

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO THE COMMITTEE PRINT
[21ST CENTURY CURES ACT]
OFFERED BY MR. UPTON OF MICHIGAN, MS.
DEGETTE OF COLORADO, MR. PITTS OF
PENNSYLVANIA, MR. PALLONE OF NEW JER-
SEY, AND MR. GENE GREEN OF TEXAS**

Strike all after the enacting clause and insert the following:

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.

TITLE I—DISCOVERY

Subtitle A—National Institutes of Health Funding

Sec. 1001. National Institutes of Health reauthorization.

Sec. 1002. NIH Innovation Fund.

Subtitle B—National Institutes of Health Planning and Administration

Sec. 1021. NIH research strategic plan.

Sec. 1022. Increasing accountability at the National Institutes of Health.

Sec. 1023. Biomedical research working group.

Sec. 1024. Exemption for the National Institutes of Health from the Paper-
work Reduction Act requirements.

Sec. 1025. NIH travel.

Sec. 1026. Other Transactions Authority.

Sec. 1027. NCATS Phase IIB Restriction.

Sec. 1028. High-risk, high-reward research.

Subtitle C—Supporting Young Emerging Scientists

Sec. 1041. Improvement of loan repayment programs of National Institutes of Health.

Sec. 1042. Report.

Subtitle D—Capstone Grant Program

Sec. 1061. Capstone award.

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

Sec. 1081. National Pediatric Research Network.

Sec. 1082. Global Pediatric Clinical Trial Network Sense of Congress.

Sec. 1083. Appropriate age groupings in clinical research.

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

Sec. 1101. Sharing of data generated through NIH-funded research.

Sec. 1102. 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 responsible use of new antimicrobial 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.

Subtitle L—Priority Review for Breakthrough Devices

- Sec. 2201. Priority review for breakthrough devices.

Subtitle M—Medical Device Regulatory Process Improvements

- Sec. 2221. Third-party quality system assessment.
- Sec. 2222. Valid scientific evidence.
- 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.

Subtitle N—Sensible Oversight for Technology Which Advances Regulatory Efficiency

- Sec. 2241. Health software.
- Sec. 2242. Applicability and inapplicability of regulation.
- Sec. 2243. Exclusion from definition of device.

Subtitle O—Streamlining Clinical Trials

- 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.

TITLE III—DELIVERY

Subtitle A—Interoperability

- Sec. 3001. Ensuring interoperability.

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.

1 **TITLE I—DISCOVERY**
2 **Subtitle A—National Institutes of**
3 **Health Funding**

4 **SEC. 1001. NATIONAL INSTITUTES OF HEALTH REAUTHOR-**
5 **IZATION.**

6 Section 402A(a)(1) of the Public Health Service Act
7 (42 U.S.C. 282a(a)(1)) is amended—

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

10 (2) in subparagraph (C), by striking at the end
11 the period and inserting “; and”; and

12 (3) by adding at the end the following new sub-
13 paragraphs:

14 “(D) \$31,811,000,000 for fiscal year
15 2016;

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

18 “(F) \$34,851,000,000 for fiscal year
19 2018.”.

20 **SEC. 1002. NIH INNOVATION FUND.**

21 (a) **USE OF INNOVATION FUND.**—Section 402(b) of
22 the Public Health Service Act is amended—

23 (1) in paragraph (23), by striking at the end
24 “and”;

1 (2) in paragraph (24), by striking at the end
2 the period and inserting “; and”; and

3 (3) by inserting after paragraph (24), the fol-
4 lowing new paragraph:

5 “(25) shall, with respect to funds appropriated
6 under section 402A(e) to the NIH Innovation Fund,
7 allocate such funds to the national research insti-
8 tutes and national centers for conducting and sup-
9 porting innovation fund initiatives identified under
10 paragraph (3) of such section.”.

11 (b) ESTABLISHMENT OF INNOVATION FUND.—Sec-
12 tion 402A of the Public Health Service Act is amended—

13 (1) by redesignating subsection (e) as sub-
14 section (f); and

15 (2) by inserting after subsection (d) the fol-
16 lowing new subsection:

17 “(e) NIH INNOVATION FUND.—

18 “(1) ESTABLISHMENT.—For the purpose of al-
19 locations under section 402(b)(25), there is estab-
20 lished a fund to be known as the NIH Innovation
21 Fund. The Director of NIH shall, with respect to
22 funds appropriated to the NIH Innovation Fund, al-
23 locate such funds to support biomedical research
24 through the funding of basic, translational, and clin-
25 ical research.

1 “(2) AMOUNTS MADE AVAILABLE TO FUND.—

2 “(A) IN GENERAL.—Subject to subpara-
3 graph (B), there is authorized to be appro-
4 priated, and appropriated, to the NIH Innova-
5 tion Fund out of any funds in the Treasury not
6 otherwise appropriated, \$2,000,000,000 for
7 each of fiscal years 2016 through 2020. The
8 amounts appropriated to the Fund by the pre-
9 ceding sentence shall be in addition to any
10 amounts otherwise made available to the Na-
11 tional Institutes of Health.

12 “(B) MAINTAINING BASE APPROPRIATIONS
13 LEVEL.—The amounts appropriated by sub-
14 paragraph (A) for a fiscal year shall not be
15 available for obligation or expenditure unless
16 and until the total amount of funds made avail-
17 able to the National Institutes of Health for
18 such fiscal year, without regard to this sub-
19 section, are not less than the total amount of
20 funds made available to the National Institutes
21 of Health for fiscal year 2016.

22 “(C) ALLOCATION OF AMOUNTS.—Of the
23 amounts made available from the NIH Innova-
24 tion Fund for allocations under section
25 402(b)(25) for a fiscal year—

1 “(i) not less than \$500,000,000 shall
2 be for the Accelerating Advancement Pro-
3 gram under paragraph (5);

4 “(ii) not less than 35 percent of such
5 amounts remaining after subtracting the
6 allocation for the Accelerating Advance-
7 ment Program shall be for research under
8 paragraph (3)(B);

9 “(iii) not less than 20 percent of such
10 amounts remaining after subtracting the
11 allocation for the Accelerating Advance-
12 ment Program shall be for high-risk, high-
13 reward research under section 409K; and

14 “(iv) not more than 10 percent of
15 such amounts (without subtracting the al-
16 location for the Accelerating Advancement
17 Program) shall be for intramural research.

18 “(D) INAPPLICABILITY OF CERTAIN PROVI-
19 SIONS.—Amounts in the NIH Innovation Fund
20 shall not be subject to—

21 “(i) any transfer authority of the Sec-
22 retary or the Director of NIH under sec-
23 tion 241, subsection (c), subsection (d), or
24 any other provision of law (other than sec-
25 tion 402(b)(25) and this subsection); or

1 “(ii) the Nonrecurring expenses fund
2 under section 223 of division G of the Con-
3 solidated Appropriations Act, 2008 (42
4 U.S.C. 3514a).

5 “(3) AUTHORIZED USES.—Amounts in the NIH
6 Innovation Fund established under paragraph (1)
7 may be used only to conduct or support innovative
8 biomedical research through the following:

9 “(A) Research in which—

10 “(i) a principal investigator has a spe-
11 cific project or specific objectives; and

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

14 “(B) Research in which—

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

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

19 “(C) Research to be carried out by an
20 early stage investigator (as defined in para-
21 graph (7)).

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

1 “(E) The Accelerating Advancement Pro-
2 gram under paragraph (5).

3 “(F) Development and implementation of
4 the strategic plan under paragraph (6).

5 “(4) COORDINATION.—In funding programs
6 and activities through the NIH Innovation Fund,
7 the Secretary, acting through the Director of NIH,
8 shall—

9 “(A) ensure coordination among the na-
10 tional research institutes, the national centers,
11 and other departments, agencies, and offices of
12 the Federal Government; and

13 “(B) minimize unnecessary duplication.

14 “(5) ACCELERATING ADVANCEMENT PRO-
15 GRAM.—The Director of NIH shall establish a pro-
16 gram, to be known as the Accelerating Advancement
17 Program, under which—

18 “(A) the Director of NIH partners with
19 national research institutes and national centers
20 to accomplish important biomedical research ob-
21 jectives; and

22 “(B) for every \$1 made available by the
23 Director of NIH to a national research institute
24 or national center for a research project, the in-
25 stitute or center makes \$1 available for such

1 project from funds that are not derived from
2 the NIH Innovation Fund.

3 “(6) STRATEGIC PLAN.—

4 “(A) IN GENERAL.—The Director of NIH
5 shall ensure that scientifically based strategic
6 planning is implemented in support of research
7 priorities, including through development, use,
8 and updating of a research strategic plan
9 that—

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

15 “(ii) identifies areas, to be known as
16 strategic focus areas, in which the re-
17 sources of the NIH Innovation Fund can
18 contribute to the goals of expanding knowl-
19 edge to address, and find more effective
20 treatments for, unmet medical needs in the
21 United States, including the areas of—

22 “(I) biomarkers;

23 “(II) precision medicine;

24 “(III) infectious diseases, includ-
25 ing pathogens listed as a qualifying

1 pathogen under section 505E(f) of the
2 Federal Food, Drug, and Cosmetic
3 Act or listed or designated as a trop-
4 ical disease under section 524 of such
5 Act; and

6 “(IV) antibiotics;

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

9 “(iv) ensures that basic research re-
10 mains a priority.

11 “(B) UPDATES AND REVIEWS.—The Direc-
12 tor shall review and, as appropriate, update the
13 research strategic plan under subparagraph (A)
14 not less than every 18 months.

15 “(7) DEFINITION.—In this subsection, the term
16 ‘early state investigator’ means an investigator
17 who—

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

20 “(B) has never been awarded, or has been
21 awarded only once, a substantial, competing
22 grant by the National Institutes of Health for
23 independent research; and

24 “(C) is within 10 years of having com-
25 pleted—

1 “(i) the investigator’s terminal degree;
2 or
3 “(ii) a medical residency (or the
4 equivalent).”.

5 **Subtitle B—National Institutes of**
6 **Health Planning and Adminis-**
7 **tration**

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

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

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

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

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

20 “(m) RESEARCH STRATEGIC PLAN.—

21 “(1) FIVE-YEAR PLANS FOR BIOMEDICAL RE-
22 SEARCH STRATEGY.—

23 “(A) IN GENERAL.—For each successive
24 five-year period beginning with the period of fis-
25 cal years 2016 through 2020, the Director of

1 NIH, in consultation with the entities described
2 in subparagraph (B), shall develop and main-
3 tain a biomedical research strategic plan.

4 “(B) ENTITIES DESCRIBED.—The entities
5 described in this subparagraph are the directors
6 of the national research institutes and national
7 centers, researchers, patient advocacy groups,
8 and industry leaders.

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

12 “(A) to identify research opportunities;
13 and

14 “(B) to develop individual strategic plans
15 for the research activities of each of the na-
16 tional research institutes and national centers
17 that—

18 “(i) have a common template; and

19 “(ii) identify strategic focus areas in
20 which the resources of the national re-
21 search institutes and national centers can
22 best contribute to the goal of expanding
23 knowledge on human health in the United
24 States through biomedical research.

25 “(3) CONTENTS OF PLANS.—

1 “(A) STRATEGIC FOCUS AREAS.—The stra-
2 tegic focus areas identified pursuant to para-
3 graph (2)(B) shall—

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

5 “(I) considers the return on in-
6 vestment to the United States public
7 through the investments of the Na-
8 tional Institutes of Health in bio-
9 medical research; and

10 “(II) contributes to expanding
11 knowledge to improve the United
12 States public’s health through bio-
13 medical research; and

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

22 “(B) RARE AND PEDIATRIC DISEASES AND
23 CONDITIONS.—In developing and maintaining a
24 strategic plan under this subsection, the Direc-

1 tor of NIH shall ensure that rare and pediatric
2 diseases and conditions remain 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 the NIH, in consulta-
15 tion with the directors of the national research
16 institutes and national centers, shall conduct
17 progress reviews for each strategic focus area
18 identified under paragraph (2)(B).

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. BIOMEDICAL RESEARCH WORKING GROUP.**

18 **【(a) ESTABLISHMENT.—**There is established a work-
19 ing group to be known as the “Biomedical Research Work-
20 ing Group”**】**

21 **【(b) DUTIES.—**The Biomedical Research Working
22 Group shall—**】**

23 **【(1)** provide recommendations to the Director
24 of the National Institutes of Health to reduce ad-
25 ministrative burdens of researchers funded by the

1 National Institutes of Health, including with respect
2 to the extent to which (and how) grant proposals,
3 grant review, and management should be restruc-
4 tured, streamlined, and simplified;】

5 【(2) evaluate and provide recommendations on
6 the extent to which it is required for Congress to
7 provide any statutory authority to implement any
8 recommendation proposed pursuant to paragraph
9 (1); and】

10 【(3) prepare a plan, including timeframes, for
11 implementing recommendations proposed pursuant
12 to paragraph (1) for which congressional action is
13 not required.】

14 【(c) MEMBERSHIP.—The Secretary shall appoint the
15 members of the Biomedical Research Working Group. The
16 Biomedical Research Working Group shall be composed
17 of—】

18 【(1) non-Federal members from the extramural
19 community;】

20 【(2) representatives of the Office of the Direc-
21 tor; and】

22 【(3) representatives of other national research
23 institutes and national centers of the National Insti-
24 tutes of Health, as determined necessary.】

1 **[(d) IMPLEMENTATION OF MEASURES TO REDUCE**
2 **ADMINISTRATIVE BURDENS.—**The Director of the Na-
3 tional Institutes of Health, taking into account the rec-
4 ommendations, evaluations, and plan described in sub-
5 section (b), shall implement measures to reduce the ad-
6 ministrative burdens of researchers funded by the Na-
7 tional Institutes of Health.]

8 **[(e) REPORTS.—]**

9 **[(1) REPORT BY WORKING GROUP ON REC-**
10 **COMMENDATIONS AND PLAN.—**Not later than one
11 year after the date of the enactment of this Act, the
12 Biomedical Research Working Group shall submit to
13 Congress a report including the recommendations,
14 evaluations, and plan described in subsection (b).]

15 **[(2) REPORT BY DIRECTOR OF NIH ON IMPLE-**
16 **MENTATION OF MEASURES TO REDUCE ADMINISTRA-**
17 **TIVE BURDENS.—**The Director of the National Insti-
18 tutes of Health shall submit to Congress a report on
19 the extent to which the Director has implemented
20 measures pursuant to subsection (d).]

21 **SEC. 1024. EXEMPTION FOR THE NATIONAL INSTITUTES OF**
22 **HEALTH FROM THE PAPERWORK REDUCTION**
23 **ACT REQUIREMENTS.**

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

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

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

5 (3) by inserting at the end the following new
6 subparagraph:

7 “(E) during the conduct of research by the
8 National Institutes of Health.”.

9 **SEC. 1025. NIH TRAVEL.**

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

13 **SEC. 1026. OTHER TRANSACTIONS AUTHORITY.**

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

16 (1) in subsection (b), by striking “the appro-
17 priation of funds as described in subsection (g)” and
18 inserting “the availability of funds as described in
19 subsection (f)”;

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

22 “(C) OTHER TRANSACTIONS AUTHORITY.—

23 The Director of the Center shall have other
24 transactions authority in entering into trans-

1 actions to fund projects in accordance with the
2 terms and conditions of this section.”;

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

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

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

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

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

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

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

15 Part B of title IV of the Public Health Service Act
16 (42 U.S.C. 284 et seq.) is amended by adding at the end
17 the following:

18 **“SEC. 409K. HIGH-RISK, HIGH-REWARD RESEARCH PRO-**
19 **GRAM.**

20 “The director of each national research institute
21 shall, as appropriate—

22 “(1) establish programs to conduct or support
23 research projects that pursue innovative approaches
24 to major contemporary challenges in biomedical re-

1 search that involve inherent high risk, but have the
2 potential to lead to breakthroughs; and

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

6 **Subtitle C—Supporting Young** 7 **Emerging Scientists**

8 **SEC. 1041. IMPROVEMENT OF LOAN REPAYMENT PRO-** 9 **GRAMS OF NATIONAL INSTITUTES OF** 10 **HEALTH.**

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

13 (1) by redesignating the second section 487F
14 (42 U.S.C. 288–6; pediatric research loan repayment
15 program) as section 487G; and

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

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

19 “(a) IN GENERAL.—The Secretary shall establish a
20 program, based on workforce and scientific needs, of en-
21 tering into contracts with qualified health professionals
22 under which such health professionals agree to engage in
23 research in consideration of the Federal Government
24 agreeing to pay, for each year of engaging in such re-

1 search, not more than \$50,000 of the principal and inter-
2 est of the educational loans of such health professionals.

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

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

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

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

1 (b) UPDATE OF OTHER LOAN REPAYMENT PRO-
2 GRAMS.—Part G of title IV of the Public Health Service
3 (42 U.S.C. 288 et seq.) is further amended—

4 (1) LOAN REPAYMENT PROGRAM FOR MINORITY
5 HEALTH DISPARITIES RESEARCH.—Section 464z-
6 5(a) of the Public Health Service Act (42
7 U.S.C.285t-2(a)) is amended—

8 (A) in subsection (a), by striking
9 “\$35,000” and inserting “\$50,000”; and

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

16 (2) LOAN REPAYMENT PROGRAM FOR RE-
17 SEARCH WITH RESPECT TO ACQUIRED IMMUNE DE-
18 FICIENCY SYNDROME.—Section 487A(a) of such Act
19 (42 U.S.C. 288-1(a)) is amended—

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

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

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

3 (3) LOAN REPAYMENT PROGRAM FOR RE-
4 SEARCH WITH RESPECT TO CONTRACEPTION AND IN-
5 FERTILITY.—Section 487B(a) of such Act (42
6 U.S.C. 288–2(a)) 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 (4) LOAN REPAYMENT PROGRAM FOR RE-
16 SEARCH GENERALLY.—Section 487C(a)(1) of such
17 Act (42 U.S.C. 288–3(a)(1)) is amended—

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

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

1 (5) LOAN REPAYMENT PROGRAM REGARDING
2 CLINICAL RESEARCHERS FROM DISADVANTAGED
3 BACKGROUNDS.—Section 487E(a)(1) of such Act
4 (42 U.S.C. 288–5(a)(1)) 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 paragraph in the same manner
11 as it applies to the maximum amount specified
12 in such subsection (a) of such section.”.

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

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

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

1 (7) PEDIATRIC RESEARCH LOAN REPAYMENT
2 PROGRAM.—Section 487F of such Act (42 U.S.C.
3 288–6, as added by section 1002(b) of Public Law
4 106–310, is amended—

5 (A) in subsection (a)(1), by striking
6 “\$35,000” and inserting “\$50,000”;

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

14 (C) by redesignating such section as sec-
15 tion 487G.

16 **SEC. 1042. REPORT.**

17 Not later than 18 months after the date of the enact-
18 ment of this Act, the Director of the National Institutes
19 of Health shall submit to Congress a report on efforts of
20 the National Institutes of Health to attract, retain, and
21 develop emerging scientists.

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

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

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

7 **“SEC. 490. CAPSTONE AWARD.**

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

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

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

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

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

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

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

7 (1) in paragraph (1)—

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

18 (B) by striking subparagraph (B);

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

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

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

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

7 It is the sense of Congress that—

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

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

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

24 (4) once a global pediatric clinical trial network
25 is established and becomes operational, the Food

1 and Drug Administration should continue to engage
2 the European Medicines Agency and other foreign
3 regulatory entities to encourage and facilitate their
4 participation in the network with the goal of enhanc-
5 ing the global reach of the network.

6 **SEC. 1083. APPROPRIATE AGE GROUPINGS IN CLINICAL RE-**
7 **SEARCH.**

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

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

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

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

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

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

3 (c) PUBLIC AVAILABILITY OF FINDINGS AND CON-
4 CLUSIONS.—The Director of the National Institutes of
5 Health shall—

6 (1) make the findings and conclusion resulting
7 from the workshop under subsection (a) available to
8 the public on the website of the National Institutes
9 of Health; and

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

16 **Subtitle F—Advancement of Na-**
17 **tional Institutes of Health Re-**
18 **search and Data Access**

19 **SEC. 1101. SHARING OF DATA GENERATED THROUGH NIH-**
20 **FUNDED RESEARCH.**

21 Part H of title IV of the Public Health Service Act
22 (42 U.S.C. 289 et seq.) is amended by adding at the end
23 the following:

1 **“SEC. 498E. SHARING OF DATA GENERATED THROUGH NIH-**
2 **FUNDED RESEARCH.**

3 “(a) **AUTHORITY.**—Subject to subsection (b), as a
4 condition on the award of a grant or the provision of other
5 financial support for research, provided that the research
6 is fully funded through such grant or other support, the
7 Director of NIH may require the recipients of such grant
8 or other support to share with the public data generated
9 from such research.

10 “(b) **LIMITATION.**—The Director of NIH shall not re-
11 quire as a condition on the award of a grant or the provi-
12 sion of other financial support for research under sub-
13 section (a) the sharing of—

14 “(1) any individually identifiable information
15 with respect to a human subject participating in the
16 research; or

17 “(2) any trade secret or commercial or financial
18 information that is privileged or confidential and
19 subject to section 552(b)(4) of title 5, United States
20 Code, or section 1905 of title 18, United States
21 Code.”.

22 **SEC. 1102. STANDARDIZATION OF DATA IN CLINICAL TRIAL**
23 **REGISTRY DATA BANK ON ELIGIBILITY FOR**
24 **CLINICAL TRIALS.**

25 (a) **STANDARDIZATION.**—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 as the Secretary may require. Any such application shall
2 include the following:

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

9 (2) A description of how each applicant will
10 compile clinical trial data in standardized formats
11 using terminologies and standards that have been
12 developed by recognized standards developing orga-
13 nizations with input from diverse stakeholder
14 groups, and a description of the methodologies to be
15 used to de-identify clinical trial data consistent with
16 the requirements of section 164.514 of title 45, Code
17 of Federal Regulations (or successor regulations).

18 (3) Documentation establishing that each appli-
19 cant has a plan in place to allow registered users to
20 access and use de-identified clinical trial data, gath-
21 ered from qualified clinical trials, available under
22 carefully controlled contractual terms as defined by
23 the Secretary.

24 (4) Evidence demonstrating the ability to en-
25 sure dissemination of the results of the research to

1 interested parties to serve as a guide to future med-
2 ical product development or scientific research.

3 (5) The plan of each applicant for securing
4 funding for the partnership described in paragraph
5 (2) from governmental sources and private founda-
6 tions, entities, and individuals.

7 (6) Evidence demonstrating a proven track
8 record of—

9 (A) being a neutral third party in working
10 with medical product manufacturers, academic
11 institutions, and the Food and Drug Adminis-
12 tration; and

13 (B) having the ability to protect confiden-
14 tial data.

15 (c) EXTENSION, EXPANSION, TERMINATION.—The
16 Secretary, acting through the Commissioner of Food and
17 Drugs and the Director of the National Institutes of
18 Health, upon the expiration of the seven-year period re-
19 ferred to in subsection (a), may extend (including perma-
20 nently), expand, or terminate the pilot program estab-
21 lished under such subsection, in whole, or in part.

22 (d) REPORTS.—

23 (1) REPORT TO SECRETARY AND CONGRESS.—

24 Not later than 6 years after the date on which the
25 pilot program is established under subsection (a),

1 the eligible entities entering into a cooperative agree-
2 ment with the Secretary under such section shall
3 submit to Congress a report that—

4 (A) contains a review of the effectiveness
5 of the pilot program; and

6 (B) makes recommendations to the Sec-
7 retary and the Congress on improvements to
8 the program.

9 (2) GAO INTERIM AND FINAL REPORT.—

10 (A) IN GENERAL.—The Comptroller Gen-
11 eral of the United States shall submit to Con-
12 gress two reports, with respect to the pilot pro-
13 gram established under subsection (a), that
14 contains the following information:

15 (i) The new discoveries, research in-
16 quires, or clinical trials that have resulted
17 from accessing clinical trial data under the
18 program.

19 (ii) The number of times scientists
20 have accessed such data, disaggregated by
21 research area and clinical trial phase.

22 (iii) An analysis of whether the pro-
23 gram has helped reduce adverse events in
24 clinical trials.

1 (iv) An analysis of whether scientists
2 have raised any concerns about the burden
3 of having to share data with the system es-
4 tablished under the program and a descrip-
5 tion, if any, of such burden.

6 (B) TIMING.—The Secretary shall submit
7 the first report under subparagraph (A) not
8 later than three years after the date on which
9 the pilot program established under subsection
10 (a) and the second such report at the end of the
11 seven-year period referred to in such subsection.

12 (3) GAO STUDY.—Not later than 6 years after
13 the date on which the pilot program is established
14 under subsection (a), the Comptroller General of the
15 United States shall conduct a study that—

16 (A) reviews the effectiveness of the pilot
17 program;

18 (B) makes recommendations to the Sec-
19 retary and the Congress on improvements to
20 the program;

21 (e) DEFINITIONS.—In this section:

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

1 (A) an institution of higher education (as
2 such term is defined in section 1001 of the
3 Higher Education Act of 1965 (20 U.S.C.
4 1001)) or a consortium of such institutions; or

5 (B) an organization described in section
6 501(c)(3) of title 26 of the Internal Revenue
7 Code of 1986 and exempt from tax under sec-
8 tion 501(a) of such title.

9 (2) The term “medical product” means a drug
10 (as defined in subsection (g) of section 201 of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 331), a device (as defined in subsection (h) of such
13 section), a biological product (as defined in section
14 351 of the Public Health Service Act (42 U.S.C.
15 262), or any combination thereof.

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

20 (A) that was—

21 (i) approved or cleared under section
22 505, 510(k), or 515, or has an exemption
23 for investigational use in effect under sec-
24 tion 505 or 520(m), of the Federal Food,

1 Drug, and Cosmetic Act (42 U.S.C. 301 et
2 seq.); or

3 (ii) licensed under section 351 of the
4 Public Health Service Act (42 U.S.C. 262)
5 or has an exemption for investigational use
6 in effect under such section 351; or

7 (B) that is an investigational product for
8 which the original development was discon-
9 tinued and with respect to which—

10 (i) no additional work to support ap-
11 proval, licensure, or clearance of such med-
12 ical product is being or is planned to be
13 undertaken by the sponsor of the original
14 development program, its successors, as-
15 signs, or collaborators; and

16 (ii) the sponsor of the original inves-
17 tigational development program has pro-
18 vided its consent to the Secretary for inclu-
19 sion of data regarding such product in the
20 system established under this section.

21 **SEC. 1122. NATIONAL NEUROLOGICAL DISEASES SURVEIL-**
22 **LANCE SYSTEM.**

23 Part P of title III of the Public Health Service Act
24 (42 U.S.C. 280g et seq.) is amended by adding at the end
25 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 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 may, for the pur-
3 poses described in subsection (b)—

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

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

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

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

19 “(1) cooperating with other entities to sponsor
20 or maintain disease registries, including disease reg-
21 istries and disease registry platforms for rare dis-
22 eases;

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

25 “(A) has the capacity to support data
26 needs across a wide range of diseases studies;

1 “(B) is easily modified as knowledge is
2 gained during such studies; and

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

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

9 “(A) the design and conduct of disease
10 studies;

11 “(B) the modification of any such ongoing
12 studies; and

13 “(C) addressing associated patient privacy
14 issues.

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

24 “(e) CONFIDENTIALITY.—Notwithstanding sub-
25 section (d), nothing in this section authorizes the dislo-

1 sure of any information that is a trade secret or commer-
2 cial or financial information that is privileged or confiden-
3 tial and subject to section 552(b)(4) of title 5, United
4 States Code, or section 1905 of title 18, United States
5 Code.

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

9 **SEC. 1124. ACCESSING, SHARING, AND USING HEALTH DATA**
10 **FOR RESEARCH PURPOSES.**

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

15 **“PART 4—ACCESSING, SHARING, AND USING**
16 **HEALTH DATA FOR RESEARCH PURPOSES**
17 **“SEC. 13441. REFERENCES.**

18 “In this part:

19 “(a) THE RULE.—References to ‘the Rule’ refer to
20 part 160 or part 164, as appropriate, of title 45, Code
21 of Federal Regulations (or any successor regulation).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 “(2) either—

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

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

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

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

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

7 **Subtitle H—Council for 21st**
8 **Century Cures**

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

10 Title II of the Public Health Service Act (42 U.S.C.
11 202 et seq.) is amended by adding at the end the fol-
12 lowing:

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

14 **“SEC. 281. ESTABLISHMENT.**

15 “A nonprofit corporation to be known as Council for
16 21st Century Cures (referred to in this part as the ‘Coun-
17 cil’) shall be established in accordance with this section.
18 The Council shall be a public-private partnership headed
19 by an Executive Director (referred to in this part as the
20 ‘Executive Director’), appointed by the members of the
21 Board of Directors. The Council shall not be an agency
22 or instrumentality of the United States Government.

23 **“SEC. 281A. PURPOSE.**

24 “The purpose of the Council is to accelerate the dis-
25 covery, development, and delivery in the United States of

1 innovative cures, treatments, and preventive measures for
2 patients.

3 **“SEC. 281B. DUTIES.**

4 “For the purpose described in section 281A, the
5 Council shall—

6 “(1) foster collaboration and coordination
7 among the entities that comprise the Council, includ-
8 ing academia, government agencies, industry, health
9 care payors and providers, patient advocates, and
10 others engaged in the cycle of discovery, develop-
11 ment, and delivery of life-saving and health-enhanc-
12 ing innovative interventions;

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

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

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

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

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

1 “(7) facilitate the interoperability of the compo-
2 nents of the discovery, development, and delivery
3 cycle;

4 “(8) propose recommendations that will facili-
5 tate precompetitive collaboration;

6 “(9) identify opportunities to work with, but
7 not duplicate the efforts of, non-profits and other
8 public-private partnerships; and

9 “(10) identify opportunities for collaboration
10 with organizations operating outside of the United
11 States, such as the Innovative Medicines Initiative of
12 the European Union.

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

14 “(a) BOARD OF DIRECTORS.—

15 “(1) ESTABLISHMENT.—

16 “(A) IN GENERAL.—The Council shall
17 have a Board of Directors (in this part referred
18 to as the ‘Board of Directors’), which shall be
19 composed of the ex officio members under sub-
20 paragraph (B) and the appointed members
21 under subparagraph (C). All members of the
22 Board shall be voting members.

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

1 “(i) The Director of the National In-
2 stitutes of Health.

3 “(ii) The Commissioner of Food and
4 Drugs.

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

7 “(iv) The heads of five other Federal
8 agencies deemed by the Secretary to be en-
9 gaged in biomedical research and develop-
10 ment.

11 “(C) APPOINTED MEMBERS.—The ap-
12 pointed members of the Board shall consist of
13 17 individuals, of whom—

14 “(i) 8 shall be by the Comptroller
15 General of the United States from a list of
16 nominations submitted by leading trade as-
17 sociations—

18 “(I) 4 of whom shall be rep-
19 resentatives of the biopharmaceutical
20 industry;

21 “(II) 2 of whom shall be rep-
22 resentatives of the medical device in-
23 dustry; and

1 “(III) 2 of whom shall be rep-
2 representatives of the information and
3 digital technology industry; and

4 “(ii) 9 shall be appointed by the
5 Comptroller General of the United States,
6 after soliciting nominations—

7 “(I) 2 of whom shall be rep-
8 representatives of academic researchers;

9 “(II) 3 of whom shall be rep-
10 representative of patients;

11 “(III) 2 of whom shall be rep-
12 representatives of health care providers;
13 and

14 “(IV) 2 of whom shall be rep-
15 representatives of health care plans and
16 insurers.

