

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. _____**

**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. Reducing administrative burdens of researchers.

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 Study 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 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 of health information technology.

Subtitle B—Telehealth

- Sec. 3021. Telehealth services under the Medicare program.

Subtitle C—Encouraging Continuing Medical Education for Physicians

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

Subtitle D—Disposable Medical Technologies

- Sec. 3061. Treatment of certain items and devices.

Subtitle E—Local Coverage Decision Reforms

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

Subtitle F—Medicare Pharmaceutical and Technology Ombudsman

- Sec. 3101. Medicare pharmaceutical and technology ombudsman.

Subtitle G—Medicare Site-of-Service Price Transparency

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

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

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

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) AVAILABILITY SUBJECT TO APPRO-
13 PRIATIONS.—Amounts in the Fund shall not be
14 available except to the extent and in such
15 amounts as are provided in advance in appro-
16 priation Acts.

17 “(C) ALLOCATION OF AMOUNTS.—Of the
18 amounts made available from the NIH Innova-
19 tion Fund for allocations under section
20 402(b)(25) for a fiscal year—

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

24 “(ii) not less than 35 percent of such
25 amounts remaining after subtracting the

1 allocation for the Accelerating Advance-
2 ment Program shall be for early stage in-
3 vestigators as defined in subsection (7);

4 “(iii) not less than 20 percent of such
5 amounts remaining after subtracting the
6 allocation for the Accelerating Advance-
7 ment Program shall be for high-risk, high-
8 reward research under section 409K; and

9 “(iv) not more than 10 percent of
10 such amounts (without subtracting the al-
11 location for the Accelerating Advancement
12 Program) shall be for intramural research.

13 “(D) INAPPLICABILITY OF CERTAIN PROVI-
14 SIONS.—Amounts in the NIH Innovation Fund
15 shall not be subject to—

16 “(i) any transfer authority of the Sec-
17 retary or the Director of NIH under sec-
18 tion 241, subsection (c), subsection (d), or
19 any other provision of law (other than sec-
20 tion 402(b)(25) and this subsection); or

21 “(ii) the Nonrecurring expenses fund
22 under section 223 of division G of the Con-
23 solidated Appropriations Act, 2008 (42
24 U.S.C. 3514a).

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

5 “(A) Research in which—

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

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

10 “(B) Research in which—

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

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

15 “(C) Research to be carried out by an
16 early stage investigator (as defined in para-
17 graph (7)).

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

21 “(E) The Accelerating Advancement Pro-
22 gram under paragraph (5).

23 “(F) Development and implementation of
24 the strategic plan under paragraph (6).

1 “(4) COORDINATION.—In funding programs
2 and activities through the NIH Innovation Fund,
3 the Secretary, acting through the Director of NIH,
4 shall—

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

9 “(B) minimize unnecessary duplication.

10 “(5) ACCELERATING ADVANCEMENT PRO-
11 GRAM.—The Director of NIH shall establish a pro-
12 gram, to be known as the Accelerating Advancement
13 Program, under which—

14 “(A) the Director of NIH partners with
15 national research institutes and national centers
16 to accomplish important biomedical research ob-
17 jectives; and

18 “(B) for every \$1 made available by the
19 Director of NIH to a national research institute
20 or national center for a research project, the in-
21 stitute or center makes \$1 available for such
22 project from funds that are not derived from
23 the NIH Innovation Fund.

24 “(6) STRATEGIC PLAN.—

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

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

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

19 “(I) biomarkers;

20 “(II) precision medicine;

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

1 ical disease under section 524 of such
2 Act; and

3 “(IV) antibiotics;

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

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

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

12 “(7) DEFINITION.—In this subsection, the term
13 ‘early stage investigator’ means an investigator
14 who—

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

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

21 “(C) is within 10 years of having com-
22 pleted—

23 “(i) the investigator’s terminal degree;
24 or

1 “(ii) a medical residency (or the
2 equivalent).”.

3 (c) SUPPLEMENT, NOT SUPPLANT; PROHIBITION
4 AGAINST TRANSFER.—Funds appropriated pursuant to
5 section 402A(e) of the Public Health Service Act, as in-
6 serted by subsection (b)—

7 (1) shall be used to supplement, not supplant,
8 the funds otherwise allocated by the National Insti-
9 tutes of Health for biomedical research; and

10 (2) notwithstanding any transfer authority in
11 any appropriation Act, shall not be used for any
12 purpose other than allocating funds for conducting
13 and supporting innovation fund initiatives as de-
14 scribed in section 402(b)(25) of the Public Health
15 Service Act, as added by subsection (a).

16 **Subtitle B—National Institutes of**
17 **Health Planning and Adminis-**
18 **tration**

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

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

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

24 “(5) shall ensure that scientifically based stra-
25 tegic planning is implemented in support of research

1 priorities as determined by the agencies of the Na-
2 tional Institutes of Health, including through devel-
3 opment, use, and updating of the research strategic
4 plan under subsection (m);” and

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

6 “(m) RESEARCH STRATEGIC PLAN.—

7 “(1) FIVE-YEAR PLANS FOR BIOMEDICAL RE-
8 SEARCH STRATEGY.—

9 “(A) IN GENERAL.—For each successive
10 five-year period beginning with the period of fis-
11 cal years 2016 through 2020, the Director of
12 NIH, in consultation with the entities described
13 in subparagraph (B), shall develop and main-
14 tain a biomedical research strategic plan that—

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

20 “(ii) identifies areas, to be known
21 strategic focus areas, in which the re-
22 sources of the National Institutes of
23 Health can best contribute to the goal of
24 expanding knowledge on human health in

1 the United States through biomedical re-
2 search; and

3 “(iii) includes objectives for each such
4 strategic focus area.

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

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

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

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

19 “(i) have a common template; and

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

1 “(3) CONTENTS OF PLANS.—

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

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

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

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

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

23 “(B) RARE AND PEDIATRIC DISEASES AND
24 CONDITIONS.—In developing and maintaining a
25 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 NIH, in consultation
15 with the directors of the national research insti-
16 tutes and national centers, shall conduct
17 progress reviews for each strategic focus area
18 identified under paragraph (1)(A)(ii).

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

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

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

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

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

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

14 “(a) APPOINTMENT; TERMS.—

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

23 “(2) TERMS.—

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

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

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

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

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

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

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

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

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

20 “(B) shall take into consideration—

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

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

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

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

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

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

19 (a) IMPLEMENTATION OF MEASURES TO REDUCE
20 ADMINISTRATIVE BURDENS.—The Director of the Na-
21 tional Institutes of Health shall implement measures to
22 reduce the administrative burdens of researchers funded
23 by the National Institutes of Health, taking into account
24 the recommendations, evaluations, and plans researched
25 by the following entities:

1 (1) The Scientific Management Review Board.

2 (2) The National Academy of Sciences.

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

6 (4) Relevant recommendations from the Re-
7 search Business Models Working Group.

8 (b) REPORTS.—The Director of the National Insti-
9 tutes of Health shall submit to Congress a report on the
10 extent to which the Director has implemented measures
11 pursuant to subsection (a).

12 **SEC. 1024. EXEMPTION FOR THE NATIONAL INSTITUTES OF**
13 **HEALTH FROM THE PAPERWORK REDUCTION**
14 **ACT REQUIREMENTS.**

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

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

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

21 (3) by inserting at the end the following new
22 subparagraph:

23 “(E) during the conduct of research by the
24 National Institutes of Health.”.

1 **SEC. 1025. NIH TRAVEL.**

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

5 **SEC. 1026. OTHER TRANSACTIONS AUTHORITY.**

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

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

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

14 “(C) OTHER TRANSACTIONS AUTHORITY.—

15 The Director of the Center shall have other
16 transactions authority in entering into trans-
17 actions to fund projects in accordance with the
18 terms and conditions of this section.”;

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

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

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

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

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

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

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

7 Part B of title IV of the Public Health Service Act
8 (42 U.S.C. 284 et seq.) is amended by adding at the end
9 the following:

10 **“SEC. 409K. HIGH-RISK, HIGH-REWARD RESEARCH PRO-**
11 **GRAM.**

12 “The director of each national research institute
13 shall, as appropriate—

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

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

1 **Subtitle C—Supporting Young**
2 **Emerging Scientists**

3 **SEC. 1041. IMPROVEMENT OF LOAN REPAYMENT PRO-**
4 **GRAMS OF NATIONAL INSTITUTES OF**
5 **HEALTH.**

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

8 (1) by redesignating the second section 487F
9 (42 U.S.C. 288–6; pediatric research loan repayment
10 program) as section 487G; and

11 (2) by inserting after section 487G, as so rededesignated,
12 the following:

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

14 “(a) IN GENERAL.—The Secretary shall establish a
15 program, based on workforce and scientific needs, of entering
16 into contracts with qualified health professionals
17 under which such health professionals agree to engage in
18 research in consideration of the Federal Government
19 agreeing to pay, for each year of engaging in such research,
20 not more than \$50,000 of the principal and interest of the
21 educational loans of such health professionals.

22 “(b) ADJUSTMENT FOR INFLATION.—Beginning with
23 respect to fiscal year 2017, the Secretary may increase
24 the maximum amount specified in subsection (a) by an

1 amount that is determined by the Secretary, on an annual
2 basis, to reflect inflation.

