section
21 3010A(g)) qualified electronic health
22 records seeking a certification of such
23 records under such program on or after
24 January 1, 2018, shall, as a condition of
25 certification (and maintenance of certifi-

1 cation) of such a record under such pro-
2 gram—

3 “(I) provide to the Secretary an
4 attestation—

5 “(aa) the entity has imple-
6 mented interoperability standards
7 and implementation specifica-
8 tions, with respect to such stand-
9 ards, adopted under section 3004
10 (including through application of
11 subsection (e) of such section);

12 “(bb) that the entity, unless
13 for a legitimate purpose specified
14 by the Secretary, has not taken
15 and will not take any action that
16 constitutes information blocking
17 (as defined in section 3010A(d)),
18 with respect to such qualified
19 electronic health records;

20 “(cc) that includes the prie-
21 ing information described in
22 clause (iii) for purposes of inclu-
23 sion under subsection (f) of such
24 information on the Internet
25 website of the Department of

1 Health and Human Services; that
2 such information will be available
3 on a public Internet website of
4 such entity; and that the entity
5 will voluntarily provide such in-
6 formation to customers prior to
7 offering any qualified electronic
8 health records or related product
9 or service (including subsequent
10 updates, add-ons, or additional
11 products or services to be pro-
12 vided during the course of an on-
13 going contract), prospective cus-
14 tomers (such as persons who re-
15 quest or receive a quotation or
16 estimate), and other persons who
17 request such information;

18 “(dd) that the technology
19 with respect to such records has
20 published application program-
21 ming interfaces, with respect to
22 health information within such
23 records, for search and indexing,
24 semantic harmonization and vo-

1 cabulary translation, and user
2 interface applications;

3 “(ee) that the entity has
4 successfully and rigorously tested
5 the real world use of the record
6 in the type of setting in which it
7 would be marketed; and

8 “(ff) that the entity has in
9 place data sharing programs or
10 capabilities based on common
11 data elements through such
12 mechanisms as application pro-
13 gramming interfaces without the
14 requirement for vendor-specific
15 interfaces;

16 “(II) publish application pro-
17 gramming interfaces and associated
18 documentation, with respect to health
19 information within such records, for
20 search and indexing, semantic harmo-
21 nization and vocabulary translation,
22 and user interface applications; and

23 “(III) demonstrate to the satis-
24 faction of the Secretary that health
25 information from such records are

1 able to be exchanged, accessed, and
2 used through the use of application
3 programming interfaces without spe-
4 cial effort, as authorized under appli-
5 cable law.

6 “(ii) DECERTIFICATION.—Under any
7 program kept or recognized under subpara-
8 graph (A), the Secretary shall ensure that
9 beginning January 1, 2019, any qualified
10 electronic health records that do not sat-
11 isfy the certification criteria described in
12 subparagraph (B) or with respect to which
13 the vendor or other entity described in
14 clause (i) does not satisfy the requirements
15 under such clause (or is determined to be
16 in violation of the terms of the attestation
17 or other requirements under such clause)
18 shall no longer be considered as certified
19 under such program.

20 “(iii) PRICING INFORMATION.—For
21 purposes of clause (i)(I)(cc), the pricing in-
22 formation described in this clause, with re-
23 spect to a vendor of or other entity offer-
24 ing a qualified electronic health record, is
25 the following:

1 “(I) Additional types of costs or
2 fees (whether fixed, recurring, trans-
3 action based, or otherwise) imposed by
4 the entity (or any third-party from
5 whom the entity purchases, licenses,
6 or obtains any technology, products,
7 or services in connection with the
8 qualified electronic health record) to
9 purchase, license, implement, main-
10 tain, upgrade, use, or otherwise enable
11 and support the use of capabilities to
12 which such record is to be certified
13 under this section; or in connection
14 with any health information generated
15 in the course of using any capability
16 to which the record is to be so cer-
17 tified.

18 “(II) Limitations, whether by
19 contract or otherwise, on the use of
20 any capability to which the record is
21 to be certified under this section for
22 any purpose within the scope of the
23 record’s certification; or in connection
24 with any health information generated
25 in the course of using any capability

1 to which the record is to be certified
2 under this section.

3 “(III) Limitations, including
4 technical or practical limitations of
5 technology or its capabilities, that
6 could prevent or impair the successful
7 implementation, configuration,
8 customization, maintenance, support,
9 or use of any capabilities to which the
10 record is to be certified under this
11 section; or that could prevent or limit
12 the access, use, exchange, or port-
13 ability of any health information gen-
14 erated in the course of using any ca-
15 pability to which the record is to be so
16 certified.

17 “(D) FLEXIBILITY THROUGH COMPAT-
18 IBILITY.—

19 “(i) IN GENERAL.—Under any pro-
20 gram kept or recognized under subpara-
21 graph (A), the Secretary shall provide for
22 a method and process by which a vendor of
23 or other entity offering to health care pro-
24 viders (as defined in section 3010A(g))
25 qualified electronic health records seeking

1 a certification of such records under such
2 program on or after January 1, 2018, may
3 demonstrate, using such mechanisms as a
4 reference implementation model or other
5 means, that the standards and implemen-
6 tation specifications applied by such entity
7 with respect to such records are compatible
8 with baseline standards and implementa-
9 tion specifications, including by dem-
10 onstrating such records are able to trans-
11 mit information that is compatible with
12 qualified electronic health records that
13 would receive such information and that
14 apply the baseline standards and imple-
15 mentation specifications. Such a method
16 and process shall ensure that any such en-
17 tity using a standard or implementation
18 specification other than a baseline stand-
19 ard or implementation specification dem-
20 onstrates, through testing, compatibility
21 with the baseline standard and implemen-
22 tation specification with respect to receiv-
23 ing information.

24 “(ii) BASELINE STANDARDS AND IM-
25 PLEMENTATION SPECIFICATIONS.—For

1 purposes of clause (i), the term ‘baseline
2 standards and implementation specifica-
3 tions’ means the interoperability standards
4 and implementation specifications, with re-
5 spect to such standards, adopted under
6 section 3004 (without application of sub-
7 section (e) of such section).”.

8 (2) ADDITIONAL ENFORCEMENT PROVISIONS
9 UNDER THE PUBLIC HEALTH SERVICE ACT.—Sub-
10 title A of title XXX of the Public Health Service Act
11 (42 U.S.C. 300jj–11 et seq.), as amended by sub-
12 sections (a)(1) and (d), is further amended by add-
13 ing at the end the following new section:

14 **“SEC. 3010A. ENFORCEMENT MECHANISMS.**

15 “(a) INSPECTOR GENERAL AUTHORITY.—The In-
16 spector General of the Department of Health and Human
17 Services shall have the authority to investigate claims of—

18 “(1)(A) vendors of, or other entities offering to
19 health care providers (as defined in subsection (g)),
20 qualified electronic health records (as defined in sec-
21 tion 3000(13)) being in violation of an attestation
22 (whether providing false information at the time of
23 such attestation or by act or practice conducted
24 after such attestation) made under section
25 3001(e)(5)(C)(i)(I), with respect to the use of such

1 records by a health care provider with respect to
2 items and services furnished under the Medicare
3 program under title XVIII of the Social Security Act
4 or Medicaid program under title XIX of such Act;
5 and

6 “(B) vendors of, or other entities offering to
7 health care providers (as defined in subsection (g)),
8 health information technology having engaged in in-
9 formation blocking (as defined in subsection (d)),
10 unless for a legitimate purpose specified by the Sec-
11 retary, with respect to the use of such technology by
12 a health care provider with respect to items and
13 services furnished under such a program;

14 “(2) health care providers having engaged in in-
15 formation blocking (as so defined), with respect to
16 the use of health information technology with re-
17 spect to items and services furnished under such a
18 program, unless for a legitimate purpose specified by
19 the Secretary; and

20 “(3) health information system providers (such
21 as operators of health information exchanges, clin-
22 ical data registries, and other systems that facilitate
23 the exchange of information) having engaged in in-
24 formation blocking (as so defined), unless for a le-
25 gitimate purpose specified by the Secretary, with re-

1 spect to the use of health information technology
2 with respect to items and services furnished under
3 such a program.

4 “(b) INFORMATION SHARING PROVISIONS.—

5 “(1) IN GENERAL.—The National Coordinator
6 may serve as a technical consultant to the Inspector
7 General of the Department of Health and Human
8 Services and the Federal Trade Commission for pur-
9 poses of carrying out this section. As such technical
10 consultant, the National Coordinator may, notwith-
11 standing any other provision of law, share informa-
12 tion related to claims or investigations under sub-
13 section (a) with the Federal Trade Commission for
14 purposes of such investigations and shall share in-
15 formation with the Inspector General, as required by
16 law.

17 “(2) PROTECTION FROM DISCLOSURE OF IN-
18 FORMATION.—Any information that is received by
19 the National Coordinator in connection with a claim
20 or suggestion of possible information blocking and
21 that could reasonably be expected to facilitate identi-
22 fication of the source of the information—

23 “(A) shall not be disclosed by the National
24 Coordinator except as may be necessary to
25 carry out the purpose of this section; and

1 “(B) shall be exempt from mandatory dis-
2 closure under section 552 of title 5, United
3 States Code, as provided by subsection (b)(3) of
4 such section.

5 Such information may be used by the Inspector Gen-
6 eral of the Department of Health and Human Serv-
7 ices or Federal Trade Commission for reporting pur-
8 poses to the extent that such information could not
9 reasonably be expected to facilitate identification of
10 the source of such information.

11 “(3) NON-APPLICATION OF PAPERWORK REDUC-
12 TION ACT.—Chapter 35 of title 44, United States
13 Code (commonly referred to as the Paperwork Re-
14 duction Act of 1995) shall not apply to the National
15 Coordinator or to the Office of the National Coordi-
16 nator for Health Information Technology with re-
17 spect to the collection of complaints relating to
18 claims described in subsection (a).

19 “(4) STANDARDIZED PROCESS.—The National
20 Coordinator shall implement a standardized process
21 for the public to submit reports on claims of—

22 “(A) health information technology prod-
23 ucts of vendors (or other entities offering such
24 products to health care providers (as defined in

1 subsection (g)) not being interoperable or re-
2 sulting in information blocking; or

3 “(B) actions by such entities, health care
4 providers, or health information system pro-
5 viders that result in such technology not being
6 interoperable or in information blocking with
7 respect to such technology; and

8 “(C) any other act described in subsection
9 (a).

10 The standardized process shall provide for the collec-
11 tion of such information as the originating institu-
12 tion, location, type of transaction, system and
13 version, timestamp, terminating institution, loca-
14 tions, system and version, failure notice, and other
15 related information.

16 “(c) PENALTY.—

17 “(1) IN GENERAL.—Any person or entity de-
18 scribed in paragraph (1), (2), or (3) of subsection
19 (a) determined to have committed on or after Janu-
20 ary 1, 2018, an act described in such respective
21 paragraph with respect to the use of a qualified elec-
22 tronic health record or health information tech-
23 nology, as applicable under such respective para-
24 graph, with respect to items and services furnished
25 under the Medicare program under title XVIII of

1 the Social Security Act or the Medicaid program
2 under title XIX of such Act, shall be subject to a
3 civil monetary penalty in such amount as determined
4 appropriate by the Secretary through rulemaking.

5 “(2) APPLICATION.—Subject to paragraph (3),
6 the provisions of section 1128A (other than sub-
7 sections (a) and (b)) of such Act (42 U.S.C. 1320a-
8 7a) shall apply to a civil money penalty applied
9 under this subsection in the same manner as they
10 apply to a civil money penalty or proceeding under
11 subsection (a) of such section 1128A.

12 “(3) RECOVERY OF FUNDS.—Notwithstanding
13 section 3302 of title 31, United States Code, or any
14 other provision of law affecting the crediting of col-
15 lections, the Inspector General of the Department of
16 Health and Human Services may receive and retain
17 for current use any amounts recovered under this
18 subsection. In addition to amounts otherwise avail-
19 able to the Inspector General, funds received by the
20 Inspector General under this paragraph shall be de-
21 posited, as an offsetting collection, to the credit of
22 any appropriation available for purposes of carrying
23 out this subsection and subsection (a) and shall be
24 available without fiscal year limitation and without
25 further appropriation.

1 “(d) INFORMATION BLOCKING.—

2 “(1) IN GENERAL.—For purposes of this sec-
3 tion and section 3010, subject to paragraph (3), the
4 term ‘information blocking’ means, with respect to
5 the access, use, and exchange of qualified electronic
6 health records and other health information tech-
7 nology, business, technical, and organizational prac-
8 tices, including practices described in paragraph (2),
9 that—

10 “(A) prevent or materially discourage the
11 access, exchange, or use of electronic health in-
12 formation; and

13 “(B) the actor knows or should know (as
14 defined in section 1128A(i)(7) of the Social Se-
15 curity Act) are likely to interfere with the ac-
16 cess, exchange, or use of electronic health infor-
17 mation.