17 “(D) CHAIR.—The Chair of the Board
18 shall be selected by the members of the Board
19 by majority vote from among the members of
20 the Board.

21 “(2) TERMS AND VACANCIES.—

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

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

3 “(i) shall not affect the power of the
4 remaining members to execute the duties
5 of the Board; and

6 “(ii) shall be filled by appointment by
7 the appointed members described in para-
8 graph (1)(C) by majority vote.

9 “(C) PARTIAL TERM.—If a member of the
10 Board does not serve the full term applicable
11 under subparagraph (A), the individual ap-
12 pointed under subparagraph (B) to fill the re-
13 sulting vacancy shall be appointed for the re-
14 mainder of the term of the predecessor of the
15 individual.

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

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

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

1 “(i) the officers, employees, agents,
2 and contractors of the Council; and

3 “(ii) the members of any committees
4 of the Council;

5 “(C) establish policies, including ethical
6 standards, for the conduct of programs and
7 other activities under section 281D; and

8 “(D) establish specific duties of the Execu-
9 tive Director.

10 “(4) MEETINGS.—

11 “(A) IN GENERAL.—the Board of Direc-
12 tors shall—

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

14 “(ii) submit to Congress, and make
15 publicly available, the minutes of such
16 meetings.

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

20 “(i) issue an agenda (in this part re-
21 ferred to as the ‘agenda’) outlining how
22 the Council will achieve the purpose de-
23 scribed in section 281A; and

1 “(ii) annually thereafter, in consulta-
2 tion with the Executive Director, review
3 and update such agenda.

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

7 “(1) the Comptroller General of the United
8 States shall appoint the appointed members of the
9 Board of Directors under subsection (a)(1)(C); and

10 “(2) the ex officio members of the Board of Di-
11 rectors under subsection (a)(1)(B) shall serve as
12 incorporators and shall take whatever actions are
13 necessary to incorporate the Council

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

19 “(1) is described in subsection (c)(3) of section
20 501 of the Internal Revenue Code of 1986; and

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

23 “(d) EXECUTIVE DIRECTOR.—The Executive Direc-
24 tor shall—

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

3 “(2) subject to the oversight of the Board of
4 Directors, be responsible for the day-to-day manage-
5 ment of the Council.

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

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

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

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

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

17 “(b) REPORT.—Not later than one year after the
18 date on which the Council is established and each year
19 thereafter, the Executive Director shall submit to the ap-
20 propriate congressional committees a report on the per-
21 formance of the Council. In preparing such report, the
22 Council shall consult with a nongovernmental consultant
23 with appropriate expertise.

1 **“SEC. 281F. FUNDING.**

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

6 **TITLE II—DEVELOPMENT**
7 **Subtitle A—Patient-Focused Drug**
8 **Development**

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

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

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

17 (2) by adding at the end the following new sub-
18 sections:

19 “(x) STRUCTURED RISK-BENEFIT ASSESSMENT
20 FRAMEWORK.—

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

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

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

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

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

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

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

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

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

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

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

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

18 (b) GUIDANCE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 (3) WORKSHOPS.—

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

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

15 (i) patients;

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

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

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

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

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

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

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

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

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

17 (3) biomedical research consortia, consisting of
18 public-private partnerships of government agencies,
19 institutions of higher education, patient advocacy
20 groups, industry representatives, clinical and sci-
21 entific experts, and other relevant entities and indi-
22 viduals can play a valuable role in helping develop
23 and qualify drug development tools.

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

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

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

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

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

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

22 (c) **QUALIFICATION OF DRUG DEVELOPMENT**
23 **TOOLS.**—Chapter V of the Federal Food, Drug, and Cos-
24 metic Act, as amended by **【sections _____】**, is further

1 amended by inserting after section 506F the following new
2 section:

3 **“SEC. 507. QUALIFICATION OF DRUG DEVELOPMENT**
4 **TOOLS.**

5 “(a) PROCESS FOR QUALIFICATION.—

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

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

13 “(ii) the Secretary shall accept or decline
14 to accept such letter of intent;

15 “(B)(i) if the Secretary accepts the letter
16 of intent, a requestor shall submit a qualifica-
17 tion plan to the Secretary; and

18 “(ii) the Secretary shall accept or decline
19 to accept the qualification plan; and

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

23 “(ii) the Secretary shall determine whether
24 to accept such qualification package for review;
25 and

1 “(iii) if the Secretary accepts such quali-
2 fication package for review, conduct such review
3 in accordance with this section.

4 “(2) ACCEPTANCE AND REVIEW OF SUBMIS-
5 SIONS.—With respect to a letter of intent, a quali-
6 fication plan, or a full qualification package sub-
7 mitted under the process described in paragraph (1)
8 (referred to in this paragraph as ‘qualification sub-
9 missions’), the following shall apply:

10 “(A) SCIENTIFIC MERIT.—The Secretary
11 shall, consistent with available resources, deter-
12 mine whether to accept a qualification submis-
13 sion based on factors which may include the sci-
14 entific merit of the submission. A determination
15 not to accept submission under paragraph (1)
16 shall not be construed as a final agency deter-
17 mination regarding the qualification of a pro-
18 posed drug development tool under paragraph
19 (1).

20 “(B) PRIORITIZATION OF QUALIFICATION
21 REVIEW.—The Secretary may prioritize the re-
22 view of a full qualification package submitted
23 under the process described in paragraph (1)
24 with respect to a drug development tool, based

1 on factors determined appropriate by the Sec-
2 retary, including—

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

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

14 “(C) ENGAGEMENT OF EXTERNAL EX-
15 PERTS.—The Secretary may, for purposes of
16 the review of qualification submissions, through
17 the use of cooperative agreements, grants, or
18 other appropriate mechanisms, consult with bio-
19 medical research consortia and may consider
20 the recommendations of such consortia with re-
21 spect to the review of any qualification plan
22 submitted under the process described in para-
23 graph (1) or the review of any full qualification
24 package under paragraph (2).

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

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

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

9 “(4) QUALIFICATION.—The Secretary shall de-
10 termine whether a drug development tool is qualified
11 for a proposed context of use based on the scientific
12 merit of a full qualification package reviewed under
13 paragraph (2).

14 “(b) EFFECT OF QUALIFICATION.—

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

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

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

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

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

7 “(3) RESCISSION OR MODIFICATION.—

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

16 “(B) MEETING FOR REVIEW.—If the Sec-
17 retary rescinds or modifies a determination to
18 qualify a drug development tool under subpara-
19 graph (A), the requestor involved shall be
20 granted a request for a meeting with the Sec-
21 retary to discuss the basis of the Secretary’s de-
22 cision to rescind or modify the determination
23 before the effective date of the rescission or
24 modification.

25 “(c) TRANSPARENCY.—

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

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

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

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

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

17 “(B) the Secretary’s formal written deter-
18 minations in response to such qualification sub-
19 missions;

20 “(C) any rescissions or modifications of a
21 determination to qualify a drug development
22 tool under subsection (b)(3);

23 “(D) summary reviews that document con-
24 clusions and recommendations for determina-

1 tions to qualify drug development tools under
2 subsection (a); and

3 “(E) a comprehensive list of all drug devel-
4 opment tools qualified under subsection (c) or
5 used in the labeling of drugs.

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

11 “(3) APPLICABILITY.—Paragraph (1) shall not
12 apply with respect to information contained in an
13 application submitted under section 505 of this Act
14 or section 351 of the Public Health Service Act, ir-
15 respective of whether such information is used to de-
16 velop the guidance to carry out this section. Nothing
17 in this section shall be construed as authorizing the
18 Secretary to disclose any information contained in
19 such an application that is confidential commercial
20 or trade secret information subject to section
21 552(b)(4) of title 5, United States Code, or section
22 1905 of title 18, United States Code.

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

1 “(1) to alter the standards of evidence under
2 subsection (c) or (d) of section 505, including the
3 substantial evidence standard in such subsection (d),
4 or under section 351 of the Public Health Service
5 Act (as applicable); or

6 “(2) to limit the authority of the Secretary to
7 approve or license products under to this Act or the
8 Public Health Service Act, as applicable (as in effect
9 before the date of the enactment of the 21st Century
10 Cures Act).

11 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
12 are authorized to be appropriated to carry out subsection
13 (a)(2)(C), \$10,000,0000 for each of fiscal years 2016
14 through 2020.

15 “(f) DEFINITIONS.—In this section:

16 “(1) BIOMARKER.—(A) The term ‘biomarker’
17 means a characteristic (such as a physiologic,
18 pathologic, or anatomic characteristic or measure-
19 ment) that is objectively measured and evaluated as
20 an indicator of normal biologic processes, pathologic
21 processes, or biological responses to a therapeutic
22 intervention.

23 “(B) Such term includes a surrogate endpoint.

24 “(2) BIOMEDICAL RESEARCH CONSORTIA.—The
25 term ‘biomedical research consortia’ means public-

1 private partnerships of government agencies, institu-
2 tions of higher education (as defined in section
3 101(a) of the Higher Education Act of 1965 (20
4 U.S.C. 1001)), patient advocacy groups, industry
5 representatives, clinical and scientific experts, and
6 other relevant entities and individuals.

7 “(3) CLINICAL OUTCOME ASSESSMENT.—(A)
8 The term ‘clinical outcome assessment’ means a
9 measurement of a patient’s symptoms, overall men-
10 tal state, or the effects of a disease or condition on
11 how the patient functions.

12 “(B) Such term includes a patient reported out-
13 come.

14 “(4) CONTEXT OF USE.—The term ‘context of
15 use’ means, with respect to a drug development tool,
16 a statement that describes the circumstances under
17 which the drug development tool is to be used in
18 drug development and regulatory review.

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

21 “(A) a biomarker;

22 “(B) a clinical outcome assessment; and

23 “(C) any other method, material, or meas-
24 ure that the Secretary determines aid drug de-

1 velopment and regulatory review for purposes of
2 this section.

3 “(6) PATIENT REPORTED OUTCOME.—The term
4 ‘patient reported outcome’ means a measurement
5 based on a report from a patient regarding the sta-
6 tus of the patient’s health condition without amend-
7 ment or interpretation of the patient’s report by a
8 clinician or any other person.

9 “(7) QUALIFICATION.—The terms ‘qualifica-
10 tion’ and ‘qualified’ mean a determination by the
11 Secretary that a drug development tool and its speci-
12 fied context of use can be relied upon to have a spe-
13 cific interpretation and application in drug develop-
14 ment and regulatory review under this Act.

15 “(8) REQUESTOR.—The term ‘requestor’ means
16 an entity or entities, including a drug sponsor or a
17 biomedical research consortia, seeking to qualify a
18 drug development tool for a proposed context of use
19 under this section.

20 “(9) SURROGATE ENDPOINT.—The term ‘surro-
21 gate endpoint’ means a marker, such as a laboratory
22 measurement, radiographic image, physical sign, or
23 other measure that—

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

4 “(B) is reasonably likely to predict clinical
5 benefit and could be used to support accelerated
6 approval of a drug or biological product in ac-
7 cordance with section 506(c).”.

8 (d) GUIDANCE.—

9 (1) IN GENERAL.—The Secretary of Health and
10 Human Services shall, in consultation with bio-
11 medical research consortia (as defined in subsection
12 (e) of section 507 the Federal, Food, Drug, and
13 Cosmetic Act (as added by subsection (c))) and
14 other interested parties through a collaborative pub-
15 lic process, issue guidance to implement such section
16 507 that—

17 (A) provides a conceptual framework de-
18 scribing appropriate standards and scientific
19 approaches to support the development of bio-
20 markers delineated under the taxonomy estab-
21 lished under paragraph (3);

22 (B) makes recommendations for dem-
23 onstrating that a surrogate endpoint is reason-
24 ably likely to predict clinical benefit for the pur-
25 pose of supporting the accelerated approval of

1 a drug under section 506(c) of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C.
3 356(c));

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

6 (i) the requirements that entities seek-
7 ing to qualify a drug development tool
8 under such section shall observe when en-
9 gaging in such process; and

10 (ii) reasonable timeframes for the Sec-
11 retary's review of letters, qualification
12 plans, or full qualification packages sub-
13 mitted under such process; and

14 (iii) establish a process by which such
15 entities or the Secretary may consult with
16 biomedical research consortia and other in-
17 dividuals and entities with expert knowl-
18 edge and insights that may assist the Sec-
19 retary in the review of qualification plans
20 and full qualification submissions under
21 such process; and

22 (D) includes such other information as the
23 Secretary determines appropriate.

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

1 shall issue draft guidance on the implementation of
2 section 507 of the Federal, Food, Drug, and Cos-
3 metic Act (as added by subsection (c)). The Sec-
4 retary shall issue final guidance on the implementa-
5 tion of such section not later than 6 months after
6 the date on which the comment period for the draft
7 guidance closes.

8 (3) TAXONOMY.—

9 (A) IN GENERAL.—For purposes of in-
10 forming guidance under this subsection, the
11 Secretary shall, in consultation with biomedical
12 research consortia and other interested parties
13 through a collaborative public process, establish
14 a taxonomy for the classification of biomarkers
15 (and related scientific concepts) for use in drug
16 development.

17 (B) PUBLIC AVAILABILITY.—Not later
18 than 12 months after the date of the enactment
19 of the 21st Century Cures Act, the Secretary
20 shall make such taxonomy publicly available in
21 draft form for public comment. The Secretary
22 shall finalize the taxonomy not later than 12
23 months after the close of the public comment
24 period.

25 (e) MEETING AND REPORT.—

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

8 (2) REPORT.—Not later than 5 years after the
9 date of the enactment of the 21st Century Cures
10 Act, the Secretary shall make publicly available on
11 the Internet website of the Food and Drug Adminis-
12 tration a report. Such report shall include, with re-
13 spect to the qualification process under section 507
14 of the Federal Food, Drug, and Cosmetic Act, as
15 added by subsection (c), information on—

16 (A) the number of requests submitted, as
17 a letter of intent, for qualification of a drug de-
18 velopment tool (as defined in subsection (e) of
19 such section);

20 (B) the number of such requests accepted
21 and determined to be eligible for submission of
22 a qualification plan or full qualification package
23 (as such terms are defined in such subsection),
24 respectively;

1 (C) the number of such requests for which
2 the Secretary utilized external scientific experts
3 in the development of a qualification plan or re-
4 view of a full qualification package; and

5 (D) the number of qualification plans and
6 full qualification packages, respectively, sub-
7 mitted to the Secretary; and

8 (3) the drug development tools qualified
9 through the process, specified by type of tool, such
10 as a biomarker or clinical outcome assessment (as
11 such terms are defined in subsection (e) of such sec-
12 tion 507).

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

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

17 “(g) ACCELERATED APPROVAL DEVELOPMENT
18 PLAN.—

19 “(1) IN GENERAL.—In the case of a drug deter-
20 mined to be eligible for accelerated approval under
21 subsection (e), at any time after the submission of
22 an application for the investigation of the drug
23 under section 505(i) of this Act or section 351(a)(3)
24 of the Public Health Service Act, the sponsor of
25 such drug may voluntarily request agreement by the

1 Secretary to an accelerated approval development
2 plan with respect to a surrogate endpoint to be used
3 to study the drug.

4 “(2) PLAN.—A plan described in paragraph (1)
5 shall include agreement on—

6 “(A) the surrogate endpoint to be assessed
7 under the plan;

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

10 “(C) the magnitude of the effect of the
11 drug on the surrogate endpoint that is the sub-
12 ject of the agreement that would be sufficient
13 to form the primary basis of a claim that the
14 drug is effective.

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

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

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

1 “(4) SPONSOR CONSULTATION.—If the Sec-
2 retary requires the modification or termination of an
3 accelerated approval development plan under para-
4 graph (3), the sponsor shall be granted a request for
5 a meeting to discuss the basis of the Secretary’s de-
6 cision before the effective date of the modification or
7 termination.

8 “(5) DEFINITION.—In this section, the term
9 ‘accelerated approval development plan’ means a de-
10 velopment plan agreed upon by the Secretary and
11 the sponsor submitting the plan that contains study
12 parameters for the use of a surrogate endpoint
13 that—

14 “(A) is reasonably likely to predict clinical
15 benefit; and

16 “(B) is intended to be the basis of the ac-
17 celerated approval of a drug under subsection
18 (c).”.

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

22 (1) by striking “(f) AWARENESS EFFORTS” and
23 inserting “(e) AWARENESS EFFORTS”; and

24 (2) by striking “(e) CONSTRUCTION” and in-
25 serting “(f) CONSTRUCTION”.

1 **Subtitle C—FDA Advancement of**
2 **Precision Medicine**

3 **SEC. 2041. PRECISION MEDICINE GUIDANCE AND OTHER**
4 **PROGRAMS OF FOOD AND DRUG ADMINIS-**
5 **TRATION.**

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

9 **“Subchapter J—Precision Medicine**

10 **“SEC. 591. GENERAL AGENCY GUIDANCE ON PRECISION**
11 **MEDICINE.**

12 “(a) IN GENERAL.—The Secretary shall issue and
13 periodically update guidance to assist sponsors in the de-
14 velopment of a precision drug or biological product. Such
15 guidance shall—

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

18 “(2) address the topics described in subsection
19 (b).

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

22 “(1) the evidence needed to support the use of
23 biomarkers (as defined in section 507(e)) that iden-
24 tify subsets of patients as likely responders to thera-

1 pies in order to streamline the conduct of clinical
2 trials;

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

6 “(3) the manner and extent to which a benefit-
7 risk assessment may be affected when clinical trials
8 are limited to patient population subsets that are
9 identified using biomarkers;

10 “(4) The development of companion diagnostics
11 in the context of a drug development program; and

12 “(5) considerations for developing biomarkers
13 that aid prescribing decisions for a drug or biological
14 product, and when information regarding a bio-
15 marker may be included in the labeling for a drug
16 or biological product approved under section 505 of
17 this Act or section 351 of the Public Health Service
18 Act.

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

1 **“SEC. 592. PRECISION MEDICINE REGARDING ORPHAN-**
2 **DRUG AND EXPEDITED-APPROVAL PRO-**
3 **GRAMS.**

4 “In the case of an application for a precision drug
5 or biological product under section 505(b)(1), or section
6 351(a) of the Public Health Service Act, that has been
7 designated under section 526 as a drug for a rare disease
8 for a serious condition, the Secretary may—

9 “(1) consistent with applicable standards for
10 approval, rely upon data or information previously
11 developed by the sponsor of the precision drug or bi-
12 ological product for a prior approved drug or indica-
13 tion (or that of another sponsor, provided the spon-
14 sor of the precision drug or biological product has
15 obtained a contractual right of reference to such
16 other sponsor’s data and information) in order to ex-
17 pedite clinical development for a precision drug or
18 indication that is using the same or similar approach
19 as that of the prior approved drug or indication; and

20 “(2) as appropriate under section 506, consider
21 the application for approval of such precision drug
22 to be eligible for expedited review, including under
23 section 506(c) (relating to accelerated approval).”.

1 **Subtitle D—Modern Trial Design**
2 **and Evidence Development**

3 **SEC. 2061. BROADER APPLICATION OF BAYESIAN STATIS-**
4 **TICS AND ADAPTIVE TRIAL DESIGNS.**

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

16 (b) GUIDANCE ADDRESSING USE OF ADAPTIVE
17 TRIAL DESIGNS AND BAYESIAN METHODS.—

18 (1) IN GENERAL.—The Secretary of Health and
19 Human Services, acting through the Commissioner
20 of Food and Drugs (in this subsection referred to as
21 the “Secretary”), shall—

22 (A) update and finalize the draft guidance
23 addressing the use of adaptive trial design for
24 drugs and biological products; and

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

5 (2) CONTENTS.—The guidances under para-
6 graph (1) shall address—

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

13 (B) how sponsors may obtain feedback
14 from the Secretary on technical issues related
15 to modeling and simulations prior to—

16 (i) completion of such modeling or
17 simulations; or

18 (ii) the submission of resulting infor-
19 mation to the Secretary;

20 (C) the types of quantitative and quali-
21 tative information that should be submitted for
22 review; and

23 (D) recommended analysis methodologies.

24 (3) PUBLIC MEETING.—Prior to updating or
25 developing the guidances required by paragraph (1),

1 the Secretary shall consult with stakeholders includ-
2 ing representatives of regulated industry, academia,
3 patient advocacy organizations, and disease research
4 foundations, through a public meeting to be held no
5 later than 1 year after the date of enactment of this
6 Act.

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

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

12 (B) the guidance required by paragraph
13 (1)(B) not later than 48 months after the date
14 of the public meeting required by paragraph
15 (3).

16 **SEC. 2062. UTILIZING EVIDENCE FROM CLINICAL EXPERI-**
17 **ENCE.**

18 Chapter V of the Federal Food, Drug, and Cosmetic
19 Act, as amended by section 1261, is further amended by
20 inserting after section 505G of such Act the following:

21 **“SEC. 505H. UTILIZING EVIDENCE FROM CLINICAL EXPERI-**
22 **ENCE.**

23 “(a) IN GENERAL.—The Secretary shall establish a
24 program to evaluate the potential use of evidence from
25 clinical experience—

1 “(1) to help support the approval of a new indi-
2 cation for a drug approved under section 505(b);
3 and

4 “(2) to help support or satisfy post-approval
5 study requirements.

6 “(b) EVIDENCE FROM CLINICAL EXPERIENCE DE-
7 FINED.—In this section, the term ‘evidence from clinical
8 experience’ means data regarding the usage, or potential
9 benefits or risks, of a drug derived from sources other
10 than randomized clinical trials, including from observa-
11 tional studies, registries, and therapeutic use.

12 “(c) PROGRAM FRAMEWORK.—

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

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

19 “(A) the current sources of data developed
20 through clinical experience, including ongoing
21 safety surveillance, registry, claims, and pa-
22 tient-centered outcomes research activities;

23 “(B) the gaps in current data collection ac-
24 tivities;

1 “(C) the current standards and methodolo-
2 gies for collection and analysis of data gen-
3 erated through clinical experience; and

4 “(D) the priority areas, remaining chal-
5 lenges, and potential pilot opportunities that
6 the program established under this section will
7 address.

8 “(3) CONSULTATION.—

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

16 “(B) PROCESS.—The consultation under
17 subparagraph (A) may be carried out through
18 approaches such as—

19 “(i) a public-private partnership with
20 such entities, in which the Secretary may
21 participate; or

22 “(ii) a contract, grant, or other ar-
23 rangement, as determined appropriate by
24 the Secretary with such a partnership or
25 an independent research organization.

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

7 “(e) GUIDANCE FOR INDUSTRY.—The Secretary
8 shall—

9 “(1) utilize the program established in sub-
10 section (d), its activities, and any subsequent pilots
11 or written reports, to inform a guidance for industry
12 on—

13 “(A) the circumstances under which spon-
14 sors of drugs and the Secretary may rely on
15 evidence from clinical experience for the pur-
16 poses described in subsections (a)(1) or (a)(2);

17 “(B) the appropriate standards and meth-
18 odologies for collection and analysis of evidence
19 from clinical experience submitted for such pur-
20 poses.

21 “(2) not later than 36 months after the date of
22 enactment of this section, issue draft guidance for
23 industry as described in subparagraph (A); and

24 “(3) not later than 48 months after the date of
25 enactment of this section, after providing an oppor-

1 tunity for public comment on the draft guidance,
2 issue final guidance.

3 “(f) RULE OF CONSTRUCTION.—

4 “(1) Subject to paragraph (2), nothing in this
5 section prohibits the Secretary from using evidence
6 from clinical experience for purposes not specified in
7 this section, provided the Secretary determines that
8 sufficient basis exists for any such non-specified use.

9 “(2) This section shall not be construed to
10 alter—

11 “(A) the standards of evidence under—

12 “(i) subsection (c) or (d) of section
13 505, including the substantial evidence
14 standard in such subsection (d); or

15 “(ii) section 351(a) of the Public
16 Health Services Act; or

17 “(B) the Secretary’s authority to require
18 post-approval studies or clinical trials, or the
19 standards of evidence under which studies or
20 trials are evaluated.

21 **["SEC. 505I. COLLECTING EVIDENCE FROM CLINICAL EXPE-**
22 **RIENCE THROUGH TARGETED EXTENSIONS**
23 **OF THE SENTINEL SYSTEM.**

24 **["(a) IN GENERAL.—**The Secretary shall, in parallel
25 to implementing the program established in section 505H

1 and in order to build capacity for utilizing the evidence
2 from clinical experience described in that section, identify
3 and execute pilot demonstrations to extend existing use
4 of the Sentinel System surveillance infrastructure author-
5 ized under section 505(k).】

6 【“(b) PILOT DEMONSTRATIONS.—】

7 【“(1) IN GENERAL.—The Secretary—】

8 【“(A) shall design and implement pilot
9 demonstrations to utilize data captured through
10 the sentinel system surveillance infrastructure
11 of the Food and Drug Administration for pur-
12 poses of, as appropriate—】

13 “(i) generating evidence from clinical
14 experience to improve characterization or
15 assessment of risks or benefits of a drug
16 approved under section 505(c);

17 “(ii) protecting the public health; or

18 “(iii) advancing patient-centered care;

19 and

20 “(B) may make strategic linkages with
21 sources of complementary public health data
22 and infrastructure the Secretary determines ap-
23 propriate and necessary.

1 【“(2) CONSULTATION.—In developing the pilot
2 demonstrations under this subsection, the Secretary
3 shall—】

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

9 【“(B) develop a framework to promote ap-
10 propriate transparency and dialogue about re-
11 search conducted by the Food and Drug Ad-
12 ministration, including by—】

13 【“(i) providing adequate notice to a
14 sponsor of a drug approved under section
15 505 or section 351 of the Public Health
16 Service Act of the Secretary’s intent to
17 conduct analyses related to assessing or re-
18 assessing the safety of such sponsor’s drug
19 or drugs;】

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

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

7 【“(3) PUBLIC HEALTH EXEMPTION.—The Sec-
8 retary may—】

9 【“(A) deem such pilot demonstrations pub-
10 lic health activities, permitting the use and dis-
11 closure of protected health information as de-
12 scribed in 164.512(b)(1)(iii) of title 45, Code of
13 Federal Regulations (or any successor regula-
14 tion) and exempted as a public health activity
15 as described in 46.101(b)(5) of title 46, Code of
16 Federal Regulations (or any successor regula-
17 tion); and】

18 【“(B) deem safety surveillance performed
19 at the request of the Food and Drug Adminis-
20 tration or under such jurisdiction by a sponsor
21 with responsibility for a drug approved under
22 this section or section 351 of the Public Health
23 Services Act using the infrastructure authorized
24 at section 505(k) of the Food, Drug, and Cos-
25 metic Act, including use of analytic tools and

1 querying capabilities developed to implement
2 the active post market surveillance system de-
3 scribed in this section, public health activities
4 as described in 164.512(b)(1)(iii) of title 45,
5 Code of Federal Regulations (or any successor
6 regulation) and exempted as a public health ac-
7 tivity as described in 46.101(b)(5) of title 46,
8 Code of Federal Regulations (or any successor
9 regulation).】

10 【“(c) AUTHORIZATION OF APPROPRIATIONS.—To
11 carry out activities under the amendment made by this
12 section there are authorized to be appropriated for each
13 of fiscal years 2016 through 2019.”.】

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

15 (a) IN GENERAL.—Chapter V of the Federal Food,
16 Drug, and Cosmetic Act is further amended by inserting
17 after section 505E of such Act (21 U.S.C. 355f) the fol-
18 lowing:

19 **“SEC. 505F. STREAMLINED DATA REVIEW PROGRAM.**

20 “(a) IN GENERAL.—The Secretary shall establish a
21 streamlined data review program under which a holder of
22 an approved application submitted under section
23 505(b)(1) or under section 351(a) of the Public Health
24 Service Act may, to support the approval or licensure (as
25 applicable) of the use of the drug that is the subject of

1 such approved application for a new qualified indication,
2 submit qualified data summaries.

3 “(b) ELIGIBILITY.—In carrying out the streamlined
4 data review program under subsection (a), the Secretary
5 may authorize the holder of the approved application to
6 include one or more qualified data summaries described
7 in subsection (a) in a supplemental application if—

8 “(1) the drug has been approved under section
9 505(c) of this Act or licensed under section 351(a)
10 of the Public Health Service Act for one or more in-
11 dications, and such approval or licensure remains in
12 effect;

13 “(2) the supplemental application is for ap-
14 proval or licensure (as applicable) under such section
15 505(c) or 351(a) of the use of the drug for a new
16 qualified indication under such section 505(c) or
17 351(a);

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

23 “(4) the supplemental application incorporates
24 or supplements the data submitted in the application

1 for approval or licensure referred to in paragraph
2 (1); and

3 “(5) the full data sets used to develop the quali-
4 fied data summaries are submitted, if the Secretary
5 determines that the full data sets are required.

6 “(c) DEFINITIONS.—In this section:

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

8 “(A) an indication for the treatment of
9 cancer, as determined appropriate by the Sec-
10 retary; or

11 “(B) such other types of indications as the
12 Secretary determines to be subject to the
13 streamlined data review program under this
14 section.

15 “(2) The term ‘qualified data summary’ means
16 a summary of clinical data intended to demonstrate
17 safety and effectiveness with respect to a qualified
18 indication for use of a drug.”.

19 (b) GUIDANCE; REGULATIONS.—The Commissioner
20 of Food and Drugs—

21 (1) shall—

22 (A) issue final guidance for implementation
23 of the streamlined data review program estab-
24 lished under section 505F of the Federal Food,
25 Drug, and Cosmetic Act, as added by sub-

1 section (a), not later than 24 months after the
2 date of enactment of this Act; and

3 (B) include in such guidance the process
4 for expanding the types of indications to be
5 subject to the streamlined data review program,
6 as authorized by section 505F(c)(1)(B) of such
7 Act; and

8 (2) in addition to issuing guidance under sub-
9 paragraph (A), may issue such regulations as may
10 be necessary for implementation of the program.

11 **Subtitle E—Expediting Patient** 12 **Access**

13 **SEC. 2081. SENSE OF CONGRESS.**

14 It is the sense of Congress that the Food and Drug
15 Administration should continue to expedite the approval
16 of drugs designated as breakthrough therapies pursuant
17 to section 506(a) of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 356(a)) by approving drugs so des-
19 ignated as early as possible in the clinical development
20 process, regardless of the phase of development, provided
21 that the Secretary of Health and Human Services deter-
22 mines that an application for such a drug meets the stand-
23 ards of evidence of safety and effectiveness under section
24 505 of such Act (21 U.S.C. 355), including the substantial
25 evidence standard under subsection (d) of such section or

1 under section 351(a) of the Public Health Service Act (42
2 U.S.C. 262(a)).

3 **SEC. 2082. EXPANDED ACCESS POLICY.**

4 Section 561 of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 360bbb) is amended—

6 (1) by redesignating subsections (d) and (e) as
7 subsections (e) and (f), respectively; and

8 (2) by inserting after subsection (c) the fol-
9 lowing new subsection:

10 “(d) EXPANDED ACCESS POLICY REQUIRED FOR IN-
11 VESTIGATIONAL DRUGS.—

12 “(1) IN GENERAL.—The manufacturer or dis-
13 tributor of one or more investigational drugs for the
14 diagnosis, monitoring, or treatment of one or more
15 serious diseases or conditions shall make publicly
16 available the policy of the sponsor on evaluating and
17 responding to requests submitted under subsection
18 (b) for provision of such drug. A sponsor may satisfy
19 the requirement of the preceding sentence by posting
20 such policy as generally applicable to all of such
21 sponsor’s investigational drugs.