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

7 “(d) APPLICABILITY OF CERTAIN PROVISIONS RE-
8 GARDING OBLIGATED SERVICE.—Except to the extent in-
9 consistent with this section, the provisions of sections
10 338B, 338C, and 338E shall apply to the program estab-
11 lished under this section to the same extent and in the
12 same manner as such provisions apply to the National
13 Health Service Corps Loan Repayment Program estab-
14 lished under section 338B.

15 “(e) AVAILABILITY OF APPROPRIATIONS.—Amounts
16 appropriated for a fiscal year for contracts under sub-
17 section (a) are authorized to remain available until the ex-
18 piration of the second fiscal year beginning after the fiscal
19 year for which the amounts were appropriated.”.

20 (b) UPDATE OF OTHER LOAN REPAYMENT PRO-
21 GRAMS.—

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

24 (A) in subsection (a), by striking
25 “\$35,000” and inserting “\$50,000”; and

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

7 (2) Section 487A(a) of such Act (42 U.S.C.
8 288–1(a)) is amended—

9 (A) by striking “\$35,000” and inserting
10 “\$50,000”; and

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

17 (3) Section 487B(a) of such Act (42 U.S.C.
18 288–2(a)) is amended—

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

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

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

3 (4) Section 487C(a)(1) of such Act (42 U.S.C.
4 288–3(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 (5) Section 487E(a)(1) of such Act (42 U.S.C.
14 288–5(a)(1)) is amended—

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

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

23 (6) Section 487F(a) of such Act (42 U.S.C.
24 288–5a(a)), as added by section 205 of Public Law
25 106–505, is amended—

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

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

9 (7) Section 487F of such Act (42 U.S.C. 288–
10 6, as added by section 1002(b) of Public Law 106–
11 310, is amended—

12 (A) in subsection (a)(1), by striking
13 “\$35,000” and inserting “\$50,000”;

14 (B) in subsection (b), by adding at the end
15 the following new sentence: “Subsection (b) of
16 section 487H shall apply with respect to the
17 maximum amount specified in subsection (a)(1)
18 in the same manner as it applies to the max-
19 imum amount specified in such subsection (a)
20 of such section.”; and

21 (C) by redesignating such section as sec-
22 tion 487G.

23 **SEC. 1042. REPORT.**

24 Not later than 18 months after the date of the enact-
25 ment of this Act, the Director of the National Institutes

1 of Health shall submit to Congress a report on efforts of
2 the National Institutes of Health to attract, retain, and
3 develop emerging scientists.

4 **Subtitle D—Capstone Grant**
5 **Program**

6 **SEC. 1061. CAPSTONE AWARD.**

7 Part G of title IV of the Public Health Service Act
8 (42 U.S.C. 288 et seq.) is amended by adding at the end
9 the following:

10 **“SEC. 490. CAPSTONE AWARD.**

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

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

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

24 “(d) LIMITATION.—Individuals who have received a
25 Capstone Award shall not be eligible to have principle in-

1 vestigator status on subsequent awards from the National
2 Institutes of Health.”.

3 **Subtitle E—Promoting Pediatric**
4 **Research Through the National**
5 **Institutes of Health**

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

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

9 (1) in paragraph (1)—

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

20 (B) by striking subparagraph (B);

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

1 (D) by striking “; or” at the end and in-
2 serting a period; and
3 (2) in paragraph (1), paragraph (2)(A), the
4 first sentence of paragraph (2)(E), and paragraph
5 (4), by striking “may” each place it appears and in-
6 serting “shall”.

7 **SEC. 1082. GLOBAL PEDIATRIC CLINICAL STUDY NETWORK**
8 **SENSE OF CONGRESS.**

9 It is the sense of Congress that—

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

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

22 (3) the Food and Drug Administration should
23 engage the European Medicines Agency and other
24 foreign regulatory entities during the formation of

1 the global pediatric clinical study network to encour-
2 age their participation; and

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

10 **SEC. 1083. APPROPRIATE AGE GROUPINGS IN CLINICAL RE-**
11 **SEARCH.**

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

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

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

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

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

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

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

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

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

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

4 **SEC. 1101. SHARING OF DATA GENERATED THROUGH NIH-**
5 **FUNDED RESEARCH.**

6 Section 402 of the Public Health Service Act (42
7 U.S.C. 282) is amended by adding at the end the fol-
8 lowing:

9 “(m) SHARING OF DATA GENERATED THROUGH
10 NIH-FUNDED RESEARCH.—

11 “(1) AUTHORITY.—Subject to paragraph (2),
12 the Director of NIH may require recipients of the
13 award of an NIH grant or other financial support,
14 provided that the research is fully funded through
15 such grant or other support, to share scientific data
16 generated from research conducted through such
17 support for research purposes.

18 “(2) LIMITATION.—The Director of NIH shall
19 not require the sharing of data that is inconsistent
20 with applicable law and policy protecting—

21 “(A) privacy and confidentiality;

22 “(B) proprietary interests;

23 “(C) business confidential information;

24 “(D) intellectual property rights; and

25 “(E) other relevant rights.”.

1 **SEC. 1102. STANDARDIZATION OF DATA IN CLINICAL TRIAL**
2 **REGISTRY DATA BANK ON ELIGIBILITY FOR**
3 **CLINICAL TRIALS.**

4 (a) STANDARDIZATION.—

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

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

9 (B) by inserting after paragraph (6) the
10 following:

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

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

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

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

24 “(i) the disease or indication being
25 studied;

1 “(ii) inclusion criteria such as age,
2 gender, diagnosis or diagnoses, lab values,
3 or imaging results; and

4 “(iii) exclusion criteria such as spe-
5 cific diagnosis or diagnoses, lab values, or
6 prohibited medications; and

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

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

18 (b) CONSULTATION.—Not later than 90 days after
19 the date of enactment of this Act, the Secretary of Health
20 and Human Services shall consult with stakeholders (in-
21 cluding patients, researchers, physicians, industry rep-
22 resentatives, health information technology providers, the
23 Food and Drug Administration, and standard setting or-
24 ganizations such as CDISC that have experience working
25 with Federal agencies to standardize health data submis-

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

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

12 **Subtitle G—Facilitating** 13 **Collaborative Research**

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

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

24 (b) APPLICATION.—Eligible entities seeking to enter
25 into a cooperative agreement, contract, or grant with the

1 Secretary under this section shall submit to the Secretary
2 an application in such time and manner, and containing
3 such information, as the Secretary may require in accord-
4 ance with this section. The Secretary shall not enter into
5 a cooperative agreement, contract, or grant with an eligi-
6 ble entity unless such entity submits an application includ-
7 ing the following:

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

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

24 (3) A description of the system the eligible enti-
25 ty will use to store and maintain such data, and in-

1 formation demonstrating that this system will com-
2 ply with applicable standards and requirements for
3 ensuring the security of the clinical trial data.

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

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

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

24 (7) Evidence demonstrating a proven track
25 record of—

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

5 (B) having the ability to protect confiden-
6 tial data.

7 (8) An agreement that the eligible entity will
8 work with the Comptroller General of the United
9 States for purposes of the study and report in sub-
10 section (d).

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

18 (d) STUDY AND REPORT.—

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

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

3 (A) review the effectiveness of the pilot
4 program established under subsection (a); and
5 (B) be designed to formulate recommenda-
6 tions on improvements to the program.

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

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

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

16 (C) An analysis of whether the program
17 has helped reduce adverse events in clinical
18 trials.

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

24 (E) An emphasis of privacy and data in-
25 tegrity practices used in the program.

1 (e) DEFINITIONS.—In this section:

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

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

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

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

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

25 (A) that was—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 “(C) diagnosis and progression markers;

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

10 “(A) the epidemiology of the diseases;

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

12 “(C) the prevention of the diseases;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 “(2) to State and local agencies.

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

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

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

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

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

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

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

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

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

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

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

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

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

21 “(a) IN GENERAL.—The Secretary may, for the pur-
22 poses described in subsection (b)—

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

1 “(2) award grants to patient advocacy groups
2 or other organizations determined appropriate by the
3 Secretary.

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

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

13 “(1) cooperating with other entities to sponsor
14 or maintain disease registries, including disease reg-
15 istries and disease registry platforms for rare dis-
16 eases;

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

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

21 “(B) is easily modified as knowledge is
22 gained during such studies; and

23 “(C) is capable of handling increasing
24 amounts of data as more studies are carried
25 out; and

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

4 “(A) the design and conduct of disease
5 studies;

6 “(B) the modification of any such ongoing
7 studies; and

8 “(C) addressing associated patient privacy
9 issues.

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

19 “(e) CONFIDENTIALITY.—Notwithstanding sub-
20 section (d), nothing in this section authorizes the disclo-
21 sure of any information that is a trade secret or commer-
22 cial or financial information that is privileged or confiden-
23 tial and subject to section 552(b)(4) of title 5, United
24 States Code, or section 1905 of title 18, United States
25 Code.