18 “(2) PRACTICES DESCRIBED.—For purposes of
19 paragraph (1), the practices described in this para-
20 graph shall include the following:

21 “(A) Contract terms, policies, or business
22 or organizational practices that restrict author-
23 ized use under applicable State or Federal law
24 of electronic health information or restrict the
25 authorized exchange under applicable State or

1 Federal law of such information for treatment
2 and other permitted purposes under such appli-
3 cable law, including transitions between cer-
4 tified EHR technologies.

5 “(B) Charging unreasonable prices or fees
6 (such as for health information exchange, port-
7 ability, interfaces, and full export of health in-
8 formation) that make accessing, exchanging, or
9 using electronic health information cost prohibi-
10 tive.

11 “(C) Developing or implementing health
12 information technology in nonstandard ways
13 that are likely to substantially increase the
14 costs, complexity, or burden of sharing elec-
15 tronic health information, especially in cases in
16 which relevant interoperability standards or
17 methods to measure interoperability have been
18 adopted by the Secretary.

19 “(D) Developing or implementing health
20 information technology in ways that are likely
21 to lock in users or electronic health information,
22 such as not allowing for the full export of
23 health information; lead to fraud, waste, or
24 abuse; or impede innovations and advancements
25 in health information access, exchange, and use,

1 including health information technology-enabled
2 care delivery.

3 “(3) EXCEPTIONS.—

4 “(A) IN GENERAL.—The term ‘information
5 blocking’ shall not include practices that—

6 “(i) are required by applicable law; or

7 “(ii) that the Secretary, through regu-
8 lation, identifies as necessary to protect
9 patient safety, to maintain the privacy or
10 security of individuals’ health information,
11 or to promote competition and consumer
12 welfare.

13 “(B) PROCESS.—For purposes of subpara-
14 graph (A)(ii), not later than 12 months after
15 the date of the enactment of this section, the
16 Secretary shall issue regulations following the
17 notice and comment procedures of section 553
18 of title 5, United States Code, except that the
19 Secretary may issue the first such regulation as
20 an interim final regulation.

21 “(C) NO ENFORCEMENT BEFORE EXCEP-
22 TIONS IDENTIFIED.—The term ‘information
23 blocking’ shall not include any practice or con-
24 duct occurring before the date that is 30 days
25 after the date on which the first regulation (as

1 described in subparagraph (B)) is issued under
2 such subparagraph.

3 “(D) CONSULTATION.—To the extent that
4 regulations issued under this paragraph define
5 practices that are necessary to promote com-
6 petition and consumer welfare, the Secretary
7 may consult with the Federal Trade Commis-
8 sion in issuing such regulations.

9 “(E) APPLICATION.—The term ‘informa-
10 tion blocking’, with respect to an individual or
11 entity, shall not include an act or practice other
12 than an act or practice committed by such indi-
13 vidual or entity.

14 “(e) TREATMENT OF VENDORS WITH RESPECT TO
15 PATIENT SAFETY ORGANIZATIONS.—In applying part C
16 of title IX—

17 “(1) vendors shall be treated as a provider (as
18 defined in section 921) for purposes of reporting re-
19 quirements under such part, to the extent that such
20 reports are related to attestation requirements under
21 section 3001(c)(5)(C)(i)(I);

22 “(2) claims of information blocking described in
23 subsection (a) shall be treated as a patient safety ac-
24 tivity under such part for purposes of reporting re-
25 quirements under such part; and

1 “(3) health care providers that are not mem-
2 bers of patient safety organizations shall be treated
3 in the same manner as health care providers that
4 are such members for purposes of such reporting re-
5 quirements with respect to claims of information
6 blocking described in subsection (a).

7 “(f) RULEMAKING AND GUIDANCE.—

8 “(1) IN GENERAL.—Not later than 12 months
9 after the date of the enactment of this section, the
10 Secretary, in consultation with the National Coordi-
11 nator and the Inspector General of the Department
12 of Health and Human Services, shall, through rule-
13 making, implement the provisions of section 3001 of
14 the 21st Century Cures Act, including amendments
15 made by such section, relating to information block-
16 ing.

17 “(2) NON-DUPLICATION OF PENALTY STRUC-
18 TURES.—In carrying out paragraph (1), in deter-
19 mining the scope of penalties, assessments, or exclu-
20 sions under such section 3001, including amend-
21 ments made by such section, relating to information
22 blocking, the Secretary shall ensure to the extent
23 possible that such penalties, assessments, and exclu-
24 sions do not duplicate penalty, assessment, and ex-
25 clusion structures that would otherwise apply with

1 respect to information blocking and the type of indi-
2 vidual or entity involved as of the day before the
3 date of the enactment of this section.

4 “(3) CLARIFICATION.—In carrying out para-
5 graph (1), the Secretary shall ensure that health
6 care providers are not penalized for actions of ven-
7 dor of, and other entities offering to such providers,
8 health information technology for the failure of such
9 technology to meet requirements for such technology
10 to be certified under this title.

11 “(4) GUIDANCE RELATING TO HIPAA.—Not
12 later than January 1, 2017, the National Coordi-
13 nator shall publish guidance to clarify the relation-
14 ship of the provisions of the HIPAA privacy and se-
15 curity law, as defined in section 3009(a)(2) to infor-
16 mation blocking, including—

17 “(A) examples of how such provisions may
18 result in information blocking; and

19 “(B) clarifying that a health care provider
20 (as defined in subsection (g)) who discloses
21 health information as allowed under applicable
22 State and Federal law is not liable for unlawful
23 actions, including breaches that occur in the
24 custody of the recipient unless the disclosure
25 proximately cause the breach.

1 “(g) HEALTH CARE PROVIDER DEFINED.—For pur-
2 poses of this section, the term ‘health care provider’ means
3 a provider of services under subsection (u) of section 1861
4 of the Social Security Act and a supplier under subsection
5 (d) of such section.

6 “(h) AUTHORIZATION OF APPROPRIATIONS.—In ad-
7 dition to amounts made available under subsection (c)(3),
8 there is authorized to be appropriated \$10,000,000 for fis-
9 cal year 2017 to carry out subsection (a), to remain avail-
10 able until expended.”.

11 (3) POSTINGS RELATING TO ENFORCEMENT ON
12 HHS INTERNET WEBSITE.—Section 3001 of the
13 Public Health Service Act (42 U.S.C. 300jj–11) is
14 amended by adding at the end the following new
15 subsection:

16 “(f) ENFORCEMENT INFORMATION POSTED ON HHS
17 INTERNET WEBSITE.—

18 “(1) PRICING INFORMATION.—Not later than
19 January 1, 2019, the National Coordinator shall
20 post the information described in subsection
21 (c)(5)(C)(I)(i)(cc) on the public Internet website of
22 the Office of the National Coordinator for Health
23 Information Technology in a manner that allows for
24 comparison of functionality, price information, and
25 other features among health information technology

1 products that aids in making informed decisions for
2 purchasing such a product.

3 “(2) ANNUAL POSTING.—For 2019 and each
4 subsequent year, the Secretary shall post on the
5 public Internet website of the Department of Health
6 and Human Services a list of any qualified electronic
7 health records with respect to which certification has
8 been withdrawn under subsection (c)(5)(C)(ii) dur-
9 ing such year and the vendor of or other entity of-
10 fering to health care providers (as defined in section
11 3010A(g)) such qualified electronic health records.

12 “(3) PERIODIC REVIEW.—The Secretary shall
13 periodically review and confirm that vendors of and
14 other entities offering to health care providers (as
15 defined in section 3010A(g)) qualified electronic
16 health records have publicly published application
17 programming interfaces and associated documenta-
18 tion as required by subsection (c)(5)(C)(i)(II) for
19 purposes of certification and maintaining certifi-
20 cation under any program kept or recognized under
21 subsection (c)(5)(A).”.

22 (4) DEMONSTRATION REQUIRED FOR MEANING-
23 FUL EHR USE UNDER MEDICARE.—

24 (A) ELIGIBLE PROFESSIONALS.—

1 (i) IN GENERAL.—Section
2 1848(o)(2)(A) of the Social Security Act
3 (42 U.S.C. 1395w-4(o)(2)(A)) is amended
4 by inserting after clause (iii) the following
5 new clause:

6 “(iv) INTEROPERABILITY.—With re-
7 spect to EHR reporting periods for pay-
8 ment years beginning with 2020, the eligi-
9 ble professional demonstrates to the satis-
10 faction of the Secretary, in accordance
11 with subparagraph (C)(i), that during such
12 period the professional has not taken any
13 action described in subsection (a)(2) of
14 section 3010A of the Public Health Service
15 Act, with respect to the use of any certified
16 EHR technology.”.

17 (ii) HARDSHIP EXEMPTION IN CASE
18 OF DECERTIFIED EHR.—Subparagraph (B)
19 of section 1848(a)(7) of the Social Security
20 Act (42 U.S.C. 1395w-4(a)(7)) is amend-
21 ed to read as follows:

22 “(B) SIGNIFICANT HARDSHIP EXCEP-
23 TION.—

24 “(i) IN GENERAL.—The Secretary
25 may, on a case-by-case basis, exempt an el-

1 eligible professional from the application of
2 the payment adjustment under subpara-
3 graph (A) if the Secretary determines, sub-
4 ject to annual renewal, that compliance
5 with the requirement for being a meaning-
6 ful EHR user would result in a significant
7 hardship, such as in the case of an eligible
8 professional who practices in a rural area
9 without sufficient Internet access.

10 “(ii) DECERTIFICATION.—The Sec-
11 retary shall exempt an eligible professional
12 from the application of the payment ad-
13 justment under subparagraph (A) if the
14 Secretary determines that such profes-
15 sional was determined to not be a mean-
16 ingful EHR user because the certified
17 EHR technology used by such professional
18 is decertified under section 3001(c)(5)(C)
19 of the Public Health Service Act. An ex-
20 emption under the previous sentence may
21 be applied to an eligible professional only,
22 subject to clause (iii), during the first pay-
23 ment year with respect to the first EHR
24 reporting period to which such decertifica-
25 tion applies.

1 “(iii) DURATION OF DECERTIFICA-
2 TION.—

3 “(I) IN GENERAL.—Notwith-
4 standing clause (iv)(I), in no case
5 shall an exemption by reason of clause
6 (ii) be for a period of less than 12
7 months.

8 “(II) EXTENSION.—An exemp-
9 tion under clause (ii) may be ex-
10 tended, on a case-by-case basis, for a
11 period of an additional 12 months
12 subject to the limitation described in
13 clause (iv)(I).

14 “(iv) LIMITATION.—

15 “(I) IN GENERAL.—Subject to
16 subclause (II), in no case may an eli-
17 gible professional be granted an ex-
18 emption under this subparagraph for
19 more than 5 years.

20 “(II) EXCEPTION.—Subclause (I)
21 shall not apply to an exemption by
22 reason of clause (ii) to the extent nec-
23 essary to satisfy clause (iii)(I).”.

24 (iii) FURTHER APPLICATION.—Section
25 1848(o)(2) of the Social Security Act (42

1 U.S.C. 1395w-4(o)(2)) is amended by add-
2 ing at the end the following new subpara-
3 graph:

4 “(E) **HARDSHIP EXEMPTION IN CASE OF**
5 **DECERTIFIED EHR.**—In the case of certified
6 EHR technology used by an eligible profes-
7 sional that is decertified under section
8 3001(c)(5)(C), during the first payment year
9 with respect to the first EHR reporting period
10 to which such decertification applies, the Sec-
11 retary shall not treat the professional as not
12 being a meaningful EHR user solely because
13 the technology used by such professional was so
14 decertified. The treatment of a professional
15 under the previous sentence shall be for a pe-
16 riod of at least 12 months and may, on a case-
17 by-case basis, be for a period of an additional
18 12 months.”.

19 (B) **ELIGIBLE HOSPITALS.**—

20 (i) **IN GENERAL.**—Section
21 1886(n)(3)(A) of the Social Security Act
22 (42 U.S.C. 1395ww(n)(3)(A)) is amended
23 by inserting after clause (iii) the following
24 new clause:

1 “(iv) INTEROPERABILITY.—With re-
2 spect to EHR reporting periods for pay-
3 ment years beginning with 2020, the hos-
4 pital demonstrates to the satisfaction of
5 the Secretary, in accordance with subpara-
6 graph (C)(i), that during such period the
7 hospital has not taken any action described
8 in subsection (a)(2) of section 3010A of
9 the Public Health Service Act, with respect
10 to the use of any certified EHR tech-
11 nology.”.