22 “(2) CONTENT OF POLICY.—A policy described
23 in paragraph (1) shall include making publicly avail-
24 able—

1 “(A) contact information for the manufac-
2 turer or distributor to facilitate communication
3 about requests described in paragraph (1);

4 “(B) procedures for making such requests;

5 “(C) the general criteria for the sponsor’s
6 consideration or approval of such requests; and

7 “(D) the length of time the sponsor antici-
8 pates will be necessary to acknowledge receipt
9 of such requests.

10 “(3) NO GUARANTEE OF ACCESS.—The posting
11 of policies by manufacturers and distributors under
12 paragraph (1) shall not serve as a guarantee of ac-
13 cess to any specific investigational drug to any indi-
14 vidual patient.

15 “(4) REVISED POLICY.—A manufacturer or dis-
16 tributor that has made a policy publicly available as
17 required by this subsection may revise the policy at
18 any time.

19 “(5) APPLICATION.—This subsection shall
20 apply to a manufacturer or distributor with respect
21 to an investigational drug beginning on the later
22 of—

23 “(A) the date that is 60 days after the
24 date of enactment of the 21st Century Cures
25 Act; or

1 “(B) the first initiation of a phase 2 or
2 phase 3 study (as such terms are defined in
3 section 312.21(b) and (c) of title 21, Code of
4 Federal Regulations (or any successor regula-
5 tions)) with respect to such a drug.”.

6 **SEC. 2083. FINALIZING DRAFT GUIDANCE ON EXPANDED**
7 **ACCESS.**

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

13 (b) **CONTENTS.**—The final guidance referred to in
14 subsection (a) shall clearly define how the Secretary of
15 Health and Human Services interprets and uses adverse
16 drug event data reported by investigators in the case of
17 data reported from use under a request submitted under
18 section 561(b) of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 360bbb(b)).

1 **Subtitle F—Facilitating Respon-**
2 **sible Manufacturer Communica-**
3 **tions**

4 **[SEC. 2101. FACILITATING DISSEMINATION OF HEALTH**
5 **CARE ECONOMIC INFORMATION.**

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

8 **[(1) by striking “(a) If its” and inserting**
9 **“(a)(1) If its”;****]**

10 **[(2) by striking “a formulary committee, or**
11 **other similar entity, in the course of the committee**
12 **or the entity carrying out its responsibilities for the**
13 **selection of drugs for managed care or other similar**
14 **organizations” and inserting “a payor, formulary**
15 **committee, or other similar entity, in the course of**
16 **the payor, committee, or other similar entity car-**
17 **rying out its responsibilities for the selection of**
18 **drugs for managed care or other similar organiza-**
19 **tions”;****]**

20 **[(3) by striking “directly relates” and inserting**
21 **“relates”;****]**

22 **[(4) by striking “and is based on competent**
23 **and reliable scientific evidence. The requirements set**
24 **forth in section 505(a) or in section 351(a) of the**
25 **Public Health Service Act shall not apply to health**

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

14 [(5) by striking “In this paragraph, the term”
15 and all that follows and inserting the following:]

16 [“(2) For purposes of this paragraph, the term
17 ‘health care economic information’ means any analysis (in-
18 cluding the data, inputs, clinical or other assumptions,
19 methods, results, and other components comprising the
20 analysis) that identifies, measures, or describes the con-
21 sequences, including the separate or aggregated clinical
22 consequences and costs of the represented health out-
23 comes, of the use of a drug. Such analyses may be com-
24 parative to the use of another drug, to another health care
25 intervention, or to no intervention.”.]

1 **SEC. 2102. FACILITATING RESPONSIBLE COMMUNICATION**
2 **OF SCIENTIFIC AND MEDICAL DEVELOP-**
3 **MENTS.**

4 (a) GUIDANCE.—Not later than 18 months after the
5 date of enactment of this Act, the Secretary of Health and
6 Human Services shall issue draft guidance on facilitating
7 the dissemination of responsible, truthful, and non-mis-
8 leading scientific and medical information not included on
9 the label of drugs.

10 (b) DEFINITION.—In this section, the term “drug”
11 has the meaning given to such term in section 201 of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

13 **Subtitle G—Antibiotic Drug**
14 **Development**

15 **SEC. 2121. APPROVAL OF CERTAIN DRUGS FOR USE IN A**
16 **LIMITED POPULATION OF PATIENTS.**

17 (a) PURPOSE.—The purpose of this section is to help
18 expedite the development and availability of treatments for
19 serious or life-threatening bacterial or fungal infections in
20 patients with unmet needs, while maintaining safety and
21 effectiveness standards for such treatments, taking into
22 account the severity of the infection and the availability
23 or lack of alternative treatments.

24 (b) APPROVAL OF CERTAIN ANTIBACTERIAL AND
25 ANTIFUNGAL DRUGS.—Section 505 of the Federal Food,
26 Drug, and Cosmetic Act (21 U.S.C. 355), as amended by

1 section 2001, is further amended by adding at the end
2 the following new subsection:

3 “(z) APPROVAL OF CERTAIN ANTIBACTERIAL AND
4 ANTIFUNGAL DRUGS FOR USE IN A LIMITED POPU-
5 LATION OF PATIENTS.—

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

10 “(A) may enter into a written agreement
11 with the sponsor for the purposes of defining
12 the process for developing data to support an
13 application for approval for use in a limited
14 population of patients, in accordance with this
15 subsection;

16 “(B) shall proceed with the development
17 and approval of such a drug in accordance with
18 this subsection only if a written agreement is
19 reached under subparagraph (A);

20 “(C) shall provide the sponsor with an op-
21 portunity to request meetings under paragraph
22 (2);

23 “(D) may approve the drug under sub-
24 section (c) for such use—

1 “(i) in a limited population of patients
2 for which there is an unmet medical need;

3 “(ii) based on a streamlined develop-
4 ment program; and

5 “(iii) only if the standards for ap-
6 proval under subsections (c) and (d) or li-
7 censure under section 351 of the Public
8 Health Service Act, as applicable, are met;

9 “(E) in approving a drug in accordance
10 with this subsection, subject to subparagraph
11 (D)(iii), may rely upon—

12 “(i) traditional endpoints, alternate
13 endpoints, or a combination of traditional
14 and alternate endpoints, and, as appro-
15 priate, data sets of a limited size;

16 “(ii)(I) additional data, including pre-
17 clinical, pharmacologic, or pathophysiologic
18 evidence;

19 “(II) nonclinical susceptibility and
20 pharmacokinetic data;

21 “(III) data from phase 2 clinical
22 trials; and

23 “(IV) such other confirmatory evi-
24 dence as the Secretary determines appro-
25 priate to approve the drug.

1 “(2) FORMAL MEETINGS.—

2 “(A) IN GENERAL.—To help expedite and
3 facilitate the development and review of a drug
4 for which a sponsor intends to request approval
5 in accordance with this subsection, the Sec-
6 retary shall, at the request of the sponsor, con-
7 duct meetings that provide early consultation,
8 timely advice, and sufficient opportunities to
9 develop an agreement described in paragraph
10 (1)(A) and help the sponsor design and conduct
11 a drug development program as efficiently as
12 possible, including the following types of meet-
13 ings:

14 “(i) An early consultation meeting.

15 “(ii) An assessment meeting.

16 “(iii) A postapproval meeting.

17 “(B) NO ALTERING OF GOALS.—Nothing
18 in this paragraph shall be construed to alter
19 agreed upon goals and procedures identified in
20 the letters described in section 101(b) of the
21 Prescription Drug User Fee Amendments of
22 2012.

23 “(C) BREAKTHROUGH THERAPIES.—In the
24 case of a drug designated as a breakthrough
25 therapy under section 506(a), the sponsor of

1 such drug may elect to utilize meetings pro-
2 vided under such section with respect to such
3 drug in lieu of meetings described in subpara-
4 graph (A).

5 “(3) LABELING REQUIREMENT.—The labeling
6 of an antibacterial or antifungal drug approved in
7 accordance with this subsection shall contain the
8 statement ‘Limited Population’ in a prominent man-
9 ner and adjacent to, and not more prominent than,
10 the brand name of the product. The prescribing in-
11 formation for such antibacterial or antifungal drug
12 required by section 201.57 of title 21, Code of Fed-
13 eral Regulations (or any successor regulation) shall
14 also include the following statement: ‘This drug is
15 indicated for use in a limited and specific population
16 of patients.’.

17 “(4) PROMOTIONAL MATERIALS.—The provi-
18 sions of section 506(c)(2)(B) shall apply with re-
19 spect to approval in accordance with this subsection
20 to the same extent and in the same manner as such
21 provisions apply with respect to accelerated approval
22 in accordance with section 506(c)(1).

23 “(5) TERMINATION OF REQUIREMENTS OR CON-
24 DITIONS.—If a drug is approved in accordance with
25 this subsection for an indication in a limited popu-

1 lation of patients and is subsequently approved or li-
2 censed under this section or section 351 of the Pub-
3 lic Health Service Act, other than in accordance with
4 this subsection, for—

5 “(A) the same indication and the same
6 conditions of use, the Secretary shall remove
7 any labeling requirements or postmarketing
8 conditions that were made applicable to the
9 drug under this subsection; or

10 “(B) a different indication or condition of
11 use, the Secretary shall not apply the labeling
12 requirements and postmarketing conditions that
13 were made applicable to the drug under this
14 subsection to the subsequent approval of the
15 drug for such different indication or condition
16 of use.

17 “(6) RELATION TO OTHER PROVISIONS.—Noth-
18 ing in this subsection shall be construed to prohibit
19 the approval of the drug for use in a limited popu-
20 lation of patients in accordance with this subsection,
21 in combination with—

22 “(A) an agreement on the design and size
23 of a clinical trial pursuant to subparagraphs
24 (B) and (C) of subsection (b)(5);

1 “(B) designation and treatment of a drug
2 as a breakthrough therapy under section
3 506(a);

4 “(C) designation and treatment of a drug
5 as a fast track product under section 506(b); or

6 “(D) accelerated approval of a drug in ac-
7 cordance with section 506(c).

8 “(7) RULE OF CONSTRUCTION.—Nothing in
9 this subsection shall be construed—

10 “(A) to alter the standards of evidence
11 under subsection (c) or (d) (including the sub-
12 stantial evidence standard in subsection (d));

13 “(B) to waive or otherwise preclude the ap-
14 plication of requirements under subsection (o);

15 “(C) to otherwise, in any way, limit the au-
16 thority of the Secretary to approve products
17 pursuant to this Act and the Public Health
18 Service Act as authorized prior to the date of
19 enactment of this subsection; or

20 “(D) to restrict in any manner, the pre-
21 scribing of antibiotics or other products by
22 health care providers, or to limit or restrict the
23 practice of health care, including the pre-
24 scribing of such drugs by physicians for pa-
25 tients.

1 “(8) EFFECTIVE IMMEDIATELY.—The Sec-
2 retary shall have the authorities vested in the Sec-
3 retary by this subsection beginning on the date of
4 enactment of this subsection, irrespective of when
5 and whether the Secretary promulgates final regula-
6 tions or guidance.

7 “(9) DEFINITIONS.—In this subsection:

8 “(A) EARLY CONSULTATION MEETING.—
9 The term ‘early consultation meeting’ means a
10 pre-investigational new drug meeting or an end-
11 of-phase 1 meeting that—

12 “(i) is conducted to review and reach
13 a written agreement—

14 “(I) on the scope of the stream-
15 lined development plan for a drug for
16 which a sponsor intends to request ap-
17 proval in accordance with this sub-
18 section; and

19 “(II) which, as appropriate, may
20 include agreement on the design and
21 size of necessary preclinical and clin-
22 ical studies early in the development
23 process, including clinical trials whose
24 data are intended to form the primary
25 basis for an effectiveness claim; and

1 “(ii) provides an opportunity to dis-
2 cuss expectations of the Secretary regard-
3 ing studies or other information that the
4 Secretary deems appropriate for purposes
5 of applying paragraph (5), relating to the
6 termination of labeling requirements or
7 postmarketing conditions.

8 “(B) ASSESSMENT MEETING.—The term
9 ‘assessment meeting’ means an end-of-phase 2
10 meeting, pre-new drug application meeting, or
11 pre-biologics license application meeting con-
12 ducted to resolve questions and issues raised
13 during the course of clinical investigations, and
14 details addressed in the written agreement re-
15 garding postapproval commitments or expan-
16 sion of approved uses.

17 “(C) POSTAPPROVAL MEETING.—The term
18 ‘postapproval meeting’ means a meeting fol-
19 lowing initial approval or licensure of the drug
20 for use in a limited population, to discuss any
21 issues identified by the Secretary or the sponsor
22 regarding postapproval commitments or expan-
23 sion of approved uses.”.

24 (c) GUIDANCE.—Not later than 18 months after the
25 date of enactment of this Act, the Secretary of Health and

1 Human Services, acting through the Commissioner of
2 Food and Drugs, shall issue draft guidance describing cri-
3 teria, process, and other general considerations for dem-
4 onstrating the safety and effectiveness of antibacterial and
5 antifungal drugs to be approved for use in a limited popu-
6 lation in accordance with 505(z) of the Federal Food,
7 Drug, and Cosmetic Act, as added by subsection (b).

8 (d) CONFORMING AMENDMENTS.—

9 (1) LICENSURE OF CERTAIN BIOLOGICAL PROD-
10 UCTS.—Section 351(j) of the Public Health Service
11 Act (42 U.S.C. 262(j)) is amended—

12 (A) by striking “(j)” and inserting
13 “(j)(1)”;

14 (B) by inserting “505(z),” after “505(p),”;
15 and

16 (C) by adding at the end the following new
17 paragraph:

18 “(2) In applying section 505(z) of the Federal Food,
19 Drug, and Cosmetic Act to the licensure of biological prod-
20 ucts under this section—

21 “(A) references to an antibacterial or antifungal
22 drug that is intended to treat a serious or life-
23 threatening infection shall be construed to refer to
24 a biological product intended to treat a serious or
25 life-threatening bacterial or fungal infection; and

1 “(B) references to approval of a drug under
2 section 505(c) of such Act shall be construed to
3 refer to a licensure of a biological product under
4 subsection (a) of this section.”.

5 (2) MISBRANDING.—Section 502 of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 352) is
7 amended by adding at the end the following new
8 subsection:

9 “(dd) If it is a drug approved in accordance with sec-
10 tion 505(z) and its labeling does not meet the require-
11 ments under paragraph (3) of such subsection, subject to
12 paragraph (5) of such subsection.”.

13 (e) EVALUATION.—

14 (1) ASSESSMENT.—Not later than 48 months
15 after the date of enactment of this Act, the Sec-
16 retary of Health and Human Services shall publish
17 for public comment an assessment of the program
18 established under section 505(z) of the Federal
19 Food, Drug, and Cosmetic Act, as added by sub-
20 section (b). Such assessment shall determine if the
21 limited-use pathway established under such section
22 505(z) has improved or is likely to improve patient
23 access to novel antibacterial or antifungal treat-
24 ments and assess how the pathway could be ex-
25 panded to cover products for serious or life-threat-

1 ening diseases or conditions beyond bacterial and
2 fungal infections.

3 (2) MEETING.—Not later than 90 days after
4 the date of the publication of such assessment, the
5 Secretary, acting through the Commissioner of Food
6 and Drugs shall hold a public meeting to discuss the
7 findings of the assessment, during which public
8 stakeholders may present their views on the success
9 of the program established under section 505(z) of
10 the Federal Food, Drug, and Cosmetic Act, as
11 added by subsection (b) and the appropriateness of
12 expanding such program.

13 (f) EXPANSION OF PROGRAM.—If the Secretary of
14 Health and Human Services determines, based on the as-
15 sessment under subsection (e)(1), evaluation of the assess-
16 ment, and any other relevant information, that the public
17 health would benefit from expansion of the limited-use
18 pathway established under section 505(z) of the Federal
19 Food, Drug, and Cosmetic Act (as added by subsection
20 (b)) beyond the drugs approved in accordance with such
21 section, the Secretary may expand such limited-use path-
22 way in accordance with such a determination. The ap-
23 proval of any drugs under any such expansion shall be
24 subject to the considerations and requirements described

1 in such section 505 for purposes of expansion to other se-
2 rious or life-threatening diseases or conditions.

3 (g) MONITORING.—The Public Health Service Act is
4 amended by inserting after section 317T (42 U.S.C.
5 247b–22) the following:

6 **“SEC. 317U. MONITORING ANTIBACTERIAL AND**
7 **ANTIFUNGAL DRUG USE AND RESISTANCE.**

8 “(a) MONITORING.—The Secretary shall use an ap-
9 propriate monitoring system to monitor—

10 “(1) the use of antibacterial and antifungal
11 drugs, including those receiving approval or licensure
12 for a limited population pursuant to section 505(z)
13 of the Federal Food, Drug, and Cosmetic Act; and

14 “(2) changes in bacterial and fungal resistance
15 to drugs.

16 “(b) PUBLIC AVAILABILITY OF DATA.—The Sec-
17 retary shall make summaries of the data derived from
18 monitoring under this section publicly available for the
19 purposes of—

20 “(1) improving the monitoring of important
21 trends in antibacterial and antifungal resistance;
22 and

23 “(2) ensuring appropriate stewardship of anti-
24 bacterial and antifungal drugs, including those re-
25 ceiving approval or licensure for a limited population

1 other requirements under this Act for anti-
2 microbial susceptibility testing devices.

3 “(2) IN GENERAL.—The Secretary shall iden-
4 tify appropriate susceptibility test interpretive cri-
5 teria with respect to antimicrobial drugs—

6 “(A) if such criteria are available on the
7 date of approval of the drug under section 505
8 of this Act or licensure of the drug under sec-
9 tion 351 of the Public Health Service Act (as
10 applicable), upon such approval or licensure; or

11 “(B) if such criteria are unavailable on
12 such date, on the date on which such criteria
13 are available for such drug.

14 “(3) BASES FOR INITIAL IDENTIFICATION.—
15 The Secretary shall identify appropriate suscepti-
16 bility test interpretive criteria under paragraph (1),
17 based on the Secretary’s review of, to the extent
18 available and relevant—

19 “(A) preclinical and clinical data, including
20 pharmacokinetic, pharmacodynamic, and epide-
21 miological data;

22 “(B) Bayesian and pharmacometric statis-
23 tical methodologies; and

24 “(C) such other evidence and information
25 as the Secretary considers appropriate.

1 “(b) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA
2 WEBSITE.—

3 “(1) IN GENERAL.—Not later than one year
4 after the date of the enactment of the 21st Century
5 Cures Act, the Secretary shall establish, and main-
6 tain thereafter, on the website of the Food and Drug
7 Administration, a dedicated website that contains a
8 list of any appropriate new or updated susceptibility
9 test interpretive criteria standards in accordance
10 with paragraph (2) (referred to in this section as the
11 ‘Interpretive Criteria Website’).

12 “(2) LISTING OF SUSCEPTIBILITY TEST INTER-
13 PRETIVE CRITERIA STANDARDS.—

14 “(A) IN GENERAL.—The list described in
15 paragraph (1) shall consist of any new or up-
16 dated susceptibility test interpretive criteria
17 standards that are—

18 “(i) established by a nationally or
19 internationally recognized standard devel-
20 opment organization that—

21 “(I) establishes and maintains
22 procedures to address potential con-
23 flicts of interest and ensure trans-
24 parent decisionmaking;

1 “(II) holds open meetings to en-
2 sure that there is an opportunity for
3 public input by interested parties, and
4 establishes and maintains processes to
5 ensure that such input is considered
6 in decisionmaking; and

7 “(III) permits its standards to be
8 made publicly available, through the
9 National Library of Medicine or an-
10 other similar source acceptable to the
11 Secretary; and

12 “(ii) recognized in whole, or in part,
13 by the Secretary under subsection (c).

14 “(B) OTHER LISTS.—The Interpretive Cri-
15 teria Website shall, in addition to the list de-
16 scribed in subparagraph (A), include a list of
17 interpretive criteria, if any, that the Secretary
18 has determined to be appropriate with respect
19 to legally marketed antimicrobial drugs,
20 where—

21 “(i) the Secretary does not recognize,
22 in whole or in part, an interpretive criteria
23 standard described under subparagraph
24 (A) otherwise applicable to such a drug;

1 “(ii) the Secretary withdraws under
2 subsection (c)(1)(B) recognition of a
3 standard, in whole or in part, otherwise
4 applicable to such a drug;

5 “(iii) the Secretary approves an appli-
6 cation under section 505 of this Act or sec-
7 tion 351 of the Public Health Service Act,
8 as applicable, with respect to marketing of
9 such a drug for which there are no rel-
10 evant interpretive criteria included in a
11 standard recognized by the Secretary
12 under subsection (c); or

13 “(iv) because the characteristics of
14 such a drug product differ from other drug
15 products with the same active ingredient,
16 the interpretive criteria with respect to
17 such drug—

18 “(I) differ from otherwise appli-
19 cable interpretive criteria included in
20 a standard listed under subparagraph
21 (A) or interpretive criteria otherwise
22 listed under this subparagraph; and

23 “(II) are determined to be appro-
24 priate for the drug.

1 “(C) REQUIRED STATEMENTS ON LIMITA-
2 TIONS OF INFORMATION.—The Interpretive Cri-
3 teria Website shall include the following:

4 “(i) A statement that—

5 “(I) the Website provides infor-
6 mation about the susceptibility of bac-
7 teria, fungi, or other microorganisms
8 to a certain drug (or drugs); and

9 “(II) the safety and efficacy of
10 the drug in treating clinical infections
11 due to such bacteria, fungi, or other
12 microorganisms may not have been es-
13 tablished in adequate and well-con-
14 trolled clinical trials and the clinical
15 significance of such susceptibility in-
16 formation in such trials is unknown.

17 “(ii) A statement that directs health
18 care practitioners to consult the approved
19 product labeling for specific drugs to deter-
20 mine the uses for which the Food and
21 Drug Administration has approved the
22 product.

23 “(iii) Any other statement that the
24 Secretary determines appropriate to ade-
25 quately convey the limitations of the data

1 supporting susceptibility test interpretive
2 criteria standard listed on the Website.

3 “(3) NOTICE.—Not later than the date on
4 which the Interpretive Criteria Website is estab-
5 lished, the Secretary shall publish a notice of that
6 establishment in the Federal Register.

7 “(4) INAPPLICABILITY OF MISBRANDING PROVI-
8 SION.—The inclusion in the approved labeling of an
9 antimicrobial drug of a reference or hyperlink to the
10 Interpretive Criteria Website, in and of itself, shall
11 not cause the drug to be misbranded in violation of
12 section 502, or the regulations promulgated there-
13 under.

14 “(5) TRADE SECRETS AND CONFIDENTIAL IN-
15 FORMATION.—Nothing in this section shall be con-
16 strued as authorizing the Secretary to disclose any
17 information that is a trade secret or confidential in-
18 formation subject to section 552(b)(4) of title 5,
19 United States Code.

20 “(c) RECOGNITION OF SUSCEPTIBILITY TEST INTER-
21 PRETIVE CRITERIA FROM STANDARD DEVELOPMENT OR-
22 GANIZATIONS.—

23 “(1) IN GENERAL.—Beginning on the date of
24 the establishment of the Interpretive Criteria

1 Website, and at least every 6 months thereafter, the
2 Secretary shall—

3 “(A) evaluate any appropriate new or up-
4 dated susceptibility test interpretive criteria
5 standards established by a nationally or inter-
6 nationally recognized standard development or-
7 ganization described in subsection (b)(2)(A)(i);
8 and

9 “(B) publish on the public website of the
10 Food and Drug Administration a notice—

11 “(i) withdrawing recognition of any
12 different susceptibility test interpretive cri-
13 teria standard, in whole or in part;

14 “(ii) recognizing the new or updated
15 standards;

16 “(iii) recognizing one or more parts of
17 the new or updated interpretive criteria
18 specified in such a standard and declining
19 to recognize the remainder of such stand-
20 ard; and

21 “(iv) making any necessary updates to
22 the lists under subsection (b)(2).

23 “(2) BASES FOR UPDATING INTERPRETIVE CRI-
24 TERIA STANDARDS.—In evaluating new or updated
25 susceptibility test interpretive criteria standards

1 under paragraph (1)(A), the Secretary may con-
2 sider—

3 “(A) the Secretary’s determination that
4 such a standard is not applicable to a particular
5 drug because the characteristics of the drug dif-
6 fer from other drugs with the same active in-
7 gredient;

8 “(B) information provided by interested
9 third parties, including public comment on the
10 annual compilation of notices published under
11 paragraph (3);

12 “(C) any bases used to identify suscepti-
13 bility test interpretive criteria under subsection
14 (a)(2); and

15 “(D) such other information or factors as
16 the Secretary determines appropriate.

17 “(3) ANNUAL COMPILATION OF NOTICES.—
18 Each year, the Secretary shall compile the notices
19 published under paragraph (1)(B) and publish such
20 compilation in the Federal Register and provide for
21 public comment. If the Secretary receives comments,
22 the Secretary will review such comments and, if the
23 Secretary determines appropriate, update pursuant
24 to this subsection susceptibility test interpretive cri-
25 teria standards—

1 “(A) recognized by the Secretary under
2 this subsection; or

3 “(B) otherwise listed on the Interpretive
4 Criteria Website under subsection (b)(2).

5 “(4) RELATION TO SECTION 514(c).—Any sus-
6 ceptibility test interpretive standard recognized
7 under this subsection or any criteria otherwise listed
8 under subsection (b)(2)(B) shall be deemed to be
9 recognized as a standard by the Secretary under sec-
10 tion 514(c)(1).

11 “(5) VOLUNTARY USE OF INTERPRETIVE CRI-
12 TERIA.—Nothing in this section prohibits a person
13 from seeking approval or clearance of a drug or de-
14 vice, or changes to the drug or the device, on the
15 basis of susceptibility test interpretive criteria stand-
16 ards which differ from those recognized pursuant to
17 paragraph (1).

18 “(d) ANTIMICROBIAL DRUG LABELING.—

19 “(1) DRUGS MARKETED PRIOR TO ESTABLISH-
20 MENT OF INTERPRETIVE CRITERIA WEBSITE.—With
21 respect to an antimicrobial drug lawfully introduced
22 or delivered for introduction into interstate com-
23 merce for commercial distribution before the estab-
24 lishment of the Interpretive Criteria Website, a hold-
25 er of an approved application under section 505 or

1 section 351 of the Public Health Service Act, as ap-
2 plicable, for each such drug—

3 “(A) not later than 1 year after establish-
4 ment of the Interpretive Criteria Website, shall
5 submit to the Secretary a supplemental applica-
6 tion for purposes of changing the drug’s label-
7 ing to substitute a reference or hyperlink to
8 such Website for any susceptibility test inter-
9 pretive criteria and related information; and

10 “(B) may begin distribution of the drug in-
11 volved upon receipt by the Secretary of the sup-
12 plemental application for such change.

13 “(2) DRUGS MARKETED SUBSEQUENT TO ES-
14 TABLISHMENT OF INTERPRETIVE CRITERIA
15 WEBSITE.—With respect to antimicrobial drugs law-
16 fully introduced or delivered for introduction into
17 interstate commerce for commercial distribution on
18 or after the date of the establishment of the Inter-
19 pretive Criteria Website, the labeling for such a drug
20 shall include, in lieu of susceptibility test interpretive
21 criteria and related information, a reference to such
22 Website.

23 “(e) SPECIAL CONDITION FOR MARKETING OF ANTI-
24 MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

1 “(1) IN GENERAL.—Notwithstanding sections
2 501, 502, 510, 513, and 515, if the conditions speci-
3 fied in paragraph (2) are met (in addition to other
4 applicable provisions under this chapter) with re-
5 spect to an antimicrobial susceptibility testing device
6 described in subsection (f)(1), the Secretary may au-
7 thorize the marketing of such device for a use de-
8 scribed in such subsection.

9 “(2) CONDITIONS APPLICABLE TO ANTI-
10 MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—
11 The conditions specified in this paragraph are the
12 following:

13 “(A) The device is used to make a deter-
14 mination of susceptibility using susceptibility
15 test interpretive criteria that are—

16 “(i) included in a standard recognized
17 by the Secretary under subsection (e); or

18 “(ii) otherwise listed on the Interpre-
19 tive Criteria Website under subsection
20 (b)(2).

21 “(B) The labeling of such device promi-
22 nently and conspicuously—

23 “(i) includes a statement that—

1 “(I) the device provides informa-
2 tion about the susceptibility of bac-
3 teria and fungi to certain drugs; and

4 “(II) the safety and efficacy of
5 such drugs in treating clinical infec-
6 tions due to such bacteria or fungi
7 may not have been established in ade-
8 quate and well-controlled clinical trials
9 and the clinical significance of such
10 susceptibility information in those in-
11 stances is unknown;

12 “(ii) includes a statement directing
13 health care practitioners to consult the ap-
14 proved labeling for drugs tested using such
15 a device, to determine the uses for which
16 the Food and Drug Administration has ap-
17 proved such drugs; and

18 “(iii) includes any other statement the
19 Secretary determines appropriate to ade-
20 quately convey the limitations of the data
21 supporting the interpretive criteria de-
22 scribed in subparagraph (A).

23 “(f) DEFINITIONS.—In this section:

24 “(1) The term ‘antimicrobial susceptibility test-
25 ing device’ means a device that utilizes susceptibility

1 test interpretive criteria to determine and report the
2 in vitro susceptibility of certain microorganisms to a
3 drug (or drugs).

4 “(2) The term ‘qualified infectious disease
5 product’ means a qualified infectious disease product
6 designated under section 505E(d).

7 “(3) The term ‘susceptibility test interpretive
8 criteria’ means—

9 “(A) one or more specific numerical values
10 which characterize the susceptibility of bacteria
11 or other microorganisms to the drug tested; and

12 “(B) related categorizations of such sus-
13 ceptibility, including categorization of the drug
14 as susceptible, intermediate, resistant, or such
15 other term as the Secretary determines appro-
16 priate.

17 “(4)(A) The term ‘antimicrobial drug’ means,
18 subject to subparagraph (B), a systemic anti-
19 bacterial or antifungal drug that—

20 “(i) is intended for human use in the treat-
21 ment of a disease or condition caused by a bac-
22 terium or fungus;

23 “(ii) may include a qualified infectious dis-
24 ease product designated under section 505E(d);
25 and

1 “(iii) is subject to section 503(b)(1).

2 “(B) If provided by the Secretary through regula-
3 tions, such term may include—

4 “(i) drugs other than systemic anti-
5 bacterial and antifungal drugs; and

6 “(ii) biological products (as such term is
7 defined in section 351 of the Public Health
8 Service Act) to the extent such products exhibit
9 antimicrobial activity.

10 “(g) RULE OF CONSTRUCTION.—Nothing in this sec-
11 tion shall be construed to—

12 “(1) alter the standards of evidence—

13 “(A) under subsection (c) or (d) of section
14 505, including the substantial evidence stand-
15 ard in section 505(d), or under section 351 of
16 the Public Health Service Act (as applicable);
17 or

18 “(B) with respect to marketing authoriza-
19 tion for devices, under sections 510, 513, or
20 515; or

21 “(2) apply with respect to any drug, device, or
22 biological product, in any context other than—

23 “(A) the use of such drug or product as an
24 antimicrobial drug; or

1 “(B) the use of an antimicrobial suscepti-
2 bility testing device to characterize and report
3 the in vitro susceptibility of certain bacteria,
4 fungi, or other microorganisms to antimicrobial
5 drugs in accordance with this section; and

6 “(3) unless specifically stated, have any effect
7 on authorities provided under other sections of this
8 Act, including any regulations issued under such
9 sections.”.