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

4 **SEC. 1124. ACCESSING, SHARING, AND USING HEALTH DATA**
5 **FOR RESEARCH PURPOSES.**

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

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

12 **“SEC. 13441. REFERENCES.**

13 “In this part:

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

17 “(b) PART 164.—References to a specified section of
18 ‘part 164’, refer to such specified section of part 164 of
19 title 45, Code of Federal Regulations (or any successor
20 section).

21 **“SEC. 13442. DEFINING HEALTH DATA RESEARCH AS PART**
22 **OF HEALTH CARE OPERATIONS.**

23 “(a) IN GENERAL.—Subject to subsection (b), the
24 Secretary shall revise or clarify the rule to allow the use
25 and disclosure of protected health information by a cov-

1 ered entity for research purposes, including studies whose
2 purpose is to obtain generalizable knowledge, to be treated
3 as the use and disclosure of such information for health
4 care operations described in subparagraph (1) of the defi-
5 nition of health care operations in section 164.501 of part
6 164.

7 “(b) MODIFICATIONS TO RULES FOR DISCLOSURES
8 FOR HEALTH CARE OPERATIONS.—In applying section
9 164.506 of part 164 to the disclosure of protected health
10 information described in subsection (a)—

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

14 “(A) another covered entity for health care
15 operations (as defined in such section 164.501
16 of part 164);

17 “(B) a business associate that has entered
18 into a contract under section 164.504(e) of part
19 164 with a disclosing covered entity to perform
20 health care operations; or

21 “(C) a business associate that has entered
22 into a contract under section 164.504(e) of part
23 164 for the purpose of data aggregation (as de-
24 fined in such section 164.501 of part 164); and

1 “(2) the Secretary shall further revise or clarify
2 the Rule so that the limitation specified by section
3 164.506(c)(4) of part 164 does not apply to disclo-
4 sures that are described by subsection (a).

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

9 **“SEC. 13443. TREATING DISCLOSURES OF PROTECTED**
10 **HEALTH INFORMATION FOR RESEARCH SIMI-**
11 **LARLY TO DISCLOSURES OF SUCH INFORMA-**
12 **TION FOR PUBLIC HEALTH PURPOSES.**

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

18 “(b) PERMITTED USES AND DISCLOSURES.—The
19 Secretary shall revise or clarify the Rule so that research
20 activities, including comparative research activities, re-
21 lated to the quality, safety, or effectiveness of a product
22 or activity that is regulated by the Food and Drug Admin-
23 istration are included as public health activities for pur-
24 poses of which a covered entity may disclose protected

1 health information to a person described in section
2 164.512(b)(1)(iii) of part 164.

3 **“SEC. 13444. PERMITTING REMOTE ACCESS TO PROTECTED**
4 **HEALTH INFORMATION BY RESEARCHERS.**

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

10 “(1) appropriate security and privacy safe-
11 guards are maintained by the covered entity and the
12 researcher; and

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

15 **“SEC. 13445. ALLOWING ONE-TIME AUTHORIZATION OF USE**
16 **AND DISCLOSURE OF PROTECTED HEALTH**
17 **INFORMATION FOR RESEARCH PURPOSES.**

18 “(a) IN GENERAL.—The Secretary shall revise or
19 clarify the Rule to specify that an authorization for the
20 use or disclosure of protected health information, with re-
21 spect to an individual, for future research purposes shall
22 be deemed to contain a sufficient description of the pur-
23 pose of the use or disclosure if the authorization—

24 “(1) sufficiently describes the purposes such
25 that it would be reasonable for the individual to ex-

1 pect that the protected health information could be
2 used or disclosed for such future research;

3 “(2) either—

4 “(A) states that the authorization will ex-
5 pire on a particular date or on the occurrence
6 of a particular event; or

7 “(B) states that the authorization will re-
8 main valid unless and until it is revoked by the
9 individual; and

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

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

21 (b) REVISION OF REGULATIONS.—Not later than 12
22 months after the date of the enactment of this Act, the
23 Secretary of Health and Human Services shall revise and
24 clarify the provisions of title 45, Code of Federal Regula-

1 tions, for consistency with part 4 of subtitle D of the
2 HITECH Act, as added by subsection (a).

3 **Subtitle H—Council for 21st**
4 **Century Cures**

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

6 Title II of the Public Health Service Act (42 U.S.C.
7 202 et seq.) is amended by adding at the end the fol-
8 lowing:

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

10 **“SEC. 281. ESTABLISHMENT.**

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

20 **“SEC. 281A. PURPOSE.**

21 “The purpose of the Council is to accelerate the dis-
22 covery, development, and delivery in the United States of
23 innovative cures, treatments, and preventive measures for
24 patients.

1 **“SEC. 281B. DUTIES.**

2 “For the purpose described in section 281A, the
3 Council shall—

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

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

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

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

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

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

23 “(7) facilitate the interoperability of the compo-
24 nents of the discovery, development, and delivery
25 cycle;

1 “(8) propose recommendations that will facili-
2 tate precompetitive collaboration;

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

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

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

11 “(a) BOARD OF DIRECTORS.—

12 “(1) ESTABLISHMENT.—

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

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

23 “(i) The Director of the National In-
24 stitutes of Health.

1 “(ii) The Commissioner of Food and
2 Drugs.

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

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

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

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

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

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

22 “(III) 2 of whom shall be rep-
23 resentatives of the information and
24 digital technology industry; and

1 “(ii) 9 shall be appointed by the
2 Comptroller General of the United States,
3 after soliciting nominations—

4 “(I) 2 of whom shall be rep-
5 resentatives of academic researchers;

6 “(II) 3 of whom shall be rep-
7 resentative of patients;

8 “(III) 2 of whom shall be rep-
9 resentatives of health care providers;
10 and

11 “(IV) 2 of whom shall be rep-
12 resentatives of health care plans and
13 insurers.

14 “(D) CHAIR.—The Chair of the Board
15 shall be selected by the members of the Board
16 by majority vote from among the members of
17 the Board.

18 “(2) TERMS AND VACANCIES.—

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

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

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

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

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

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

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

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

23 “(i) the officers, employees, agents,
24 and contractors of the Council; and

1 “(ii) the members of any committees
2 of the Council;

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

6 “(D) establish specific duties of the Execu-
7 tive Director.

8 “(4) MEETINGS.—

9 “(A) IN GENERAL.—the Board of Direc-
10 tors shall—

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

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

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

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

22 “(ii) annually thereafter, in consulta-
23 tion with the Executive Director, review
24 and update such agenda.

1 “(b) APPOINTMENT AND INCORPORATION.—Not
2 later than 6 months after the date of enactment of the
3 21st Century Cures Act—

4 “(1) the Comptroller General of the United
5 States shall appoint the appointed members of the
6 Board of Directors under subsection (a)(1)(C); and

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

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

16 “(1) is described in subsection (c)(3) of section
17 501 of the Internal Revenue Code of 1986; and

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

20 “(d) EXECUTIVE DIRECTOR.—The Executive Direc-
21 tor shall—

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

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

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

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

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

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

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

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

22 **“SEC. 281F. FUNDING.**

23 “For the each of fiscal years 2016 through 2023,
24 there is authorized to be appropriated \$10,000,000 to the

1 Council for purposes of carrying out the duties of the
2 Council under this part.”.

3 **TITLE II—DEVELOPMENT**
4 **Subtitle A—Patient-Focused Drug**
5 **Development**

6 **SEC. 2001. DEVELOPMENT AND USE OF PATIENT EXPERI-**
7 **ENCE DATA TO ENHANCE STRUCTURED RISK-**
8 **BENEFIT ASSESSMENT FRAMEWORK.**

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

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

14 (2) by adding at the end the following new sub-
15 sections:

16 “(x) STRUCTURED RISK-BENEFIT ASSESSMENT
17 FRAMEWORK.—

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

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

23 “(B) to develop and implement a con-
24 sistent and systematic approach to the discus-
25 sion of, regulatory decisionmaking with respect

1 to, and the communication of, the benefits and
2 risks of new drugs.

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

6 “(y) DEVELOPMENT AND USE OF PATIENT EXPERI-
7 ENCE DATA TO ENHANCE STRUCTURED RISK-BENEFIT
8 ASSESSMENT FRAMEWORK.—

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

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

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

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

21 “(B) the Secretary may request such an
22 entity to submit such documents, data, and
23 summaries and analyses; and

24 “(C) patient experience data may be devel-
25 oped and used to enhance the structured risk-

1 benefit assessment framework under subsection
2 (x).

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

13 (b) GUIDANCE.—

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

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

1 (i) specifying the timelines for the re-
2 view of such documents, data, or sum-
3 maries and analyses by the Secretary; and

4 (ii) on how the Secretary will use such
5 documents, data, or summaries and anal-
6 yses to update any guidance documents
7 published under this subsection or publish
8 new guidance;

9 (B) with respect to the collection and anal-
10 ysis of patient experience data (as defined in
11 paragraph (2) of such subsection (y)), guidance
12 on—

13 (i) methodological considerations for
14 the collection of patient experience data,
15 which may include structured approaches
16 to gathering information on—

17 (I) the experience of a patient liv-
18 ing with a particular disease;

19 (II) the burden of living with or
20 managing the disease;

21 (III) the impact of the disease on
22 daily life and long-term functioning;
23 and

1 (IV) the effect of current thera-
2 peutic options on different aspects of
3 the disease; and

4 (ii) the establishment and mainte-
5 nance of registries designed to increase un-
6 derstanding of the natural history of a dis-
7 ease;

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

12 (D) methodologies, standards, and poten-
13 tial experimental designs for patient-reported
14 outcomes.