12 (ii) HARDSHIP EXEMPTION IN CASE
13 OF DECERTIFIED EHR.—Subclause (II) of
14 section 1886(b)(3)(B)(ix) of the Social Se-
15 curity Act (42 U.S.C.
16 1395ww(b)(3)(B)(ix)) is amended to read
17 as follows:

18 “(II)(aa) The Secretary may, on a
19 case-by-case basis, exempt a subsection (d)
20 hospital from the application of subclause
21 (I) with respect to a fiscal year if the Sec-
22 retary determines, subject to annual re-
23 newal, that requiring such hospital to be a
24 meaningful EHR user during such fiscal
25 year would result in a significant hardship,

1 such as in the case of a hospital in a rural
2 area without sufficient Internet access.

3 “(bb) The Secretary shall exempt a
4 subsection (d) hospital from the applica-
5 tion of subclause (I) with respect to a fis-
6 cal year if the Secretary determines that
7 such hospital was determined to not be a
8 meaningful EHR user because the certified
9 EHR technology used by such hospital is
10 decertified under section 3001(c)(5)(C) of
11 the Public Health Service Act. An exemp-
12 tion under the previous sentence may be
13 applied to a subsection (d) hospital only,
14 subject to items (cc) and (dd), during the
15 first payment year with respect to the first
16 EHR reporting period to which such decer-
17 tification applies.

18 “(cc) Notwithstanding item (ee), in no
19 case shall an exemption by reason of item
20 (bb) be for a period of less than 12
21 months.

22 “(dd) An exemption under item (bb)
23 may, on a case-by-case basis, be extended
24 for a period of an additional 12 months

1 subject to the limitation described in item
2 (ee).

3 “(ee) Subject to item (ff), in no case
4 may a hospital be granted an exemption
5 under this subclause for more than 5
6 years.

7 “(ff) Item (ee) shall not apply to an
8 exemption by reason of item (bb) to the ex-
9 tent necessary to satisfy item (cc).”.

10 (C) DEMONSTRATION REQUIRED FOR
11 MEANINGFUL EHR USE UNDER MEDICAID.—
12 Section 1903(t)(2) of the Social Security Act
13 (42 U.S.C. 1396b(t)(2)) is amended by adding
14 at the end the following: “An eligible profes-
15 sional shall not qualify as a Medicaid provider
16 under this subsection, with respect to a year be-
17 ginning with 2020, unless such provider dem-
18 onstrates to the Secretary, through means such
19 as an attestation, that the provider has not
20 taken any action described in subsection (a)(2)
21 of section 3010A of the Public Health Service
22 Act, with respect to the use of any certified
23 EHR technology.”.

24 (5) GUIDANCE.—Not later than January 1,
25 2018, the Secretary of Health and Human Services

1 shall issue guidance to further the voluntary transi-
2 tion of health care providers between different cer-
3 tified EHR technology (as defined in section
4 3000(1) of the Public Health Service Act (42 U.S.C.
5 300jj(1)) by removing disincentives to such transi-
6 tion, which may include applying to instances of
7 such a transition the hardship exemption authority
8 under section 1848(a)(7) of the Social Security Act
9 (42 U.S.C. 1395w-4(a)(7)), section
10 1886(b)(3)(B)(ix) of such Act (42 U.S.C.
11 1395ww(b)(3)(B)(ix)), and other provisions of law in
12 existence as of the date of the enactment of this Act.
13 In developing such guidance, the Secretary may con-
14 sult with the relevant Federal agencies.

15 (f) DEFINITIONS.—

16 (1) CERTIFIED EHR TECHNOLOGY.—Paragraph
17 (1) of section 3000 of the Public Health Service Act
18 (42 U.S.C. 300jj) is amended to read as follows:

19 “(1) CERTIFIED EHR TECHNOLOGY.—The term
20 ‘certified EHR technology’ means a qualified elec-
21 tronic health record that is certified pursuant to sec-
22 tion 3001(c)(5) as meeting the certification criteria
23 defined in subparagraph (B) of such section that are
24 applicable to the type of record involved (as deter-
25 mined by the Secretary, such as an ambulatory elec-

1 tronic health record for office-based physicians or an
2 inpatient hospital electronic health record for hos-
3 pitals) including, beginning January 1, 2018, with
4 respect to which the vendor or other entity offering
5 such technology is in compliance with the require-
6 ments under section 3001(c)(5)(C)(i).”.

7 (2) WIDESPREAD INTEROPERABILITY.—Section
8 3000 of the Public Health Service Act (42 U.S.C.
9 300jj) is amended by adding at the end the following
10 new paragraph:

11 “(15) WIDESPREAD INTEROPERABILITY.—The
12 term ‘widespread interoperability’ means that, on a
13 nationwide basis—

14 “(A) health information technology is
15 interoperable, in accordance with section 3010;
16 and

17 “(B) such technology is employed by mean-
18 ingful EHR users under the Medicare program
19 under title XVIII of the Social Security Act and
20 the Medicaid program under title XIX of such
21 Act and by other clinicians and health care pro-
22 viders.”.

23 (g) CONFORMING AMENDMENTS.—

1 (1) VOLUNTARY USE OF STANDARDS.—Section
2 3006 of the Public Health Service Act (42 U.S.C.
3 300jj–16) is amended—

4 (A) in subsection (a)(1), by inserting “, in-
5 cluding an interoperability standard or imple-
6 mentation specification, with respect to such
7 interoperability standard, adopted under such
8 section” after “section 3004”.

9 (B) in subsection (b), by inserting “, in-
10 cluding the interoperability standards and im-
11 plementation specifications, with respect to such
12 interoperability standards, adopted under such
13 section” after “section 3004”.

14 (2) HIPAA PRIVACY AND SECURITY LAW DEFINI-
15 TION CORRECTION.—Section 3009(a)(2)(A) of the
16 Public Health Service Act (42 U.S.C. 300jj–
17 19(a)(2)(A)) is amended by striking “title IV” and
18 inserting “title XIII”.

19 (3) COORDINATION OF FEDERAL ACTIVITIES.—
20 Section 13111 of the HITECH Act is amended—

21 (A) in subsection (a), by inserting before
22 the period at the end the following: “(and, be-
23 ginning on January 1, 2018, that are also
24 interoperable under section 3010 of such Act
25 and in compliance with interoperability stand-

1 ards and implementation specifications, with re-
2 spect to such interoperability standards, adopt-
3 ed under section 3004 of such Act)”; and

4 (B) in subsection (b), by inserting “(and,
5 beginning on January 1, 2018, including an
6 interoperability standard or implementation
7 specification, with respect to such interoper-
8 ability standard, adopted under section 3004 of
9 such Act)” before “the President”.

10 (4) APPLICATION TO PRIVATE ENTITIES.—Sec-
11 tion 13112 of the HITECH Act is amended by in-
12 serting before the period at the end the following:
13 “(and, beginning on January 1, 2018, that are also
14 interoperable under section 3010 of such Act and in
15 compliance with interoperability standards and im-
16 plementation specifications, with respect to such
17 interoperability standards, adopted under section
18 3004 of such Act)”.

19 (5) NIST TESTING.—Section 13201 of the
20 HITECH Act (42 U.S.C. 17911) is amended—

21 (A) in subsection (a), by inserting “(or, be-
22 ginning January 1, 2018, in coordination with
23 the entities with contracts under section 3003A,
24 with respect to standards, and implementation

1 specifications under section 3004)” before “,
2 the Director”; and

3 (B) in subsection (b), by inserting “(or, be-
4 ginning January 1, 2018, in coordination with
5 the entities with contracts under section 3003A,
6 with respect to standards and implementation
7 specifications under section 3004)” before “,
8 the Director”; and

9 (C) by adding at the end the following new
10 subsection:

11 “(c) FUNDING.—For purposes of carrying out this
12 section, in addition to any other funds made available to
13 carry out this section, there is authorized to be appro-
14 priated \$15,000,000, to remain available until expended.”.

15 (6) COORDINATION WITH RECOMMENDATIONS
16 FOR ACHIEVING WIDESPREAD EHR INTEROPER-
17 ABILITY.—Section 106 of the Medicare Access and
18 CHIP Reauthorization Act of 2015 (Public Law
19 114–10) is amended by striking subsection (b).”.

20 (h) PATIENT ENGAGEMENT AND EMPOWERMENT.—
21 It is the sense of Congress that—

22 (1) if the strategic goals that Congress set forth
23 in the HITECH Act are to be achieved, interoper-
24 ability is best achieved with individuals and author-
25 ized representatives having equal access to the

1 health information of such individuals in electronic
2 format;

3 (2) patients have the right to the entirety of the
4 health information of such individuals, including
5 such information contained in an electronic health
6 record of such individuals;

7 (3) such right extends to both structured and
8 unstructured data;

9 (4) such right extends to authorized representa-
10 tives of the individual involved, such as care takers
11 of such individual, family members of such indi-
12 vidual, and guardians of such individual; and

13 (5) to further facilitate access of an individual
14 to health information of such individual—

15 (A) health care providers should not have
16 the ability to deny a request of the individual
17 for access to the entirety of such health infor-
18 mation of such individual;

19 (B) health care providers do not need the
20 consent of individuals to share personal health
21 information of such individuals with other cov-
22 ered entities, in compliance with the HIPAA
23 privacy regulations promulgated pursuant to
24 section 264(c) of the Health Insurance Port-
25 ability and Accountability Act of 1996 for the

1 purposes of supporting patient care, except in
2 situations where consent is specifically required
3 under such regulations, such as in cases related
4 to the psychiatric records of the individual in-
5 volved;

6 (C) mechanisms should be utilized that
7 allow for the bidirectional exchange of informa-
8 tion through such mechanisms as web portals,
9 appointments, and prescription refills, for the
10 purpose of patients partnering with providers to
11 assist in managing health and care;

12 (D) mechanisms described in subparagraph
13 (C) should allow for connecting individuals
14 across the continuum of care;

15 (E) an individual has the right to access
16 the health information of the individual without
17 cost to the individual;

18 (F) mechanisms described in subparagraph
19 (C) should allow for data of an individual gen-
20 erated by the individual to be integrated into
21 such platforms as electronic health records;

22 (G) such access should be timely, in ac-
23 cordance with the HIPAA privacy regulations
24 described in subparagraph (B), and take into

1 account communications preferences of the indi-
2 vidual involved;

3 (H) an individual should have the right to
4 be confident that the data in the electronic
5 health record of the individual pertains to such
6 individual; and

7 (I) the right described in subparagraph
8 (H) will promote safety and care coordination
9 for individuals.

10 **Subtitle B—Telehealth**

11 **SEC. 3021. TELEHEALTH SERVICES UNDER THE MEDICARE** 12 **PROGRAM.**

13 (a) PROVISION OF INFORMATION BY CENTERS FOR
14 MEDICARE & MEDICAID SERVICES.—Not later than 1
15 year after the date of the enactment of this Act, the Ad-
16 ministrator of the Centers for Medicare & Medicaid Serv-
17 ices shall provide to the committees of jurisdiction of the
18 House of Representatives and the Senate information on
19 the following:

20 (1) The populations of Medicare beneficiaries,
21 such as those who are dually eligible for the Medi-
22 care program under title XVIII of the Social Secu-
23 rity Act (42 U.S.C. 1395 et seq.) and the Medicaid
24 program under title XIX of such Act (42 U.S.C.
25 1396 et seq.) and those with chronic conditions,

1 whose care may be improved most in terms of qual-
2 ity and efficiency by the expansion, in a manner that
3 meets or exceeds the existing in-person standard of
4 care under the Medicare program under title XVIII
5 of such Act, of telehealth services under section
6 1834(m)(4) of such Act (42 U.S.C. 1395m(m)(4)).

7 (2) Activities by the Center for Medicare and
8 Medicaid Innovation which examine the use of tele-
9 health services in models, projects, or initiatives
10 funded through section 1115A of the Social Security
11 Act (42 U.S.C. 1315a).

12 (3) The types of high volume services (and re-
13 lated diagnoses) under such title XVIII which might
14 be suitable to the furnishing of services via tele-
15 health.

16 (4) Barriers that might prevent the expansion
17 of telehealth services under section 1834(m)(4) of
18 the Social Security Act (42 U.S.C. 1395m(m)(4))
19 beyond such services that are in effect as of the date
20 of the enactment of this Act.

21 (b) PROVISION OF INFORMATION BY MEDPAC.—Not
22 later than March 15, 2017, the Medicare Payment Advi-
23 sory Commission established under section 1805 of the So-
24 cial Security Act (42 U.S.C. 1395b–6) shall, using quan-
25 titative and qualitative research methods, provide informa-

1 tion to the committees of jurisdiction of the House of Rep-
2 resentatives and the Senate that identifies—

3 (1) the telehealth services for which payment
4 can be made, as of the date of the enactment of this
5 Act, under the fee-for-service program under parts A
6 and B of title XVIII of such Act;

7 (2) the telehealth services for which payment
8 can be made, as of such date, under private health
9 insurance plans;

10 (3) with respect to services identified under
11 paragraph (2) but not under paragraph (1), ways in
12 which payment for such services might be incor-
13 porated into such fee-for-service program (including
14 any recommendations for ways to accomplish this in-
15 corporation).