10 (b) CONFORMING AMENDMENTS.—

11 (1) REPEAL OF RELATED AUTHORITY.—Section
12 1111 of the Food and Drug Administration Amend-
13 ments Act of 2007 (42 U.S.C. 247d–5a; relating to
14 identification of clinically susceptible concentrations
15 of antimicrobials) is repealed.

16 (2) MISBRANDING.—Section 502 of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 352), as
18 amended by section 2121, is further amended by
19 adding at the end the following:

20 “(ee) If it is an antimicrobial drug and its labeling
21 fails to conform with the requirements under section
22 511(d).”.

23 (3) RECOGNITION OF INTERPRETIVE CRITERIA
24 AS DEVICE STANDARD.—Section 514(e)(1)(A) of the
25 Federal Food, Drug, and Cosmetic Act (21 U.S.C.

1 360d(e)(1)(A)) is amended by inserting after “the
2 Secretary shall, by publication in the Federal Reg-
3 ister” the following: “(or, with respect to suscepti-
4 bility test interpretive criteria or standards recog-
5 nized or otherwise listed under section 511, by post-
6 ing on the Interpretive Criteria website in accord-
7 ance with such section)”.

8 (c) REPORT TO CONGRESS.—Not later than two
9 years after the date of enactment of this Act, the Sec-
10 retary of Health and Human Services shall submit to the
11 Committee on Energy and Commerce of the House of
12 Representatives and the Committee on Health, Education,
13 Labor, and Pensions of the Senate a report on the
14 progress made in implementing section 511 of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 360a), as
16 amended by this section.

17 (d) REQUESTS FOR UPDATES TO INTERPRETIVE CRI-
18 TERIA WEBSITE.—Chapter 35 of title 44, United States
19 Code, shall not apply to the collection of information from
20 interested parties regarding the updating of lists under
21 paragraph (2) of subsection (b) section 511 of the Federal
22 Food, Drug, and Cosmetic Act, as amended by subsection
23 (a), and posted on the Interpretive Criteria Website estab-
24 lished under paragraph (1) of such subsection (b).

1 (e) NO EFFECT ON HEALTH CARE PRACTICE.—
2 Nothing in this subtitle (including the amendments made
3 by this subtitle) shall be construed to restrict, in any man-
4 ner, the prescribing or administering of antibiotics or
5 other products by health care practitioners, or to limit the
6 practice of health care.

7 **[SEC. 2123. ENCOURAGING THE DEVELOPMENT AND RE-**
8 **SPONSIBLE USE OF NEW ANTIMICROBIAL**
9 **DRUGS.**

10 **[(a) ADDITIONAL PAYMENT FOR NEW ANTI-**
11 **MICROBIAL DRUGS UNDER MEDICARE.—**Section
12 1886(d)(5) of the Social Security Act (42 U.S.C.
13 1395ww(d)(5)) is amended by adding at the end the fol-
14 lowing new subparagraph:】

15 **【“(M)(i) Effective for discharges beginning**
16 **on or after October 1, 2015, the Secretary**
17 **shall, after notice and opportunity for public**
18 **comment (in the publications required by sub-**
19 **section (e)(5) for a fiscal year or otherwise),**
20 **recognize the costs of new antimicrobial drugs**
21 **under the payment system established under**
22 **this subparagraph.】**

23 **【“(ii) Pursuant to clause (i), the Secretary**
24 **shall provide for additional payment to be made**
25 **under this subsection with respect to discharges**

1 involving new antimicrobial drugs in the
2 amount provided for under section A for drugs
3 and biological products that are described in
4 section 1842(o)(1)(C).】

5 【“(iii) For purposes of this subparagraph,
6 the term ‘new antimicrobial drug’ means a
7 product that is approved for use, or a product
8 for which an indication is first approved for
9 use, by the Food and Drug Administration on
10 or after January 1, 2015, and—】

11 【“(I)(aa) is intended to treat an in-
12 fection caused by, or likely to be caused by,
13 a qualifying pathogen (as defined under
14 section 505E(f) of the Federal Food,
15 Drug, and Cosmetic Act); or】

16 【“(bb) meets the definition of a quali-
17 fied infectious disease product under sec-
18 tion 505E(g) of the Federal Food, Drug,
19 and Cosmetic Act;】

20 【“(II) for which there is an ‘unmet
21 medical need’ as determined by the Food
22 and Drug Administration;】

23 【“(III) which is associated with high
24 rates of mortality or significant patient
25 morbidity, as determined by the Secretary,

1 in consultation with the Director of the
2 Centers for Disease Control and Preven-
3 tion and the infectious disease professional
4 community; and】

5 【“(IV) is used in facilities that par-
6 ticipate in the National Healthcare Safety
7 Network of the Centers for Disease Con-
8 trol and Prevention (or, to the extent a
9 similar reporting program relating to anti-
10 microbial drugs is determined by the Sec-
11 retary to be available to such facilities,
12 such similar reporting program as the Sec-
13 retary may specify).】

14 【“(iv)(I) The manufacturer or sponsor of a
15 drug may request the Secretary to designate a
16 drug as a new antimicrobial drug at any time
17 before or after the submission of an application
18 under section 505(b) of the Federal Food,
19 Drug, and Cosmetic Act or section 351(a) of
20 the Public Health Service Act for such drug.
21 The Secretary shall, not later than 60 days
22 after the submission of such a request, deter-
23 mine whether the drug is a new antimicrobial
24 drug.】

1 【“(II) Except as provided in subclause
2 (III), a designation under this subsection shall
3 not be withdrawn for any reason.”】

4 【“(III) The Secretary may revoke a des-
5 ignation of a drug as a new antimicrobial drug
6 product if the Secretary finds that the request
7 for such designation contained an untrue state-
8 ment of material fact.”】

9 【“(v) Not later than July 1, 2015, the
10 Secretary shall first publish in the Federal Reg-
11 ister a list of the new antimicrobial drugs.”】

12 【(b) STUDY AND REPORT ON REMOVING BARRIERS
13 TO DEVELOPMENT OF NEW ANTIMICROBIAL DRUGS.—】

14 【(1) STUDY.—The Comptroller General of the
15 United States shall, in consultation with the Direc-
16 tor of the National Institutes of Health, the Com-
17 missioner of Food and Drugs, and the Director of
18 the Centers for Disease Control and Prevention, con-
19 duct a study to—】

20 【(A) identify and examine the barriers
21 that prevent the development of new anti-
22 microbial drugs, as defined in section
23 1886(d)(5)(M)(iii) of the Social Security Act
24 (42 U.S.C. 1395ww(d)(5)(M)(iii)); and】

1 【(B) develop recommendations for actions
2 to be taken in order to overcome any barriers
3 identified under subparagraph (A).】

4 【(2) REPORT.—Not later than 1 year after the
5 date of the enactment of this Act, the Comptroller
6 General shall submit to Congress a report on the
7 study conducted under paragraph (1).】

8 **Subtitle H— Vaccine Access,**
9 **Certainty, and Innovation**

10 **SEC. 2141. TIMELY REVIEW OF VACCINES BY THE ADVISORY**
11 **COMMITTEE ON IMMUNIZATION PRACTICES.**

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

15 “(10) ADVISORY COMMITTEE ON IMMUNIZATION
16 PRACTICES.—

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

24 “(B) EXPEDITED REVIEW PURSUANT TO
25 REQUEST BY SPONSOR OR MANUFACTURER.—If

1 the Advisory Committee does not make rec-
2 ommendations with respect to the use of a vac-
3 cine at the Advisory Committee’s first regularly
4 scheduled meeting after the licensure of the
5 vaccine or any new indication for the vaccine,
6 the Advisory Committee, at the request of the
7 sponsor of the vaccine, shall make such rec-
8 ommendations on an expedited basis.

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

18 “(D) DEFINITION.—In this paragraph, the
19 terms ‘Advisory Committee on Immunization
20 Practices’ and ‘Advisory Committee’ mean the
21 advisory committee on immunization practices
22 established by the Secretary pursuant to section
23 222, acting through the Director of the Centers
24 for Disease Control and Prevention.”.

1 **SEC. 2142. REVIEW OF PROCESSES AND CONSISTENCY OF**
2 **ACIP RECOMMENDATIONS.**

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

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

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

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

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

22 (c) STAKEHOLDERS.—In carrying out the review
23 under subsection (a), the Director of the Centers for Dis-
24 ease Control and Prevention shall solicit input from vac-
25 cine stakeholders.

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

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

15 **SEC. 2143. MEETINGS BETWEEN CDC AND VACCINE DEVEL-**
16 **OPERS.**

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

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

22 “(A)(i) the development of a vaccine with the
23 intent to pursue licensing of the vaccine by the Food
24 and Drug Administration; or

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

3 “(B) vaccine research.

4 “(2)(A) Upon the submission of a written request for
5 a meeting by a vaccine developer, that includes a justifica-
6 tion for the meeting, the Secretary, acting through the Di-
7 rector of the Centers for Disease Control and Prevention,
8 shall convene a meeting of representatives of the vaccine
9 developer and experts from the Centers for Disease Con-
10 trol and Prevention in immunization programs, epidemi-
11 ology, and other relevant areas at which the Director (or
12 the Director’s designee), for the purpose of informing the
13 vaccine developer’s understanding of public health needs
14 and priorities, shall provide the perspectives of the Centers
15 for Disease Control and Prevention and other relevant
16 Federal agencies regarding—

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

20 “(ii) potential implications of such perspectives
21 for the vaccine developer’s vaccine research and de-
22 velopment planning.

23 “(B) In addition to the representatives specified in
24 subparagraph (A), the Secretary may, with the agreement
25 of the vaccine developer requesting a meeting under such

1 subparagraph, include in such meeting representatives
2 of—

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

4 “(ii) the National Vaccine Program.

5 “(C) The Secretary shall convene a meeting re-
6 requested under subparagraph (A) not later than 120 days
7 after receipt of the request for the meeting.

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

14 “(i) are specified in the request;

15 “(ii) have been published;

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

18 “(iv) are not a trade secret or commercial or fi-
19 nancial information that is privileged or confidential
20 and subject to section 552(b)(4) of title 5, United
21 States Code, or section 1905 of title 18, United
22 States Code; and

23 “(v) do not contain individually identifiable in-
24 formation.

1 “(B) The Secretary shall provide analyses requested
2 by a vaccine manufacturer under subparagraph (A) not
3 later than 90 calendar days after receipt of the request
4 for the analyses.

5 “(4) The Secretary shall promptly notify a vaccine
6 developer if—

7 “(A) the Secretary becomes aware of any
8 change to information that was—

9 “(i) shared by the Secretary with the vac-
10 cine developer during a meeting under para-
11 graph (2); or

12 “(ii) provided by the Secretary to the vac-
13 cine developer in one or more analyses under
14 paragraph (3); and

15 “(B) the change may have implications for the
16 vaccine developer’s vaccine research and develop-
17 ment.”.

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 section 2063, is
10 further amended by inserting after section 505F of such
11 Act the following:

12 **“SEC. 505G. 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 this
18 subsection 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 seven and one-half year
16 periods described in subsections (c)(3)(E)(ii) and
17 (j)(5)(F)(ii) of section 505, the 3-year periods de-
18 scribed in clauses (iii) and (iv) of subsection
19 (c)(3)(E) and clauses (iii) and (iv) of subsection
20 (j)(5)(F) of section 505, and the 7-year period de-
21 scribed in section 527, as applicable, shall be ex-
22 tended by 6 months; 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) REGULATIONS.—

12 “(1) IN GENERAL.—Not later than 2 years
13 after the date of enactment of this section, the Sec-
14 retary shall adopt final regulations implementing
15 this section.

16 “(2) PROCEDURE.—In promulgating a regula-
17 tion implementing this section, the Secretary shall—

18 “(A) issue a notice of proposed rulemaking
19 that includes the proposed regulation;

20 “(B) provide a period of not less than 60
21 days for comments on the proposed regulation;
22 and

23 “(C) publish the final regulation not less
24 than 30 days before the effective date of the
25 regulation.

1 “(3) RESTRICTIONS.—Notwithstanding any
2 other provision of law, the Secretary shall promul-
3 gate regulations implementing this section only as
4 described in paragraph (2), except that the Sec-
5 retary may issue interim guidance for sponsors seek-
6 ing to submit an application or supplemental appli-
7 cation described in subsection (a) prior to the pro-
8 mulgation of such regulations.

9 “(4) DESIGNATION PRIOR TO REGULATIONS.—
10 The Secretary shall designate drugs under sub-
11 section (a) prior to the promulgation of regulations
12 under this subsection, if such drugs meet the criteria
13 described in subsection (a).

14 “(f) DEFINITION.—In this section, the term ‘rare dis-
15 ease or condition’ has the meaning given to such term in
16 section 526(a)(2).”.

17 (b) APPLICATION.—Section 505G of the Federal
18 Food, Drug, and Cosmetic Act, as added by subsection
19 (a), applies only with respect to a drug for which an appli-
20 cation or supplemental application described in subsection
21 (a)(1)(B)(i) of such section 505G is first approved under
22 section 505(c) of such Act (21 U.S.C. 355(c)) or section
23 351(a) of the Public Health Service Act (42 U.S.C.
24 262(a)) on or after the date of the enactment of this Act.

25 (c) CONFORMING AMENDMENTS.—

1 (1) RELATION TO PEDIATRIC EXCLUSIVITY FOR
2 DRUGS.—Section 505A of the Federal Food, Drug,
3 and Cosmetic Act (21 U.S.C. 355a) is amended—

4 (A) in subsection (b), by adding at the end
5 the following:

6 “(3) RELATION TO EXCLUSIVITY FOR A DRUG
7 APPROVED FOR A NEW INDICATION FOR A RARE DIS-
8 EASE OR CONDITION.—Notwithstanding the ref-
9 erences in subsection (b)(1) to the lengths of the ex-
10 clusivity periods after application of pediatric exclu-
11 sivity, the 6-month extensions described in sub-
12 section (b)(1) shall be in addition to any extensions
13 under section 505G.”; and

14 (B) in subsection (c), by adding at the end
15 the following:

16 “(3) RELATION TO EXCLUSIVITY FOR A DRUG
17 APPROVED FOR A NEW INDICATION FOR A RARE DIS-
18 EASE OR CONDITION.—Notwithstanding the ref-
19 erences in subsection (c)(1) to the lengths of the ex-
20 clusivity periods after application of pediatric exclu-
21 sivity, the 6-month extensions described in sub-
22 section (c)(1) shall be in addition to any extensions
23 under section 505G.”.

24 (2) RELATION TO EXCLUSIVITY FOR NEW
25 QUALIFIED INFECTIOUS DISEASE PRODUCTS THAT

1 ARE DRUGS.—Subsection (b) of section 505E of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 355f) is amended—

4 (A) by amending the subsection heading to
5 read as follows: “RELATION TO PEDIATRIC EX-
6 CLUSIVITY AND EXCLUSIVITY FOR A DRUG AP-
7 PROVED FOR A NEW INDICATION FOR A RARE
8 DISEASE OR CONDITION”; and

9 (B) by striking “any extension of the pe-
10 riod under section 505A” and inserting “any
11 extension of the periods under sections 505A
12 and 505G, as applicable,”.

13 (3) RELATION TO PEDIATRIC EXCLUSIVITY FOR
14 BIOLOGICAL PRODUCTS.—Section 351(m) of the
15 Public Health Service Act (42 U.S.C. 262(m)) is
16 amended by adding at the end the following:

17 “(5) RELATION TO EXCLUSIVITY FOR A BIO-
18 LOGICAL PRODUCT APPROVED FOR A NEW INDICA-
19 TION FOR A RARE DISEASE OR CONDITION.—Not-
20 withstanding the references in paragraphs (2)(A),
21 (2)(B), (3)(A), and (3)(B) to the lengths of the ex-
22 clusivity periods after application of pediatric exclu-
23 sivity, the 6-month extensions described in such
24 paragraphs shall be in addition to any extensions
25 under section 505G.”.

1 **【SEC. 2152. REAUTHORIZATION OF RARE PEDIATRIC DIS-**
2 **EASE PRIORITY REVIEW VOUCHER INCEN-**
3 **TIVE PROGRAM.**

4 Section 529 of the Federal Food, Drug, and Cosmetic
5 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 and life-**
10 **threatening disease in which the serious and**
11 **life-threatening manifestations primarily affect**
12 **individuals aged from birth to 18 years, includ-**
13 **ing age groups often called neonates, infants,**
14 **children, and adolescents.”; and】**

15 **【(B) in paragraph (4)(A)—】**

16 **【(i) in subparagraph (E), by striking**
17 **“and”;】**

18 **【(ii) in subparagraph (F), by striking**
19 **the period and inserting “; and”; and】**

20 **【(iii) by adding at the end the fol-**
21 **lowing:】**

22 **【“(G) is for a drug or biological product**
23 **for which a priority review voucher has not been**
24 **issued under section 524 (relating to tropical**
25 **disease products).”; and】**

1 【(2) in subsection (b), by striking paragraph
2 (5) and inserting the following:】

3 【“(5) TERMINATION OF AUTHORITY.—The Sec-
4 retary may not award any priority review vouchers
5 under paragraph (1) after June 30, 2022.”.】

6 **Subtitle J—Domestic Manufac-**
7 **turing and Export Efficiencies**

8 **SEC. 2161. GRANTS FOR STUDYING THE PROCESS OF CON-**
9 **TINUOUS DRUG MANUFACTURING.**

10 (a) IN GENERAL.—The Commissioner of Food and
11 Drugs may award grants to institutions of higher edu-
12 cation and nonprofit organizations for the purpose of
13 studying and recommending improvements to the process
14 of continuous manufacturing of drugs and biological prod-
15 ucts and similar innovative monitoring and control tech-
16 niques.

17 (b) DEFINITIONS.—In this section:

18 (1) The term “drug” has the meaning given to
19 such term in section 201 of the Federal Food, Drug,
20 and Cosmetic Act (21 U.S.C. 321).

21 (2) The term “biological product” has the
22 meaning given to such term in section 351(i) of the
23 Public Health Service Act (42 U.S.C. 262(i)).

24 (3) The term “institution of higher education”
25 has the meaning given to such term in section 101

1 of the Higher Education Act of 1965 (20 U.S.C.
2 1001).

3 (c) AUTHORIZATION OF APPROPRIATIONS.—There is
4 authorized to be appropriated \$5,000,000 for each of fis-
5 cal years 2016 through 2020 to carry out this section.

6 **SEC. 2162. RE-EXPORTATION AMONG MEMBERS OF THE EU-**
7 **ROPEAN ECONOMIC AREA.**

8 Section 1003(f) of the Controlled Substances Import
9 and Export Act (21 U.S.C. 953(f)) is amended—

10 (1) in paragraph (5)—

11 (A) by striking “(5)” and inserting
12 “(5)(A)”;

13 (B) by inserting “, except that the con-
14 trolled substance may be exported from the sec-
15 ond country to another country that is a mem-
16 ber of the European Economic Area” before the
17 period at the end; and

18 (C) by adding at the end the following:

19 “(B) Subsequent to any re-exportation de-
20 scribed in subparagraph (A), a controlled substance
21 may continue to be exported from any country that
22 is a member of the European Economic Area to any
23 other such country, provided that—

24 “(i) the conditions applicable with respect
25 to the first country under paragraphs (1), (2),

1 (3), (4), (6), and (7) are met by each subse-
2 quent country from which the controlled sub-
3 stances is exported pursuant to this paragraph;
4 and

5 “(ii) the conditions applicable with respect
6 to the second country under such paragraphs
7 are met by each subsequent country to which
8 the controlled substance is exported pursuant to
9 this paragraph.”; and

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

11 “(g) LIMITATION.—The Attorney General shall not
12 promulgate nor enforce any regulation, subregulatory
13 guidance, or enforcement policy which impedes re-expor-
14 tation among European Economic Area countries (as pro-
15 vided in subsection (f)(5)), including by promulgating or
16 enforcing any requirement that—

17 “(1) re-exportation from the first country to the
18 second country or re-exportation from the second
19 country to another country (as such terms are used
20 in subsection (f)) occur within a specified period of
21 time; or

22 “(2) information concerning the consignee,
23 country, and product be provided prior to expor-
24 tation of the controlled substance from the United
25 States.”.

1 **Subtitle K—Enhancing**
2 **Combination Products Review**

3 **SEC. 2181. ENHANCING COMBINATION PRODUCTS REVIEW.**

4 Section 503(g)(4)(C) of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 353(g)(4)(C)) is amended by
6 adding at the end the following new clause:

7 “(iii) Not later than 18 months after the date
8 of the enactment of the 21st Century Cures Act, the
9 Secretary shall issue final guidance that describes
10 the responsibilities of each agency center regarding
11 its review of combination products. The Secretary
12 shall, after soliciting public comment, review and up-
13 date the guidance periodically.”.

14 **Subtitle L—Priority Review for**
15 **Breakthrough Devices**

16 **SEC. 2201. PRIORITY REVIEW FOR BREAKTHROUGH DE-**
17 **VICES.**

18 (a) IN GENERAL.—Chapter V of the Federal Food,
19 Drug, and Cosmetic Act is amended—

20 (1) in section 515(d)—

21 (A) by striking paragraph (5); and

22 (B) by redesignating paragraph (6) as
23 paragraph (5); and

24 (2) by inserting after section 515A (21 U.S.C.
25 360e–1) the following:

1 **“SEC. 515B. PRIORITY REVIEW FOR BREAKTHROUGH DE-**
2 **VICES.**

3 “(a) IN GENERAL.—In order to provide for more ef-
4 fective treatment or diagnosis of life-threatening or irre-
5 versibly debilitating human diseases or conditions, the
6 Secretary shall establish a program to provide priority re-
7 view for devices—

8 “(1) representing breakthrough technologies;

9 “(2) for which no approved alternatives exist;

10 “(3) offering significant advantages over exist-
11 ing approved or cleared alternatives, including the
12 potential to, compared to existing approved or
13 cleared alternatives, reduce or eliminate the need for
14 hospitalization, improve patient quality of life, facili-
15 tate patients’ ability to manage their own care (such
16 as through self-directed personal assistance), or es-
17 tablish long-term clinical efficiencies; or

18 “(4) the availability of which is in the best in-
19 terest of patients.

20 “(b) REQUEST FOR DESIGNATION.—A sponsor of a
21 device may request that the Secretary designate the device
22 for priority review under this section. Any such request
23 for designation may be made at any time prior to the sub-
24 mission of an application under section 515(c), a petition
25 for classification under section 513(f)(2), or a notification
26 under section 510(k).

1 “(c) DESIGNATION PROCESS.—

2 “(1) IN GENERAL.—Not later than 60 calendar
3 days after the receipt of a request under subsection
4 (b), the Secretary shall determine whether the device
5 that is the subject of the request meets the criteria
6 described in subsection (a). If the Secretary deter-
7 mines that the device meets the criteria, the Sec-
8 retary shall designate the device for priority review.

9 “(2) REVIEW.—Review of a request under sub-
10 section (b) shall be undertaken by a team that is
11 composed of experienced staff and managers of the
12 Food and Drug Administration and is chaired by a
13 senior manager.

14 “(3) DESIGNATION DETERMINATION.—A deter-
15 mination approving or denying a request under sub-
16 section (b) shall be considered a significant decision
17 under section 517A and the Secretary shall provide
18 a written, substantive summary of the basis for the
19 determination in accordance with section 517A(a).

20 “(4) RECONSIDERATION.—

21 “(A) REQUEST FOR RECONSIDERATION.—
22 Any person whose request under subsection (b)
23 is denied may, within 30 days of the denial, re-
24 quest reconsideration of the denial in accord-
25 ance with section 517A(b)—

1 “(i) based upon the submission of
2 documents by such person; or

3 “(ii) based upon such documents and
4 a meeting or teleconference.

5 “(B) RESPONSE.—Reconsideration of a
6 designation determination under this paragraph
7 shall be conducted in accordance with section
8 517A(b).

9 “(5) WITHDRAWAL.—If the Secretary approves
10 a priority review designation for a device under this
11 section, the Secretary may not withdraw the des-
12 ignation based on the fact that the criteria specified
13 in subsection (a) are no longer met because of the
14 subsequent clearance or approval of another device
15 that was designated under—

16 “(A) this section; or

17 “(B) section 515(d)(5) (as in effect imme-
18 diately prior to the enactment of the 21st Cen-
19 tury Cures Act).

20 “(d) PRIORITY REVIEW.—

21 “(1) ACTIONS.—For purposes of expediting the
22 development and review of devices designated under
23 subsection (c), the Secretary shall—

24 “(A) assign a team of staff, including a
25 team leader with appropriate subject matter ex-

1 pertise and experience, for each device for
2 which a request is submitted under subsection
3 (b);

4 “(B) provide for oversight of the team by
5 senior agency personnel to facilitate the effi-
6 cient development of the device and the efficient
7 review of any submission described in sub-
8 section (b) for the device;

9 “(C) adopt an efficient process for timely
10 dispute resolution;

11 “(D) provide for interactive communication
12 with the sponsor of the device during the review
13 process;

14 “(E) expedite the Secretary’s review of
15 manufacturing and quality systems compliance,
16 as applicable;

17 “(F) disclose to the sponsor in advance the
18 topics of any consultation concerning the spon-
19 sor’s device that the Secretary intends to under-
20 take with external experts or an advisory com-
21 mittee and provide the sponsor an opportunity
22 to recommend such external experts;

23 “(G) for applications submitted under sec-
24 tion 515(c), provide for advisory committee
25 input, as the Secretary determines appropriate

1 (including in response to the request of the
2 sponsor); and

3 “(H) assign staff to be available within a
4 reasonable time to address questions by institu-
5 tional review committees concerning the condi-
6 tions and clinical testing requirements applica-
7 ble to the investigational use of the device pur-
8 suant to an exemption under section 520(g).

9 “(2) ADDITIONAL ACTIONS.—In addition to the
10 actions described in paragraph (1), for purposes of
11 expediting the development and review of devices
12 designated under subsection (c), the Secretary, in
13 collaboration with the device sponsor, may, as appro-
14 priate—

15 “(A) coordinate with the sponsor regarding
16 early agreement on a data development plan;

17 “(B) take steps to ensure that the design
18 of clinical trials is as efficient as practicable,
19 such as through adoption of shorter or smaller
20 clinical trials, application of surrogate
21 endpoints, and use of adaptive trial designs and
22 Bayesian statistics, to the extent scientifically
23 appropriate;

24 “(C) facilitate, to the extent scientifically
25 appropriate, expedited and efficient develop-

1 ment and review of the device through utiliza-
2 tion of timely postmarket data collection, with
3 regard to applications for approval under sec-
4 tion 515(e); and

5 “(D) agree to clinical protocols that the
6 Secretary will consider binding on the Secretary
7 and the sponsor, subject to—

8 “(i) changes agreed to by the sponsor
9 and the Secretary;

10 “(ii) changes that the Secretary deter-
11 mines are required to prevent an unreason-
12 able risk to the public health; or

13 “(iii) the identification of a substan-
14 tial scientific issue determined by the Sec-
15 retary to be essential to the safety or effec-
16 tiveness of the device involved.

17 “(e) PRIORITY REVIEW GUIDANCE.—

18 “(1) CONTENT.—The Secretary shall issue
19 guidance on the implementation of this section. Such
20 guidance shall include the following:

21 “(A) The process for a person to seek a
22 priority review designation.

23 “(B) A template for requests under sub-
24 section (b).

1 “(C) The criteria the Secretary will use in
2 evaluating a request for priority review.

3 “(D) The standards the Secretary will use
4 in assigning a team of staff, including team
5 leaders, to review devices designated for priority
6 review, including any training required for such
7 personnel on effective and efficient review.

8 “(2) PROCESS.—Prior to finalizing the guid-
9 ance under paragraph (1), the Secretary shall pro-
10 pose such guidance for public comment.

11 “(f) CONSTRUCTION.—

12 “(1) PURPOSE.—This section is intended to en-
13 courage the Secretary and provide the Secretary suf-
14 ficient authorities to apply efficient and flexible ap-
15 proaches to expedite the development of, and
16 prioritize the agency’s review of, devices that rep-
17 resent breakthrough technologies.

18 “(2) CONSTRUCTION.—Nothing in this section
19 shall be construed to alter the criteria and standards
20 for evaluating an application pursuant to section
21 515(c), a report and request for classification under
22 section 513(f)(2), or a report under section 510(k),
23 including the recognition of valid scientific evidence
24 as described in section 513(a)(3)(B), and consider-
25 ation of the least burdensome means of evaluating

1 device effectiveness or demonstrating substantial
2 equivalence between devices with differing techno-
3 logical characteristics, as applicable. Nothing in this
4 section alters the authority of the Secretary to act
5 on an application pursuant to section 515(d) before
6 completion of an establishment inspection, as the
7 Secretary deems appropriate.”.

8 (b) CONFORMING AMENDMENT RELATED TO DES-
9 IGNATION DETERMINATIONS.—Section 517A(a)(1) of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g-
11 1(a)(1)) is amended by inserting “a request for designa-
12 tion under section 515B,” after “an application under sec-
13 tion 515,”.

14 **Subtitle M—Medical Device**
15 **Regulatory Process Improvements**

16 **SEC. 2221. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

17 (a) ESTABLISHMENT OF THIRD-PARTY QUALITY
18 SYSTEM ASSESSMENT PROGRAM.—Chapter V of the Fed-
19 eral Food, Drug, and Cosmetic Act is amended by insert-
20 ing after section 524A (21 U.S.C. 360n–1) the following
21 new section:

22 **“SEC. 524B. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

23 **“(a) ACCREDITATION AND ASSESSMENT.—**

24 **“(1) IN GENERAL; CERTIFICATION OF DEVICE**
25 **QUALITY SYSTEM.—The Secretary shall in accord-**

1 ance with this section establish a third-party quality
2 system assessment program—

3 “(A) to accredit persons to assess whether
4 a requestor’s quality system, including its de-
5 sign controls, can reasonably assure the safety
6 and effectiveness of in-scope devices subject to
7 device-related changes (as defined in paragraph
8 (2));

9 “(B) under which accredited persons shall
10 as applicable certify that a requestor’s quality
11 system meets the criteria issued under para-
12 graph (5) with respect to the in-scope devices at
13 issue; and

14 “(C) under which the Secretary shall rely
15 on such certifications for purposes of deter-
16 mining the safety and effectiveness of in-scope
17 devices subject to the device-related changes in-
18 volved, in lieu of compliance with the following
19 submission requirements:

20 “(i) A thirty-day notice (as defined in
21 paragraph (2)).

22 “(ii) A Special PMA supplement (as
23 defined in paragraph (2)).

24 “(2) DEFINITIONS.—For purposes of this sec-
25 tion—

1 “(A) the term ‘device-related changes’
2 means changes made by a requestor with re-
3 spect to in-scope devices, which are—

4 “(i) manufacturing changes subject to
5 a 30-day notice;

6 “(ii) changes that qualify for a Spe-
7 cial PMA Supplement; and

8 “(iii) such other changes relating to
9 the devices or the device manufacturing
10 process as the Secretary determines appro-
11 priate;

12 “(B) the term ‘in-scope device’ means a
13 device within the scope of devices agreed to by
14 the requestor and the accredited person for pur-
15 poses of a request for certification under this
16 section;

17 “(C) the term ‘quality system’ means a
18 quality system described in section 520(f);

19 “(D) the term ‘requestor’ means a device
20 manufacturer that is seeking certification under
21 this section of a quality system used by such
22 manufacturer;

23 “(E) the term ‘Special PMA’ means a Spe-
24 cial PMA supplement under section 814.39(d)

1 of title 21, Code of Federal Regulations (or any
2 successor regulations); and

3 “(F) the term ‘thirty-day notice’ means a
4 notice described in section 515(d)(6).