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

25 (3) WORKSHOPS.—

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

10 (B) ATTENDEES.—A workshop convened
11 under this paragraph shall include—

12 (i) patients;

13 (ii) representatives from patient advo-
14 cacy organizations, biopharmaceutical com-
15 panies, and disease research foundations;

16 (iii) representatives of the reviewing
17 divisions of the Food and Drug Adminis-
18 tration; and

19 (iv) methodological experts with sig-
20 nificant expertise in patient experience
21 data.

22 (4) PUBLIC MEETING.—Not later than 90 days
23 after the date on which the draft guidance is pub-
24 lished under this subsection, the Secretary of Health

1 and Human Services shall convene a public meeting
2 to solicit input on the guidance.

3 **Subtitle B—Qualification and Use**
4 **of Drug Development Tools**

5 **SEC. 2021. QUALIFICATION OF DRUG DEVELOPMENT**
6 **TOOLS.**

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

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

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

14 (3) Biomedical research consortia (as defined in
15 section 507(f) of section 507 of the Federal Food,
16 Drug, and Cosmetic Act, as added by subsection (c))
17 can play a valuable role in helping develop and qual-
18 ify drug development tools.

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

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

24 (A) to develop, through a transparent pub-
25 lic process, data standards and scientific ap-

1 proaches to data collection accepted by the
2 medical and clinical research community for
3 purposes of qualifying drug development tools;

4 (B) to coordinate efforts toward developing
5 and qualifying drug development tools in key
6 therapeutic areas; and

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

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

17 (c) **QUALIFICATION OF DRUG DEVELOPMENT**
18 **TOOLS.**—Chapter V of the Federal Food, Drug, and Cos-
19 metic Act is amended by inserting after section 506F the
20 following new section:

21 **“SEC. 507. QUALIFICATION OF DRUG DEVELOPMENT**
22 **TOOLS.**

23 “(a) **PROCESS FOR QUALIFICATION.**—

24 “(1) **IN GENERAL.**—The Secretary shall estab-
25 lish a process for the qualification of drug develop-

1 ment tools for a proposed context of use under
2 which—

3 “(A)(i) a requestor initiates such process
4 by submitting a letter of intent to the Sec-
5 retary; and

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

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

11 “(ii) the Secretary shall accept or decline
12 to accept the qualification plan; and

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

16 “(ii) the Secretary shall determine whether
17 to accept such qualification package for review;
18 and

19 “(iii) if the Secretary accepts such quali-
20 fication package for review, conduct such review
21 in accordance with this section.

22 “(2) ACCEPTANCE AND REVIEW OF SUBMIS-
23 SIONS.—

24 “(A) IN GENERAL.—The succeeding provi-
25 sions of this paragraph shall apply with respect

1 to the treatment of a letter of intent, a quali-
2 fication plan, or a full qualification package
3 submitted under paragraph (1) (referred to in
4 this paragraph as ‘qualification submissions’).

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

17 “(C) PRIORITIZATION OF QUALIFICATION
18 REVIEW.—The Secretary may prioritize the re-
19 view of a full qualification package submitted
20 under paragraph (1) with respect to a drug de-
21 velopment tool, based on factors determined ap-
22 propriate by the Secretary, including—

23 “(i) as applicable, the severity, rarity,
24 or prevalence of the disease or condition
25 targeted by the drug development tool and

1 the availability or lack of alternative treat-
2 ments for such disease or condition; and

3 “(ii) the identification, by the Sec-
4 retary or by biomedical research consortia
5 and other expert stakeholders, of such a
6 drug development tool and its proposed
7 context of use as a public health priority.

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

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

21 “(A) conduct a comprehensive review of a
22 full qualification package accepted under para-
23 graph (1)(C); and

1 “(B) determine whether the drug develop-
2 ment tool at issue is qualified for its proposed
3 context of use.

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

9 “(b) EFFECT OF QUALIFICATION.—

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

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

18 “(A) supporting or obtaining approval or
19 licensure (as applicable) of a drug or biological
20 product (including in accordance with section
21 506(c)) under section 505 of this Act or section
22 351 of the Public Health Service Act; or

23 “(B) supporting the investigational use of
24 a drug or biological product under section

1 505(i) of this Act or section 351(a)(3) of the
2 Public Health Service Act.

3 “(3) RESCISSION OR MODIFICATION.—

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

13 “(B) MEETING FOR REVIEW.—If the Sec-
14 retary rescinds or modifies under subparagraph
15 (A) a determination to qualify a drug develop-
16 ment tool, the requestor involved shall be grant-
17 ed a request for a meeting with the Secretary
18 to discuss the basis of the Secretary’s decision
19 to rescind or modify the determination before
20 the effective date of the rescission or modifica-
21 tion.

22 “(c) TRANSPARENCY.—

23 “(1) IN GENERAL.—Subject to paragraph (3),
24 the Secretary shall make publicly available, and up-
25 date on at least a biannual basis, on the Internet

1 website of the Food and Drug Administration the
2 following:

3 “(A) Information with respect to each
4 qualification submission under the qualification
5 process under subsection (a), including—

6 “(i) the stage of the review process
7 applicable to the submission;

8 “(ii) the date of the most recent
9 change in stage status;

10 “(iii) whether the external scientific
11 experts were utilized in the development of
12 a qualification plan or the review of a full
13 qualification package; and

14 “(iv) submissions from requestors
15 under the qualification process under sub-
16 section (a), including any data and evi-
17 dence contained in such submissions, and
18 any updates to such submissions.

19 “(B) The Secretary’s formal written deter-
20 minations in response to such qualification sub-
21 missions.

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

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

5 “(E) A comprehensive list of—

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

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

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

20 “(3) APPLICABILITY.—Nothing in this section
21 shall be construed as authorizing the Secretary to
22 disclose any information contained in an application
23 submitted under section 505 of this Act or section
24 351 of the Public Health Service Act that is con-
25 fidential commercial or trade secret information sub-

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

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

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

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

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

19 “(f) DEFINITIONS.—In this section:

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

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

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

4 “(2) BIOMEDICAL RESEARCH CONSORTIA.—The
5 term ‘biomedical research consortia’ means collabo-
6 rative groups that may take the form of public-pri-
7 vate partnerships and may include government agen-
8 cies, institutions of higher education (as defined in
9 section 101(a) of the Higher Education Act of 1965
10 (20 U.S.C. 1001)), patient advocacy groups, indus-
11 try representatives, clinical and scientific experts,
12 and other relevant entities and individuals.

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

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

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

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

3 “(A) a biomarker;

4 “(B) a clinical outcome assessment; and

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

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

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

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

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

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

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

13 (d) GUIDANCE.—

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

22 (A) provides a conceptual framework de-
23 scribing appropriate standards and scientific
24 approaches to support the development of bio-

1 markers delineated under the taxonomy estab-
2 lished under paragraph (3);

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

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

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

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

20 (iii) establishes a process by which
21 such entities or the Secretary may consult
22 with biomedical research consortia and
23 other individuals and entities with expert
24 knowledge and insights that may assist the
25 Secretary in the review of qualification

1 plans and full qualification submissions
2 under such section; and

3 (D) includes such other information as the
4 Secretary determines appropriate.

5 (2) TIMING.—Not later than 24 months after
6 the date of the enactment of this Act, the Secretary
7 shall issue draft guidance under paragraph (1) on
8 the implementation of section 507 of the Federal
9 Food, Drug, and Cosmetic Act (as added by sub-
10 section (c)). The Secretary shall issue final guidance
11 on the implementation of such section not later than
12 6 months after the date on which the comment pe-
13 riod for the draft guidance closes.

14 (3) TAXONOMY.—

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

23 (B) PUBLIC AVAILABILITY.—Not later
24 than 12 months after the date of the enactment
25 of this Act, the Secretary shall make such tax-

1 onomy publicly available in draft form for pub-
2 lic comment. The Secretary shall finalize the
3 taxonomy not later than 12 months after the
4 close of the public comment period.

5 (e) MEETING AND REPORT.—

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

13 (2) REPORT.—Not later than 5 years after the
14 date of the enactment of this Act, the Secretary
15 shall make publicly available on the Internet website
16 of the Food and Drug Administration a report. Such
17 report shall include, with respect to the qualification
18 process under section 507 of the Federal Food,
19 Drug, and Cosmetic Act, as added by subsection (c),
20 information on—

21 (A) the number of requests submitted, as
22 a letter of intent, for qualification of a drug de-
23 velopment tool (as defined in subsection (f) of
24 such section);

1 (B) the number of such requests accepted
2 and determined to be eligible for submission of
3 a qualification plan or full qualification package
4 (as such terms are defined in such subsection),
5 respectively;

6 (C) the number of such requests for which
7 external scientific experts were utilized in the
8 development of a qualification plan or review of
9 a full qualification package; and

10 (D) the number of qualification plans and
11 full qualification packages, respectively, sub-
12 mitted to the Secretary; and

13 (3) the drug development tools qualified
14 through such qualification process, specified by type
15 of tool, such as a biomarker or clinical outcome as-
16 sessment (as such terms are defined in subsection
17 (f) of such section 507).