16 (c) SENSE OF CONGRESS.—It is the sense of Con-
17 gress that—

18 (1) eligible originating sites should be expanded
19 beyond those originating sites described in section
20 1834(m)(4)(C) of the Social Security Act (42 U.S.C.
21 1395m(m)(4)(C)); and

22 (2) any expansion of telehealth services under
23 the Medicare program should—

24 (A) recognize that telemedicine is the deliv-
25 ery of safe, effective, quality health care serv-

1 ices, by a health care provider, using technology
2 as the mode of care delivery;

3 (B) meet or exceed the conditions of cov-
4 erage and payment with respect to the Medicare
5 program under title XVIII unless specifically
6 address in subsequent statute, of such Act if
7 the service were furnished in person, including
8 standards of care; and

9 (C) involve clinically appropriate means to
10 furnish such services.

11 **Subtitle C—Encouraging Con-**
12 **tinuing Medical Education for**
13 **Physicians**

14 **SEC. 3041. EXEMPTING FROM MANUFACTURER TRANS-**
15 **PARENCY REPORTING CERTAIN TRANSFERS**
16 **USED FOR EDUCATIONAL PURPOSES.**

17 (a) IN GENERAL.—Section 1128G(e)(10)(B) of the
18 Social Security Act (42 U.S.C. 1320a–7h(e)(10)(B)) is
19 amended—

20 (1) in clause (iii), by inserting “, including
21 peer-reviewed journals, journal reprints, journal sup-
22 plements, medical conference reports, and medical
23 textbooks” after “patient use”; and

24 (2) by adding at the end the following new
25 clause:

1 “(xiii) In the case of a covered recipi-
2 ent who is a physician, an indirect pay-
3 ment or transfer of value to the covered re-
4 cipient—

5 “(I) for speaking at, or preparing
6 educational materials for, an edu-
7 cational event for physicians or other
8 health care professionals that does not
9 commercially promote a covered drug,
10 device, biological, or medical supply;
11 or

12 “(II) that serves the sole purpose
13 of providing the covered recipient with
14 medical education, such as by pro-
15 viding the covered recipient with the
16 tuition required to attend an edu-
17 cational event or with materials pro-
18 vided to physicians at an educational
19 event.”.

20 (b) **EFFECTIVE DATE.**—The amendments made by
21 this section shall apply with respect to transfers of value
22 made on or after the date of the enactment of this Act.

1 **Subtitle D—Disposable Medical**
2 **Technologies**

3 **SEC. 3061. TREATMENT OF CERTAIN ITEMS AND DEVICES.**

4 (a) IN GENERAL.—Section 1834 of the Social Secu-
5 rity Act (42 U.S.C. 1395m) is amended by adding at the
6 end the following new subsection:

7 “(r) PAYMENT FOR CERTAIN DISPOSABLE DE-
8 VICES.—

9 “(1) IN GENERAL.—The Secretary shall make
10 separate payment in the amount established under
11 paragraph (3) to a home health agency for a device
12 described in paragraph (2) when furnished to an in-
13 dividual who receives home health services for which
14 payment is made under section 1895(b).

15 “(2) DEVICE DESCRIBED.—For purposes of
16 paragraph (1), a device described in this paragraph
17 is a disposable device for which, as of January 1,
18 2015, there is—

19 “(A) a Level I Healthcare Common Proce-
20 dure Coding System (HCPCS) code for which
21 the description for a professional service in-
22 cludes the furnishing of such device; and

23 “(B) a separate Level I HCPCS code for
24 a professional service that uses durable medical
25 equipment instead of such device.

1 “(3) PAYMENT AMOUNT.—The Secretary shall
2 establish the separate payment amount for such a
3 device such that such amount does not exceed the
4 payment that would be made for the HCPCS code
5 described in paragraph (2)(A) under section 1833(t)
6 (relating to payment for covered OPD services).”.

7 (b) CONFORMING AMENDMENT.—Section
8 1861(m)(5) of the Social Security Act (42 U.S.C.
9 1395x(m)(5)) is amended by inserting “and devices de-
10 scribed in section 1834(r)(2)” after “durable medical
11 equipment”.

12 (c) EFFECTIVE DATE.—The amendments made by
13 this section shall apply to devices furnished on or after
14 January 1, 2017.

15 **Subtitle E—Local Coverage** 16 **Decision Reforms**

17 **SEC. 3081. IMPROVEMENTS IN THE MEDICARE LOCAL COV-** 18 **ERAGE DETERMINATION (LCD) PROCESS.**

19 (a) IN GENERAL.—Section 1862(l)(5) of the Social
20 Security Act (42 U.S.C. 1395y(l)(5)) is amended by add-
21 ing at the end the following new subparagraph:

22 “(D) LOCAL COVERAGE DETERMINA-
23 TIONS.—The Secretary shall require each medi-
24 care administrative contractor that develops a
25 local coverage determination to make available

1 on the website of such contractor and on the
2 Medicare website, at least 45 days before the
3 effective date of such determination, the fol-
4 lowing information:

5 “(i) Such determination in its en-
6 tirety.

7 “(ii) Where and when the proposed
8 determination was first made public.

9 “(iii) Hyperlinks to the proposed de-
10 termination and a response to comments
11 submitted to the contractor with respect to
12 such proposed determination.

13 “(iv) A summary of evidence that was
14 considered by the contractor during the de-
15 velopment of such determination and a list
16 of the sources of such evidence.

17 “(v) An explanation of the rationale
18 that supports such determination.”.

19 (b) EFFECTIVE DATE.—The amendment made by
20 subsection (a) shall apply with respect to local coverage
21 determinations that are proposed or revised on or after
22 the date that is 180 days after the date of the enactment
23 of this Act.

1 **Subtitle F—Medicare Pharma-**
2 **ceutical and Technology Om-**
3 **budsman**

4 **SEC. 3101. MEDICARE PHARMACEUTICAL AND TECH-**
5 **NOLOGY OMBUDSMAN.**

6 Section 1808(c) of the Social Security Act (42 U.S.C.
7 1395b–9(c)) is amended by adding at the end the fol-
8 lowing new paragraph:

9 “(4) PHARMACEUTICAL AND TECHNOLOGY OM-
10 BUDSMAN.—Not later than 12 months after the date
11 of the enactment of this paragraph, the Secretary
12 shall provide for a pharmaceutical and technology
13 ombudsman within the Centers for Medicare & Med-
14 icaid Services who shall receive and respond to com-
15 plaints, grievances, and requests that—

16 “(A) are from entities that manufacture
17 pharmaceutical, biotechnology, medical device,
18 or diagnostic products that are covered or for
19 which coverage is being sought under this title;
20 and

21 “(B) are with respect to coverage, coding,
22 or payment under this title for such products.

23 The second sentence of paragraph (2) shall apply to
24 this paragraph in the same manner as such sentence
25 applies to paragraph (2).”.

1 **Subtitle G—Medicare Site-of-**
2 **Service Price Transparency**

3 **SEC. 3121. MEDICARE SITE-OF-SERVICE PRICE TRANS-**
4 **PARENCY.**

5 Section 1834 of the Social Security Act (42 U.S.C.
6 1395m), as amended by section 3061, is further amended
7 by adding at the end the following new subsection:

8 “(s) SITE-OF-SERVICE PRICE TRANSPARENCY.—

9 “(1) IN GENERAL.—In order to facilitate price
10 transparency with respect to items and services for
11 which payment may be made either to a hospital
12 outpatient department or to an ambulatory surgical
13 center under this title, the Secretary shall, for 2017
14 and each year thereafter, make available to the pub-
15 lic via a searchable website, with respect to an ap-
16 propriate number of such items and services—

17 “(A) the estimated payment amount for
18 the item or service under the outpatient depart-
19 ment fee schedule under subsection (t) of sec-
20 tion 1833 and the ambulatory surgical center
21 payment system under subsection (i) of such
22 section; and

23 “(B) the estimated amount of beneficiary
24 liability applicable to the item or service.

1 “(2) CALCULATION OF ESTIMATED BENE-
2 FICIARY LIABILITY.—For purposes of paragraph
3 (1)(B), the estimated amount of beneficiary liability,
4 with respect to an item or service, is the amount for
5 such item or service for which an individual who
6 does not have coverage under a medicare supple-
7 mental policy certified under section 1882 or any
8 other supplemental insurance coverage is respon-
9 sible.

10 “(3) IMPLEMENTATION.—In carrying out this
11 subsection, the Secretary—

12 “(A) shall include in the notice described
13 in section 1804(a) a notification of the avail-
14 ability of the estimated amounts made available
15 under paragraph (1); and

16 “(B) may utilize mechanisms in existence
17 on the date of the enactment of this subsection,
18 such as the portion of the website of the Cen-
19 ters for Medicare & Medicaid Services on which
20 information comparing physician performance is
21 posted (commonly referred to as the Physician
22 Compare website), to make available such esti-
23 mated amounts under such paragraph.

24 “(4) FUNDING.—For purposes of implementing
25 this subsection, the Secretary shall provide for the

1 transfer, from the Supplemental Medical Insurance
2 Trust Fund under section 1841 to the Centers for
3 Medicare & Medicaid Services Program Management
4 Account, of \$6,000,000 for fiscal year 2015, to re-
5 main available until expended.”.

6 **Subtitle H—Medicare Part D Pa-**
7 **tient Safety and Drug Abuse**
8 **Prevention**

9 **SEC. 3141. PROGRAMS TO PREVENT PRESCRIPTION DRUG**
10 **ABUSE UNDER MEDICARE PARTS C AND D.**

11 (a) DRUG MANAGEMENT PROGRAM FOR AT-RISK
12 BENEFICIARIES.—

13 (1) IN GENERAL.—Section 1860D–4(c) of the
14 Social Security Act (42 U.S.C. 1395w–10(c)) is
15 amended by adding at the end the following:

16 “(5) DRUG MANAGEMENT PROGRAM FOR AT-
17 RISK BENEFICIARIES.—

18 “(A) AUTHORITY TO ESTABLISH.—A PDP
19 sponsor may establish a drug management pro-
20 gram for at-risk beneficiaries under which, sub-
21 ject to subparagraph (B), the PDP sponsor
22 may, in the case of an at-risk beneficiary for
23 prescription drug abuse who is an enrollee in a
24 prescription drug plan of such PDP sponsor,
25 limit such beneficiary’s access to coverage for

1 frequently abused drugs under such plan to fre-
2 quently abused drugs that are prescribed for
3 such beneficiary by one or more prescribers se-
4 lected under subparagraph (D), and dispensed
5 for such beneficiary by one or more pharmacies
6 selected under such subparagraph.

7 “(B) REQUIREMENT FOR NOTICES.—

8 “(i) IN GENERAL.—A PDP sponsor
9 may not limit the access of an at-risk ben-
10 eficiary for prescription drug abuse to cov-
11 erage for frequently abused drugs under a
12 prescription drug plan until such spon-
13 sor—

14 “(I) provides to the beneficiary
15 an initial notice described in clause
16 (ii) and a second notice described in
17 clause (iii); and

18 “(II) verifies with the providers
19 of the beneficiary that the beneficiary
20 is an at-risk beneficiary for prescrip-
21 tion drug abuse.

22 “(ii) INITIAL NOTICE.—An initial no-
23 tice described in this clause is a notice that
24 provides to the beneficiary—

1 “(I) notice that the PDP sponsor
2 has identified the beneficiary as po-
3 tentially being an at-risk beneficiary
4 for prescription drug abuse;

5 “(II) information describing all
6 State and Federal public health re-
7 sources that are designed to address
8 prescription drug abuse to which the
9 beneficiary has access, including men-
10 tal health services and other coun-
11 seling services;

12 “(III) notice of, and information
13 about, the right of the beneficiary to
14 appeal such identification under sub-
15 section (h) and the option of an auto-
16 matic escalation to external review;

17 “(IV) a request for the bene-
18 ficiary to submit to the PDP sponsor
19 preferences for which prescribers and
20 pharmacies the beneficiary would pre-
21 fer the PDP sponsor to select under
22 subparagraph (D) in the case that the
23 beneficiary is identified as an at-risk
24 beneficiary for prescription drug
25 abuse as described in clause (iii)(I);

1 “(V) an explanation of the mean-
2 ing and consequences of the identi-
3 fication of the beneficiary as poten-
4 tially being an at-risk beneficiary for
5 prescription drug abuse, including an
6 explanation of the drug management
7 program established by the PDP
8 sponsor pursuant to subparagraph
9 (A);

10 “(VI) clear instructions that ex-
11 plain how the beneficiary can contact
12 the PDP sponsor in order to submit
13 to the PDP sponsor the preferences
14 described in subclause (IV) and any
15 other communications relating to the
16 drug management program for at-risk
17 beneficiaries established by the PDP
18 sponsor; and

19 “(VII) contact information for
20 other organizations that can provide
21 the beneficiary with assistance regard-
22 ing such drug management program
23 (similar to the information provided
24 by the Secretary in other standardized
25 notices provided to part D eligible in-

1 individuals enrolled in prescription drug
2 plans under this part).