5 “(3) ACCREDITATION PROCESS; ACCREDITATION
6 RENEWAL.—Except as inconsistent with this section,
7 the process and qualifications for accreditation of
8 persons and renewal of such accreditation under sec-
9 tion 704(g) shall apply with respect to accreditation
10 of persons and renewal of such accreditation under
11 this section.

12 “(4) USE OF ACCREDITED PARTIES TO CON-
13 DUCT ASSESSMENTS.—

14 “(A) INITIATION OF ASSESSMENT SERV-
15 ICES.—

16 “(i) DATE ASSESSMENTS AUTHOR-
17 IZED.—Beginning after issuance of the
18 final guidance under paragraph (5), an ac-
19 credited person may conduct an assess-
20 ment under this section.

21 “(ii) INITIATION OF ASSESSMENTS.—
22 Use of one or more accredited persons to
23 assess a requestor’s quality system under
24 this section with respect to in-scope devices
25 shall be at the initiation of the person who

1 registers and lists the devices at issue
2 under section 510.

3 “(B) COMPENSATION.—Compensation for
4 such accredited persons shall—

5 “(i) be determined by agreement be-
6 tween the accredited person and the person
7 who engages the services of the accredited
8 person; and

9 “(ii) be paid by the person who en-
10 gages such services.

11 “(C) ACCREDITED PERSON SELECTION.—
12 Each person who chooses to use an accredited
13 person to assess a requestor’s quality system,
14 as described in this section, shall select the ac-
15 credited person from a list of such persons pub-
16 lished by the Secretary in accordance with sec-
17 tion 704(g)(4).

18 “(5) GUIDANCE; CRITERIA FOR CERTIFI-
19 CATION.—

20 “(A) IN GENERAL.—The criteria for cer-
21 tification of a quality system under this section
22 shall be as specified by the Secretary in guid-
23 ance issued under this paragraph.

1 “(B) CONTENTS; CERTIFICATION CRI-
2 TERIA.—The guidance under this paragraph
3 shall include specification of—

4 “(i) evaluative criteria to be used by
5 an accredited person to assess and as ap-
6 plicable certify a requestor’s quality system
7 under this section with respect to in-scope
8 devices ; and

9 “(ii) criteria for accredited persons to
10 apply a waiver of and exemptions from the
11 certification criteria under clause (i).

12 “(C) TIMEFRAME FOR ISSUING GUID-
13 ANCE.—The Secretary shall issue under this
14 paragraph—

15 “(i) draft guidance not later than 12
16 months after the enactment of the 21st
17 Century Cures Act; and

18 “(ii) final guidance not later than 12
19 months after issuance of the draft guid-
20 ance under clause (i).

21 “(b) USE OF THIRD-PARTY ASSESSMENT.—

22 “(1) ASSESSMENT SUMMARY; CERTIFI-
23 CATION.—

24 “(A) SUBMISSION OF ASSESSMENT TO SEC-
25 RETARY.—An accredited person who assesses a

1 requestor’s quality system under subsection (a)
2 shall submit to the Secretary a summary of the
3 assessment—

4 “(i) within 30 days of the assessment;
5 and

6 “(ii) which as applicable shall in-
7 clude—

8 “(I) the accredited person’s cer-
9 tification that the requestor has satis-
10 fied the criteria issued under sub-
11 section (a)(5) for quality system cer-
12 tification with respect to the in-scope
13 devices at issue ; and

14 “(II) any waivers or exemptions
15 from such criteria applied by the ac-
16 credited person.

17 “(B) TREATMENT OF ASSESSMENTS.—
18 Subject to action by the Secretary under sub-
19 paragraph (C), with respect to assessments
20 which include a certification under this sec-
21 tion—

22 “(i) the Secretary’s review of the as-
23 sessment summary shall be deemed com-
24 plete on the day that is 30 days after the

1 date on which the Secretary receives the
2 summary under subparagraph (A); and

3 “(ii) the assessment summary and
4 certification of the requestor shall be
5 deemed accepted by the Secretary on such
6 30th day.

7 “(C) ACTIONS BY SECRETARY.—

8 “(i) IN GENERAL.—Within 30 days of
9 receiving an assessment summary and cer-
10 tification under subparagraph (A), the Sec-
11 retary may, by written notice to the ac-
12 credited person submitting such assess-
13 ment certification , deem any such certifi-
14 cation to be provisional beyond such 30-
15 day period, suspended pending further re-
16 view by the Secretary, or otherwise quali-
17 fied or cancelled, based on the Secretary’s
18 determination that (as applicable)—

19 “(I) additional information is
20 needed to support such certification;

21 “(II) such assessment or certifi-
22 cation is unwarranted; or

23 “(III) such action with regard to
24 the certification is otherwise justified

1 according to such factors and criteria
2 as the Secretary finds appropriate.

3 “(ii) ACCEPTANCE OF CERTIFI-
4 CATION.—If following action by the Sec-
5 retary under clause (i) with respect to a
6 certification, the Secretary determines that
7 such certification is acceptable, the Sec-
8 retary shall issue written notice to the ap-
9 plicable accredited person indicating such
10 acceptance.

11 “(2) NOTIFICATIONS TO SECRETARY BY CER-
12 TIFIED MANUFACTURERS FOR PROGRAM EVALUA-
13 TION PURPOSES.—

14 “(A) PERIODIC NOTIFICATION FOR MANU-
15 FACTURING CHANGES OTHERWISE SUBJECT TO
16 THIRTY-DAY NOTICE.—A requestor certified
17 under this section that effectuates device-re-
18 lated changes with respect to in-scope devices ,
19 without prior submission of a thirty-day notice,
20 shall provide notification to the Secretary of
21 such changes in the requestor’s next periodic
22 report under section 814.84(b) of title 21, Code
23 of Federal Regulations (or any successor regu-
24 lation). Such notification shall—

25 “(i) describe the changes made; and

1 “(ii) indicate the effective dates of
2 such changes.

3 “(B) PERIODIC NOTIFICATION FOR DE-
4 VICE-RELATED CHANGES OTHERWISE SUBJECT
5 TO SPECIAL PMA SUPPLEMENT.—A requestor
6 certified under this section that effectuates de-
7 vice-related changes with respect to in-scope de-
8 vices , without prior submission of a Special
9 PMA Supplement, shall provide notification to
10 the Secretary of such changes in the requestor’s
11 next periodic report under section 814.84(b) of
12 title 21, Code of Federal Regulations (or any
13 successor regulation). Such notification shall—

14 “(i) describe the changes made, in-
15 cluding a full explanation of the basis for
16 the changes; and

17 “(ii) indicate the effective dates of
18 such changes.

19 “(C) USE OF NOTIFICATIONS FOR PRO-
20 GRAM EVALUATION PURPOSES.—Information
21 submitted to the Secretary under subpara-
22 graphs (A) and (B) shall be used by the Sec-
23 retary for purposes of the program evaluation
24 under subsection (d).

1 “(c) DURATION AND EFFECT OF CERTIFICATION.—

2 A certification under this section—

3 “(1) shall remain in effect for a period of two
4 years from the date such certification is accepted by
5 the Secretary, subject to paragraph (6);

6 “(2) may be renewed through the process de-
7 scribed in subsection (a)(3);

8 “(3) shall continue to apply with respect to de-
9 vice-related changes made during such two-year pe-
10 riod, provided the certification remains in effect, ir-
11 respective of whether such certification is renewed
12 after such two-year period;

13 “(4) shall have no effect on the need to comply
14 with applicable submission requirements specified in
15 subsection (a)(1)(C) with respect to any change per-
16 taining to in-scope devices which is not a device-re-
17 lated change under subsection (a)(2);

18 “(5) shall have no effect on the authority of the
19 Secretary to conduct an inspection or otherwise de-
20 termine the requestor’s conformance with the appli-
21 cable requirements of this Act; and

22 “(6) shall be considered to be revoked if the
23 Secretary provides written notification to the cer-
24 tified requestor that its quality system does not sat-
25 isfy the certification criteria issued under subsection

1 (a)(5) with respect to the in-scope devices at issue
2 , such that the applicable submission requirements
3 specified in subsection (a)(1)(C) must be met for
4 changes made after receipt of such written notifica-
5 tion, with respect to such devices.

6 “(d) PROGRAM EVALUATION; SUNSET.—

7 “(1) PROGRAM EVALUATION AND REPORT.—

8 “(A) EVALUATION.—The Secretary shall
9 complete an evaluation of the third-party qual-
10 ity system assessment program under this sec-
11 tion no later than January 31, 2021, based
12 on—

13 “(i) analysis of information from a
14 representative group of device manufactur-
15 ers obtained from notifications provided by
16 certified requestors under subsection
17 (b)(2); and

18 “(ii) such other available information
19 and data as the Secretary determines ap-
20 propriate.

21 “(B) REPORT.—No later than one year
22 after completing the evaluation under subpara-
23 graph (A), the Secretary shall issue a report of
24 the evaluation’s findings on the website of the
25 Food and Drug Administration, which shall in-

1 clude the Secretary’s recommendations with re-
2 spect to continuation and as applicable expansion
3 of the program under this section to in-
4 clude additional types of submissions and addi-
5 tional types of changes beyond those identified
6 in subsection (a)(1)(C), including changes to
7 devices cleared under section 510(k). At the
8 discretion of the Secretary, the program may be
9 expanded prior to January 31, 2021.

10 “(2) SUNSET.—This section shall cease to be
11 effective October 1, 2022.

12 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-
13 tion shall be construed to limit the authority of the Sec-
14 retary to request and review the complete assessment of
15 a certified requestor under this section on a for-cause
16 basis.”.

17 (b) CONFORMING AMENDMENTS.—

18 (1) REQUIREMENTS FOR PREMARKET AP-
19 PROVAL SUPPLEMENTS.—Section 515(d)(6)(A)(i) of
20 the Federal Food, Drug, and Cosmetic Act (21
21 U.S.C. 360e(d)(6)(A)(i)) is amended by inserting “,
22 subject to section 524B,” after “that affects safety
23 or effectiveness”.

24 (2) REQUIREMENTS FOR THIRTY-DAY NO-
25 TICE.—Section 515(d)(6)(A)(ii) of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C.
2 360e(d)(6)(A)(ii)) is amended by inserting “, subject
3 to section 524B,” after “the date on which the Sec-
4 retary receives the notice”.

5 **SEC. 2222. VALID SCIENTIFIC EVIDENCE.**

6 Section 513(a)(3)(B) of the Federal Food, Drug, and
7 Cosmetic Act (21 U.S.C. 360c(a)(3)(B)) is amended—

8 (1) by redesignating clauses (i) and (ii) as sub-
9 clauses (I) and (II), respectively;

10 (2) by striking “(B) If the Secretary” and in-
11 sserting “(B)(i) If the Secretary”; and

12 (3) by adding at the end the following:

13 “(ii) Valid scientific evidence for purposes
14 of clause (i) may include:

15 “(I) evidence described in well-docu-
16 mented case histories, including registry
17 data, that are collected and monitored
18 under an acceptable protocol;

19 “(II) studies published in peer-re-
20 viewed journals; and

21 “(III) data collected in countries other
22 than the United States so long as such
23 data otherwise meets the criteria specified
24 in this subparagraph.

1 “(iii) In the case of a study published in
2 a peer-reviewed journal that is offered as valid
3 scientific evidence for purposes of clause (i), the
4 Secretary may request data underlying the
5 study if—

6 “(I) the Secretary, in making such re-
7 quest, complies with the requirement of
8 subparagraph (D)(ii) to consider the least
9 burdensome appropriate means of evalu-
10 ating device effectiveness or subsection
11 (i)(1)(D) to consider the least burdensome
12 means of determining substantial equiva-
13 lence, as applicable;

14 “(II) the Secretary furnishes a written
15 rationale for so requesting the underlying
16 data accompanies such request; and

17 “(III) if the requested underlying data
18 for such a study are unavailable, the Sec-
19 retary shall consider such study to be part
20 of the totality of the evidence with respect
21 to the device, as the Secretary determines
22 appropriate.”.

1 **SEC. 2223. TRAINING AND OVERSIGHT IN LEAST BURDEN-**
2 **SOME APPROPRIATE MEANS CONCEPT.**

3 (a) IN GENERAL.— Section 513 of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by
5 inserting after subsection (i) the following:

6 “(j) TRAINING AND OVERSIGHT IN LEAST BURDEN-
7 SOME APPROPRIATE MEANS CONCEPT.—

8 “(1) TRAINING.—Each employee of the Food
9 and Drug Administration who is involved in the re-
10 view of premarket submissions under section 515 or
11 section 510(k), including supervisors, shall receive
12 training regarding the meaning and implementation
13 of the least burdensome appropriate means concept
14 in the context of the use of that term in subsections
15 (a)(3)(D) and (i)(1)(D) of this section and in section
16 515(c)(5).

17 “(2) GUIDANCE DOCUMENTS.—

18 “(A) DRAFT UPDATED GUIDANCE.—Not
19 later than 12 months after the date of enact-
20 ment of the 21st Century Cures Act, the Sec-
21 retary shall issue a draft guidance document
22 updating the October 4, 2002, guidance docu-
23 ment entitled ‘The Least Burdensome provision
24 of the FDA Modernization Act of 1997: Con-
25 cept and Principles; Final 11 Guidance for
26 FDA and Industry’.

1 “(B) MEETING OF STAKEHOLDERS.—In
2 developing such draft guidance document, the
3 Secretary shall convene a meeting of stake-
4 holders to ensure a full record to support the
5 publication of such document.

6 “(3) OMBUDSMAN AUDIT.—Not later than 18
7 months after the date of issuance of final version of
8 the draft guidance under paragraph (2), the om-
9 budsman for the organizational unit of the Food and
10 Drug Administration responsible for the premarket
11 review of devices shall—

12 “(A) conduct, or have conducted, an audit
13 of the training described in paragraph (1); and

14 “(B) include in such audit interviews with
15 a representative sample of persons from indus-
16 try regarding their experience in the device pre-
17 market review process.”.

18 (b) ADDITIONAL INFORMATION REGARDING PRE-
19 MARKET APPLICATIONS.—Subsection (c) of section 515 of
20 the Federal Food, Drug, and Cosmetic Act (21 U.S. C.
21 29 360e) is amended by adding at the end the follows:

22 “(5)(A) Whenever the Secretary requests additional
23 information from an applicant regarding an application
24 under paragraph (1), the Secretary shall consider the least
25 burdensome appropriate means necessary to demonstrate

1 device safety and effectiveness, and request information
2 accordingly.

3 “(B) For purposes of subparagraph (A), the term
4 ‘necessary’ means the minimum required information that
5 would support a determination by the Secretary that an
6 application provides a reasonable assurance of the safety
7 and effectiveness of the device.

8 “(C) Nothing in this paragraph alters the standards
9 for premarket approval of a device.”.

10 **SEC. 2224. RECOGNITION OF STANDARDS.**

11 Section 514(c) of the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 360d(c)) is amended—

13 (1) in paragraph (1), by inserting after sub-
14 paragraph (B) the following new subparagraphs:

15 “(C)(i) Any person may submit a request
16 for recognition under subparagraph (A) of all
17 or part of an appropriate standard established
18 by a nationally or internationally recognized
19 standard organization.

20 “(ii) Not later than 60 days after the Sec-
21 retary receives such a request, the Secretary
22 shall—

23 “(I) make a determination to recog-
24 nize all, part, or none of the standard that
25 is the subject of the request; and

1 “(II) issue to the person who sub-
2 mitted such request a respond in writing
3 that states the Secretary’s rationale for
4 that determination, including the scientific,
5 technical, regulatory, or other basis for
6 such determination;

7 “(iii) The Secretary make a response
8 issued under clause (ii)(II) publicly available, in
9 such manner as the Secretary determines ap-
10 propriate.

11 “(iv) The Secretary shall take such actions
12 as may be necessary to implement all or part of
13 a standard recognized under subclause (I), in
14 accordance with subparagraph (A).

15 “(D) The Secretary shall make publicly
16 available, in such manner as the Secretary de-
17 termines appropriate, the rationale for recogni-
18 tion under subparagraph (A) of part of a stand-
19 ard, including the scientific, technical, regu-
20 latory, or other basis for such recognition. ”;
21 and

22 (2) by adding at the end the following new
23 paragraphs:

24 “(4) TRAINING ON USE OF STANDARDS.—The
25 Secretary shall provide to all employees of the Food

1 and Drug Administration who review premarket sub-
2 missions for devices periodic training on the concept
3 and use of recognized standards for purposes of
4 meeting a premarket submission requirement or
5 other applicable requirement under this Act, includ-
6 ing standards relevant to an employee's area of de-
7 vice review.

8 “(5) GUIDANCE.—

9 “(A) DRAFT GUIDANCE.—The Secretary
10 shall publish guidance identifying the principles
11 for recognizing standards under this section. In
12 publishing such guidance, the Secretary shall
13 consider the experience with, and reliance on, a
14 standard by other Federal regulatory authori-
15 ties and the device industry, and whether rec-
16 ognition of a standard will promote harmoni-
17 zation among regulatory authorities in the regu-
18 lation of devices.

19 “(B) TIMING.—The Secretary shall pub-
20 lish—

21 “(i) draft guidance under subpara-
22 graph (A) not later than 12 months after
23 the date of the enactment of the 21st Cen-
24 tury Cures Act; and

1 “(ii) final guidance not later than 12
2 months of the close of the public comment
3 period for the draft guidance under clause
4 (i).”.

5 **SEC. 2225. EASING REGULATORY BURDEN WITH RESPECT**
6 **TO CERTAIN CLASS I AND CLASS II DEVICES.**

7 (a) CLASS I DEVICES.—Section 510(l) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is
9 amended—

10 (1) by striking “A report under subsection (k)”
11 and inserting “(1) A report under subsection (k)”;
12 and

13 (2) by adding at the end the following new
14 paragraph:

15 “(2) Not later than 120 days after the date of the
16 enactment of the 21st Century Cures Act, the Secretary
17 shall identify, through publication in the Federal Register,
18 any type of class I device that the Secretary determines
19 no longer requires a report under subsection (k) to provide
20 reasonable assurance of safety and effectiveness. Upon
21 such publication—

22 “(A) each type of class I device so identified
23 shall be exempt from the requirement for a report
24 under 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 (b) CLASS II DEVICES.—Section 510(m) of the Fed-
5 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360(m))
6 is amended—

7 (1) by striking paragraph (1) and inserting the
8 following new paragraph:

9 “(1) The Secretary shall—

10 “(A) not later than 60 days after the date of
11 the enactment of the 21st Century Cures Act —

12 “(i) publish in the Federal Register a no-
13 tice that contains a list of each type of class II
14 device that the Secretary determines no longer
15 requires a report under subsection (k) to pro-
16 vide reasonable assurance of safety and effec-
17 tiveness; and

18 “(ii) provide for a period of not less than
19 60 days for public comment beginning on the
20 date of the publication of such notice; and

21 “(B) not later than 180 days after the date of
22 the enactment of 21st Century Cures Act, publish in
23 the Federal Register a list representing the Sec-
24 retary’s final determination with respect to the de-

1 vices contained in the list published under subpara-
2 graph (A).”;

3 (2) in paragraph (2)—

4 (A) by striking “1 day after the date of
5 publication of a list under this subsection,” and
6 inserting “1 day after the date of publication of
7 the final list under paragraph (1)(B),”; and

8 (B) by striking “30-day period” and in-
9 serting “60-day period”; and

10 (3) by adding at the end the following new
11 paragraph:

12 “(3) Upon the publication of the final list under para-
13 graph (1)(B)—

14 “(A) each type of class II device so listed shall
15 be exempt from exempt from the requirement for a
16 report under subsection (k); and

17 “(B) the classification regulation applicable to
18 each such type of device shall be deemed amended
19 to incorporate such exemption”.

20 **SEC. 2226. ADVISORY COMMITTEE PROCESS.**

21 (a) CLASSIFICATION PANELS.—Paragraph (5) of sec-
22 tion 513(b) of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 360c(b)) is amended—

24 (1) by striking “(5)” and inserting “(5)(A)”;

25 and

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

2 “(B) For review by a classification panel of
3 a premarket submission for a device, the Sec-
4 retary shall—

5 “(i) provide an opportunity for the
6 person whose premarket submission is sub-
7 ject to panel review to provide rec-
8 ommendations on the expertise needed
9 among the voting members of the panel;
10 and

11 “(ii) give due consideration to such
12 recommendations and ensure that adequate
13 expertise is represented on advisory panels
14 to assess—

15 “(I) the disease or condition for
16 which the device is intended to cure,
17 treat, mitigate, prevent, or diagnose;
18 and

19 “(II) the technology of the de-
20 vice.

21 “(C) For purposes of subparagraph (B)(ii),
22 the term ‘adequate expertise’ means that the
23 membership of the classification panel reviewing
24 a premarket submission includes—

1 “(i) two or more voting members, with
2 a specialty or other expertise clinically rel-
3 evant to the device under review; and

4 “(ii) at least one voting member who
5 is knowledgeable about the technology of
6 the device.”.

7 (b) PANEL REVIEW PROCESS.—Section 513(b)(6) of
8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 360e(b)(6)) is amended—

10 (1) in subparagraph (A)(iii), by inserting before
11 the period at the end “, including by designating a
12 representative who will be provided a time during
13 the panel meeting to address the panel individually
14 (or accompanied by experts selected by such rep-
15 resentative) for the purpose of correcting
16 misstatements of fact or providing clarifying infor-
17 mation, subject to the discretion of panel chair-
18 person.”.

19 (2) by striking subparagraph (B) and inserting
20 the following new subparagraph:

21 “(B)(i) Any meeting of a classification
22 panel with respect to the review of a premarket
23 submission for a device shall—

24 “(I) provide adequate time for initial
25 presentations by the person whose pre-

1 market submission is specifically the sub-
2 ject of such review and by the Secretary;
3 and

4 “(II) encourage free and open partici-
5 pation by all interested persons.

6 “(ii) Following the initial presentations de-
7 scribed in clause (i), the panel may—

8 “(I) pose questions to a designated
9 representative described in subparagraph
10 (A)(iii); and

11 “(II) consider the responses to such
12 questions in the panel’s review of the pre-
13 market submission.”.

14 **SEC. 2227. HUMANITARIAN DEVICE EXEMPTION APPLICA-**
15 **TION.**

16 (a) IN GENERAL.—Section 520(m) of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amend-
18 ed—

19 (1) in paragraph (1) by striking “fewer than
20 4,000” and inserting “not more than 8,000”;

21 (2) in paragraph (2)(A) by striking “fewer than
22 4,000” and inserting “not more than 8,000”; and

23 (3) in paragraph (6)(A)(ii), by striking “4,000”
24 and inserting “8,000”

1 (b) GUIDANCE DOCUMENT ON PROBABLE BEN-
2 EFIT.—Not later than 18 months after the date of enact-
3 ment of this Act, the Secretary of Health and Human
4 Services, acting through the Commissioner of Food and
5 Drugs, shall publish a draft guidance document that de-
6 fines the criteria for establishing “probable benefit” as
7 that term is used in section 520(m)(2)(C) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)(C)).

9 **SEC. 2228. CLIA WAIVER STUDY DESIGN GUIDANCE FOR IN**
10 **VITRO DIAGNOSTICS.**

11 (a) DRAFT REVISED GUIDANCE.—Not later than 12
12 months after the date of the enactment of this Act, the
13 Secretary of Health and Human Services shall publish a
14 draft guidance that—

15 (1) revises section “V. Demonstrating Insignifi-
16 cant Risk of an Erroneous Result” – “Accuracy” of
17 the guidance entitled “Recommendations for Clinical
18 Laboratory Improvement Amendments of 1988
19 (CLIA) Waiver Applications for Manufacturers of In
20 Vitro Diagnostic Devices” and dated January 30,
21 2008; and

22 (2) includes guidance on the appropriate use of
23 comparable performance between a waived user and
24 a moderately complex laboratory user to dem-
25 onstrate accuracy.

1 (b) FINAL REVISED GUIDANCE.—The Secretary of
2 Health and Human Services shall finalize the draft guid-
3 ance published under subsection (a) not later than 12
4 months after the comment period for such draft guidance
5 closes.

6 **Subtitle N—Sensible Oversight for**
7 **Technology Which Advances**
8 **Regulatory Efficiency**

9 **SEC. 2241. HEALTH SOFTWARE.**

10 Section 201 of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 321) is amended by adding at the end the
12 following:

13 “(ss)(1) The term ‘health software’ means software
14 that does not, through use of an in vitro diagnostic device
15 or signal acquisition system, acquire, process, or analyze
16 an image or physiological signal, is not an accessory, is
17 not an integral part of a device necessary to support the
18 use of the device, and—

19 “(A) is intended for use for administrative
20 or operational support or the processing and
21 maintenance of financial records;

22 “(B) is intended for use in clinical, labora-
23 tory, or administrative workflow and related
24 recordkeeping;

1 “(C)(i) is intended for use solely in the
2 transfer, aggregation, conversion (in accordance
3 with a present specification), storage, manage-
4 ment, retrieval, or transmission of data or in-
5 formation;

6 “(ii) utilizes a connectivity software plat-
7 form, electronic or electrical hardware, or a
8 physical communications infrastructure; and

9 “(iii) is not intended for use—

10 “(I) in active patient monitoring; or

11 “(II) in controlling or altering the
12 functions or parameters of a device that is
13 connected to such software;

14 “(D) is intended for use to organize and
15 present information for health or wellness edu-
16 cation or for use in maintaining a healthy life-
17 style, including medication adherence and
18 health management tools;

19 “(E) is intended for use to analyze infor-
20 mation to provide general health information
21 that does not include patient-specific rec-
22 ommended options to consider in the preven-
23 tion, diagnosis, treatment, cure, or mitigation of
24 a particular disease or condition; or

1 “(F) is intended for use to analyze infor-
2 mation to provide patient-specific recommended
3 options to consider in the prevention, diagnosis,
4 treatment, cure, or mitigation of a particular
5 disease or condition.

6 “(2) The term ‘accessory’ means a product that—

7 “(A) is intended for use with one or more par-
8 ent devices;

9 “(B) is intended to support, supplement, or
10 augment the performance of one or more parent de-
11 vices; and

12 “(C) shall be classified by the Secretary—

13 “(i) according to its intended use; and

14 “(ii) independently of any classification of
15 any parent device with which it is used.”.

16 **SEC. 2242. APPLICABILITY AND INAPPLICABILITY OF REGU-**
17 **LATION.**

18 Subchapter A of chapter V of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
20 ed by adding at the end the following:

21 **“SEC. 524B. HEALTH SOFTWARE.**

22 “(a) **INAPPLICABILITY OF REGULATION TO HEALTH**
23 **SOFTWARE.**—Subject to subsection (b), health software
24 shall not be subject to regulation under this Act.

1 “(b) EXCEPTION.—Subsection (a) shall not apply in
2 the case of a software product of a type described in sub-
3 paragraph (F) of section 201(ss)(1) that the Secretary de-
4 termines poses a significant risk to patient safety. In mak-
5 ing such a determination for such product, the Secretary
6 shall consider the following:

7 “(1) The likelihood and severity of patient
8 harm if the product were to not perform as in-
9 tended.

10 “(2) The extent to which the product is in-
11 tended to support the clinical judgment of a medical
12 professional.

13 “(3) Whether there is a reasonable opportunity
14 for a medical professional to review the basis of the
15 information or treatment recommendation provided
16 by the product.

17 “(4) The intended use of the product, including
18 the intended user and user environment, such as
19 whether a medical professional will use a software
20 product of a type described in subparagraph (F) of
21 section 201(ss)(1).

22 “(c) DELEGATION.—The Secretary shall delegate pri-
23 mary jurisdiction for regulating a software product deter-
24 mined under subsection (b) to be subject to regulation

1 under this Act to the center at the Food and Drug Admin-
2 istration charged with regulating devices.

3 “(d) REGULATION OF SOFTWARE.—

4 “(1) IN GENERAL.—The Secretary shall review
5 existing regulations and guidance regarding the reg-
6 ulation of software under this Act. The Secretary
7 may implement a new framework for the regulation
8 of software and shall, as appropriate, modify such
9 regulations and guidance or issue new regulations or
10 guidance.

11 “(2) ISSUANCE BY ORDER.—Notwithstanding
12 subchapter II of chapter 5 of title 5, United States
13 Code, the Secretary may modify or issue regulations
14 for the regulation of software under this Act by ad-
15 ministrative order published in the Federal Register
16 following the publication of a proposed order.

17 “(3) AREAS UNDER REVIEW.—The review of ex-
18 isting regulations and guidance under paragraph (1)
19 may include review of the following areas:

20 “(A) Classification of software.

21 “(B) Standards for development of soft-
22 ware.

23 “(C) Standards for validation and
24 verification of software.

25 “(D) Review of software.

1 “(E) Modifications to software.

2 “(F) Manufacturing of software.

3 “(G) Quality systems for software.

4 “(H) Labeling requirements for software.

5 “(I) Postmarketing requirements for re-
6 porting of adverse events.

7 “(4) PROCESS FOR ISSUING PROPOSED REGU-
8 LATIONS, ADMINISTRATIVE ORDER, AND GUID-
9 ANCE.—Not later than 18 months after the date of
10 enactment of this section, the Secretary shall consult
11 with external stakeholders (including patients, indus-
12 try, health care providers, academia, and govern-
13 ment) to gather input before issuing regulations, an
14 administrative order, and guidance under this sub-
15 section.”.

16 **SEC. 2243. EXCLUSION FROM DEFINITION OF DEVICE.**

17 Section 201(h) of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 321) is amended—

19 (1) in subparagraph (2), by striking “or” after
20 “or other animals,”;

21 (2) in subparagraph (3), by striking “and” and
22 inserting “or”; and

23 (3) by inserting after subparagraph (3) the fol-
24 lowing:

1 “(4) is not health software (other than software
2 determined to be a risk to patient safety under sec-
3 tion 524B(b)), and”.