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

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

22 “(g) ACCELERATED APPROVAL DEVELOPMENT
23 PLAN.—

24 “(1) IN GENERAL.—In the case of a drug that
25 the Secretary determines may be eligible for acceler-

1 ated approval in accordance with subsection (c), the
2 sponsor of such drug may request, at any time after
3 the submission of an application for the investigation
4 of the drug under section 505(i) of this Act or sec-
5 tion 351(a)(3) of the Public Health Service Act, that
6 the Secretary agree to an accelerated approval devel-
7 opment plan described in paragraph (2).

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

12 “(A) the surrogate endpoint to be assessed
13 under such plan;

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

16 “(C) the magnitude of the effect of the
17 drug on the surrogate endpoint that is the sub-
18 ject of the agreement that would be sufficient
19 to form the primary basis of a claim that the
20 drug is effective.

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

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

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

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

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

19 “(A) is reasonably likely to predict clinical
20 benefit; and

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

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

4 (1) by striking “(f) AWARENESS EFFORTS” and
5 inserting “(e) AWARENESS EFFORTS”; and

6 (2) by striking “(e) CONSTRUCTION” and in-
7 serting “(f) CONSTRUCTION”.

8 **Subtitle C—FDA Advancement of**
9 **Precision Medicine**

10 **SEC. 2041. PRECISION MEDICINE GUIDANCE AND OTHER**
11 **PROGRAMS OF FOOD AND DRUG ADMINIS-**
12 **TRATION.**

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

16 **“Subchapter J—Precision Medicine**

17 **“SEC. 591. GENERAL AGENCY GUIDANCE ON PRECISION**
18 **MEDICINE.**

19 “(a) IN GENERAL.—The Secretary shall issue and
20 periodically update guidance to assist sponsors in the de-
21 velopment of a precision drug or biological product. Such
22 guidance shall—

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

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

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

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

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

13 “(3) the manner and extent to which a benefit-
14 risk assessment may be affected when clinical trials
15 are limited to patient population subsets that are
16 identified using biomarkers;

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

19 “(5) considerations for developing biomarkers
20 that inform prescribing decisions for a drug or bio-
21 logical product, and when information regarding a
22 biomarker may be included in the approved prescrip-
23 tion labeling for a precision drug or biological prod-
24 uct.

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

5 **“SEC. 592. PRECISION MEDICINE REGARDING ORPHAN-**
6 **DRUG AND EXPEDITED-APPROVAL PRO-**
7 **GRAMS.**

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

15 “(1) consistent with applicable standards for
16 approval, rely upon data or information previously
17 submitted by the sponsor of the precision drug or bi-
18 ological product, or another sponsor, provided that
19 the sponsor of the precision drug or biological prod-
20 uct has obtained a contractual right of reference to
21 such other sponsor’s data and information, in an ap-
22 plication approved under section 505(c) or licensed
23 under section 351(a) of the Public Health Service
24 Act, as applicable—

1 “(A) for a different drug or biological
2 product; or

3 “(B) for a different indication for such
4 precision drug or biological product,

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

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

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

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

22 “(2) confer any new rights, beyond those au-
23 thorized under this Act prior to enactment of this
24 section, with respect to a sponsor’s ability to ref-
25 erence information contained in another application

1 submitted under section 505(b)(1) of this Act or sec-
2 tion 351(a) of the Public Health Service Act.”.

3 **Subtitle D—Modern Trial Design**
4 **and Evidence Development**

5 **SEC. 2061. BROADER APPLICATION OF BAYESIAN STATIS-**
6 **TICS AND ADAPTIVE TRIAL DESIGNS.**

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

18 (b) GUIDANCE ADDRESSING USE OF ADAPTIVE
19 TRIAL DESIGNS AND BAYESIAN METHODS.—

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

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

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

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

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

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

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

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

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

1 (D) recommended analysis methodologies.

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

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

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

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

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

21 Chapter V of the Federal Food, Drug, and Cosmetic
22 Act, as amended by section 2021, is further amended by
23 inserting after section 505E of such Act (21 U.S.C. 355f)
24 the following:

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

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

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

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

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

17 “(c) PROGRAM FRAMEWORK.—

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

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

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

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

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

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

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

12 “(3) CONSULTATION.—

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

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

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

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

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

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

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

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

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

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

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

8 “(f) RULE OF CONSTRUCTION.—

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

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

16 “(A) the standards of evidence under—

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

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

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

1 **“SEC. 505G. COLLECTING EVIDENCE FROM CLINICAL EXPE-**
2 **RIENCE THROUGH TARGETED EXTENSIONS**
3 **OF THE SENTINEL SYSTEM.**

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

11 “(b) PILOT DEMONSTRATIONS.—

12 “(1) IN GENERAL.—The Secretary—

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

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

22 “(ii) protecting the public health; or

23 “(iii) advancing patient-centered care;

24 and

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

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

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

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

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

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

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

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

7 “(3) 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 section 164.512(b)(1)(iii) of title 45,
13 Code of Federal Regulations (or any successor
14 regulation) and exempted as a public health ac-
15 tivity as described in section 46.101(b)(5) of
16 title 46, Code of Federal Regulations (or any
17 successor regulation); and

18 “(B) deem safety surveillance performed at
19 the request of the Food and Drug Administra-
20 tion 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 Sentinel System surveil-
24 lance infrastructure authorized under section
25 505(k), including use of analytic tools and

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

10 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
11 are authorized to be appropriated to carry out this section
12 \$3,000,000 for each of fiscal years 2016 through 2020.”.

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

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

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

19 “(a) IN GENERAL.—The Secretary shall establish a
20 streamlined data review program under which a holder of
21 an approved application submitted under section
22 505(b)(1) or under section 351(a) of the Public Health
23 Service Act may, to support the approval or licensure (as
24 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, unless the Sec-
5 retary determines that the full data sets are not re-
6 quired.

7 “(c) PUBLIC AVAILABILITY OF INFORMATION ON
8 PROGRAM.—The Secretary shall post on the public website
9 of the Food and Drug Administration and update annu-
10 ally—

11 “(1) the number of applications reviewed under
12 the streamlined data review program;

13 “(2) the average time for completion of review
14 under the streamlined data review program versus
15 other review of applications for new indications; and

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

20 “(d) DEFINITIONS.—In this section:

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

22 “(A) an indication for the treatment of
23 cancer, as determined appropriate by the Sec-
24 retary; or

1 “(B) such other types of indications as the
2 Secretary determines to be subject to the
3 streamlined data review program under this
4 section.

5 “(2) The term ‘qualified data summary’ means
6 a summary of clinical data intended to demonstrate
7 safety and effectiveness with respect to a qualified
8 indication for use of a drug.”.

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

16 (c) GUIDANCE; REGULATIONS.—The Commissioner
17 of Food and Drugs—

18 (1) shall—

19 (A) issue final guidance for implementation
20 of the streamlined data review program estab-
21 lished under section 505H of the Federal Food,
22 Drug, and Cosmetic Act, as added by sub-
23 section (a), not later than 24 months after the
24 date of enactment of this Act; and

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

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

9 **Subtitle E—Expediting Patient** 10 **Access**

11 **SEC. 2081. SENSE OF CONGRESS.**

12 It is the sense of Congress that the Food and Drug
13 Administration should continue to expedite the approval
14 of drugs designated as breakthrough therapies pursuant
15 to section 506(a) of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 356(a)) by approving drugs so des-
17 ignated as early as possible in the clinical development
18 process, regardless of the phase of development, provided
19 that the Secretary of Health and Human Services deter-
20 mines that an application for such a drug meets the stand-
21 ards of evidence of safety and effectiveness under section
22 505 of such Act (21 U.S.C. 355), including the substantial
23 evidence standard under subsection (d) of such section or
24 under section 351(a) of the Public Health Service Act (42
25 U.S.C. 262(a)).

1 **SEC. 2082. EXPANDED ACCESS POLICY.**

2 Chapter V of the Federal Food, Drug, and Cosmetic
3 Act is amended by inserting after section 561 (21 U.S.C.
4 360bbb) the following:

5 **“SEC. 561A. EXPANDED ACCESS POLICY REQUIRED FOR IN-**
6 **VESTIGATIONAL DRUGS.**

7 “(a) IN GENERAL.—The manufacturer or distributor
8 of one or more investigational drugs for the diagnosis,
9 monitoring, or treatment of one or more serious diseases
10 or conditions shall make publicly available the policy of
11 the manufacturer or distributor on evaluating and re-
12 sponding to requests submitted under section 561(b) for
13 provision of such a drug. A manufacturer or distributor
14 may satisfy the requirement of the preceding sentence by
15 posting such policy as generally applicable to all of such
16 manufacturer’s or distributor’s investigational drugs.