3 “(iii) SECOND NOTICE.—A second no-
4 tice described in this clause is a notice that
5 provides to the beneficiary notice—

6 “(I) that the PDP sponsor has
7 identified the beneficiary as an at-risk
8 beneficiary for prescription drug
9 abuse;

10 “(II) that such beneficiary is
11 subject to the requirements of the
12 drug management program for at-risk
13 beneficiaries established by such PDP
14 sponsor for such plan;

15 “(III) of the prescriber (or pre-
16 scribers) and pharmacy (or phar-
17 macies) selected for such individual
18 under subparagraph (D);

19 “(IV) of, and information about,
20 the beneficiary’s right to appeal such
21 identification under subsection (h)
22 and the option of an automatic esca-
23 lation to external review;

24 “(V) that the beneficiary can, in
25 the case that the beneficiary has not

1 previously submitted to the PDP
2 sponsor preferences for which pre-
3 scribers and pharmacies the bene-
4 ficiary would prefer the PDP sponsor
5 select under subparagraph (D), sub-
6 mit such preferences to the PDP
7 sponsor; and

8 “(VI) that includes clear instruc-
9 tions that explain how the beneficiary
10 can contact the PDP sponsor.

11 “(iv) TIMING OF NOTICES.—

12 “(I) IN GENERAL.—Subject to
13 subclause (II), a second notice de-
14 scribed in clause (iii) shall be provided
15 to the beneficiary on a date that is
16 not less than 60 days after an initial
17 notice described in clause (ii) is pro-
18 vided to the beneficiary.

19 “(II) EXCEPTION.—In the case
20 that the PDP sponsor, in conjunction
21 with the Secretary, determines that
22 concerns identified through rule-
23 making by the Secretary regarding
24 the health or safety of the beneficiary
25 or regarding significant drug diversion

1 activities require the PDP sponsor to
2 provide a second notice described in
3 clause (iii) to the beneficiary on a
4 date that is earlier than the date de-
5 scribed in subclause (I), the PDP
6 sponsor may provide such second no-
7 tice on such earlier date.

8 “(C) AT-RISK BENEFICIARY FOR PRE-
9 SCRIPTION DRUG ABUSE.—

10 “(i) IN GENERAL.—For purposes of
11 this paragraph, the term ‘at-risk bene-
12 ficiary for prescription drug abuse’ means
13 a part D eligible individual who is not an
14 exempted individual described in clause (ii)
15 and—

16 “(I) who is identified as such an
17 at-risk beneficiary through the use of
18 clinical guidelines developed by the
19 Secretary in consultation with PDP
20 sponsors and other stakeholders de-
21 scribed in section 3141(f)(2)(A) of the
22 21st Century Cures Act; or

23 “(II) with respect to whom the
24 PDP sponsor of a prescription drug
25 plan, upon enrolling such individual in

1 such plan, received notice from the
2 Secretary that such individual was
3 identified under this paragraph to be
4 an at-risk beneficiary for prescription
5 drug abuse under the prescription
6 drug plan in which such individual
7 was most recently previously enrolled
8 and such identification has not been
9 terminated under subparagraph (F).

10 “(ii) EXEMPTED INDIVIDUAL DE-
11 SCRIBED.—An exempted individual de-
12 scribed in this clause is an individual
13 who—

14 “(I) receives hospice care under
15 this title;

16 “(II) is a resident of a long-term
17 care facility, of an intermediate care
18 facility for the mentally retarded, or
19 of another facility for which fre-
20 quently abused drugs are dispensed
21 for residents through a contract with
22 a single pharmacy; or

23 “(III) the Secretary elects to
24 treat as an exempted individual for
25 purposes of clause (i).

1 “(D) SELECTION OF PRESCRIBERS AND
2 PHARMACIES.—

3 “(i) IN GENERAL.—With respect to
4 each at-risk beneficiary for prescription
5 drug abuse enrolled in a prescription drug
6 plan offered by such sponsor, a PDP spon-
7 sor shall, based on the preferences sub-
8 mitted to the PDP sponsor by the bene-
9 ficiary pursuant to clauses (ii)(IV) and
10 (iii)(V) of subparagraph (B) (except as
11 otherwise provided in this subparagraph),
12 select—

13 “(I) one or more individuals who
14 are authorized to prescribe frequently
15 abused drugs (referred to in this
16 paragraph as ‘prescribers’) who may
17 write prescriptions for such drugs for
18 such beneficiary; and

19 “(II) one or more pharmacies
20 that may dispense such drugs to such
21 beneficiary.

22 “(ii) REASONABLE ACCESS.—In mak-
23 ing the selections under this subpara-
24 graph—

1 “(I) a PDP sponsor shall ensure
2 that the beneficiary continues to have
3 reasonable access to frequently abused
4 drugs (as defined in subparagraph
5 (G)), taking into account geographic
6 location, beneficiary preference, im-
7 pact on costsharing, and reasonable
8 travel time; and

9 “(II) a PDP sponsor shall ensure
10 such access (including access to pre-
11 scribers and pharmacies with respect
12 to frequently abused drugs) in the
13 case of individuals with multiple resi-
14 dences and in the case of natural dis-
15 asters and similar emergency situa-
16 tions.

17 “(iii) BENEFICIARY PREFERENCES.—
18 If an at-risk beneficiary for prescription
19 drug abuse submits preferences for which
20 in-network prescribers and pharmacies the
21 beneficiary would prefer the PDP sponsor
22 select in response to a notice under sub-
23 paragraph (B), the PDP sponsor shall—

24 “(I) review such preferences;

1 “(II) select or change the selec-
2 tion of prescribers and pharmacies for
3 the beneficiary based on such pref-
4 erences; and

5 “(III) inform the beneficiary of
6 such selection or change of selection.

7 “(iv) EXCEPTION REGARDING BENE-
8 FICIARY PREFERENCES.—In the case that
9 the PDP sponsor determines that a change
10 to the selection of prescriber or pharmacy
11 under clause (iii)(II) by the PDP sponsor
12 is contributing or would contribute to pre-
13 scription drug abuse or drug diversion by
14 the beneficiary, the PDP sponsor may
15 change the selection of prescriber or phar-
16 macy for the beneficiary without regard to
17 the preferences of the beneficiary described
18 in clause (iii).

19 “(v) CONFIRMATION.—Before select-
20 ing a prescriber (or prescribers) or phar-
21 macy (or pharmacies) under this subpara-
22 graph, a PDP sponsor must request and
23 receive confirmation from such a prescriber
24 or pharmacy acknowledging and accepting
25 that the beneficiary involved is in the drug

1 management program for at-risk bene-
2 ficiaries.

3 “(E) TERMINATIONS AND APPEALS.—The
4 identification of an individual as an at-risk ben-
5 efiary for prescription drug abuse under this
6 paragraph, a coverage determination made
7 under a drug management program for at-risk
8 beneficiaries, and the selection of prescriber or
9 pharmacy under subparagraph (D) with respect
10 to such individual shall be subject to reconsider-
11 ation and appeal under subsection (h) and the
12 option of an automatic escalation to external re-
13 view to the extent provided by the Secretary.

14 “(F) TERMINATION OF IDENTIFICATION.—

15 “(i) IN GENERAL.—The Secretary
16 shall develop standards for the termination
17 of identification of an individual as an at-
18 risk beneficiary for prescription drug abuse
19 under this paragraph. Under such stand-
20 ards such identification shall terminate as
21 of the earlier of—

22 “(I) the date the individual dem-
23 onstrates that the individual is no
24 longer likely, in the absence of the re-
25 strictions under this paragraph, to be

1 an at-risk beneficiary for prescription
2 drug abuse described in subparagraph
3 (C)(i); and

4 “(II) the end of such maximum
5 period of identification as the Sec-
6 retary may specify.

7 “(ii) RULE OF CONSTRUCTION.—
8 Nothing in clause (i) shall be construed as
9 preventing a plan from identifying an indi-
10 vidual as an at-risk beneficiary for pre-
11 scription drug abuse under subparagraph
12 (C)(i) after such termination on the basis
13 of additional information on drug use oc-
14 ccurring after the date of notice of such ter-
15 mination.

16 “(G) FREQUENTLY ABUSED DRUG.—For
17 purposes of this subsection, the term ‘frequently
18 abused drug’ means a drug that is a controlled
19 substance that the Secretary determines to be
20 frequently abused or diverted.

21 “(H) DATA DISCLOSURE.—In the case of
22 an at-risk beneficiary for prescription drug
23 abuse whose access to coverage for frequently
24 abused drugs under a prescription drug plan
25 has been limited by a PDP sponsor under this

1 paragraph, such PDP sponsor shall disclose
2 data, including any necessary individually iden-
3 tifiable health information, in a form and man-
4 ner specified by the Secretary, about the deci-
5 sion to impose such limitations and the limita-
6 tions imposed by the sponsor under this part to
7 other PDP sponsors that request such data.

8 “(I) EDUCATION.—The Secretary shall
9 provide education to enrollees in prescription
10 drug plans of PDP sponsors and providers re-
11 garding the drug management program for at-
12 risk beneficiaries described in this paragraph,
13 including education—

14 “(i) provided by medicare administra-
15 tive contractors through the improper pay-
16 ment outreach and education program de-
17 scribed in section 1874A(h); and

18 “(ii) through current education efforts
19 (such as State health insurance assistance
20 programs described in subsection (a)(1)(A)
21 of section 119 of the Medicare Improve-
22 ments for Patients and Providers Act of
23 2008 (42 U.S.C. 1395b–3 note)) and ma-
24 terials directed toward such enrollees.

1 “(J) APPLICATION UNDER MA–PD
2 PLANS.—Pursuant to section 1860D—21(c)(1),
3 the provisions of this paragraph apply under
4 part D to MA organizations offering MA–PD
5 plans to MA eligible individuals in the same
6 manner as such provisions apply under this
7 part to a PDP sponsor offering a prescription
8 drug plan to a part D eligible individual.”.

9 (2) INFORMATION FOR CONSUMERS.—Section
10 1860D–4(a)(1)(B) of the Social Security Act (42
11 U.S.C. 1395w–104(a)(1)(B)) is amended by adding
12 at the end the following:

13 “(v) The drug management program
14 for at-risk beneficiaries under subsection
15 (c)(5).”.

16 (b) UTILIZATION MANAGEMENT PROGRAMS.—Sec-
17 tion 1860D–4(c) of the Social Security Act (42 U.S.C.
18 1395w–104(c)), as amended by subsection (a)(1), is fur-
19 ther amended—

20 (1) in paragraph (1), by inserting after sub-
21 paragraph (D) the following new subparagraph:

22 “(E) A utilization management tool to pre-
23 vent drug abuse (as described in paragraph
24 (6)(A)).”; and

1 (2) by adding at the end the following new
2 paragraph:

3 “(6) UTILIZATION MANAGEMENT TOOL TO PRE-
4 VENT DRUG ABUSE.—

5 “(A) IN GENERAL.—A tool described in
6 this paragraph is any of the following:

7 “(i) A utilization tool designed to pre-
8 vent the abuse of frequently abused drugs
9 by individuals and to prevent the diversion
10 of such drugs at pharmacies.

11 “(ii) Retrospective utilization review
12 to identify—

13 “(I) individuals that receive fre-
14 quently abused drugs at a frequency
15 or in amounts that are not clinically
16 appropriate; and

17 “(II) providers of services or sup-
18 pliers that may facilitate the abuse or
19 diversion of frequently abused drugs
20 by beneficiaries.

21 “(iii) Consultation with the contractor
22 described in subparagraph (B) to verify if
23 an individual enrolling in a prescription
24 drug plan offered by a PDP sponsor has
25 been previously identified by another PDP

1 sponsor as an individual described in
2 clause (ii)(I).

3 “(B) REPORTING.—A PDP sponsor offer-
4 ing a prescription drug plan (and an MA orga-
5 nization offering an MA–PD plan) in a State
6 shall submit to the Secretary and the Medicare
7 drug integrity contractor with which the Sec-
8 retary has entered into a contract under section
9 1893 with respect to such State a report, on a
10 monthly basis, containing information on—

11 “(i) any provider of services or sup-
12 plier described in subparagraph (A)(ii)(II)
13 that is identified by such plan sponsor (or
14 organization) during the 30-day period be-
15 fore such report is submitted; and

16 “(ii) the name and prescription
17 records of individuals described in para-
18 graph (5)(C).”.