4 **Subtitle O—Streamlining Clinical**
5 **Trials**

6 **[SEC. 2261. PROTECTION OF HUMAN SUBJECTS IN RE-**
7 **SEARCH; APPLICABILITY OF RULES.**

8 Part H of title IV of the Public Health Service Act
9 (42 U.S.C. 289 et seq.) is amended by inserting after sec-
10 tion 491 the following section:】

11 **[“SEC. 491A. PROTECTION OF HUMAN SUBJECTS IN RE-**
12 **SEARCH; APPLICABILITY OF RULES.**

13 **[“(a) PROTECTION OF HUMAN SUBJECTS.—”]**

14 **[“(1) IN GENERAL.—**All human subject re-
15 search described in paragraph (2)(A) shall be con-
16 ducted in accordance with the HHS Human Subject
17 Regulations, and as applicable to the human sub-
18 jects involved in such research, with the vulnerable-
19 populations rules.】

20 **[“(2) APPLICABILITY.—”]**

21 **[“(A) IN GENERAL.—**This section applies
22 to human subject research that is—】

23 **[“(i) conducted or supported by the**
24 Department of Health and Human Serv-
25 ices; or】

1 【“(ii) otherwise subject to regulation
2 by the Department under a provision of
3 Federal law (other than this section).】

4 【“(B) OTHER FEDERAL DEPARTMENTS
5 AND AGENCIES.—The Secretary shall make
6 available assistance to any Federal department
7 or agency seeking—】

8 【“(i) to improve the regulation or
9 oversight of human subject research; or】

10 【“(ii) to apply the HHS Human Sub-
11 ject Regulations or the vulnerable-popu-
12 lations rules to human subject research
13 that is conducted, supported, or regulated
14 by such department or agency.】

15 【“(b) HHS HUMAN SUBJECT REGULATIONS; OTHER
16 DEFINITIONS.—】

17 【“(1) HHS HUMAN SUBJECT REGULATIONS;
18 VULNERABLE-POPULATIONS RULES.—For purposes
19 of this section:】

20 【“(A) The term ‘HHS Human Subject
21 Regulations’—】

22 【“(i) subject to clause (ii), means the
23 provisions of subpart A of part 46 of title
24 45, Code of Federal Regulations (or any
25 successor regulations); or】

1 **【“(ii) in the case of human subject re-**
2 **search that is subject to the Federal Food,**
3 **Drug, and Cosmetic Act or to section 351**
4 **of this Act, means the provisions of parts**
5 **50, 56, 312, and 812 of title 21, Code of**
6 **Federal Regulations (or any successor reg-**
7 **ulations).】**

8 **【“(B) The term ‘vulnerable-populations**
9 **rules’—】**

10 **【“(i) subject to clause (ii), means the**
11 **provisions of subparts B through D of**
12 **such part 46 (or any successor regula-**
13 **tions); or】**

14 **【“(ii) as applicable to the human sub-**
15 **jects involved in research described in sub-**
16 **paragraph (A), means the provisions appli-**
17 **cable to vulnerable populations under part**
18 **56 of such title 21 (or any successor regu-**
19 **lations) and subpart D of part 50 of such**
20 **title 21 (or any successor regulations).】**

21 **【“(2) HUMAN SUBJECT RESEARCH.—For pur-**
22 **poses of this section:】**

23 **【“(A) Except as provided in subparagraph**
24 **(B), the term ‘human subject research’ means**
25 **research, as defined in subpart A of part 46 of**

1 title 45, Code of Federal Regulations (or any
2 successor regulations), that involves a human
3 subject, as defined in such subpart A (or any
4 successor regulations).】

5 【“(B) In the case of an investigation that
6 is subject to the provisions of part 50 of title
7 21, Code of Federal Regulations (or any suc-
8 cessor regulations), the term ‘human subject’
9 has the meaning given such term in such part
10 50, and the term ‘human subject research’
11 means a clinical investigation as defined in such
12 part 50.】

13 【“(3) OTHER DEFINITIONS.—For purposes of
14 this section:】

15 【“(A) The term ‘institutional review
16 board’ has the meaning that applies to the term
17 ‘institutional review board’ under the HHS
18 Human Subject Regulations.】

19 【“(B) The term ‘lead institutional review
20 board’ means an institutional review board that
21 otherwise meets the requirements of the HHS
22 Human Subject Regulations and enters into a
23 written agreement with an institution, another
24 institutional review board, a sponsor, or a prin-
25 cipal investigator to approve and oversee human

1 subject research that is conducted at multiple
2 locations. References to an institutional review
3 board include an institutional review board that
4 serves a single institution as well as a lead in-
5 stitutional review board.】

6 【“(c) SCOPE OF AUTHORITY OF SECRETARY.—】

7 【“(1) IN GENERAL.—The HHS Human Subject
8 Regulations (including provisions regarding exemp-
9 tions) and the vulnerable-populations rules, as in ef-
10 fect on the day before the date of the enactment of
11 the 21st Century Cures Act, continue to be in effect
12 on and after such date, subject to paragraph (2).】

13 【“(2) MODIFICATIONS.—】

14 【“(A) COMPLIANCE WITH LAW.—Promptly
15 after the date of the enactment of the Act re-
16 ferred to in paragraph (1), the Secretary shall
17 promulgate regulations to make such modifica-
18 tions to the provisions of the HHS Human
19 Subject Regulations as may be necessary to en-
20 sure that such provisions implement, and do not
21 conflict with, this section.】

22 【“(B) OTHER MODIFICATIONS.—This sec-
23 tion may not be construed as affecting the au-
24 thority of the Secretary to modify the provisions
25 of the HHS Human Subject Regulations or the

1 vulnerable-populations rules, except to the ex-
2 tent that any such modification is in conflict
3 with this section. Any such modification shall
4 be made by regulation or guidance, as applica-
5 ble.】

6 【“(d) AVOIDING REGULATORY DUPLICATION AND
7 UNNECESSARY DELAYS.—】

8 【“(1) IN GENERAL.—The Secretary shall—】

9 【“(A) make such modifications to the pro-
10 visions of the HHS Human Subject Regulations
11 and the vulnerable-populations rules as may be
12 necessary—】

13 【“(i) to reduce regulatory duplication
14 and unnecessary delays;】

15 【“(ii) to modernize such provisions in
16 the context of multisite and cooperative re-
17 search projects;】

18 【“(iii) to incorporate local consider-
19 ations, community values, and mechanisms
20 to protect vulnerable populations; and】

21 【“(iv) to ensure that human subject
22 research that is subject to the Federal
23 Food, Drug, and Cosmetic Act or to sec-
24 tion 351 of this Act, and is therefore sub-
25 ject to parts 50, 56, 312, and 812 of title

1 21, Code of Federal Regulations (or any
2 successor regulations), is not subject to
3 subpart A of part 46 of title 45, Code of
4 Federal Regulations (or any successor reg-
5 ulations); and】

6 【“(B) ensure that human subject research
7 that is described in subparagraph (A)(iv), or is
8 cooperative research as such term is defined in
9 section 46.114 of title 45, Code of Federal Reg-
10 ulations (or any successor regulations), may—
11 】

12 【“(i) use joint or shared review;】

13 【“(ii) rely upon the review of—】

14 【“(I) an independent institu-
15 tional review board; or】

16 【“(II) an institutional review
17 board of an entity other than the
18 sponsor of the research; or】

19 【“(iii) use similar arrangements to
20 avoid duplication of effort.】

21 【“(2) REGULATIONS AND GUIDANCE.—Not
22 later than 12 months after the date of enactment of
23 the 21st Century Cures Act, the Secretary, acting
24 through the relevant agencies and offices of the De-
25 partment of Health and Human Services, including

1 the Office for Human Research Protections and rel-
2 evant agencies and offices of the Food and Drug Ad-
3 ministration, shall issue such regulations and guid-
4 ance and take such other actions as may be nec-
5 essary to implement this subsection. Such regula-
6 tions and guidance shall include clarification of re-
7 quirements and policies relating to the following:】

8 【“(A) Arrangements to avoid duplication
9 described in paragraph (1)(C), including—】

10 【“(i) delineating the roles of institu-
11 tional review boards in multisite or cooper-
12 ative, multisite studies where one or more
13 local institutional review boards are relied
14 upon, or similar arrangements are used;】

15 【“(ii) the risks and benefits to human
16 subjects;】

17 【“(iii) standardization of informed
18 consent and other processes and legal doc-
19 uments; and】

20 【“(iv) incorporating community values
21 through the use of local institutional re-
22 view boards while continuing to use central
23 or lead institutional review boards.】

24 【“(B) Concerns about regulatory and legal
25 liability contributing to decisions by the spon-

1 sors of research to rely on local institutional re-
2 view boards for multisite research.】

3 【“(3) CONSULTATION.—In issuing regulations
4 or guidance pursuant to paragraph (2), the Sec-
5 retary shall consult with stakeholders (including re-
6 searchers, academic organizations, hospitals, institu-
7 tional research boards, pharmaceutical, bio-
8 technology and medical device developers, clinical re-
9 search organizations, patient groups, and others).”】

10 **SEC. 2262. USE OF NON-LOCAL INSTITUTIONAL REVIEW**
11 **BOARDS FOR REVIEW OF INVESTIGATIONAL**
12 **DEVICE EXEMPTIONS AND HUMAN DEVICE**
13 **EXEMPTIONS.**

14 (a) IN GENERAL.—Section 520 of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 360(j)) is amended—

16 (1) in subsection (g)(3)—

17 (A) by striking “local” each place it ap-
18 pears; and

19 (B) in subparagraph (A)(i), by striking
20 “which has been”; and

21 (2) in subsection (m)(4)—

22 (A) by striking “local” each place it ap-
23 pears; and

24 (B) by striking subparagraph (A) and in-
25 serting the following new subparagraph:

1 “(A) in facilities in which clinical testing of de-
2 vices is supervised by an institutional review com-
3 mittee established in accordance with the regulations
4 of the Secretary, and”.

5 (b) REGULATIONS.—Not later than 12 months after
6 the date of the enactment of this Act, the Secretary of
7 Health and Human Services shall revise or issue such reg-
8 ulations or guidance as may be necessary to carry out the
9 amendments made by subsection (a).

10 **SEC. 2263. ALTERATION OR WAIVER OF INFORMED CON-**
11 **SENT FOR CLINICAL INVESTIGATIONS.**

12 (a) DEVICES.—Section 520(g)(3) of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(3)) is
14 amended—

15 (1) in subparagraph (D), by striking “except
16 where subject to such conditions as the Secretary
17 may prescribe, the investigator” and inserting the
18 following: “except where, subject to such conditions
19 as the Secretary may prescribe—

20 “(i) the proposed clinical testing poses
21 no more than minimal risk to the human
22 subject and includes appropriate safe-
23 guards to protect the rights, safety, and
24 welfare of the human subject; or

25 “(ii) the investigator”; and

1 (2) in the matter following subparagraph (D),
2 by striking “subparagraph (D)” and inserting “sub-
3 paragraph (D)(ii)”.

4 (b) DRUGS.—Section 505(i)(4) of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) is amended
6 by striking “except where it is not feasible or it is contrary
7 to the best interests of such human beings” and inserting
8 “except where it is not feasible, it is contrary to the best
9 interests of such human beings, or the proposed clinical
10 testing poses no more than minimal risk to such human
11 beings and includes appropriate safeguards as prescribed
12 to protect the rights, safety, and welfare of such human
13 beings”.

14 **Subtitle P—Improving Scientific**
15 **Expertise and Outreach at FDA**

16 **SEC. 2281. SILVIO O. CONTE SENIOR BIOMEDICAL RE-**
17 **SEARCH SERVICE.**

18 (a) HIRING AND RETENTION AUTHORITY.—Section
19 228 of the Public Health Service Act (42 U.S.C. 237) is
20 amended—

21 (1) in the section heading, by inserting “AND
22 BIOMEDICAL PRODUCT ASSESSMENT” after “RE-
23 SEARCH”;

24 (2) in subsection (a)(1), by striking “Silvio O.
25 Conte Senior Biomedical Research Service, not to

1 exceed 500 members” and inserting “Silvio O. Conte
2 Senior Biomedical Research and Biomedical Product
3 Assessment Service (in this section referred to as the
4 ‘Service’), the purpose of which is to recruit and re-
5 tain competitive and qualified scientific and tech-
6 nical experts outstanding in the field of biomedical
7 research, clinical research evaluation, and biomedical
8 product assessment”;

9 (3) by amending subsection (a)(2) to read as
10 follows:

11 “(2) The authority established in paragraph (1) may
12 not be construed to require the Secretary to reduce the
13 number of employees serving under any other employment
14 system in order to offset the number of members serving
15 in the Service.”;

16 (4) in subsection (b)—

17 (A) in the matter preceding paragraph (1),
18 by striking “or clinical research evaluation” and
19 inserting “, clinical research evaluation or bio-
20 medical product assessment” after “evalua-
21 tion”; and

22 (B) in paragraph (1), by inserting “or a
23 masters level degree in engineering,
24 bioinformatics, or a related or emerging field,”
25 after the comma;

1 (5) in subsection (d), by striking “and shall not
2 exceed the rate payable for level I of the Executive
3 Schedule unless approved by the President under
4 section 5377(d)(2) of title 5, United States Code”
5 and inserting “and shall not exceed the rate payable
6 for the President”;

7 (6) by striking subsection (e); and

8 (7) by redesignating subsections (f) and (g) as
9 subsections (e) and (f), respectively.

10 (b) **REPORT.**—Not later than three years after the
11 date of the enactment of this Act, the Secretary of Health
12 and Human Services shall submit, and publish on the
13 Website of the Department of Health and Human Services
14 a report on the implementation of the amendments made
15 by subsection (a), including whether the amendments have
16 improved the ability of the Food and Drug Administration
17 to hire and retain qualified experts to fulfill obligations
18 specified under user fee agreements.

19 **SEC. 2282. ENABLING FDA SCIENTIFIC ENGAGEMENT.**

20 It is the sense of Congress that participation in or
21 sponsorship of scientific conferences and meetings is es-
22 sential to the mission of the Food and Drug Administra-
23 tion.

1 **SEC. 2283. REAGAN-UDALL FOUNDATION FOR THE FOOD**
2 **AND DRUG ADMINISTRATION.**

3 (a) BOARD OF DIRECTORS.—

4 (1) COMPOSITION AND SIZE.—Section
5 770(d)(1)(C) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 379dd(d)(1)(C)) is amended—

7 (A) by redesignating clause (ii) as clause
8 (iii);

9 (B) by inserting after clause (i) the fol-
10 lowing:

11 “(ii) ADDITIONAL MEMBERS.—The
12 Board, through amendments to the bylaws
13 of the Foundation, may provide that the
14 number of voting members of the Board
15 shall be a number (to be specified in such
16 amendment) greater than 14. Any Board
17 positions that are established by any such
18 amendment shall be appointed (by majority
19 vote) by the individuals who, as of the date
20 of such amendment, are voting members of
21 the Board and persons so appointed may
22 represent any of the categories specified in
23 subclauses (I) through (V) of clause (i), so
24 long as no more than 30 percent of the
25 total voting members of the Board (includ-
26 ing members whose positions are estab-

1 lished by such amendment) are representa-
2 tives of the general pharmaceutical, device,
3 food, cosmetic, and biotechnology indus-
4 tries.”; and

5 (C) in clause (iii)(I), as redesignated by
6 subparagraph (A), by striking “The ex officio
7 members shall ensure” and inserting “The ex
8 officio members, acting pursuant to clause (i),
9 and the Board, acting pursuant to clause (ii),
10 shall ensure”.

11 (2) FEDERAL EMPLOYEES ALLOWED TO SERVE
12 ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C)
13 of the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 379dd(d)(1)(C)), as redesignated by para-
15 graph (1)(A), is amended by adding at the end the
16 following: “For purposes of this section, the term
17 ‘employee of the Federal Government’ does not in-
18 clude a ‘special Government employee’, as that term
19 is defined in section 202(a) of title 18, United
20 States Code.”.

21 (3) STAGGERED TERMS.—Subparagraph (A) of
22 section 770(d)(3) of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 379dd(d)(3)) is amended
24 to read as follows:

1 “(A) TERM.—The term of office of each
2 member of the Board appointed under para-
3 graph (1)(C)(i), and the term of office of any
4 member of the Board whose position is estab-
5 lished pursuant to paragraph (1)(C)(ii), shall be
6 4 years, except that—

7 “(i) the terms of offices for the mem-
8 bers of the Board initially appointed under
9 paragraph (1)(C)(i) shall expire on a stag-
10 gered basis as determined by the ex officio
11 members; and

12 “(ii) the terms of office for the per-
13 sons initially appointed to positions estab-
14 lished pursuant to paragraph (1)(C)(ii)
15 may be made to expire on a staggered
16 basis, as determined by the individuals
17 who, as of the date of the amendment es-
18 tablishing such positions, are members of
19 the Board.”.

20 (b) EXECUTIVE DIRECTOR COMPENSATION.—Section
21 770(g)(2) of the Federal Food, Drug, and Cosmetic Act
22 (21 U.S.C. 379dd(g)(2)) is amended by striking “but shall
23 not be greater than the compensation of the Commis-
24 sioner”.

1 (c) SEPARATION OF FUNDS.—Section 770(m) of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 379dd(m)) is amended by striking “are held in separate
4 accounts from funds received from entities under sub-
5 section (i)” and inserting “are managed as individual pro-
6 grammatic funds under subsection (i), according to best
7 accounting practices”.

8 **SEC. 2284. COLLECTION OF CERTAIN VOLUNTARY INFOR-**
9 **MATION EXEMPTED FROM PAPERWORK RE-**
10 **DUCTION ACT.**

11 Chapter VII of the Federal Food, Drug, and Cos-
12 metic Act is amended by inserting after section 708 of
13 such Act (21 U.S.C. 379) the following:

14 **“SEC. 708A. COLLECTION OF CERTAIN VOLUNTARY INFOR-**
15 **MATION EXEMPTED FROM PAPERWORK RE-**
16 **DUCTION ACT.**

17 “Chapter 35 of title 44, United States Code, shall
18 not apply to the collection from patients, industry, aca-
19 demia, and other stakeholders, of voluntary information
20 such as through voluntary surveys or questionnaires, initi-
21 ated by the Secretary.”.

1 **TITLE III—DELIVERY**
2 **Subtitle A—Interoperability**

3 **SEC. 3001. ENSURING INTEROPERABILITY.**

4 (a) DEVELOPMENT OF AND RECOMMENDATIONS FOR
5 METHODS TO MEASURE INTEROPERABILITY.—Subtitle A
6 of title XXX of the Public Health Service Act (42 U.S.C.
7 300jj–11 et seq.) is amended by adding at the end the
8 following new section:

9 **“SEC. 3010. ENSURING INTEROPERABILITY OF [QUALIFIED**
10 **ELECTRONIC HEALTH RECORDS]/[HEALTH**
11 **INFORMATION TECHNOLOGY].**

12 “(a) INTEROPERABILITY.—In order for [qualified
13 electronic health record]/[health information technology]
14 to be considered interoperable, such [record]/[tech-
15 nology] must satisfy the following criteria:

16 “(1) SECURE TRANSFER.—The [record]/[tech-
17 nology] allows the secure transfer of the entirety of
18 a patient’s data from any and all [qualified elec-
19 tronic health records]/[health information tech-
20 nology] for [authorized use].

21 “(2) COMPLETE ACCESS TO HEALTH DATA.—
22 The [record]/[technology] allows access to the en-
23 tirety of a patient’s data for [authorized use] with-
24 out special effort, as defined by recommendations
25 adopted in accordance with this section, by the re-

1 questor of such data unless such data is not
2 disclosable under applicable law.

3 “(3) NO INFORMATION BLOCKING.—The
4 **【record】/【technology】** is not **【configured, set up, or**
5 **implemented】** to engage in information blocking, as
6 defined in section 3010A(f).

7 “(b) DETERMINING METHODS BY WHICH TO MEAS-
8 URE IF **【QUALIFIED ELECTRONIC HEALTH RECORDS】/**
9 **【HEALTH INFORMATION TECHNOLOGY】【ARE】/【IS】**
10 INTEROPERABLE.—

11 “(1) IN GENERAL.—The Secretary shall adopt,
12 in accordance with this section and section
13 3004(e)—

14 “(A) methods by which to measure if
15 **【qualified electronic health records】/【health in-**
16 **formation technology】** satisfy the criteria de-
17 scribed in subsection (a); and

18 “(B) as appropriate, modifications (includ-
19 ing additions) to such methods, that are in ac-
20 cordance with the policies developed by the HIT
21 Policy Committee under section 3002(b)(2)(A)
22 with respect to such methods.

23 “(2) RULES FOR ADOPTION.—

24 “(A) IN GENERAL.—Except as provided in
25 subparagraph (B), any method adopted under

1 section 3004(c) or modification to such a meth-
2 od adopted under subsection (c)(2)(B)(ii), pur-
3 suant to this subsection, shall be a method that
4 has been recommended by the Charter Organi-
5 zation established under subsection (c).

6 “(B) SPECIAL RULES.—

7 “(i) DIFFERENT METHODS.—The
8 Secretary may adopt a method that is dif-
9 ferent from any method recommended
10 under subsection (c) by the Charter Orga-
11 nization, if—

12 “(I) the different method will
13 substantially reduce administrative
14 costs to health care providers and
15 health plans compared to the alter-
16 natives; and

17 “(II) the method is promulgated
18 in accordance with the rulemaking
19 procedures of subchapter III of chap-
20 ter 5 of title 5, United States Code.

21 “(ii) NO METHOD BY CHARTER ORGA-
22 NIZATION.—If the Charter Organization
23 under subsection (c) has not recommended
24 any method relating to a criteria described
25 in subsection (a)—

1 “(I) subparagraph (A) shall not
2 apply; and

3 “(II) paragraph (3) shall apply.

4 “(C) CONSULTATION REQUIREMENT.—

5 “(i) IN GENERAL.—The Secretary, in
6 complying with paragraph (3), may not
7 adopt under this subsection a method that
8 has not been recommended by the Charter
9 Organization under subsection (c) unless
10 the Secretary consulted with each of the
11 organizations described in clause (ii) before
12 adopting the method.

13 “(ii) ORGANIZATIONS DESCRIBED.—
14 The organizations referred to in clause (i)
15 are each of the health care standards de-
16 velopment organizations accredited by the
17 American National Standards Institute.

18 “(D) EFFECTIVE DATE.—Any method
19 adopted under clause (i) or (ii) of paragraph
20 (2)(B) shall be effective 12 months after the
21 date of publication of the final rule to adopt
22 such method.

23 “(3) ASSISTANCE TO THE SECRETARY.—In
24 complying with the requirements of this subsection,
25 the Secretary shall rely on the recommendations of

1 the National Committee on Vital and Health Statis-
2 tics established under section 306(k) of the Public
3 Health Service Act (42 U.S.C. 242k(k)), and shall
4 consult with appropriate Federal and State agencies
5 and private organizations. The Secretary shall pub-
6 lish in the Federal Register any recommendation of
7 the National Committee on Vital and Health Statis-
8 tics regarding the adoption of a method under this
9 subsection. Any method adopted pursuant to this
10 paragraph shall be promulgated in accordance with
11 the rulemaking procedures of subchapter III of
12 chapter 5 of title 5, United States Code.

13 “(4) APPLICATION TO MODIFICATION OF METH-
14 ODS.—Paragraphs (2) and (3) shall apply to a modi-
15 fication to a method (including an addition to a
16 method) adopted pursuant to paragraph (1)(B) in
17 the same manner as such paragraphs apply to an
18 initial method adopted pursuant to paragraph
19 (1)(A).

20 “(c) CHARTER ORGANIZATION.—

21 “(1) ESTABLISHMENT.—Not later than 180
22 days after the date of the enactment of this section,
23 the Secretary shall seek to enter into a contract with
24 health care standards development organizations ac-
25 credited by the American National Standards Insti-

1 tute to establish a committee to be known as the
2 ‘Charter Organization’. Under such contract, the
3 Charter Organization shall provide to the HIT
4 Standards Committee for adoption under this sec-
5 tion and section 3004(c), as applicable, rec-
6 ommendations, in accordance with this section, for
7 methods in which to measure if [qualified electronic
8 health records]/[health information technology] sat-
9 isfy the criteria described in subsection (a) and
10 modifications to such methods, which are in accord-
11 ance with the policies developed by the HIT Policy
12 Committee under section 3002(b)(2)(A) with respect
13 to such methods.

14 “(2) RECOMMENDATIONS.—

15 “(A) INITIAL METHODS.—Not later than
16 one year after the date of the enactment of this
17 section, the Charter Organization shall submit
18 to the HIT Standards Committee recommenda-
19 tions for an initial set of methods described in
20 paragraph (1).

21 “(B) MODIFICATIONS AND ADDITIONS.—

22 “(i) EVALUATIONS AND REPORTS.—

23 “(I) HEARINGS.—Not later than
24 three years after the date of the en-
25 actment of this section, and not less

1 than biennially thereafter, the Sec-
2 retary, acting through the Charter Or-
3 ganization, shall conduct hearings to
4 evaluate and review the methods
5 adopted under section 3004(c) and
6 subsection (b)(2)(B).

7 “(II) REPORT.—Not later than
8 five years after the date of the enact-
9 ment of this section, and not less than
10 biennially thereafter, the Charter Or-
11 ganization shall provide recommenda-
12 tions to the HIT Standards Com-
13 mittee for updating and improving
14 such methods, in accordance with the
15 policies developed by the HIT Policy
16 Committee under section
17 3002(b)(2)(A) with respect to such
18 methods.

19 “(ii) INTERIM FINAL RULEMAKING.—

20 “(I) IN GENERAL.—Subject to
21 subclause (III) and subsection
22 (b)(2)(B) and notwithstanding section
23 3004, any recommendations submitted
24 by the Charter Organization under
25 clause (i)(II) shall be adopted by the

1 Secretary through promulgation of an
2 interim final rule not later than 90
3 days after receipt by the Secretary of
4 the organization's submission from
5 the HIT Standards Committee.

6 “(II) PUBLIC COMMENT.—The
7 Secretary shall accept and consider
8 public comments on any interim final
9 rule published under this clause for
10 60 days after the date of such publi-
11 cation.

12 “(III) AUTHORITY NOT TO
13 ADOPT.—The Secretary, after the pe-
14 riod of public comment described in
15 subclause (II), may determine not to
16 adopt a recommendation to amend an
17 adopted method. Not later than 90
18 days after the date of such determina-
19 tion, the Secretary shall publish in the
20 Federal Register the reason for such
21 determination not to adopt such rec-
22 ommendation.

23 “(IV) EFFECTIVE DATE.—The
24 effective date of any amendment to
25 existing methods that is adopted

1 through an interim final rule pub-
2 lished under this paragraph shall be
3 12 months following the close of the
4 public comment period described in
5 subclause (II).

6 “(3) MEMBERSHIP.—The Charter Organization
7 shall consist of one representative from each of the
8 health care standards development organizations ac-
9 credited by the American National Standards Insti-
10 tute.

11 “(4) AUTHORIZATION OF APPROPRIATIONS.—
12 There is authorized to be appropriated \$10,000,000
13 for a contract with the Charter Organization entered
14 into under paragraph (1), to remain available until
15 expended.

16 “(d) HARMONIZATION.—In carrying out this section,
17 the Secretary shall recognize methods, with respect to
18 interoperability of **【qualified electronic health records】**/
19 **【health information technology】**, from an entity or enti-
20 ties for the purpose of harmonizing or updating methods
21 in order to achieve uniform and consistent implementation
22 of the methods.

23 “(e) PILOT TESTING OF METHODS.—In the develop-
24 ment, harmonization, or recognition of methods under this
25 section, the Secretary shall, as appropriate, provide for the

1 testing of such methods by the National Institute for
2 Standards and Technology under section 13201(a) of the
3 Health Information Technology for Economic and Clinical
4 Health Act.

5 “(f) CONSISTENCY.—The methods recommended
6 under this section shall be consistent with the standards
7 for information transactions and data elements adopted
8 pursuant to section 1173 of the Social Security Act.”.

9 (b) MODIFICATIONS TO HIT POLICY COMMITTEE TO
10 INCORPORATE POLICIES FOR UPDATES TO INTEROPER-
11 ABILITY METHODS.—Section 3002(b)(2) of the Public
12 Health Service Act (42 U.S.C. 300jj–12(b)(2)) is amend-
13 ed—

14 (1) in subparagraph (A), in the first sentence—

15 (A) by striking “The HIT Policy Com-
16 mittee” and inserting “Subject to subparagraph
17 (D), the HIT Policy Committee”;

18 (B) by inserting “(and the areas in which
19 modifications and additions to methods to
20 measure if **qualified electronic health records**/
21 **health information** satisfy the criteria de-
22 scribed in subsection (a) of section 3010 are
23 needed for the electronic exchange and use of
24 health information for purposes of adoption of
25 such modifications and additions under sub-

1 section (c)(2)(B) of such section)” after “sec-
2 tion 3004”; and

3 (C) by striking “such standards, specifica-
4 tions, and certification criteria” and inserting
5 “such standards, specifications, certification cri-
6 teria, and methods”; and

7 (2) by adding at the end the following new sub-
8 paragraph:

9 “(D) SPECIAL RULE RELATED TO INTER-
10 OPERABILITY.—Any recommendation made by
11 the HIT Policy Committee on or after the date
12 of the enactment of this subparagraph with re-
13 spect to interoperability of [qualified electronic
14 health records]/[health information tech-
15 nology] shall be consistent with the criteria de-
16 scribed in subsection (a) of section 3010.”.

17 (c) MODIFICATIONS TO HIT STANDARDS COM-
18 MITTEE TO INCORPORATE INTEROPERABILITY REC-
19 OMMENDATIONS.—Section 3003 of the Public Health
20 Service Act (42 U.S.C. 300jj–13) is amended—

21 (1) in subsection (a), by inserting before the pe-
22 riod at the end the following: “and, in accordance
23 with subsection (b)(1)(E), to submit to the Secretary
24 methods in which to measure if [qualified electronic
25 health records]/[health information technology] sat-

1 isfy the criteria described in subsection (a) of section
2 3010 (and modifications to such methods) that are
3 recommended to the HIT Standards Committee
4 under subsection (c) of such section for adoption
5 under section 3004(c)”; and

6 (2) in subsection (b)(1), by adding at the end
7 the following new subparagraph:

8 “(E) METHODS TO MEASURE INTEROPER-
9 ABILITY.—The HIT Standards Committee shall
10 submit to the Secretary, in accordance with sec-
11 tion 3010, recommendations submitted by the
12 Charter Organization under subsection (c) of
13 such section (along with comments by the HIT
14 Standards Committee with respect to such rec-
15 ommendations) for methods in which to meas-
16 ure if **【qualified electronic health records】**/
17 **【health information technology】** satisfy the cri-
18 teria described in subsection (a) of such section
19 (and for modifications to such methods) for
20 adoption by the Secretary under section
21 3004(c). To the extent that any such rec-
22 ommendation submitted to the Secretary for
23 such adoption is inconsistent with or duplicative
24 of a recommendation under subparagraph (A),
25 the recommendation under this subparagraph

1 shall supercede the recommendation under sub-
2 paragraph (A).”.

3 (d) ADOPTION.—Section 3004 of the Public Health
4 Service Act (42 U.S.C. 300jj–14) is amended—

5 (1) in subsection (b), by adding at the end the
6 following new paragraph:

7 “(4) LIMITATION.—The Secretary may not
8 adopt any standards, implementation specifications,
9 or certification criteria under this subsection or sub-
10 section (a) that are inconsistent with or duplicative
11 of a method adopted under subsection (c) or section
12 3010. In the case of a standard, specification, or cri-
13 terion that has been adopted under this section and
14 is inconsistent or duplicative of a method that is
15 subsequently adopted under subsection (c) or section
16 3010, such method shall supercede such standard,
17 specification, or criterion and such standard, speci-
18 fication, or criterion shall no longer be considered
19 adopted under this section beginning on the date
20 that such method becomes effective.”; and

21 (2) by adding at the end the following new sub-
22 section:

23 “(c) ADOPTION OF METHODS TO MEASURE INTER-
24 OPERABILITY.—

1 “(1) REVIEW OF METHODS.—Not later than 90
2 days after the date of receipt of recommendations
3 for methods, the Secretary, in consultation with the
4 National Coordinator and representatives of other
5 relevant Federal agencies, shall jointly review such
6 methods and shall determine whether or not to pro-
7 pose adoption of such methods.

8 “(2) DETERMINATION TO ADOPT.—If the Sec-
9 retary determines—

10 “(A) to propose adoption of such methods,
11 the Secretary shall, by regulation under section
12 553 of title 5, United States Code, determine
13 whether or not to adopt such methods; or

14 “(B) not to propose adoption of such
15 methods, the Secretary shall notify the National
16 Coordinator and the HIT Standards Committee
17 and Charter Organization under section
18 3010(c) in writing of such determination and
19 the reasons for not proposing the adoption of
20 the recommendation for such methods.