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

19 “(1) contact information for the manufacturer
20 or distributor to facilitate communication about re-
21 quests described in subsection (a);

22 “(2) procedures for making such requests;

23 “(3) the general criteria the manufacturer or
24 distributor will consider or use to approve such re-
25 quests; and

1 “(4) the length of time the manufacturer or dis-
2 tributor anticipates will be necessary to acknowledge
3 receipt of such requests.

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

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

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

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

16 “(2) the first initiation of a phase 2 or phase
17 3 study (as such terms are defined in section
18 312.21(b) and (c) of title 21, Code of Federal Regu-
19 lations (or any successor regulations)) with respect
20 to such investigational new drug.”.

21 **SEC. 2083. FINALIZING DRAFT GUIDANCE ON EXPANDED**
22 **ACCESS.**

23 (a) IN GENERAL.—Not later than 12 months after
24 the date of enactment of this Act, the Secretary of Health
25 and Human Services shall finalize the draft guidance enti-

1 tled “Expanded Access to Investigational Drugs for Treat-
2 ment Use—Qs & As” and dated May 2013.

3 (b) CONTENTS.—The final guidance referred to in
4 subsection (a) shall clearly define how the Secretary of
5 Health and Human Services interprets and uses adverse
6 drug event data reported by investigators in the case of
7 data reported from use under a request submitted under
8 section 561(b) of the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 360bbb(b)).

10 **Subtitle F—Facilitating Respon-**
11 **sible Manufacturer Communica-**
12 **tions**

13 **SEC. 2101. FACILITATING DISSEMINATION OF HEALTH**
14 **CARE ECONOMIC INFORMATION.**

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

17 (1) by striking “(a) If its” and inserting
18 “(a)(1) If its”;

19 (2) by striking “a formulary committee, or
20 other similar entity, in the course of the committee
21 or the entity carrying out its responsibilities for the
22 selection of drugs for managed care or other similar
23 organizations” and inserting “a payor, formulary
24 committee, or other similar entity with knowledge
25 and expertise in the area of health care economic

1 analysis, carrying out its responsibilities for the se-
2 lection of drugs for coverage or reimbursement”;

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

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

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

1 “(2)(A) For purposes of this paragraph, the term
2 ‘health care economic information’ means any analysis (in-
3 cluding the clinical data, inputs, clinical or other assump-
4 tions, methods, results, and other components underlying
5 or comprising the analysis) that identifies, measures, or
6 describes the economic consequences, which may be based
7 on the separate or aggregated clinical consequences of the
8 represented health outcomes, of the use of a drug. Such
9 analyses may be comparative to the use of another drug,
10 to another health care intervention, or to no intervention.

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

15 **SEC. 2102. FACILITATING RESPONSIBLE COMMUNICATION**
16 **OF SCIENTIFIC AND MEDICAL DEVELOP-**
17 **MENTS.**

18 (a) GUIDANCE.—Not later than 18 months after the
19 date of enactment of this Act, the Secretary of Health and
20 Human Services shall issue draft guidance on facilitating
21 the responsible dissemination of truthful and non-mis-
22 leading scientific and medical information not included in
23 the approved labeling of drugs and devices.

24 (b) DEFINITION.—In this section, the terms “drug”
25 and “device” have the meaning given to such terms in sec-

1 tion 201 of the Federal Food, Drug, and Cosmetic Act
2 (21 U.S.C. 321).

3 **Subtitle G—Antibiotic Drug**
4 **Development**

5 **SEC. 2121. APPROVAL OF CERTAIN DRUGS FOR USE IN A**
6 **LIMITED POPULATION OF PATIENTS.**

7 (a) PURPOSE.—The purpose of this section is to help
8 expedite the development and availability of treatments for
9 serious or life-threatening bacterial or fungal infections in
10 patients with unmet needs, while maintaining safety and
11 effectiveness standards for such treatments, taking into
12 account the severity of the infection and the availability
13 or lack of alternative treatments.

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

19 “(z) APPROVAL OF CERTAIN ANTIBACTERIAL AND
20 ANTIFUNGAL DRUGS FOR USE IN A LIMITED POPU-
21 LATION OF PATIENTS.—

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

1 “(A) may execute a written agreement
2 with the sponsor on the process for developing
3 data to support an application for approval of
4 such drug, for use in a limited population of pa-
5 tients in accordance with this subsection;

6 “(B) shall proceed with the development
7 and approval of such a drug in accordance with
8 this subsection only if a written agreement is
9 reached under subparagraph (A);

10 “(C) shall provide the sponsor with an op-
11 portunity to request meetings under paragraph
12 (2);

13 “(D) if a written agreement is reached
14 under subparagraph (A), may approve the drug
15 under this subsection for such use —

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

18 “(ii) based on a streamlined develop-
19 ment program; and

20 “(iii) only if the standards for ap-
21 proval under subsections (c) and (d) of this
22 section or licensure under section 351 of
23 the Public Health Service Act, as applica-
24 ble, are met; and

1 “(E) in approving a drug in accordance
2 with this subsection, subject to subparagraph
3 (D)(iii), may rely upon—

4 “(i) traditional endpoints, alternate
5 endpoints, or a combination of traditional
6 and alternate endpoints, and, as appro-
7 priate, data sets of a limited size; and

8 “(ii)(I) additional data, including pre-
9 clinical, pharmacologic, or pathophysiologic
10 evidence;

11 “(II) nonclinical susceptibility and
12 pharmacokinetic data;

13 “(III) data from phase 2 clinical
14 trials; and

15 “(IV) such other confirmatory evi-
16 dence as the Secretary determines appro-
17 priate to approve the drug.

18 “(2) FORMAL MEETINGS.—

19 “(A) IN GENERAL.—To help expedite and
20 facilitate the development and review of a drug
21 for which a sponsor intends to request approval
22 in accordance with this subsection, the Sec-
23 retary may, at the request of the sponsor, con-
24 duct meetings that provide early consultation,
25 timely advice, and sufficient opportunities to

1 develop an agreement described in paragraph
2 (1)(A) and help the sponsor design and conduct
3 a drug development program as efficiently as
4 possible, including the following types of meet-
5 ings:

6 “(i) An early consultation meeting.

7 “(ii) An assessment meeting.

8 “(iii) A postapproval meeting.

9 “(B) NO ALTERING OF GOALS.—Nothing
10 in this paragraph shall be construed to alter
11 agreed upon goals and procedures identified in
12 the letters described in section 101(b) of the
13 Prescription Drug User Fee Amendments of
14 2012.

15 “(C) BREAKTHROUGH THERAPIES.—In the
16 case of a drug designated as a breakthrough
17 therapy under section 506(a), the sponsor of
18 such drug may elect to utilize meetings pro-
19 vided under such section with respect to such
20 drug in lieu of meetings described in subpara-
21 graph (A).

22 “(3) LABELING REQUIREMENT.—The labeling
23 of an antibacterial or antifungal drug approved in
24 accordance with this subsection shall contain the
25 statement ‘Limited Population’ in a prominent man-

1 ner and adjacent to, and not more prominent than,
2 the brand name of the product. The prescribing in-
3 formation for such antibacterial or antifungal drug
4 required by section 201.57 of title 21, Code of Fed-
5 eral Regulations (or any successor regulation) shall
6 also include the following statement: ‘This drug is
7 indicated for use in a limited and specific population
8 of patients.’.

9 “(4) PROMOTIONAL MATERIALS.—The provi-
10 sions of section 506(c)(2)(B) shall apply with re-
11 spect to approval in accordance with this subsection
12 to the same extent and in the same manner as such
13 provisions apply with respect to accelerated approval
14 in accordance with section 506(c)(1).

15 “(5) TERMINATION OF REQUIREMENTS OR CON-
16 DITIONS.—If a drug is approved in accordance with
17 this subsection for an indication in a limited popu-
18 lation of patients and is subsequently approved or li-
19 censed under this section or section 351 of the Pub-
20 lic Health Service Act, other than in accordance with
21 this subsection, for—

22 “(A) the same indication and the same
23 conditions of use, the Secretary shall remove
24 any labeling requirements or postmarketing

1 conditions that were made applicable to the
2 drug under this subsection; or

3 “(B) a different indication or condition of
4 use, the Secretary shall not apply the labeling
5 requirements and postmarketing conditions that
6 were made applicable to the drug under this
7 subsection to the subsequent approval of the
8 drug for such different indication or condition
9 of use.

10 “(6) RELATION TO OTHER PROVISIONS.—Noth-
11 ing in this subsection shall be construed to prohibit
12 the approval of a drug for use in a limited popu-
13 lation of patients in accordance with this subsection,
14 in combination with—

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

18 “(B) designation and treatment of the
19 drug as a breakthrough therapy under section
20 506(a);

21 “(C) designation and treatment of the
22 drug as a fast track product under section
23 506(b); or

24 “(D) accelerated approval of the drug in
25 accordance with section 506(c).

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

3 “(A) to alter the standards of evidence
4 under subsection (c) or (d) (including the sub-
5 stantial evidence standard in subsection (d));

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

8 “(C) to otherwise, in any way, limit the au-
9 thority of the Secretary to approve products
10 pursuant to this Act and the Public Health
11 Service Act as authorized prior to the date of
12 enactment of this subsection; or

13 “(D) to restrict in any manner, the pre-
14 scribing of antibiotics or other products by
15 health care providers, or to otherwise limit or
16 restrict the practice of health care.