19 (c) EXPANDING ACTIVITIES OF MEDICARE DRUG IN-
20 TEGRITY CONTRACTORS (MEDICS).—

21 (1) IN GENERAL.—Section 1893 of the Social
22 Security Act (42 U.S.C. 1395ddd) is amended by
23 adding at the end the following new subsection:

24 “(j) EXPANDING ACTIVITIES OF MEDICARE DRUG
25 INTEGRITY CONTRACTORS (MEDICS).—

1 “(1) ACCESS TO INFORMATION.—Under con-
2 tracts entered into under this section with Medicare
3 drug integrity contractors (including any successor
4 entity to a Medicare drug integrity contractor), the
5 Secretary shall authorize such contractors to directly
6 accept prescription and necessary medical records
7 from entities such as pharmacies, prescription drug
8 plans, MA–PD plans, and physicians with respect to
9 an individual in order for such contractors to pro-
10 vide information relevant to the determination of
11 whether such individual is an at-risk beneficiary for
12 prescription drug abuse, as defined in section
13 1860D–4(c)(5)(C).

14 “(2) REQUIREMENT FOR ACKNOWLEDGMENT
15 OF REFERRALS.—If a PDP sponsor or MA organiza-
16 tion refers information to a contractor described in
17 paragraph (1) in order for such contractor to assist
18 in the determination described in such paragraph,
19 the contractor shall—

20 “(A) acknowledge to the sponsor or organi-
21 zation receipt of the referral; and

22 “(B) in the case that any PDP sponsor or
23 MA organization contacts the contractor re-
24 questing to know the determination by the con-
25 tractor of whether or not an individual has been

1 determined to be an individual described such
2 paragraph, shall inform such sponsor or organi-
3 zation of such determination on a date that is
4 not later than 15 days after the date on which
5 the sponsor or organization contacts the con-
6 tractor.

7 “(3) MAKING DATA AVAILABLE TO OTHER EN-
8 TITIES.—

9 “(A) IN GENERAL.—For purposes of car-
10 rying out this subsection, subject to subpara-
11 graph (B), the Secretary shall authorize MED-
12 ICs to respond to requests for information from
13 PDP sponsors and MA organizations, State
14 prescription drug monitoring programs, and
15 other entities delegated by such sponsors or or-
16 ganizations using available programs and sys-
17 tems in the effort to prevent fraud, waste, and
18 abuse.

19 “(B) HIPAA COMPLIANT INFORMATION
20 ONLY.—Information may only be disclosed by a
21 MEDIC under subparagraph (A) if the dislo-
22 sure of such information is permitted under the
23 Federal regulations (concerning the privacy of
24 individually identifiable health information) pro-
25 mulgated under section 264(c) of the Health

1 Insurance Portability and Accountability Act of
2 1996 (42 U.S.C. 1320d–2 note).”.

3 (2) OIG STUDY AND REPORT ON EFFECTIVE-
4 NESS OF MEDICS.—

5 (A) STUDY.—The Inspector General of the
6 Department of Health and Human Services
7 shall conduct a study on the effectiveness of
8 Medicare drug integrity contractors with which
9 the Secretary of Health and Human Services
10 has entered into a contract under section 1893
11 of the Social Security Act (42 U.S.C. 1395ddd)
12 in identifying, combating, and preventing fraud
13 under the Medicare program, including under
14 the authority provided under section 1893(j) of
15 the Social Security Act, added by paragraph
16 (1).

17 (B) REPORT.—Not later than 1 year after
18 the date of the enactment of this Act, the In-
19 spector General shall submit to Congress a re-
20 port on the study conducted under subpara-
21 graph (A). Such report shall include such rec-
22 ommendations for improvements in the effec-
23 tiveness of such contractors as the Inspector
24 General determines appropriate.

1 (d) TREATMENT OF CERTAIN COMPLAINTS FOR PUR-
2 POSES OF QUALITY OR PERFORMANCE ASSESSMENT.—
3 Section 1860D–42 of the Social Security Act (42 U.S.C.
4 1395w–152) is amended by adding at the end the fol-
5 lowing new subsection:

6 “(d) TREATMENT OF CERTAIN COMPLAINTS FOR
7 PURPOSES OF QUALITY OR PERFORMANCE ASSESS-
8 MENT.—In conducting a quality or performance assess-
9 ment of a PDP sponsor, the Secretary shall develop or
10 utilize existing screening methods for reviewing and con-
11 sidering complaints that are received from enrollees in a
12 prescription drug plan offered by such PDP sponsor and
13 that are complaints regarding the lack of access by the
14 individual to prescription drugs due to a drug manage-
15 ment program for at-risk beneficiaries.”.

16 (e) SENSE OF CONGRESS REGARDING USE OF TECH-
17 NOLOGY TOOLS TO COMBAT FRAUD.—It is the sense of
18 Congress that MA organizations and PDP sponsors
19 should consider using e-prescribing and other health infor-
20 mation technology tools to support combating fraud under
21 MA–PD plans and prescription drug plans under parts C
22 and D of the Medicare program.

23 (f) EFFECTIVE DATE.—

24 (1) IN GENERAL.—The amendments made by
25 this section shall apply to prescription drug plans

1 (and MA–PD plans) for plan years beginning more
2 than 1 year after the date of the enactment of this
3 Act.

4 (2) STAKEHOLDER MEETINGS PRIOR TO EFFEC-
5 TIVE DATE.—

6 (A) IN GENERAL.—Not later than January
7 1, 2016, the Secretary of Health and Human
8 Services shall convene stakeholders, including
9 individuals entitled to benefits under part A of
10 title XVIII of the Social Security Act or en-
11 rolled under part B of such title of such Act,
12 advocacy groups representing such individuals,
13 physicians, pharmacists, and other clinicians,
14 retail pharmacies, plan sponsors, entities dele-
15 gated by plan sponsors, and biopharmaceutical
16 manufacturers for input regarding the topics
17 described in subparagraph (B).

18 (B) TOPICS DESCRIBED.—The topics de-
19 scribed in this subparagraph are the topics of—

20 (i) the anticipated impact of drug
21 management programs for at-risk bene-
22 ficiaries under paragraph (5) of section
23 1860D–4(c) of the Social Security Act (42
24 U.S.C. 1395w–104(c)) on cost-sharing and
25 ensuring accessibility to prescription drugs

1 for enrollees in prescription drug plans of
2 PDP sponsors, and enrollees in MA–PD
3 plans, who are at-risk beneficiaries for pre-
4 scription drug abuse (as defined in sub-
5 paragraph (C) of such paragraph);

6 (ii) the use of an expedited appeals
7 process under which such an enrollee may
8 appeal an identification of such enrollee as
9 an at-risk beneficiary for prescription drug
10 abuse under such paragraph (similar to the
11 processes established under the Medicare
12 Advantage program under part C of title
13 XVIII of the Social Security Act that allow
14 an automatic escalation to external review
15 of claims submitted under such part);

16 (iii) the types of enrollees that should
17 be treated as exempted individuals, as de-
18 scribed in subparagraph (C)(ii) of such
19 paragraph;

20 (iv) the manner in which terms and
21 definitions in such paragraph should be ap-
22 plied, such as the use of clinical appro-
23 priateness in determining whether an en-
24 rollee is an at-risk beneficiary for prescrip-

1 tion drug abuse as defined in subpara-
2 graph (C) of such paragraph;

3 (v) the information to be included in
4 the notices described in subparagraph (B)
5 of such paragraph and the standardization
6 of such notices; and

7 (vi) with respect to a PDP sponsor
8 (or Medicare Advantage organization) that
9 establishes a drug management program
10 for at-risk beneficiaries under such para-
11 graph, the responsibilities of such PDP
12 sponsor (or organization) with respect to
13 the implementation of such program.

14 (g) RULEMAKING.—The Secretary of Health and
15 Human Services shall promulgate regulations based on the
16 input gathered pursuant to subsection (f)(2)(A).

17 **TITLE IV—MEDICAID, MEDI-**
18 **CARE, AND OTHER REFORMS**

19 **Subtitle A—Medicaid and Medicare**
20 **Reforms**

21 **SEC. 4001. LIMITING FEDERAL MEDICAID REIMBURSEMENT**
22 **TO STATES FOR DURABLE MEDICAL EQUIP-**
23 **MENT (DME) TO MEDICARE PAYMENT RATES.**

24 (a) MEDICAID REIMBURSEMENT.—

1 (1) IN GENERAL.—Section 1903(i) of the Social
2 Security Act (42 U.S.C. 1396b(i)) is amended—

3 (A) in paragraph (25), by striking “or” at
4 the end;

5 (B) in paragraph (26), by striking the pe-
6 riod at the end and inserting “; or”; and

7 (C) by inserting after paragraph (26) the
8 following new paragraph:

9 “(27) with respect to any amounts expended by
10 the State on the basis of a fee schedule for items de-
11 scribed in section 1861(n), as determined in the ag-
12 gregate with respect to each class of such items as
13 defined by the Secretary, in excess of the aggregate
14 amount, if any, that would be paid for such items
15 within such class on a fee-for-service basis under the
16 program under part B of title XVIII, including, as
17 applicable, under a competitive acquisition program
18 under section 1847 in an area of the State.”.

19 (2) EFFECTIVE DATE.—The amendments made
20 by this subsection shall be effective with respect to
21 payments for items furnished on or after January 1,
22 2020.

23 (b) MEDICARE OMBUDSMAN.—Section 1808(c) of the
24 Social Security Act (42 U.S.C. 1395b(c)), as amended by

1 section 3101, is further amended by adding at the end
2 the following new paragraph:

3 “(5) MONITORING DME REIMBURSEMENT
4 UNDER MEDICAID.—The ombudsmen under each of
5 paragraphs (1) and (4) shall evaluate the impact of
6 the competitive acquisition program under section
7 1847, including as applied under section
8 1903(i)(27), on beneficiary health status and health
9 outcomes.”.

10 **SEC. 4002. EXCLUDING AUTHORIZED GENERICS FROM CAL-**
11 **CULATION OF AVERAGE MANUFACTURER**
12 **PRICE.**

13 (a) IN GENERAL.—Subparagraph (C) of section
14 1927(k)(1) of the Social Security Act (42 U.S.C. 1396r–
15 8(k)(1)) is amended—

16 (1) in the subparagraph heading, by striking
17 “INCLUSION” and inserting “EXCLUSION”;

18 (2) by striking “a new drug application” and
19 inserting “the manufacturer’s new drug applica-
20 tion”; and

21 (3) by striking “inclusive” and inserting “exclu-
22 sive”.

23 (b) EFFECTIVE DATE.—The amendments made by
24 this section take effect on October 1, 2015.

1 **SEC. 4003. MEDICARE PAYMENT INCENTIVE FOR THE TRAN-**
2 **SITION FROM TRADITIONAL X-RAY IMAGING**
3 **TO DIGITAL RADIOGRAPHY AND OTHER**
4 **MEDICARE IMAGING PAYMENT PROVISION.**

5 (a) **PHYSICIAN FEE SCHEDULE.**—

6 (1) **PAYMENT INCENTIVE FOR TRANSITION.**—

7 (A) **IN GENERAL.**—Section 1848(b) of the
8 Social Security Act (42 U.S.C. 1395w-4(b)) is
9 amended by adding at the end the following
10 new paragraph:

11 “(9) **SPECIAL RULE TO INCENTIVIZE TRANSI-**
12 **TION FROM TRADITIONAL X-RAY IMAGING TO DIG-**
13 **ITAL RADIOGRAPHY.**—

14 “(A) **LIMITATION ON PAYMENT FOR FILM**
15 **X-RAY IMAGING SERVICES.**—In the case of an
16 imaging service (including the imaging portion
17 of a service) that is an X-ray taken using film
18 and that is furnished during 2017 or a subse-
19 quent year, the payment amount for the tech-
20 nical component (including the technical compo-
21 nent portion of a global service) of such service
22 that would otherwise be determined under this
23 section (without application of this paragraph
24 and before application of any other adjustment
25 under this section) for such year shall be re-
26 duced by 20 percent.