21 “(3) PUBLICATION.—The Secretary shall pro-
22 vide for publication in the Federal Register of all de-
23 terminations made by the Secretary under para-
24 graph (1).

1 “(4) APPLICATION.—Any method adopted
2 under this subsection shall be effective 12 months
3 after the date of publication of the determination to
4 adopt such method.”.

5 (e) REPORTS AND NOTIFICATIONS.—Section 3010 of
6 the Public Health Service Act, as added by subsection (a),
7 is amended by adding at the end the following new sub-
8 section:

9 “(g) DISSEMINATION OF INFORMATION.—

10 “(1) INITIAL SUMMARY REPORT.—Not later
11 than July 1, 2016, the Secretary, after consultation
12 with relevant stakeholders, shall submit to Congress
13 and provide for publication in the Federal Register
14 and the posting on the Internet website of the Office
15 of the National Coordinator for Health Information
16 Technology of a report on the following:

17 “(A) The initial set of methods adopted
18 under this section and section 3004(e).

19 “(B) The strategies for achieving wide-
20 spread interoperability.

21 “(C) An overview of the extent to which
22 **【qualified electronic health records】/【health in-**
23 **formation technology】** offered as of such date
24 satisfy such initial set.

1 “(D) Any barriers that are preventing
2 widespread interoperability.

3 “(E) The plan and milestones, including
4 specific steps, to achieve widespread interoper-
5 ability.

6 “(2) FOLLOW-UP DETERMINATION AND REPORT
7 ON WIDESPREAD INTEROPERABILITY.—Not later
8 than **【December 31, 2017】**, the Secretary shall pro-
9 vide for publication in the Federal Register and the
10 posting on the Internet website of the Office of the
11 National Coordinator for Health Information Tech-
12 nology of the following:

13 “(A) A determination by the Secretary
14 whether the goal of widespread interoperability
15 has been achieved.

16 “(B) A list identifying the vendors of, or
17 other entities offering, **【qualified electronic**
18 **health records】/【health information tech-**
19 **nology】**, which categorizes such entities, with
20 respect to such records, as in compliance or not
21 in compliance with the certification criteria de-
22 scribed in section 3001(c)(5)(B)(ii) and with
23 the requirements under clause (i) of section
24 3001(c)(5)(C) (including with the terms of the

1 attestation and other requirements under such
2 clause).

3 “(C) Actions that may be taken by entities
4 identified under subparagraph (B) as not being
5 in compliance with such criteria and require-
6 ments in order for such entities to become in
7 compliance with such criteria and requirements.

8 “(D) Penalties described in section
9 3010A(b) to which entities, with respect to such
10 **【qualified electronic health records】/【health in-**
11 **formation technology】**, beginning January 1,
12 2019, are subject if such technology and enti-
13 ties are not in compliance with the certification
14 criteria described in section 3001(c)(5)(B)(ii)
15 and with the requirements under clause (i) of
16 section 3001(c)(5)(C), respectively.

17 “(3) ONGOING PUBLICATION OF RECOMMENDA-
18 TIONS.—The Secretary shall provide for publication
19 in the Federal Register and the posting on the
20 Internet website of the Office of the National Coor-
21 dinator for Health Information Technology of all
22 recommendations made under this section.”.

23 (f) CERTIFICATION AND OTHER ENFORCEMENT PRO-
24 VISIONS.—

1 (1) CERTIFICATION OF **【QUALIFIED ELEC-**
2 **TRONIC HEALTH RECORD】/【HEALTH INFORMATION】**
3 TECHNOLOGY.—

4 (A) IN GENERAL.—Section 3007(b) of the
5 Public Health Service Act (42 U.S.C. 300jj–
6 17(b)) is amended by striking “under section
7 3001(c)(3) to be in compliance with” and all
8 that follows through the period at the end and
9 inserting “under section 3001(c)(3)—

10 “(1) for certifications made before January 1,
11 2018, to be in compliance with applicable standards
12 adopted under subsections (a) and (b) of section
13 3004; and

14 “(2) for certifications made on or after January
15 1, 2018, to be in compliance with applicable stand-
16 ards adopted under subsections (a) and (b) of sec-
17 tion 3004 and to be interoperable in accordance with
18 section 3010, including as measured by the methods
19 adopted under such section and methods adopted
20 under subsection (c) of section 3004.”.

21 (B) REQUIREMENTS OF SECRETARY.—Sec-
22 tion 3001(c)(5) of the Public Health Service
23 Act (42 U.S.C. 300jj–11(c)(5)) is amended—

24 (i) by amending subparagraph (B) of
25 such section to read as follows:

1 “(B) CERTIFICATION CRITERIA DE-
2 SCRIBED.—In this title, the term ‘certification
3 criteria’ means, with respect to [qualified elec-
4 tronic health records]—

5 “(i) for certifications made before
6 January 1, 2018, criteria to establish that
7 the technology meets standards and imple-
8 mentation specifications adopted under
9 subsections (a) and (b) of section 3004 for
10 [qualified electronic health records]/
11 [health information technology]; and

12 “(ii) for certifications made on or
13 after January 1, 2018, criteria described
14 in clause (i) and criteria to establish that
15 the technology is interoperable, in accord-
16 ance with section 3010, including as meas-
17 ured by the methods adopted under such
18 section and the methods adopted under
19 subsection (c) of section 3004.”; and

20 (ii) by adding at the end the following
21 new subparagraph:

22 “(C) ENFORCEMENT;
23 DECERTIFICATIONS.—

24 “(i) REQUIREMENTS.—Under any
25 program kept or recognized under subpara-

1 graph (A), the Secretary shall ensure that
2 any vendor of or other entity offering
3 **【qualified electronic health records】**/
4 **【health information technology】** seeking a
5 certification of such records under such
6 program on or after January 1, 2018,
7 shall, as a condition of certification (and
8 maintenance of certification) of such
9 records under such program—

10 “(I) provide to the Secretary an
11 attestation—

12 “(aa) that the entity, unless
13 for a legitimate purpose specified
14 by the Secretary, has not taken
15 any action, including through any
16 financial, administrative, or tech-
17 nological barrier, which the entity
18 **【knows or should know (as de-
19 fined in section 1128A(i)(7) of
20 the Social Security Act)】**, is to
21 limit or restrict the exchange of
22 information or to prevent or
23 disincentivize widespread inter-
24 operability between any providers
25 using such records or other

1 【qualified electronic health
2 records】/【health information
3 technology】 in connection with
4 such records;

5 “(bb) on the pricing infor-
6 mation on data transmission and
7 other services affiliated with the
8 use of 【qualified electronic health
9 records】/【health information
10 technology】;

11 “(cc) that the software with
12 respect to such records have pub-
13 lished application programming
14 interfaces for medical records
15 data, search and indexing, se-
16 mantic harmonization and vocab-
17 ulary translation, and user inter-
18 face applications; and

19 “(dd) that the entity has in
20 place data sharing programs or
21 capabilities based on common
22 data elements through applica-
23 tion programming interfaces
24 without the requirement for spe-

1 cial middleware or vendor-specific
2 interfaces;

3 “(II) publish application pro-
4 gramming interfaces and associated
5 documentation, with respect to such
6 records, for medical records data,
7 search and indexing, semantic harmo-
8 nization and vocabulary translation,
9 and user interface applications; and

10 “(III) demonstrate to the satis-
11 faction of the Secretary that data
12 from such records is able to be ex-
13 changed through the use of applica-
14 tion programming interfaces and used
15 in a manner that allows for exchange
16 and everyday use of such **【records】/**
17 **【technology】** by **【authorized users】**.

18 “(ii) DECERTIFICATION.—Under any
19 program kept or recognized under subpara-
20 graph (A), the Secretary shall ensure that
21 beginning January 1, 2019, any **【qualified**
22 **electronic health record】/【health informa-**
23 **tion technology】** that does not satisfy the
24 certification criteria described in section
25 3001(c)(5)(B)(ii) or with respect to which

1 the vendor or other entity described in
2 clause (i) does not satisfy the requirements
3 under such clause (or is determined to be
4 in violation of the terms of the attestation
5 or other requirements under such clause)
6 shall no longer be considered as certified
7 under such program.

8 “(iii) ANNUAL PUBLICATION.—For
9 2019 and each subsequent year, the Sec-
10 retary shall post on the public Internet
11 website of the Department of Health and
12 Human Services a list of any vendors of or
13 other entities offering **【qualified electronic**
14 **health records】/【health information tech-**
15 **nology】** with respect to which certification
16 has been withdrawn under clause (ii) dur-
17 ing such year.

18 “(iv) PERIODIC REVIEW.—The Sec-
19 retary shall periodically review and confirm
20 that vendors of and other entities offering
21 **【qualified electronic health records】/**
22 **【health information technology】** have pub-
23 licly published application programming
24 interfaces and associated documentation as
25 required by clause (i)(II) for purposes of

1 certification and maintaining certification
2 under any program kept or recognized
3 under subparagraph (A).”.

4 (2) ADDITIONAL ENFORCEMENT PROVISIONS
5 UNDER THE PUBLIC HEALTH SERVICE ACT.—Sub-
6 title A of title XXX of the Public Health Service Act
7 (42 U.S.C. 300jj–11 et seq.), as amended by sub-
8 section (a)(1), is further amended by adding at the
9 end the following new section:

10 **“SEC. 3010A. ENFORCEMENT MECHANISMS.**

11 “(a) INSPECTOR GENERAL AUTHORITY.—The In-
12 spector General of the Department of Health and Human
13 Services shall have the authority to investigate claims of—

14 “(1) vendors of, or other entities offering,
15 **【qualified electronic health records】**—

16 “(A) being in violation of an attestation
17 made under section 3001(c)(5)(C)(i)(I), with
18 respect to the use of such **【records】** by a health
19 care provider under a specified Medicare incen-
20 tive program; and

21 “(B) having engaged in information block-
22 ing (as defined in subsection (f)), unless for a
23 legitimate purpose specified by the Secretary,
24 with respect to the use of such **【records】** by a
25 health care provider under such a program;

1 “(2) health care providers, with respect to the
2 use of such **【records】** under a specified Medicare in-
3 centive program, having, unless for a legitimate pur-
4 pose specified by the Secretary, engaged in informa-
5 tion blocking (as so defined); and

6 “(3) health information system providers de-
7 scribed in subsection (b) having engaged in informa-
8 tion blocking (as so defined), unless for a legitimate
9 purpose specified by the Secretary, with respect to
10 the use of such **【records】** under a specified Medi-
11 care incentive program.

12 “(b) HEALTH INFORMATION SYSTEM PROVIDERS.—
13 The Inspector General of the Department of Health and
14 Human Services shall, in coordination with the Federal
15 Trade Commission, ensure that health information system
16 providers (such as operators of health information ex-
17 changes and other systems that facilitate the exchange of
18 information between **【qualified electronic health records】**)
19 investigate claims of information blocking, with respect to
20 the use of such records under a specified Medicare incen-
21 tive program.

22 “(c) INFORMATION SHARING PROVISIONS.—

23 “(1) IN GENERAL.—The National Coordinator
24 may serve as a technical consultant to the Inspector
25 General of the Department of Health and Human

1 Services and the Federal Trade Commission for pur-
2 poses of carrying out this section. As such technical
3 consultant, the National Coordinator may, notwith-
4 standing any other provision of law, share informa-
5 tion related to claims or investigations under sub-
6 section (a) or (b) with the Inspector General and
7 Federal Trade Commission for purposes of such in-
8 vestigations.

9 “(2) PROTECTION FROM DISCLOSURE OF IN-
10 FORMATION.—Any information shared by the Na-
11 tional Coordinator under paragraph (1) shall not be
12 subject to the provisions of section 552 of title 5,
13 United States Code (commonly referred to as the
14 Freedom of Information Act). Any information ac-
15 quired pursuant to paragraph (1) shall be held in
16 confidence and shall not be disclosed to any person
17 except as may be necessary to carry out the pur-
18 poses of subsection (a).

19 “(3) NON-APPLICATION OF PAPERWORK REDUC-
20 TION ACT.—Chapter 35 of title 44, United States
21 Code (commonly referred to as the Paperwork Re-
22 duction Act of 1995) shall not apply to the National
23 Coordinator or to the Office of the National Coordi-
24 nator for Health Information Technology with re-

1 spect to the collection of complaints relating to
2 claims described in subsection (a).

3 “(d) PENALTY.—Any person or entity determined to
4 have committed an act described in subsection (a), in con-
5 nection with a specified Medicare incentive program, shall
6 be subject to the provisions of sections 1128, 1128A, and
7 1128B in the same manner as a person or entity deter-
8 mined to have committed an act described in such respec-
9 tive section. The provisions of section 1128A (other than
10 subsections (a) and (b)) shall apply to a civil money pen-
11 alty applied under this subsection in the same manner as
12 they apply to a civil money penalty or proceeding under
13 section 1128A(a).

14 “(e) SPECIFIED MEDICARE INCENTIVE PROGRAM.—
15 For purposes of this section, the term ‘specified Medicare
16 incentive program’ includes the following:

17 “(1) The incentive payments under subsection
18 (o) of section 1848 of the Social Security Act (42
19 U.S.C. 1395w-4) and adjustments under subsection
20 (a)(7) of such section.

21 “(2) The incentive payments under subsection
22 (n) of section 1848 of such Act (42 U.S.C. 1395ww)
23 and adjustments under subsection (b)(3)(B) of such
24 section.

1 “(3) The incentive payments and adjustments
2 made under subsections (l) and (m) of section 1853
3 of such Act (42 U.S.C. 1395w-23).

4 “(4) The incentive payment under paragraph
5 (3) of section 1814(l) of such Act (42 U.S.C.
6 1395f(l)) and adjustment under paragraph (4) of
7 such section.

8 “(5) The shared savings program under section
9 1899 of the Social Security Act (42 U.S.C. 1395jjj).

10 “(f) INFORMATION BLOCKING.—

11 “(1) IN GENERAL.—For purposes of this sec-
12 tion and section 3010, the term ‘information block-
13 ing’ means, with respect to the use of [qualified
14 electronic health records] under a specified Medicare
15 incentive program, business, technical, and organiza-
16 tional practices, including practices described in
17 paragraph (2), that—

18 “(A) interfere with the exchange of elec-
19 tronic health information;

20 “(B) the actor [knows or should know (as
21 defined in section 1128A(i)(7) of the Social Se-
22 curity Act)] is likely to interfere with the ex-
23 change or use of electronic health information;
24 and

1 “(C) do not serve to protect patient safety,
2 maintain the privacy and security of individ-
3 uals’ health information or promote competition
4 and consumer welfare.

5 “(2) PRACTICES DESCRIBED.—For purposes of
6 paragraph (1), the practices described in this para-
7 graph are the following:

8 “(A) Contract terms, policies, or other
9 business or organizational practices that restrict
10 individuals’ access to their electronic health in-
11 formation or restrict the exchange or use of
12 that information for treatment and other per-
13 mitted purposes.

14 “(B) Charging prices or fees (such as for
15 data exchange, portability, and interfaces) that
16 make exchanging and using electronic health in-
17 formation cost prohibitive.

18 “(C) Developing or implementing health
19 information technology in non-standard ways
20 that are likely to substantially increase the
21 costs, complexity, or burden of sharing elec-
22 tronic health information, especially in cases in
23 which relevant interoperability standards or
24 methods to measure interoperability have been
25 adopted by the Secretary.

1 “(D) Developing or implementing health
2 information technology in ways that are likely
3 to lock in users or electronic health information,
4 such as not allowing for the full export of data;
5 lead to fraud, waste, or abuse; or impede inno-
6 vations and advancements in health information
7 exchange and health information technology-en-
8 abled care delivery.

9 “(g) TREATMENT OF VENDORS WITH RESPECT TO
10 PATIENT SAFETY ORGANIZATIONS.—In applying part C
11 of title IX—

12 “(1) vendors shall be treated as a provider (as
13 defined in section 921) for purposes of reporting re-
14 quirements under such part, to the extent that such
15 reports are related to attestation requirements under
16 section 3001(c)(5)(C)(i)(I);

17 “(2) claims of information blocking described in
18 subsection (a) shall be treated as a patient safety ac-
19 tivity under such part for purposes of reporting re-
20 quirements under such part; and

21 “(3) health care providers that are not mem-
22 bers of patient safety organizations shall be treated
23 in the same manner as health care providers that
24 are such members for purposes of such reporting re-

1 requirements with respect to claims of information
2 blocking described in subsection (a).”.

3 (3) DEMONSTRATION REQUIRED FOR MEANING-
4 FULL EHR USE INCENTIVES UNDER MEDICARE.—

5 (A) INCENTIVES FOR PROFESSIONALS.—

6 (i) IN GENERAL.—Section
7 1848(o)(2)(C) of the Social Security Act
8 (42 U.S.C. 1395w-4(o)(2)(C)) is amended
9 by adding at the end the following new
10 clause:”.

11 “(iii) INTEROPERABILITY.—With re-
12 spect to EHR reporting periods for pay-
13 ment years beginning with 2018, the
14 means described in clause (i) specified by
15 the Secretary shall include a demonstra-
16 tion, through means such as an attesta-
17 tion, that the professional has not taken
18 any action described in subsection (a)(2) of
19 section 3010A of the Public Health Service
20 Act with respect to which the professional
21 **【**knows or should know (as defined in sec-
22 tion 1128A(i)(7)) about**】**, with respect to
23 the use of any certified EHR technology.”.

24 (ii) HARDSHIP EXEMPTION IN CASE
25 OF DECERTIFIED EHR.—Subparagraph (B)

1 of section 1848(a)(7) of the Social Security
2 Act (42 U.S.C. 1395w-4(a)(7)(B)) is
3 amended to read as follows:

4 “(B) SIGNIFICANT HARDSHIP EXCEP-
5 TION.—

6 “(i) IN GENERAL.—The Secretary
7 may, on a case-by-case basis, exempt an el-
8 igible professional from the application of
9 the payment adjustment under subpara-
10 graph (A) if the Secretary determines, sub-
11 ject to annual renewal, that compliance
12 with the requirement for being a meaning-
13 ful EHR user would result in a significant
14 hardship, such as in the case of an eligible
15 professional who practices in a rural area
16 without sufficient Internet access.

17 “(ii) DECERTIFICATION.—

18 “(I) IN GENERAL.—The Sec-
19 retary may, on a case-by-case basis,
20 exempt an eligible professional from
21 the application of the payment adjust-
22 ment under subparagraph (A) if the
23 Secretary determines that such pro-
24 fessional was determined to not be a
25 meaningful EHR user because the

1 **【qualified electronic health record】/**
2 **【health information technology】** used
3 by such professional was decertified
4 under section 3001(c)(5)(C) of the
5 Public Health Service Act. An exemp-
6 tion under the previous sentence may
7 be applied to an eligible professional
8 only during the first year with respect
9 to which such decertification applies.

10 “(II) DURATION.—In no case
11 shall an exemption by reason of this
12 clause be for a period of less than 12
13 months.

14 “(iii) LIMITATION.—Subject to clause
15 (ii)(II), in no case may an eligible profes-
16 sional be granted an exemption under this
17 subparagraph for more than 5 years.”.

18 (B) INCENTIVES FOR HOSPITALS.—

19 (i) IN GENERAL.—Section 1886(o)(1)
20 of the Social Security Act (42 U.S.C.
21 1395ww(o)(1)) is amended—

22 (I) in subparagraph (A), by in-
23 serting before the period at the end
24 the following: “and, for performance
25 periods for fiscal year 2018 or a sub-

1 sequent fiscal year, that provide a
2 demonstration described in subpara-
3 graph (D) to the Secretary”; and

4 (II) by adding at the end the fol-
5 lowing new subparagraph:

6 “(D) DEMONSTRATION DESCRIBED.—The
7 demonstration described in this subparagraph is
8 a demonstration, through means such as an at-
9 testation, that the hospital has not taken any
10 action described in subsection (a)(2) of section
11 3010A of the Public Health Service Act with
12 respect to which the hospital **【**knows or should
13 know (as defined in section 1128A(i)(7) of the
14 Social Security Act) about**】**, with respect to the
15 use of any **【**certified EHR technology**】**.”.

16 (ii) HARDSHIP EXEMPTION IN CASE
17 OF DECERTIFIED EHR.—Subclause (II) of
18 section 1886(b)(3)(B)(ix) of the Social Se-
19 curity Act (42 U.S.C.
20 1395ww(b)(3)(B)(ix)) is amended to read
21 as follows:

22 “(II)(aa) The Secretary may, on
23 a case-by-case basis, exempt a sub-
24 section (d) hospital from the applica-
25 tion of subclause (I) with respect to a

1 fiscal year if the Secretary deter-
2 mines, subject to annual renewal, that
3 requiring such hospital to be a mean-
4 ingful EHR user during such fiscal
5 year would result in a significant
6 hardship, such as in the case of a hos-
7 pital in a rural area without sufficient
8 Internet access.

9 “(bb) The Secretary may, on a
10 case-by-case basis, exempt a sub-
11 section (d) hospital from the applica-
12 tion of subclause (I) with respect to a
13 fiscal year if the Secretary deter-
14 mines, subject to annual renewal, that
15 such hospital was determined to not
16 be a meaningful EHR user because
17 the [qualified electronic health
18 record]/[health information tech-
19 nology] used by such hospital was de-
20 certified under section 3001(c)(5)(C)
21 of the Public Health Service Act. An
22 exemption under the previous sentence
23 may be applied to a subsection (d)
24 hospital only during the first fiscal

1 year with respect to which such decer-
2 tification applies.

3 “(cc) In no case shall an exemp-
4 tion by reason of item (bb) be for a
5 period of less than 12 months.

6 “(dd) Subject to item (cc), in no
7 case may a hospital be granted an ex-
8 emption under this subclause for more
9 than 5 years.”.

10 (C) DEMONSTRATION REQUIRED FOR
11 MEANINGFUL EHR USE INCENTIVES UNDER
12 MEDICAID.—Section 1903(t)(2) of the Social
13 Security Act (42 U.S.C. 1396b(t)(2)) is amend-
14 ed by adding at the end the following: “An eli-
15 gible professional shall not qualify as a Med-
16 icaid provider under this subsection, with re-
17 spect to a year beginning with 2018, unless
18 such provider demonstrates to the Secretary,
19 through means such as an attestation, that the
20 provider has not taken any action described in
21 subsection (a)(2) of section 3010A of the Public
22 Health Service Act with respect to which the
23 provider **█**knows or should know (as defined in
24 section 1128A(i)(7) of the Social Security Act)

1 about**】**, with respect to the use of any certified
2 EHR technology.”.

3 (g) DEFINITIONS.—

4 (1) CERTIFIED EHR TECHNOLOGY.—Paragraph
5 (1) of section 3000 of the Public Health Service Act
6 (42 U.S.C. 300jj) is amended to read as follows:

7 “(1) CERTIFIED EHR TECHNOLOGY.—The term
8 ‘certified EHR technology’ means a **【**qualified elec-
9 tronic health record**】** that is certified pursuant to
10 section 3001(c)(5) as meeting the certification cri-
11 teria defined in subparagraph (B) of such section
12 that are applicable to the type of record involved (as
13 determined by the Secretary, such as an ambulatory
14 electronic health record for office-based physicians
15 or an inpatient hospital electronic health record for
16 hospitals) and, beginning January 1, 2018, with re-
17 spect to which the vendor or other entity offering
18 such technology is in compliance with the require-
19 ments under section 3001(c)(5)(C)(i).”.

20 (2) WIDESPREAD INTEROPERABILITY.—Section
21 3000 of the Public Health Service Act (42 U.S.C.
22 300jj) is amended by adding at the end the following
23 new paragraph:

1 “(15) WIDESPREAD INTEROPERABILITY.—The
2 term ‘widespread interoperability’ means that, on a
3 nationwide basis—

4 “(A) **【qualified electronic health records】**/
5 **【health information technology】** are interoper-
6 able, in accordance with section 3010, including
7 as measured by the methods adopted under
8 such section; and

9 “(B) such records are employed by mean-
10 ingful EHR users under the specified Medicare
11 incentive programs (as defined in section
12 3010A(e)) and other clinicians and health care
13 providers.”.

14 (h) CONFORMING AMENDMENTS.—

15 (1) VOLUNTARY USE OF STANDARDS.—Section
16 3006 of the Public Health Service Act (42 U.S.C.
17 300jj–16) is amended—

18 (A) in subsection (a)—

19 (i) in paragraph (1), by inserting “or
20 a method adopted under section 3010 or
21 3004(c)” after “section 3004”; and

22 (ii) in paragraph (2), by striking “or
23 implementation specification” and insert-
24 ing “implementation specification, or meth-
25 od”; and

1 (B) in subsection (b), by inserting “or the
2 methods adopted under section 3010 and
3 3004(c)” after “section 3004”.

4 (2) HIPAA PRIVACY AND SECURITY LAW DEFINI-
5 TION CORRECTION.—Section 3009(a)(2)(A) of the
6 Public Health Service Act (42 U.S.C. 300jj–
7 19(a)(2)(A)) is amended by striking “title IV” and
8 inserting “title XIII”.

9 (3) COORDINATION OF FEDERAL ACTIVITIES.—
10 Section 13111 of the HITECH Act is amended—

11 (A) in subsection (a), by inserting before
12 the period at the end the following: “(and, be-
13 ginning on January 1, 2018, that are also
14 interoperable under section 3010 of such Act,
15 including as measured by the methods adopted
16 under such section and section 3004(c) of such
17 Act)”; and

18 (B) in subsection (b)—

19 (i) by inserting “(and, beginning on
20 January 1, 2018, a method adopted under
21 section 3010 of such Act or section
22 3004(c) of such Act)” before “the Presi-
23 dent”; and

24 (ii) by inserting “(or method)” before
25 “, respectively”.

1 (4) APPLICATION TO PRIVATE ENTITIES.—Sec-
2 tion 13112 of the HITECH Act is amended by in-
3 serting before the period at the end the following
4 “(and, beginning on January 1, 2018, that are also
5 interoperable under section 3010 of such Act, in-
6 cluding as measured by the methods adopted under
7 such section and under section 3004(c) of such
8 Act)”.

9 (5) NIST TESTING.—Section 13201(a) of the
10 HITECH Act is amended—

11 (A) by inserting “and methods under sec-
12 tion 3010 of such Act” after “under such sec-
13 tion”; and

14 (B) by striking each place it appears “such
15 standards and implementation specifications”
16 and inserting “such standards, implementation
17 specifications, and methods”.

18 (6) COORDINATION WITH RECOMMENDATIONS
19 FOR ACHIEVING WIDESPREAD EHR INTEROPER-
20 ABILITY.—Section 106(b)(1) of the Medicare Access
21 and CHIP Reauthorization Act of 2015 (Public Law
22 114-10) is amended by adding at the end the fol-
23 lowing new subparagraph:

24 “(E) COORDINATION.—Any recommenda-
25 tion submitted under subparagraph (D) shall be

1 consistent with the criteria specified under sub-
2 section (a) of section 3010 of the Public Health
3 Service Act.”.

4 (i) PATIENT EMPOWERMENT.—It is the sense of Con-
5 gress that—

6 (1) patients have the right to the entirety of the
7 health information of such patient, including such
8 information contained in an electronic health record
9 of such patient;

10 (2) such right extends to both structured and
11 unstructured data; and

12 (3) to further facilitate patient ownership over
13 health information of such patient—

14 (A) health care providers should not have
15 the ability to deny a patient’s request for access
16 to the entirety of such health information of
17 such patient; and

18 (B) health care providers do not need the
19 consent of their patients to share personal
20 health information of such patients with other
21 covered entities, in compliance with the HIPAA
22 privacy regulations promulgated pursuant to
23 section 264(c) of the Health Insurance Port-
24 ability and Accountability Act of 1996 for the
25 purposes of supporting patient care, except in

1 situations where consent is specifically required
2 under such regulations, such as in cases related
3 to the psychiatric records of the patient.

4 **Subtitle B—Telehealth**

5 **SEC. 3021. TELEHEALTH SERVICES UNDER THE MEDICARE** 6 **PROGRAM.**

7 (a) PROVISION OF INFORMATION BY CENTERS FOR
8 MEDICARE & MEDICAID SERVICES.—Not later than one
9 year after the date of the enactment of this Act, the Ad-
10 ministrator of the Centers for Medicare & Medicaid Serv-
11 ices shall provide to the committees of jurisdiction of the
12 House of Representatives and the Senate information on
13 the following:

14 (1) The populations of Medicare beneficiaries,
15 such as those who are dually eligible for the Medi-
16 care program under title XVIII of the Social Secu-
17 rity Act and the Medicaid program under title XIX
18 of such Act and those with chronic conditions, whose
19 care may be improved most in terms of quality and
20 efficiency by the expansion, in a manner that meets
21 or exceeds the existing in-person standard of care
22 under the Medicare program under title XVIII of
23 such Act, of telehealth services under section
24 1834(m)(4) of such Act (42 U.S.C. 1395m(m)(4)).

1 (2) Activities by the Center for Medicare and
2 Medicaid Innovation which examine the use of tele-
3 health services in models, projects, or initiatives
4 funded through section 1115A of the Social Security
5 Act (42 U.S.C. 1315a).

6 (3) The types of high volume procedures codes
7 or diagnoses under such title XVIII which might be
8 suitable to the furnishing of services via telehealth.

9 (4) Barriers that might prevent the expansion
10 of telehealth services under section 1834(m)(4) of
11 the Social Security Act (42 U.S.C. 1395m(m)(4))
12 beyond such services that are in effect as of the date
13 of the enactment of this Act.

14 (b) PROVISION OF INFORMATION BY MEDPAC.—Not
15 later than one year after the date of the enactment of this
16 Act, the Medicare Payment Advisory Commission estab-
17 lished under section 1805 of the Social Security Act (42
18 U.S.C. 1395b–6) shall, using data from the Medicare Ad-
19 vantage program under part C of title XVIII of such Act,
20 provide information to the committees of jurisdiction of
21 the House of Representatives and the Senate that identi-
22 fies—

23 (1) services—

24 (A) for which payment could not be made,
25 as of the date of the enactment of this Act,

1 under the fee-for-service program under parts A
2 and B of such title by reason of any limitation
3 imposed under section 1834(m) of such Act (42
4 U.S.C. 1395m(m)); and

5 (B) that are services that are rec-
6 ommended by the Commission to be included as
7 telehealth services for which payment may be
8 made under the fee-for-service program under
9 parts A and B of such title; and

10 (2) barriers to furnishing telehealth services for
11 which payment may be made under such title XVIII
12 and solutions to address such barriers.

13 (c) SENSE OF CONGRESS.—It is the sense of Con-
14 gress that—

15 (1) States should collaborate, through the use
16 of State medical board compacts or other mecha-
17 nisms, to create common licensure requirements for
18 providing telehealth services in order to facilitate
19 multi-State practices and allow for health care pro-
20 viders to provide such services across State lines;

21 (2) eligible originating sites should be expanded
22 beyond those originating sites described in section
23 1834(m)(4)(C) of the Social Security Act (42 U.S.C.
24 1395m(m)(4)(C)); and

1 (3) any expansion of telehealth services under
2 the Medicare program should—

3 (A) recognize that telemedicine is the deliv-
4 ery of safe, effective, quality health care serv-
5 ices, by a health care provider, using technology
6 as the mode of care delivery;

7 (B) meet or exceed the conditions of cov-
8 erage and payment with respect to the Medicare
9 program under title XVIII unless specifically
10 address in subsequent statute, of such Act if
11 the service were furnished in person, including
12 standards of care; and

13 (C) involve clinically appropriate means to
14 furnish such services.