17 “(8) EFFECTIVE IMMEDIATELY.—The Sec-
18 retary shall have the authorities vested in the Sec-
19 retary by this subsection beginning on the date of
20 enactment of this subsection, irrespective of when
21 and whether the Secretary promulgates final regula-
22 tions or guidance.

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

24 “(A) EARLY CONSULTATION MEETING.—

25 The term ‘early consultation meeting’ means a

1 pre-investigational new drug meeting or an end-
2 of-phase 1 meeting that—

3 “(i) is conducted to review and reach
4 a written agreement—

5 “(I) on the scope of the stream-
6 lined development plan for a drug for
7 which a sponsor intends to request ap-
8 proval in accordance with this sub-
9 section; and

10 “(II) which, as appropriate, may
11 include agreement on the design and
12 size of necessary preclinical and clin-
13 ical studies early in the development
14 process, including clinical trials whose
15 data are intended to form the primary
16 basis for an effectiveness claim; and

17 “(ii) provides an opportunity to dis-
18 cuss expectations of the Secretary regard-
19 ing studies or other information that the
20 Secretary deems appropriate for purposes
21 of applying paragraph (5), relating to the
22 termination of labeling requirements or
23 postmarketing conditions.

24 “(B) ASSESSMENT MEETING.—The term
25 ‘assessment meeting’ means an end-of-phase 2

1 meeting, pre-new drug application meeting, or
2 pre-biologics license application meeting con-
3 ducted to resolve questions and issues raised
4 during the course of clinical investigations, and
5 details addressed in the written agreement re-
6 garding postapproval commitments or expan-
7 sion of approved uses.

8 “(C) POSTAPPROVAL MEETING.—The term
9 ‘postapproval meeting’ means a meeting fol-
10 lowing initial approval or licensure of the drug
11 for use in a limited population, to discuss any
12 issues identified by the Secretary or the sponsor
13 regarding postapproval commitments or expan-
14 sion of approved uses.”.

15 (c) GUIDANCE.—Not later than 18 months after the
16 date of enactment of this Act, the Secretary of Health and
17 Human Services, acting through the Commissioner of
18 Food and Drugs, shall issue draft guidance describing cri-
19 teria, process, and other general considerations for dem-
20 onstrating the safety and effectiveness of antibacterial and
21 antifungal drugs to be approved for use in a limited popu-
22 lation in accordance with section 505(z) of the Federal
23 Food, Drug, and Cosmetic Act, as added by subsection
24 (b).

25 (d) CONFORMING AMENDMENTS.—

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

4 (A) by striking “(j)” and inserting
5 “(j)(1)”;

6 (B) by inserting “505(z),” after “505(p),”;
7 and

8 (C) by adding at the end the following new
9 paragraph:

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

13 “(A) references to an antibacterial or antifungal
14 drug that is intended to treat a serious or life-
15 threatening infection shall be construed to refer to
16 a biological product intended to treat a serious or
17 life-threatening bacterial or fungal infection; and

18 “(B) references to approval of a drug under
19 section 505(c) of such Act shall be construed to
20 refer to a licensure of a biological product under
21 subsection (a) of this section.”.

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

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

5 (e) EVALUATION.—

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

20 (2) MEETING.—Not later than 90 days after
21 the date of the publication of such assessment, the
22 Secretary, acting through the Commissioner of Food
23 and Drugs shall hold a public meeting to discuss the
24 findings of the assessment, during which public
25 stakeholders may present their views on the success

1 of the program established under section 505(z) of
2 the Federal Food, Drug, and Cosmetic Act, as
3 added by subsection (b), and the appropriateness of
4 expanding such program.

5 (f) EXPANSION OF PROGRAM.—If the Secretary of
6 Health and Human Services determines, based on the as-
7 sessment under subsection (e)(1), evaluation of the assess-
8 ment, and any other relevant information, that the public
9 health would benefit from expansion of the limited-use
10 pathway established under section 505(z) of the Federal
11 Food, Drug, and Cosmetic Act (as added by subsection
12 (b)) beyond the drugs approved in accordance with such
13 section, the Secretary may expand such limited-use path-
14 way in accordance with such a determination. The ap-
15 proval of any drugs under any such expansion shall be
16 subject to the considerations and requirements described
17 in such section 505(z) for purposes of expansion to other
18 serious or life-threatening diseases or conditions.

19 (g) MONITORING.—The Public Health Service Act is
20 amended by inserting after section 317T (42 U.S.C.
21 247b–22) the following:

22 **“SEC. 317U. MONITORING ANTIBACTERIAL AND**
23 **ANTIFUNGAL DRUG USE AND RESISTANCE.**

24 **“(a) MONITORING.—**The Secretary shall use an ap-
25 **propriate monitoring system to monitor—**

1 “(1) the use of antibacterial and antifungal
2 drugs, including those receiving approval or licensure
3 for a limited population pursuant to section 505(z)
4 of the Federal Food, Drug, and Cosmetic Act; and
5 “(2) changes in bacterial and fungal resistance
6 to drugs.

7 “(b) PUBLIC AVAILABILITY OF DATA.—The Sec-
8 retary shall make summaries of the data derived from
9 monitoring under this section publicly available for the
10 purposes of—

11 “(1) improving the monitoring of important
12 trends in antibacterial and antifungal resistance;
13 and

14 “(2) ensuring appropriate stewardship of anti-
15 bacterial and antifungal drugs, including those re-
16 ceiving approval or licensure for a limited population
17 pursuant to section 505(z) of the Federal Food,
18 Drug, and Cosmetic Act.”.

19 **SEC. 2122. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA**
20 **FOR MICROORGANISMS.**

21 (a) IN GENERAL.—Section 511 of the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 360a) is amended to
23 read as follows:

1 **“SEC. 511. IDENTIFYING AND UPDATING SUSCEPTIBILITY**
2 **TEST INTERPRETIVE CRITERIA FOR MICRO-**
3 **ORGANISMS.**

4 “(a) PURPOSE; IDENTIFICATION OF CRITERIA.—

5 “(1) PURPOSE.—The purpose of this section is
6 to provide the Secretary with an expedited, flexible
7 method for—

8 “(A) clearance or premarket approval of
9 antimicrobial susceptibility testing devices uti-
10 lizing updated, recognized susceptibility test in-
11 terpretive criteria to characterize the in vitro
12 susceptibility of particular bacteria, fungi, or
13 other microorganisms to antimicrobial drugs;
14 and

15 “(B) providing public notice of the avail-
16 ability of recognized interpretive criteria to
17 meet premarket submission requirements or
18 other requirements under this Act for anti-
19 microbial susceptibility testing devices.

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

23 “(A) if such criteria are available on the
24 date of approval of the drug under section 505
25 of this Act or licensure of the drug under sec-

1 tion 351 of the Public Health Service Act (as
2 applicable), upon such approval or licensure; or

3 “(B) if such criteria are unavailable on
4 such date, on the date on which such criteria
5 are available for such drug.

6 “(3) BASES FOR INITIAL IDENTIFICATION.—

7 The Secretary shall identify appropriate suscepti-
8 bility test interpretive criteria under paragraph (2),
9 based on the Secretary’s review of, to the extent
10 available and relevant—

11 “(A) preclinical and clinical data, including
12 pharmacokinetic, pharmacodynamic, and epide-
13 miological data;

14 “(B) Bayesian and pharmacometric statis-
15 tical methodologies; and

16 “(C) such other evidence and information
17 as the Secretary considers appropriate.

18 “(b) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA
19 WEBSITE.—

20 “(1) IN GENERAL.—Not later than 1 year after
21 the date of the enactment of the 21st Century Cures
22 Act, the Secretary shall establish, and maintain
23 thereafter, on the website of the Food and Drug Ad-
24 ministration, a dedicated website that contains a list
25 of any appropriate new or updated susceptibility test

1 interpretive criteria standards in accordance with
2 paragraph (2) (referred to in this section as the ‘In-
3 terpretive Criteria Website’).

4 “(2) LISTING OF SUSCEPTIBILITY TEST INTER-
5 PRETIVE CRITERIA STANDARDS.—

6 “(A) IN GENERAL.—The list described in
7 paragraph (1) shall consist of any new or up-
8 dated susceptibility test interpretive criteria
9 standards that are—

10 “(i) established by a nationally or
11 internationally recognized standard devel-
12 opment organization that—

13 “(I) establishes and maintains
14 procedures to address potential con-
15 flicts of interest and ensure trans-
16 parent decisionmaking;

17 “(II) holds open meetings to en-
18 sure that there is an opportunity for
19 public input by interested parties, and
20 establishes and maintains processes to
21 ensure that such input is considered
22 in decisionmaking; and

23 “(III) permits its standards to be
24 made publicly available, through the
25 National Library of Medicine or an-

1 other similar source acceptable to the
2 Secretary; and

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

5 “(B) OTHER LIST.—The Interpretive Cri-
6 teria Website shall, in addition to the list de-
7 scribed in subparagraph (A), include a list of
8 interpretive criteria, if any, that the Secretary
9 has determined to be appropriate with respect
10 to legally marketed antimicrobial drugs,
11 where—

12 “(i) the Secretary does not recognize,
13 in whole or in part, an interpretive criteria
14 standard described under subparagraph
15 (A) otherwise applicable to such a drug;

16 “(ii) the Secretary withdraws under
17 subsection (c)(1)(B) recognition of a
18 standard, in whole or in part, otherwise
19 applicable to such a drug;

20 “(iii) the Secretary approves an appli-
21 cation under section 505 of this Act or sec-
22 tion 351 of the Public Health Service Act,
23 as applicable, with respect to marketing of
24 such a drug for which there are no rel-
25 evant interpretive criteria included in a

1 standard recognized by the Secretary
2 under subsection (c); or

3 “(iv) because the characteristics of
4 such a drug differ from other drugs with
5 the same active ingredient, the interpretive
6 criteria with respect to such drug—

7 “(I) differ from otherwise appli-
8 cable interpretive criteria included in
9 a standard listed under subparagraph
10 (A) or interpretive criteria otherwise
11 listed under this subparagraph; and

12 “(II) are determined by the Sec-
13 retary to be appropriate for the drug.