1 “(B) PHASED-IN LIMITATION ON PAYMENT
2 FOR COMPUTED RADIOGRAPHY IMAGING SERV-
3 ICES.—In the case of an imaging service (in-
4 cluding the imaging portion of a service) that is
5 an X-ray taken using computed radiography
6 technology—

7 “(i) in the case of such a service fur-
8 nished during 2018, 2019, 2020, 2021, or
9 2022, the payment amount for the tech-
10 nical component (including the technical
11 component portion of a global service) of
12 such service that would otherwise be deter-
13 mined under this section (without applica-
14 tion of this paragraph and before applica-
15 tion of any other adjustment under this
16 section) for such year shall be reduced by
17 7 percent; and

18 “(ii) in the case of such a service fur-
19 nished during 2023 or a subsequent year,
20 the payment amount for the technical com-
21 ponent (including the technical component
22 portion of a global service) of such service
23 that would otherwise be determined under
24 this section (without application of this
25 paragraph and before application of any

1 lished beginning with 2018, reduced
2 expenditures attributable to subpara-
3 graph (B) of such subsection.”.

4 (2) ELIMINATION OF APPLICATION OF MUL-
5 TIPLE PROCEDURE PAYMENT REDUCTION.—

6 (A) IN GENERAL.—Section 1848(b)(4) of
7 the Social Security Act (42 U.S.C. 1395w-
8 4(b)(4)) is amended by adding at the end the
9 following new subparagraph:

10 “(E) ELIMINATION OF APPLICATION OF
11 MULTIPLE PROCEDURE PAYMENT REDUC-
12 TION.—

13 “(i) IN GENERAL.—For services fur-
14 nished on or after January 1, 2017, the
15 Secretary shall not apply a multiple proce-
16 dure payment reduction to the professional
17 component of imaging services unless the
18 Secretary has published as part of a Medi-
19 care Physician Fee Schedule Proposed
20 Rule the empirical analysis described in
21 clause (ii) with tables made available on
22 the website of the Centers for Medicare &
23 Medicaid Services.

24 “(ii) EMPIRICAL ANALYSIS DE-
25 SCRIBED.—The empirical analysis de-

1 scribed in this clause is an analysis of the
2 Resource-Based Relative Value Scale Data
3 Manager information or other information
4 that is used to determine what, if any, effi-
5 ciencies exist within the professional com-
6 ponent of imaging services when two or
7 more studies are furnished to the same in-
8 dividual on the same day. Such empirical
9 analysis shall include—

10 “(I) information detailing which
11 physician work activities overlap and
12 the reductions applicable to such over-
13 lap;

14 “(II) a discussion of the clinical
15 aspects that informed the assignment
16 of the reduction percentages described
17 in subclause (I);

18 “(III) to the extent that such re-
19 ductions are used for proposed pay-
20 ment reductions, an explanation of
21 how the percentage reductions for pre-
22 service, intra-service, and post-service
23 work were determined and calculated;

24 “(IV) other data used to deter-
25 mine a reduction; and

1 “(V) a demonstration that the
2 Secretary has consulted with prac-
3 ticing radiologists to gain knowledge
4 of how radiologists interpret studies of
5 multiple body parts on the same indi-
6 vidual on the same day.”.

7 (B) CONFORMING AMENDMENT.—Section
8 220(i) of the Protecting Access to Medicare Act
9 of 2014 (42 U.S.C. 1395w-4 note) is repealed.

10 (b) PAYMENT INCENTIVE FOR TRANSITION UNDER
11 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYS-
12 TEM.—Section 1833(t)(16) of the Social Security Act (42
13 U.S.C. 1395(t)(16)) is amended by adding at the end the
14 following new subparagraph:

15 “(F) PAYMENT INCENTIVE FOR THE TRAN-
16 SITION FROM TRADITIONAL X-RAY IMAGING TO
17 DIGITAL RADIOGRAPHY.—Notwithstanding the
18 previous provisions of this subsection:

19 “(i) LIMITATION ON PAYMENT FOR
20 FILM X-RAY IMAGING SERVICES.—In the
21 case of an imaging service that is an X-ray
22 taken using film and that is furnished dur-
23 ing 2017 or a subsequent year, the pay-
24 ment amount for such service (including
25 the X-ray component of a packaged serv-

1 ice) that would otherwise be determined
2 under this section (without application of
3 this paragraph and before application of
4 any other adjustment under this sub-
5 section) for such year shall be reduced by
6 20 percent.

7 “(ii) PHASED-IN LIMITATION ON PAY-
8 MENT FOR COMPUTED RADIOGRAPHY IM-
9 AGING SERVICES.—In the case of an imag-
10 ing service that is an X-ray taken using
11 computed radiography technology (as de-
12 fined in section 1848(b)(9)(C))—

13 “(I) in the case of such a service
14 furnished during 2018, 2019, 2020,
15 2021, or 2022, the payment amount
16 for such service (including the X-ray
17 component of a packaged service) that
18 would otherwise be determined under
19 this section (without application of
20 this paragraph and before application
21 of any other adjustment under this
22 subsection) for such year shall be re-
23 duced by 7 percent; and

24 “(II) in the case of such a service
25 furnished during 2023 or a subse-

1 quent year, the payment amount for
2 such service (including the X-ray com-
3 ponent 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 10 percent.

10 “(iii) APPLICATION WITHOUT REGARD
11 TO BUDGET NEUTRALITY.—The reductions
12 made under this paragraph—

13 “(I) shall not be considered an
14 adjustment under paragraph (2)(E);
15 and

16 “(II) shall not be implemented in
17 a budget neutral manner.

18 “(iv) IMPLEMENTATION.—In order to
19 implement this subparagraph, the Sec-
20 retary shall adopt appropriate mechanisms
21 which may include use of modifiers.”.

22 **SEC. 4004. TREATMENT OF INFUSION DRUGS FURNISHED**
23 **THROUGH DURABLE MEDICAL EQUIPMENT.**

24 Section 1842(o)(1) of the Social Security Act (42
25 U.S.C. 1395u(o)(1)) is amended—

1 (1) in subparagraph (C), by inserting “(and in-
2 cluding a drug or biological described in subpara-
3 graph (D)(i) furnished on or after January 1,
4 2017)” after “2005”; and

5 (2) in subparagraph (D)—

6 (A) by striking “infusion drugs” and in-
7 serting “infusion drugs or biologicals” each
8 place it appears; and

9 (B) in clause (i)—

10 (i) by striking “2004” and inserting
11 “2004, and before January 1, 2017”; and

12 (ii) by striking “for such drug”.

13 **SEC. 4005. EXTENSION AND EXPANSION OF PRIOR AUTHOR-**
14 **IZATION FOR POWER MOBILITY DEVICES**
15 **(PMDs) AND ACCESSORIES AND PRIOR AU-**
16 **THORIZATION AUDIT LIMITATIONS.**

17 Section 1834(a) of the Social Security Act (42 U.S.C.
18 1395m(a)) is amended—

19 (1) in paragraph (15), by adding at the end the
20 following new subparagraph:

21 “(D) **LIMITATION ON AUDITS AFTER AD-**
22 **VANCE DETERMINATION.**—A claim for an item
23 that has received a provisional affirmation
24 under an advance determination under this
25 paragraph or a prior authorization under para-

1 graph (23) shall not be subject to review under
2 section 1893(h) but may be subject to audits
3 for potential fraud, inappropriate utilization,
4 changes in billing patterns, or information that
5 could not have been considered during the ad-
6 vance determination (such as proof of item de-
7 livery).”; and

8 (2) by adding at the end the following new
9 paragraph:

10 “(23) PRIOR AUTHORIZATION FOR POWER MO-
11 BILITY DEVICES (PMDs) AND ACCESSORIES.—Not
12 later than 90 days after the date of the enactment
13 of this paragraph, the Secretary shall, using funds
14 provided under paragraph (2) of section 402(a) of
15 the Social Security Amendments of 1967 and other
16 funds available to the Secretary—

17 “(A) extend at least through August 31,
18 2018, the PMD Prior Authorization Dem-
19 onstration (being conducted under paragraph
20 (1)(J) of such section);

21 “(B) begin to expand, as appropriate, such
22 demonstration to include additional power mo-
23 bility devices and accessories as part of initial
24 claims for payment under this part for such de-
25 vices; and

1 “(C) begin to expand such demonstration
2 to such additional States or geographic areas as
3 may be appropriate.”.

4 **SEC. 4006. CIVIL MONETARY PENALTIES FOR VIOLATIONS**
5 **RELATED TO GRANTS, CONTRACTS, AND**
6 **OTHER AGREEMENTS.**

7 (a) IN GENERAL.—Section 1128A of the Social Secu-
8 rity Act (42 U.S.C. 1320a–7a) is amended by adding at
9 the end the following new subsection:

10 “(o) Any person (including an organization, agency,
11 or other entity, but excluding a program beneficiary, as
12 defined in subsection (r)(4)) that, with respect to a grant,
13 contract, or other agreement for which the Secretary of
14 Health and Human Services provides funding—

15 “(1) knowingly presents or causes to be pre-
16 sented a specified claim (as defined in subsection
17 (r)(6)) under such grant, contract, or other agree-
18 ment that the person knows or should know is false
19 or fraudulent;

20 “(2) knowingly makes, uses, or causes to be
21 made or used any false statement, omission, or mis-
22 representation of a material fact in any application,
23 proposal, bid, progress report, or other document
24 that is required to be submitted in order to directly
25 or indirectly receive or retain funds provided in

1 whole or in part by such Secretary pursuant to such
2 grant, contract, or other agreement;

3 “(3) knowingly makes, uses, or causes to be
4 made or used, a false record or statement material
5 to a false or fraudulent specified claim under such
6 grant, contract, or other agreement;

7 “(4) knowingly makes, uses, or causes to be
8 made or used, a false record or statement material
9 to an obligation to pay or transmit funds or property
10 to such Secretary with respect to such grant, con-
11 tract, or other agreement, or knowingly conceals or
12 knowingly and improperly avoids or decreases an ob-
13 ligation to pay or transmit funds or property to such
14 Secretary with respect to such grant, contract, or
15 other agreement; or

16 “(5) fails to grant timely access, upon reason-
17 able request (as defined by such Secretary in regula-
18 tions), to the Inspector General of the Department,
19 for the purpose of audits, investigations, evaluations,
20 or other statutory functions of such Inspector Gen-
21 eral in matters involving such grants, contracts, or
22 other agreements;

23 shall be subject, in addition to any other penalties that
24 may be prescribed by law, to a civil money penalty in cases
25 under paragraph (1), of not more than \$10,000 for each

1 specified claim; in cases under paragraph (2), not more
2 than \$50,000 for each false statement, omission, or mis-
3 representation of a material fact; in cases under para-
4 graph (3), not more than \$50,000 for each false record
5 or statement; in cases under paragraph (4), not more than
6 \$50,000 for each false record or statement or \$10,000 for
7 each day that the person knowingly conceals or knowingly
8 and improperly avoids or decreases an obligation to pay;
9 or in cases under paragraph (5), not more than \$15,000
10 for each day of the failure described in such paragraph.
11 In addition, in cases under paragraphs (1) and (3), such
12 a person shall be subject to an assessment of not more
13 than 3 times the amount claimed in the specified claim
14 described in such paragraph in lieu of damages sustained
15 by the United States or a specified State agency because
16 of such specified claim, and in cases under paragraphs (2)
17 and (4), such a person shall be subject to an assessment
18 of not more than 3 times the total amount of the funds
19 described in paragraph (2) or (4), respectively (or, in the
20 case of an obligation to transmit property to the Secretary
21 Health and Human Services described in paragraph (4),
22 of the value of the property described in such paragraph)
23 in lieu of damages sustained by the United States or a
24 specified State agency because of such case. In addition,
25 the Secretary of Health and Human Services may make

1 a determination in the same proceeding to exclude the per-
2 son from participation in the Federal health care pro-
3 grams (as defined in section 1128B(f)(1)) and to direct
4 the appropriate State agency to exclude the person from
5 participation in any State health care program.

6 “(p) The provisions of subsections (c), (d), and (g)
7 shall apply to a civil money penalty or assessment under
8 subsection (o) in the same manner as such provisions
9 apply to a penalty, assessment, or proceeding under sub-
10 section (a).

11 “(q) With respect to a penalty or assessment under
12 subsection (o), the Inspector General of the Department
13 is authorized to receive, and to retain for current use, such
14 amounts of such penalty or assessment as are necessary
15 to provide reimbursement for the costs of conducting in-
16 vestigations and audits with respect to such subsection
17 and for monitoring compliance plans with respect to such
18 subsection when such penalty or assessment is ordered by
19 a court, voluntarily agreed to by the payor, or otherwise.
20 Funds received by such Inspector General as reimburse-
21 ment under the preceding sentence shall be deposited to
22 the credit of the appropriations from which initially paid,
23 or to appropriations for similar purposes currently avail-
24 able at the time of deposit, and shall remain available for

1 obligation for 1 year from the date of the deposit of such
2 funds.

3 “(r) For purposes of this subsection and subsections
4 (o), (p), and (q):

5 “(1) The term ‘Department’ means the Depart-
6 ment of Health and Human Services.

7 “(2) The term ‘material’ means having a nat-
8 ural tendency to influence, or be capable of influ-
9 encing, the payment or receipt of money or property.