15 **Subtitle C—Encouraging Con-**
16 **tinuing Medical Education for**
17 **Physicians**

18 **SEC. 3041. EXEMPTING FROM MANUFACTURER TRANS-**
19 **PARENCY REPORTING CERTAIN TRANSFERS**
20 **USED FOR EDUCATIONAL PURPOSES.**

21 (a) IN GENERAL.—Section 1128G(e)(10)(B) of the
22 Social Security Act (42 U.S.C. 1320a-7h(e)(10)(B)) is
23 amended—

24 (1) in clause (iii), by inserting “, including
25 peer-reviewed journals, journal reprints, journal sup-

1 plements, medical conference reports, and medical
2 textbooks” after “patient use”; and

3 (2) by adding at the end the following new
4 clause:

5 “(xiii) In the case of a covered recipi-
6 ent who is a physician, an indirect pay-
7 ment or transfer of value to the covered re-
8 cipient—

9 “(I) for speaking at, or preparing
10 educational materials for, an edu-
11 cational event for physicians or other
12 health care professionals that does not
13 commercially promote a covered drug,
14 device, biological, or medical supply;
15 or

16 “(II) that serves the sole purpose
17 of providing the covered recipient with
18 medical education, such as by pro-
19 viding the covered recipient with the
20 tuition required to attend an edu-
21 cational event or with materials pro-
22 vided to physicians at an educational
23 event.”.

1 (b) EFFECTIVE DATE.—The amendments made by
2 this section shall apply with respect to transfers of value
3 made on or after the date of the enactment of this Act.

4 **Subtitle D—Disposable Medical** 5 **Technologies**

6 **[SEC. 3061. TREATMENT OF CERTAIN ITEMS AND DEVICES.**

7 **[(a) PAYMENT FOR DURABLE MEDICAL ITEMS**
8 **(DMI).—]**

9 **[(1) IN GENERAL.—**Section 1861(s)(2) of the
10 Social Security Act (42 U.S.C. 1395x(s)(2)) is
11 amended—**]**

12 **[(A) in subparagraph (EE), by striking**
13 **“and” at the end;]**

14 **[(B) in subparagraph (FF), by adding**
15 **“and” at the end; and]**

16 **[(C) by adding at the end the following**
17 **new subparagraph:]**

18 **[(“GG) a durable medical item that admin-**
19 **isters a drug described in section 1927(k)(2)(C) that**
20 **would otherwise be self-administered multiple times**
21 **per day and includes a disposable component and at**
22 **least one component that can withstand repeated**
23 **use, and supplies used in conjunction with such item**
24 **(including the drug administered by such item);”.]**

25 **[(2) PAYMENT.—**

1 **[(A) PAYMENT AMOUNT FOR DMI.—**Sec-
2 tion 1834 of the Social Security Act (42 U.S.C.
3 1395m) is amended by adding at the end the
4 following new subsection: **]**

5 **["(r) PAYMENT METHODOLOGY FOR DURABLE**
6 **MEDICAL ITEMS (DMI).—**The Secretary shall establish a
7 payment methodology for a durable medical item described
8 in section 1861(s)(2)(GG) and supplies used in conjunc-
9 tion with such item (other than a drug administered by
10 such item) such that the estimated average total payment
11 per individual for a period for such items and supplies
12 does not exceed the estimated average total payment per
13 individual for such period that would otherwise be made
14 (taking into account the application of section 1847) for
15 the durable medical equipment for which it is a substitute
16 and for supplies used in conjunction with such equipment
17 (other than such a drug) as determined appropriate by
18 the Secretary.” **]**

19 **[(B) PAYMENT FOR DRUG.—**Section
20 1842(o)(1)(D) of the Social Security Act (42
21 U.S.C. 1395u(o)(1)(D)) is amended— **]**

22 **[(i) in clause (i), by inserting “or**
23 drugs administered by a durable medical
24 item covered under section 1861(s)(2)(GG)

1 on or after January 1, 2017,” after “after
2 January 1, 2004,”; and】

3 【(ii) in clause (ii), by striking “infu-
4 sion”.】

5 【(C) COMPETITIVE ACQUISITION.—Section
6 1847(a)(2) of the Social Security Act (42
7 U.S.C. 1395w–3(a)(2)) is amended by adding
8 at the end the following new subparagraph:】

9 【“(D) DURABLE MEDICAL ITEM.—A dura-
10 ble medical item and supplies used in conjunc-
11 tion with such item, described in section
12 1861(s)(2)(GG).”】

13 【(3) CONFORMING AMENDMENT.—Section
14 1833(a)(1) of the Social Security Act (42 U.S.C.
15 1395l(a)(1)) is amended—】

16 【(A) by striking “and” before “(Z)”]; and】

17 【(B) by inserting before the semicolon at
18 the end the following: “, and (AA) with respect
19 to durable medical items described in section
20 1861(s)(2)(GG), the amount paid shall be equal
21 to 80 percent of the lesser of the actual charge
22 or the amount determined under section
23 1834(r)”】

1 **[(4) EFFECTIVE DATE.—**The amendments
2 made by this subsection shall apply to items fur-
3 nished on or after January 1, 2017.**]**

4 **[(b) PAYMENT FOR CERTAIN DISPOSABLE DE-**
5 **VICES.—]**

6 **[(1) IN GENERAL.—**Section 1834 of the Social
7 Security Act (42 U.S.C. 1395m), as amended by
8 subsection (a)(2), is further amended by adding at
9 the end the following new subsection:**]**

10 **["(s) PAYMENT FOR CERTAIN DISPOSABLE DE-**
11 **VICES.—]**

12 **["(1) IN GENERAL.—**The Secretary shall make
13 separate payment in the amount established under
14 paragraph (3) to a home health agency for a device
15 described in paragraph (2) when furnished to an in-
16 dividual who receives home health services for which
17 payment is made under section 1895(b).**]**

18 **["(2) DEVICE DESCRIBED.—**For purposes of
19 paragraph (1), a device described in this paragraph
20 is a disposable device for which, as of January 1,
21 2015, there is—**]**

22 **["(A) a Level I Healthcare Common Pro-**
23 cedure Coding System (HCPCS) code for which
24 the description for a professional service in-
25 cludes the furnishing of such device; and**]**

1 【“(B) a separate Level I HCPCS code for
2 a professional service that uses durable medical
3 equipment instead of such device.”】

4 【“(3) PAYMENT AMOUNT.—The Secretary shall
5 establish the separate payment amount for such a
6 device such that such amount does not exceed the
7 payment that would be made for the HCPCS code
8 described in paragraph (2)(A) under section 1833(t)
9 (relating to payment for covered OPD services).”】

10 【(2) CONFORMING AMENDMENT.—Section
11 1861(m)(5) of the Social Security Act (42 U.S.C.
12 1395x(m)(5)) is amended by inserting “and devices
13 described in section 1834(s)(2)” after “durable med-
14 ical equipment”】

15 【(3) EFFECTIVE DATE.—The amendments
16 made by this subsection shall apply to devices fur-
17 nished on or after January 1, 2017.】

18 **Subtitle E—Local Coverage**

19 **Decision Reforms**

20 **SEC. 3081. IMPROVEMENTS IN THE MEDICARE LOCAL COV-** 21 **ERAGE DETERMINATION (LCD) PROCESS.**

22 (a) IN GENERAL.—Section 1862(l)(5) of the Social
23 Security Act (42 U.S.C. 1395y(l)(5)) is amended by add-
24 ing at the end the following new subparagraph:

1 “(D) LOCAL COVERAGE DETERMINA-
2 TIONS.—The Secretary shall require each medi-
3 care administrative contractor that develops a
4 local coverage determination to make available
5 on the website of such contractor and in the
6 coverage database on the Medicare website, at
7 least 45 days before the effective date of such
8 determination, the following information:

9 “(i) Such determination in its en-
10 tirety.

11 “(ii) Where and when the proposed
12 determination was first made public.

13 “(iii) Links to the proposed deter-
14 mination and a response to comments sub-
15 mitted to the contractor with respect to
16 such proposed determination.

17 “(iv) A summary of evidence that was
18 considered by the contractor during the de-
19 velopment of such determination and a list
20 of the sources of such evidence.

21 “(v) An explanation of the rationale
22 that supports such determination.”.

23 (b) EFFECTIVE DATE.—The amendment made by
24 subsection (a) shall apply with respect to local coverage
25 determinations that are proposed or revised on or after

1 the date that is 180 days after the date of the enactment
2 of this Act.

3 **Subtitle F—Medicare Pharma-**
4 **ceutical and Technology Om-**
5 **budsman**

6 **SEC. 3101. MEDICARE PHARMACEUTICAL AND TECH-**
7 **NOLOGY OMBUDSMAN.**

8 Section 1808(c) of the Social Security Act (42 U.S.C.
9 1395b–9(c)) is amended by adding at the end the fol-
10 lowing new paragraph:

11 “(4) PHARMACEUTICAL AND TECHNOLOGY OM-
12 BUDSMAN.—Not later than 12 months after the date
13 of the enactment of this paragraph, the Secretary
14 shall provide for a pharmaceutical and technology
15 ombudsman within the Centers for Medicare & Med-
16 icaid Services who shall receive and respond to com-
17 plaints, grievances, and requests that—

18 “(A) are from entities that manufacture
19 pharmaceutical, biotechnology, medical device,
20 or diagnostic products that are covered or for
21 which coverage is being sought under this title;
22 and

23 “(B) regard coverage, coding, or payment
24 under this title for such products.”.

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) is amended by adding at the end the following
7 new subsection:

8 “(r) 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 surgery
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 such items and services under the outpatient
19 department fee schedule under subsection (t) of
20 section 1833 and the ambulatory surgical cen-
21 ter payment system under subsection (i) of such
22 section; and

23 “(B) the estimated amount of beneficiary
24 liability applicable to such an item or service.

1 “(2) CALCULATION OF ESTIMATED BENE-
2 FICIARY LIABILITY.—For purposes of subsection (a),
3 the estimated beneficiary liability, with respect to an
4 item or service, is the amount for such item or serv-
5 ice for which an individual who does not have cov-
6 erage under a medicare supplemental policy certified
7 under section 1882 or any other supplemental insur-
8 ance coverage is responsible.

9 “(3) IMPLEMENTATION.—In carrying out this
10 section, the Secretary—

11 “(A) shall include in the notice described
12 in section 1804(a) a notification of the avail-
13 ability of the anticipated costs made available
14 under subsection (a); and

15 “(B) may utilize existing mechanisms, such
16 as the portion of the website of the Centers for
17 Medicare & Medicaid Services on which infor-
18 mation comparing physician performance is
19 posted (commonly referred to as the Physician
20 Compare website), to make available such an-
21 ticipated costs under such subsection.

22 “(4) FUNDING.—For purposes of implementing
23 this subsection, the Secretary shall provide for the
24 transfer, from the Supplemental Medical Insurance
25 Trust Fund under section 1841 to the Centers for

1 Medicare & Medicaid Services Program Management
2 Account, of \$6,000,000 for fiscal year 2015, to re-
3 main available until expended.”.

4 **Subtitle H—Medicare Part D Pa-**
5 **tient Safety and Drug Abuse**
6 **Prevention**

7 **SEC. 3141. PROGRAMS TO PREVENT PRESCRIPTION DRUG**
8 **ABUSE UNDER MEDICARE PARTS C AND D.**

9 (a) DRUG MANAGEMENT PROGRAM FOR AT-RISK
10 BENEFICIARIES.—

11 (1) IN GENERAL.—Section 1860D–4(c) of the
12 Social Security Act (42 U.S.C. 1395w–10(c)) is
13 amended by adding at the end the following:

14 “(5) DRUG MANAGEMENT PROGRAM FOR AT-
15 RISK BENEFICIARIES.—

16 “(A) AUTHORITY TO ESTABLISH.—A PDP
17 sponsor may establish a drug management pro-
18 gram for at-risk beneficiaries under which, sub-
19 ject to subparagraph (B), the PDP sponsor
20 may, in the case of an at-risk beneficiary for
21 prescription drug abuse who is an enrollee in a
22 prescription drug plan of such PDP sponsor,
23 limit such beneficiary’s access to coverage for
24 frequently abused drugs under such plan to fre-
25 quently abused drugs that are prescribed for

1 such beneficiary by a prescriber selected under
2 subparagraph (D), and dispensed for such bene-
3 ficiary by a pharmacy selected under such sub-
4 paragraph.

5 “(B) REQUIREMENT FOR NOTICES.—

6 “(i) IN GENERAL.—A PDP sponsor
7 may not limit the access of an at-risk ben-
8 eficiary for prescription drug abuse to cov-
9 erage for frequently abused drugs under a
10 prescription drug plan until such spon-
11 sor—

12 “(I) provides to the beneficiary
13 an initial notice described in clause
14 (ii) and a second notice described in
15 clause (iii); and

16 “(II) verifies with the providers
17 of the beneficiary that the beneficiary
18 is an at-risk beneficiary for prescrip-
19 tion drug abuse.

20 “(ii) INITIAL NOTICE.—An initial no-
21 tice described in this clause is a notice that
22 provides to the beneficiary—

23 “(I) notice that the PDP sponsor
24 has identified the beneficiary as po-

1 tentially being an at-risk beneficiary
2 for prescription drug abuse;

3 “(II) information describing all
4 State and Federal public health re-
5 sources that are designed to address
6 prescription drug abuse to which the
7 beneficiary has access, including men-
8 tal health services and other coun-
9 seling services;

10 “(III) notice of, and information
11 about, the right of the beneficiary to
12 appeal such identification under sub-
13 section (h) and the option of an auto-
14 matic escalation to external review;

15 “(IV) a request for the bene-
16 ficiary to submit to the PDP sponsor
17 preferences for which prescribers and
18 pharmacies the beneficiary would pre-
19 fer the PDP sponsor to select under
20 subparagraph (D) in the case that the
21 beneficiary is identified as an at-risk
22 beneficiary for prescription drug
23 abuse as described in clause (iii)(I);

24 “(V) an explanation of the mean-
25 ing and consequences of the identi-

1 fication of the beneficiary as poten-
2 tially being an at-risk beneficiary for
3 prescription drug abuse, including an
4 explanation of the drug management
5 program established by the PDP
6 sponsor pursuant to subparagraph
7 (A);

8 “(VI) clear instructions that ex-
9 plain how the beneficiary can contact
10 the PDP sponsor in order to submit
11 to the PDP sponsor the preferences
12 described in subclause (IV) and any
13 other communications relating to the
14 drug management program for at-risk
15 beneficiaries established by the PDP
16 sponsor; and

17 “(VII) contact information for
18 other organizations that can provide
19 the beneficiary with assistance regard-
20 ing such drug management program
21 (similar to the information provided
22 by the Secretary in other standardized
23 notices provided to part D eligible in-
24 dividuals enrolled in prescription drug
25 plans under this part).

1 “(iii) SECOND NOTICE.—A second no-
2 tice described in this clause is a notice that
3 provides to the beneficiary notice—

4 “(I) that the PDP sponsor has
5 identified the beneficiary as an at-risk
6 beneficiary for prescription drug
7 abuse;

8 “(II) that such beneficiary is
9 subject to the requirements of the
10 drug management program for at-risk
11 beneficiaries established by such PDP
12 sponsor for such plan;

13 “(III) of the prescriber and phar-
14 macy selected for such individual
15 under subparagraph (D);

16 “(IV) of, and information about,
17 the beneficiary’s right to appeal such
18 identification under subsection (h)
19 and the option of an automatic esca-
20 lation to external review;

21 “(V) that the beneficiary can, in
22 the case that the beneficiary has not
23 previously submitted to the PDP
24 sponsor preferences for which pre-
25 scribers and pharmacies the bene-

1 beneficiary would prefer the PDP sponsor
2 select under subparagraph (D), sub-
3 mit such preferences to the PDP
4 sponsor; and

5 “(VI) that includes clear instruc-
6 tions that explain how the beneficiary
7 can contact the PDP sponsor.

8 “(iv) TIMING OF NOTICES.—

9 “(I) IN GENERAL.—Subject to
10 subclause (II), a second notice de-
11 scribed in clause (iii) shall be provided
12 to the beneficiary on a date that is
13 not less than 60 days after an initial
14 notice described in clause (ii) is pro-
15 vided to the beneficiary.

16 “(II) EXCEPTION.—In the case
17 that the PDP sponsor, in conjunction
18 with the Secretary, determines that
19 concerns identified through rule-
20 making by the Secretary regarding
21 the health or safety of the beneficiary
22 or regarding significant drug diversion
23 activities require the PDP sponsor to
24 provide a second notice described in
25 clause (iii) to the beneficiary on a

1 date that is earlier than the date de-
2 scribed in subclause (II), the PDP
3 sponsor may provide such second no-
4 tice on such earlier date.

5 “(C) AT-RISK BENEFICIARY FOR PRE-
6 SCRIPTIION DRUG ABUSE.—

7 “(i) IN GENERAL.—For purposes of
8 this paragraph, the term ‘at-risk bene-
9 ficiary for prescription drug abuse’ means
10 a part D eligible individual who is not an
11 exempted individual described in clause (ii)
12 and—

13 “(I) who is identified through the
14 use of clinical guidelines developed by
15 the Secretary in consultation with
16 PDP sponsors and other stakeholders
17 described in section 3151(f)(2)(A) of
18 the 21st Century Cures Act; or

19 “(II) with respect to whom the
20 PDP sponsor of a prescription drug
21 plan, upon enrolling such individual in
22 such plan, received notice from the
23 Secretary that such individual was
24 identified under this paragraph to be
25 an at-risk beneficiary for prescription

1 drug abuse under the prescription
2 drug plan in which such individual
3 was most recently previously enrolled
4 and such identification has not been
5 terminated under subparagraph (F).

6 “(ii) EXEMPTED INDIVIDUAL DE-
7 SCRIBED.—An exempted individual de-
8 scribed in this clause is an individual
9 who—

10 “(I) an individual who receives
11 hospice care under this title; or

12 “(II) an individual, such as an
13 individual who is a resident of a long-
14 term care facility, who the Secretary
15 elects to treat as an exempted indi-
16 vidual for purposes of clause (i).

17 “(D) SELECTION OF PRESCRIBERS.—

18 “(i) IN GENERAL.—With respect to
19 each at-risk beneficiary for prescription
20 drug abuse enrolled in a prescription drug
21 plan offered by such sponsor, a PDP spon-
22 sor shall, based on the preferences sub-
23 mitted to the PDP sponsor by the bene-
24 ficiary pursuant to clauses (ii)(IV) and
25 (iii)(V) of subparagraph (B), select—

1 “(I) one or more individuals who
2 are authorized to prescribe frequently
3 abused drugs (referred to in this
4 paragraph as ‘prescribers’) who may
5 write prescriptions for such drugs for
6 such beneficiary; and

7 “(II) one or more pharmacies
8 that may dispense such drugs to such
9 beneficiary.

10 “(ii) REASONABLE ACCESS.—In mak-
11 ing the selection under this subparagraph,
12 a PDP sponsor shall ensure that the bene-
13 ficiary continues to have reasonable access
14 to drugs described in subparagraph (G),
15 taking into account geographic location,
16 beneficiary preference, impact on cost-
17 sharing, and reasonable travel time.

18 “(iii) BENEFICIARY PREFERENCES.—

19 “(I) IN GENERAL.—If an at-risk
20 beneficiary for prescription drug
21 abuse submits preferences for which
22 in-network prescribers and pharmacies
23 the beneficiary would prefer the PDP
24 sponsor select in response to a notice

1 under subparagraph (B), the PDP
2 sponsor shall—

3 “(aa) review such pref-
4 erences;

5 “(bb) select or change the
6 selection of a prescriber or phar-
7 macy for the beneficiary based on
8 such preferences; and

9 “(cc) inform the beneficiary
10 of such selection or change of se-
11 lection.

12 “(II) EXCEPTION.—In the case
13 that the PDP sponsor determines that
14 a change to the selection of a pre-
15 scriber or pharmacy under item (bb)
16 by the PDP sponsor is contributing or
17 would contribute to prescription drug
18 abuse or drug diversion by the bene-
19 ficiary, the PDP sponsor may change
20 the selection of a prescriber or phar-
21 macy for the beneficiary without re-
22 gard to the preferences of the bene-
23 ficiary described in subclause (I).

24 “(iv) CONFIRMATION.—Before select-
25 ing a prescriber or pharmacy under this

1 subparagraph, a PDP sponsor must re-
2 quest and receive confirmation from the
3 prescriber or pharmacy acknowledging and
4 accepting that the beneficiary involved is in
5 the drug management program for at-risk
6 beneficiaries.

7 “(E) TERMINATIONS AND APPEALS.—The
8 identification of an individual as an at-risk ben-
9 eficiary for prescription drug abuse under this
10 paragraph, a coverage determination made
11 under a drug management program for at-risk
12 beneficiaries, and the selection of a prescriber
13 or pharmacy under subparagraph (D) with re-
14 spect to such individual shall be subject to re-
15 consideration and appeal under subsection (h)
16 and the option of an automatic escalation to ex-
17 ternal review to the extent provided by the Sec-
18 retary.

19 “(F) TERMINATION OF IDENTIFICATION.—
20 “(i) IN GENERAL.—The Secretary
21 shall develop standards for the termination
22 of identification of an individual as an at-
23 risk beneficiary for prescription drug abuse
24 under this paragraph. Under such stand-

1 ards such identification shall terminate as
2 of the earlier of—

3 “(I) the date the individual dem-
4 onstrates that the individual is no
5 longer likely, in the absence of the re-
6 strictions under this paragraph, to be
7 an at-risk beneficiary for prescription
8 drug abuse described in subparagraph
9 (C)(i); or

10 “(II) the end of such maximum
11 period of identification as the Sec-
12 retary may specify.

13 “(ii) RULE OF CONSTRUCTION.—
14 Nothing in clause (i) shall be construed as
15 preventing a plan from identifying an indi-
16 vidual as an at-risk beneficiary for pre-
17 scription drug abuse under subparagraph
18 (C)(i) after such termination on the basis
19 of additional information on drug use oc-
20 curring after the date of notice of such ter-
21 mination.

22 “(G) FREQUENTLY ABUSED DRUG.—For
23 purposes of this subsection, the term ‘frequently
24 abused drug’ means a drug that is a controlled

1 substance that the Secretary determines to be
2 frequently abused or diverted.

3 “(H) DATA DISCLOSURE.—In the case of
4 an at-risk beneficiary for prescription drug
5 abuse whose access to coverage for frequently
6 abused drugs under a prescription drug plan
7 has been limited by a PDP sponsor under this
8 paragraph, such PDP sponsor shall disclose
9 data, including any necessary individually iden-
10 tifiable health information, in a form and man-
11 ner specified by the Secretary, about the deci-
12 sion to impose such limitations and the limita-
13 tions imposed by the sponsor under this part.

14 “(I) EDUCATION.—The Secretary shall
15 provide education to enrollees in prescription
16 drug plans of PDP sponsors and providers re-
17 garding the drug management program for at-
18 risk beneficiaries described in this paragraph,
19 including education—

20 “(i) provided by medicare administra-
21 tive contractors through the improper pay-
22 ment outreach and education program de-
23 scribed in section 1874A(h); and

24 “(ii) through current education efforts
25 (such as State health insurance assistance

1 programs described in subsection (a)(1)(A)
2 of section 119 of the Medicare Improve-
3 ments for Patients and Providers Act of
4 2008 (42 U.S.C. 1395b-3 note)) and ma-
5 terials directed toward such enrollees.

6 “(J) APPLICATION UNDER MA-PD
7 PLANS.—Pursuant to section 1860D-21(c)(1),
8 the provisions of this paragraph apply under
9 part D to MA organizations offering MA-PD
10 plans to MA eligible individuals in the same
11 manner as such provisions apply under this
12 part to a PDP sponsor offering a prescription
13 drug plan to a part D eligible individual.”.

14 (2) INFORMATION FOR CONSUMERS.—Section
15 1860D-4(a)(1)(B) of the Social Security Act (42
16 U.S.C. 1395w-104(a)(1)(B)) is amended by adding
17 at the end the following:

18 “(v) The drug management program
19 for at-risk beneficiaries under subsection
20 (c)(5).”.

21 (b) UTILIZATION MANAGEMENT PROGRAMS.—Sec-
22 tion 1860D-4(c) of the Social Security Act (42 U.S.C.
23 1395w-104(c)), as amended by subsection (a)(1), is fur-
24 ther amended—

1 (1) in paragraph (1), by inserting after sub-
2 paragraph (D) the following new subparagraph:

3 “(E) A utilization management tool to pre-
4 vent drug abuse (as described in paragraph
5 (6)(A)).”; and

6 (2) by adding at the end the following new
7 paragraph:

8 “(6) UTILIZATION MANAGEMENT TOOL TO PRE-
9 VENT DRUG ABUSE.—

10 “(A) IN GENERAL.—A tool described in
11 this paragraph is any of the following:

12 “(i) A utilization tool designed to pre-
13 vent the abuse of frequently abused drugs
14 by individuals and to prevent the diversion
15 of such drugs at pharmacies.

16 “(ii) Retrospective utilization review
17 to identify—

18 “(I) individuals that receive fre-
19 quently abused drugs at a frequency
20 or in amounts that are not clinically
21 appropriate; and

22 “(II) providers of services or sup-
23 pliers that may facilitate the abuse or
24 diversion of frequently abused drugs
25 by beneficiaries.

1 “(iii) Consultation with the Con-
2 tractor described in subparagraph (B) to
3 verify if an individual enrolling in a pre-
4 scription drug plan offered by a PDP
5 sponsor has been previously identified by
6 another PDP sponsor as an individual de-
7 scribed in clause (ii)(I).

8 “(B) REPORTING.—A PDP sponsor offer-
9 ing a prescription drug plan (and an MA orga-
10 nization offering an MA-PD plan) in a State
11 shall submit to the Secretary and the Medicare
12 drug integrity contractor with which the Sec-
13 retary has entered into a contract under section
14 1893 with respect to such State a report, on a
15 monthly basis, containing information on—

16 “(i) any provider of services or sup-
17 plier described in subparagraph (A)(ii)(II)
18 that is identified by such plan sponsor (or
19 organization) during the 30-day period be-
20 fore such report is submitted; and

21 “(ii) the name and prescription
22 records of individuals described in para-
23 graph (5)(C).”.

24 (c) EXPANDING ACTIVITIES OF MEDICARE DRUG IN-
25 TEGRITY CONTRACTORS (MEDICS).—

1 (1) IN GENERAL.—Section 1893 of the Social
2 Security Act (42 U.S.C. 1395ddd) is amended by
3 adding at the end the following new subsection:

4 “(j) EXPANDING ACTIVITIES OF MEDICARE DRUG
5 INTEGRITY CONTRACTORS (MEDICs).—

6 “(1) ACCESS TO INFORMATION.—Under con-
7 tracts entered into under this section with Medicare
8 drug integrity contractors, the Secretary shall au-
9 thorize such contractors to directly accept prescrip-
10 tion and necessary medical records from entities
11 such as pharmacies, prescription drug plans, MA-PD
12 plans, and physicians with respect to an individual
13 in order for such contractors to provide information
14 relevant to the determination of whether such indi-
15 vidual is an at-risk beneficiary for prescription drug
16 abuse, as defined in section 1860D–4(c)(5)(C).

17 “(2) REQUIREMENT FOR ACKNOWLEDGMENT
18 OF REFERRALS.—If a PDP sponsor or MA organiza-
19 tion refers information to a contractor described in
20 paragraph (1) in order for such contractor to assist
21 in the determination described in such paragraph,
22 the contractor shall—

23 “(A) acknowledge to the sponsor or organi-
24 zation receipt of the referral; and

1 “(B) in the case that any PDP sponsor or
2 MA organization contacts the contractor re-
3 questing to know the determination by the con-
4 tractor of whether or not an individual has been
5 determined to be an individual described such
6 paragraph, shall inform such sponsor or organi-
7 zation of such determination on a date that is
8 not later than 15 days after the date on which
9 the sponsor or organization contacts the con-
10 tractor.

11 “(3) MAKING DATA AVAILABLE TO OTHER EN-
12 TITIES.—

13 “(A) IN GENERAL.—For purposes of car-
14 rying out this subsection, subject to subpara-
15 graph (B), the Secretary shall authorize MED-
16 ICs to respond to requests for information from
17 PDP sponsors and MA organizations, State
18 prescription drug monitoring programs, and
19 other entities delegated by such sponsors or or-
20 ganizations using available programs and sys-
21 tems in the effort to prevent fraud, waste, and
22 abuse.

23 “(B) HIPAA COMPLIANT INFORMATION
24 ONLY.—Information may only be disclosed by a
25 MEDIC under subparagraph (A) if the dislo-

1 sure of such information is permitted under the
2 Federal regulations (concerning the privacy of
3 individually identifiable health information) pro-
4 mulgated under section 264(c) of the Health
5 Insurance Portability and Accountability Act of
6 1996 (42 U.S.C. 1320d-2 note).”.

7 (2) **OIG STUDY AND REPORT ON EFFECTIVE-**
8 **NESS OF MEDICS.—**

9 (A) **STUDY.—**The Inspector General of the
10 Department of Health and Human Services
11 shall conduct a study on the effectiveness of
12 Medicare drug integrity contractors in identi-
13 fying combating, and preventing fraud under
14 the Medicare program, including under the au-
15 thority provided under section 1893(j) of the
16 Social Security Act, added by paragraph (1).

17 (B) **REPORT.—**Not later than 1 year after
18 the date of the enactment of this Act, the In-
19 specter 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) SENATE OF CONGRESS REGARDING USE OF
17 TECHNOLOGY TOOLS TO COMBAT FRAUD.—It is the sense
18 of 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 clinicians, plan sponsors, entities delegated by
14 plan sponsors, and biopharmaceutical manufac-
15 turers for input regarding the topics described
16 in subparagraph (B).

17 (B) TOPICS DESCRIBED.—The topics de-
18 scribed in this subparagraph are the topics of—

19 (i) the impact on cost-sharing and en-
20 suring accessibility to prescription drugs
21 for enrollees in prescription drug plans of
22 PDP sponsors, and enrollees in MA-PD
23 plans, who are at-risk beneficiaries for pre-
24 scription drug abuse (as defined in sub-
25 paragraph (C) of paragraph (5) of section

1 1860D–4(c) of the Social Security Act (42
2 U.S.C. 1395w–104(c));

3 (ii) the use of an expedited appeals
4 process under which such an enrollee may
5 appeal an identification of such enrollee as
6 an at-risk beneficiary for prescription drug
7 abuse under such paragraph (similar to the
8 processes established under the Medicare
9 Advantage program under part C of title
10 XVIII of the Social Security Act that allow
11 an automatic escalation to external review
12 of claims submitted under such part);

13 (iii) the types of enrollees that should
14 be treated as exempted individuals, as de-
15 scribed in subparagraph (C)(ii) of such
16 paragraph;

17 (iv) the manner in which terms and
18 definitions in such paragraph should be ap-
19 plied, such as the use of clinical appro-
20 priateness in determining whether an en-
21 rollee is an at-risk beneficiary for prescrip-
22 tion drug abuse as defined in subpara-
23 graph (C) of such paragraph;

24 (v) the information to be included in
25 the notices described in subparagraph (B)

1 of such paragraph and the standardization
2 of such notices; and

3 (vi) with respect to a PDP sponsor
4 (or Medicare Advantage organization) that
5 establishes a drug management program
6 for at-risk beneficiaries under such para-
7 graph, the responsibilities of such PDP
8 sponsor (or organization) with respect to
9 the implementation of such program.

10 (g) RULEMAKING.—The Secretary of Health and
11 Human Services shall promulgate regulations based on the
12 input gathered pursuant to subsection (f)(2)(A).