10 “(3) The term ‘other agreement’ includes a co-
11 operative agreement, scholarship, fellowship, loan,
12 subsidy, payment for a specified use, donation agree-
13 ment, award, or sub-award (regardless of whether
14 one or more of the persons entering into the agree-
15 ment is a contractor or sub-contractor).

16 “(4) The term ‘program beneficiary’ means, in
17 the case of a grant, contract, or other agreement de-
18 signed to accomplish the objective of awarding or
19 otherwise furnishing benefits or assistance to indi-
20 viduals and for which the Secretary of Health and
21 Human Services provides funding, an individual who
22 applies for, or who receives, such benefits or assist-
23 ance from such grant, contract, or other agreement.
24 Such term does not include, with respect to such
25 grant, contract, or other agreement, an officer, em-

1 ployee, or agent of a person or entity that receives
2 such grant or that enters into such contract or other
3 agreement.

4 “(5) The term ‘recipient’ includes a sub-recipient
5 or subcontractor.

6 “(6) The term ‘specified claim’ means any application,
7 request, or demand under a grant, contract, or other agreement for money or property,
8 whether or not the United States or a specified
9 State agency has title to the money or property, that
10 State agency has title to the money or property, that
11 is not a claim (as defined in subsection (i)(2)) and
12 that—

13 “(A) is presented or caused to be presented
14 to an officer, employee, or agent of the
15 Department or agency thereof, or of any specified
16 State agency; or

17 “(B) is made to a contractor, grantee, or
18 any other recipient if the money or property is
19 to be spent or used on the Department’s behalf
20 or to advance a Department program or interest,
21 and if the Department—

22 “(i) provides or has provided any portion
23 of the money or property requested or
24 demanded; or

1 “(ii) will reimburse such contractor,
2 grantee or other recipient for any portion
3 of the money or property which is re-
4 quested or demanded.

5 “(7) The term ‘specified State agency’ means
6 an agency of a State government established or des-
7 ignated to administer or supervise the administra-
8 tion of a grant, contract, or other agreement funded
9 in whole or in part by the Secretary of Health and
10 Human Services.

11 “(s) For purposes of subsection (o), the term ‘obliga-
12 tion’ means an established duty, whether or not fixed, aris-
13 ing from an express or implied contractual, grantor-grant-
14 ee, or licensor-licensee relationship, for a fee-based or
15 similar relationship, from statute or regulation, or from
16 the retention of any overpayment.”.

17 (b) CONFORMING AMENDMENTS.—Section 1128A of
18 the Social Security Act (42 U.S.C. 1320a–7a) is amend-
19 ed—

20 (1) in subsection (d)—

21 (A) in paragraph (1), by inserting “or
22 specified claims” after “claims”;

23 (B) in paragraph (2), by inserting “or
24 specified claims” after “claims”;

1 (2) in subsection (e), by inserting “or specified
2 claim” after “claim”; and

3 (3) in subsection (f)—

4 (A) by inserting “or specified claim (as de-
5 fined in subsection (r)(6))” after “district
6 where the claim”;

7 (B) by inserting “(or, with respect to a
8 person described in subsection (o), the person)”
9 after “claimant”;

10 (C) by inserting “that are not received by
11 the Inspector General of the Department of
12 Health and Human Services under subsection
13 (q) as reimbursement” after “amounts recov-
14 ered”; and

15 (D) by inserting “(or, in the case of a pen-
16 alty or assessment under subsection (o), by a
17 specified State agency (as defined in subsection
18 (r)(7))” after “or a State agency”.

19 **Subtitle B—Other Reforms**

20 **SEC. 4041. SPR DRAWDOWN.**

21 (a) DRAWDOWN AND SALE.—Notwithstanding sec-
22 tion 161 of the Energy Policy and Conservation Act (42
23 U.S.C. 6241), except as provided in subsection (b) the
24 Secretary of Energy shall draw down and sell—

1 (1) 4,000,000 barrels of crude oil from the
2 Strategic Petroleum Reserve during fiscal year
3 2018;

4 (2) 5,000,000 barrels of crude oil from the
5 Strategic Petroleum Reserve during fiscal year
6 2019;

7 (3) 8,000,000 barrels of crude oil from the
8 Strategic Petroleum Reserve during fiscal year
9 2020;

10 (4) 8,000,000 barrels of crude oil from the
11 Strategic Petroleum Reserve during fiscal year
12 2021;

13 (5) 10,000,000 barrels of crude oil from the
14 Strategic Petroleum Reserve during fiscal year
15 2022;

16 (6) 15,000,000 barrels of crude oil from the
17 Strategic Petroleum Reserve during fiscal year
18 2023;

19 (7) 15,000,000 barrels of crude oil from the
20 Strategic Petroleum Reserve during fiscal year
21 2024; and

22 (8) 15,000,000 barrels of crude oil from the
23 Strategic Petroleum Reserve during fiscal year
24 2025.

1 Amounts received for a sale under this subsection shall
2 be deposited in the General Fund of the Treasury during
3 the fiscal year in which the sale occurs.

4 (b) EMERGENCY PROTECTION.—The Secretary shall
5 not draw down and sell crude oil under this section in
6 amounts that would result in a Strategic Petroleum Re-
7 serve that contains an inventory of petroleum products
8 representing less than 90 days of emergency reserves,
9 based on the average daily level of net imports of crude
10 oil and petroleum products in the previous calendar year.

11 (c) PROCEEDS.—Proceeds from a sale under this sec-
12 tion shall be deposited into the general fund of the Treas-
13 ury of the United States.

14 **Subtitle C—Miscellaneous**

15 **SEC. 4061. LYME DISEASE AND OTHER TICK-BORNE DIS-** 16 **EASES.**

17 (a) IN GENERAL.—Title III of the Public Health
18 Service Act (42 U.S.C. 241 et seq.) is amended by adding
19 at the end the following new part:

20 **“PART W—LYME DISEASE AND OTHER TICK-** 21 **BORNE DISEASES**

22 **“SEC. 3990O. RESEARCH.**

23 “(a) IN GENERAL.—The Secretary shall conduct or
24 support epidemiological, basic, translational, and clinical

1 research regarding Lyme disease and other tick-borne dis-
2 eases.

3 “(b) BIENNIAL REPORTS.—The Secretary shall en-
4 sure that each biennial report under section 403 includes
5 information on actions undertaken by the National Insti-
6 tutes of Health to carry out subsection (a) with respect
7 to Lyme disease and other tick-borne diseases, including
8 an assessment of the progress made in improving the out-
9 comes of Lyme disease and such other tick-borne diseases.

10 **“SEC. 39900-1. WORKING GROUP.**

11 “(a) ESTABLISHMENT.—The Secretary shall estab-
12 lish a permanent working group, to be known as the Inter-
13 agency Lyme and Tick-Borne Disease Working Group (in
14 this section and section 39900-2 referred to as the
15 ‘Working Group’), to review all efforts within the Depart-
16 ment of Health and Human Services concerning Lyme dis-
17 ease and other tick-borne diseases to ensure interagency
18 coordination, minimize overlap, and examine research pri-
19 orities.

20 “(b) RESPONSIBILITIES.—The Working Group
21 shall—

22 “(1) not later than 24 months after the date of
23 enactment of this part, and every 24 months there-
24 after, develop or update a summary of—

1 “(A) ongoing Lyme disease and other tick-
2 borne disease research related to causes, pre-
3 vention, treatment, surveillance, diagnosis,
4 diagnostics, duration of illness, intervention,
5 and access to services and supports for individ-
6 uals with Lyme disease or other tick-borne dis-
7 eases;

8 “(B) advances made pursuant to such re-
9 search;

10 “(C) the engagement of the Department of
11 Health and Human Services with persons that
12 participate at the public meetings required by
13 paragraph (5); and

14 “(D) the comments received by the Work-
15 ing Group at such public meetings and the Sec-
16 retary’s response to such comments;

17 “(2) ensure that a broad spectrum of scientific
18 viewpoints is represented in each such summary;

19 “(3) monitor Federal activities with respect to
20 Lyme disease and other tick-borne diseases;

21 “(4) make recommendations to the Secretary
22 regarding any appropriate changes to such activities;
23 and

24 “(5) ensure public input by holding annual pub-
25 lic meetings that address scientific advances, re-

1 search questions, surveillance activities, and emerg-
2 ing strains in species of pathogenic organisms.

3 “(c) MEMBERSHIP.—

4 “(1) IN GENERAL.—The Working Group shall
5 be composed of a total of 14 members as follows:

6 “(A) FEDERAL MEMBERS.—Seven Federal
7 members, consisting of one or more representa-
8 tives of each of—

9 “(i) the Office of the Assistant Sec-
10 retary for Health;

11 “(ii) the Food and Drug Administra-
12 tion;

13 “(iii) the Centers for Disease Control
14 and Prevention;

15 “(iv) the National Institutes of
16 Health; and

17 “(v) such other agencies and offices of
18 the Department of Health and Human
19 Services as the Secretary determines ap-
20 propriate.

21 “(B) NON-FEDERAL PUBLIC MEMBERS.—
22 Seven non-Federal public members, consisting
23 of representatives of the following categories:

24 “(i) Physicians and other medical pro-
25 viders with experience in diagnosing and

1 treating Lyme disease and other tick-borne
2 diseases.

3 “(ii) Scientists or researchers with ex-
4 pertise.

5 “(iii) Patients and their family mem-
6 bers.

7 “(iv) Nonprofit organizations that ad-
8 vocate for patients with respect to Lyme
9 disease and other tick-borne diseases.

10 “(v) Other individuals whose expertise
11 is determined by the Secretary to be bene-
12 ficial to the functioning of the Working
13 Group.

14 “(2) APPOINTMENT.—The members of the
15 Working Group shall be appointed by the Secretary,
16 except that of the non-Federal public members
17 under paragraph (1)(B)—

18 “(A) one shall be appointed by the Speaker
19 of the House of Representatives; and

20 “(B) one shall be appointed by the major-
21 ity leader of the Senate.

22 “(3) DIVERSITY OF SCIENTIFIC PERSPEC-
23 TIVES.—In making appointments under paragraph
24 (2), the Secretary, the Speaker of the House of Rep-
25 resentatives, and the majority leader of the Senate

1 shall ensure that the non-Federal public members of
2 the Working Group represent a diversity of scientific
3 perspectives.

4 “(4) TERMS.—The non-Federal public members
5 of the Working Group shall each be appointed to
6 serve a 4-year term and may be reappointed at the
7 end of such term.

8 “(d) MEETINGS.—The Working Group shall meet as
9 often as necessary, as determined by the Secretary, but
10 not less than twice each year.

11 “(e) APPLICABILITY OF FACCA.—The Working Group
12 shall be treated as an advisory committee subject to the
13 Federal Advisory Committee Act.

14 “(f) REPORTING.—Not later than 24 months after
15 the date of enactment of this part, and every 24 months
16 thereafter, the Working Group—

17 “(1) shall submit a report on its activities, in-
18 cluding an up-to-date summary under subsection
19 (b)(1) and any recommendations under subsection
20 (b)(4), to the Secretary, the Committee on Energy
21 and Commerce of the House of Representatives, and
22 the Committee on Health, Education, Labor and
23 Pensions of the Senate;

1 “(2) shall make each such report publicly avail-
2 able on the website of the Department of Health and
3 Human Services; and

4 “(3) shall allow any member of the Working
5 Group to include in any such report minority views.

6 **“SEC. 39900-2. STRATEGIC PLAN.**

7 “Not later than 3 years after the date of enactment
8 of this section, and every 5 years thereafter, the Secretary
9 shall submit to the Congress a strategic plan, informed
10 by the most recent summary under section 39900-
11 1(b)(1), for the conduct and support of Lyme disease and
12 tick-borne disease research, including—

13 “(1) proposed budgetary requirements;

14 “(2) a plan for improving outcomes of Lyme
15 disease and other tick-borne diseases, including
16 progress related to chronic or persistent symptoms
17 and chronic or persistent infection and co-infections;

18 “(3) a plan for improving diagnosis, treatment,
19 and prevention;

20 “(4) appropriate benchmarks to measure
21 progress on achieving the improvements described in
22 paragraphs (2) and (3); and

23 “(5) a plan to disseminate each summary under
24 section 39900-1(b)(1) and other relevant informa-
25 tion developed by the Working Group to the public,

1 including health care providers, public health depart-
2 ments, and other relevant medical groups.”.

3 (b) NO ADDITIONAL AUTHORIZATION OF APPRO-
4 PRIATIONS.—No additional funds are authorized to be ap-
5 propriated for the purpose of carrying out this section and
6 the amendment made by this section, and this section and
7 such amendment shall be carried out using amounts other-
8 wise available for such purpose.