14 “(C) REQUIRED STATEMENTS OF LIMITA-
15 TIONS OF INFORMATION.—The Interpretive Cri-
16 teria Website shall include the following:

17 “(i) A statement that—

18 “(I) the website provides infor-
19 mation about the susceptibility of bac-
20 teria, fungi, or other microorganisms
21 to a certain drug (or drugs); and

22 “(II) the safety and efficacy of
23 the drug in treating clinical infections
24 due to such bacteria, fungi, or other
25 microorganisms may not have been es-

1 tablished in adequate and well-con-
2 trolled clinical trials and the clinical
3 significance of such susceptibility in-
4 formation in such trials is unknown.

5 “(ii) A statement that directs health
6 care practitioners to consult the approved
7 product labeling for specific drugs to deter-
8 mine the uses for which the Food and
9 Drug Administration has approved the
10 product.

11 “(iii) Any other statement that the
12 Secretary determines appropriate to ade-
13 quately convey the limitations of the data
14 supporting susceptibility test interpretive
15 criteria standard listed on the website.

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

20 “(4) INAPPLICABILITY OF MISBRANDING PROVI-
21 SION.—The inclusion in the approved labeling of an
22 antimicrobial drug of a reference or hyperlink to the
23 Interpretive Criteria Website, in and of itself, shall
24 not cause the drug to be misbranded in violation of

1 section 502, or the regulations promulgated there-
2 under.

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

9 “(c) RECOGNITION OF SUSCEPTIBILITY TEST INTER-
10 PRETIVE CRITERIA FROM STANDARD DEVELOPMENT OR-
11 GANIZATIONS.—

12 “(1) IN GENERAL.—Beginning on the date of
13 the establishment of the Interpretive Criteria
14 Website, and at least every 6 months thereafter, the
15 Secretary shall—

16 “(A) evaluate any appropriate new or up-
17 dated susceptibility test interpretive criteria
18 standards established by a nationally or inter-
19 nationally recognized standard development or-
20 ganization described in subsection (b)(2)(A)(i);
21 and

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

1 “(i) withdrawing recognition of any
2 different susceptibility test interpretive cri-
3 teria standard, in whole or in part;

4 “(ii) recognizing the new or updated
5 standards;

6 “(iii) recognizing one or more parts of
7 the new or updated interpretive criteria
8 specified in such a standard and declining
9 to recognize the remainder of such stand-
10 ard; and

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

13 “(2) BASES FOR UPDATING INTERPRETIVE CRI-
14 TERIA STANDARDS.—In evaluating new or updated
15 susceptibility test interpretive criteria standards
16 under paragraph (1)(A), the Secretary may con-
17 sider—

18 “(A) the Secretary’s determination that
19 such a standard is not applicable to a particular
20 drug because the characteristics of the drug dif-
21 fer from other drugs with the same active in-
22 gredient;

23 “(B) information provided by interested
24 third parties, including public comment on the

1 annual compilation of notices published under
2 paragraph (3);

3 “(C) any bases used to identify suscepti-
4 bility test interpretive criteria under subsection
5 (a)(2); and

6 “(D) such other information or factors as
7 the Secretary determines appropriate.

8 “(3) ANNUAL COMPILATION OF NOTICES.—
9 Each year, the Secretary shall compile the notices
10 published under paragraph (1)(B) and publish such
11 compilation in the Federal Register and provide for
12 public comment. If the Secretary receives comments,
13 the Secretary will review such comments and, if the
14 Secretary determines appropriate, update pursuant
15 to this subsection susceptibility test interpretive cri-
16 teria standards—

17 “(A) recognized by the Secretary under
18 this subsection; or

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

21 “(4) RELATION TO SECTION 514(c).—Any sus-
22 ceptibility test interpretive standard recognized
23 under this subsection or any criteria otherwise listed
24 under subsection (b)(2)(B) shall be deemed to be

1 recognized as a standard by the Secretary under sec-
2 tion 514(c)(1).

3 “(5) VOLUNTARY USE OF INTERPRETIVE CRI-
4 TERIA.—Nothing in this section prohibits a person
5 from seeking approval or clearance of a drug or de-
6 vice, or changes to the drug or the device, on the
7 basis of susceptibility test interpretive criteria stand-
8 ards which differ from those recognized pursuant to
9 paragraph (1).

10 “(d) ANTIMICROBIAL DRUG LABELING.—

11 “(1) DRUGS MARKETED PRIOR TO ESTABLISH-
12 MENT OF INTERPRETIVE CRITERIA WEBSITE.—With
13 respect to an antimicrobial drug lawfully introduced
14 or delivered for introduction into interstate com-
15 merce for commercial distribution before the estab-
16 lishment of the Interpretive Criteria Website, a hold-
17 er of an approved application under section 505 or
18 section 351 of the Public Health Service Act, as ap-
19 plicable, for each such drug—

20 “(A) not later than 1 year after establish-
21 ment of the Interpretive Criteria Website, shall
22 submit to the Secretary a supplemental applica-
23 tion for purposes of changing the drug’s label-
24 ing to substitute a reference or hyperlink to

1 such Website for any susceptibility test inter-
2 pretive criteria and related information; and

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

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

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

18 “(1) IN GENERAL.—Notwithstanding sections
19 501, 502, 510, 513, and 515, if the conditions speci-
20 fied in paragraph (2) are met (in addition to other
21 applicable provisions under this chapter) with re-
22 spect to an antimicrobial susceptibility testing device
23 described in subsection (f)(1), the Secretary may au-
24 thorize the marketing of such device for a use de-
25 scribed in such subsection.

1 “(2) CONDITIONS APPLICABLE TO ANTI-
2 MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

3 The conditions specified in this paragraph are the
4 following:

5 “(A) The device is used to make a deter-
6 mination of susceptibility using susceptibility
7 test interpretive criteria that are—

8 “(i) included in a standard recognized
9 by the Secretary under subsection (c); or

10 “(ii) otherwise listed on the Interpre-
11 tive Criteria Website under subsection
12 (b)(2).

13 “(B) The labeling of such device promi-
14 nently and conspicuously—

15 “(i) includes a statement that—

16 “(I) the device provides informa-
17 tion about the susceptibility of bac-
18 teria and fungi to certain drugs; and

19 “(II) the safety and efficacy of
20 such drugs in treating clinical infec-
21 tions due to such bacteria or fungi
22 may not have been established in ade-
23 quate and well-controlled clinical trials
24 and the clinical significance of such

1 susceptibility information in those in-
2 stances is unknown;

3 “(ii) includes a statement directing
4 health care practitioners to consult the ap-
5 proved labeling for drugs tested using such
6 a device, to determine the uses for which
7 the Food and Drug Administration has ap-
8 proved such drugs; and

9 “(iii) includes any other statement the
10 Secretary determines appropriate to ade-
11 quately convey the limitations of the data
12 supporting the interpretive criteria de-
13 scribed in subparagraph (A).

14 “(f) DEFINITIONS.—In this section:

15 “(1) The term ‘antimicrobial susceptibility test-
16 ing device’ means a device that utilizes susceptibility
17 test interpretive criteria to determine and report the
18 in vitro susceptibility of certain microorganisms to a
19 drug (or drugs).

20 “(2) The term ‘qualified infectious disease
21 product’ means a qualified infectious disease product
22 designated under section 505E(d).

23 “(3) The term ‘susceptibility test interpretive
24 criteria’ means—

1 “(A) one or more specific numerical values
2 which characterize the susceptibility of bacteria
3 or other microorganisms to the drug tested; and

4 “(B) related categorizations of such sus-
5 ceptibility, including categorization of the drug
6 as susceptible, intermediate, resistant, or such
7 other term as the Secretary determines appro-
8 priate.

9 “(4)(A) The term ‘antimicrobial drug’ means,
10 subject to subparagraph (B), a systemic anti-
11 bacterial or antifungal drug that—

12 “(i) is intended for human use in the treat-
13 ment of a disease or condition caused by a bac-
14 terium or fungus;

15 “(ii) may include a qualified infectious dis-
16 ease product designated under section 505E(d);
17 and

18 “(iii) is subject to section 503(b)(1).

19 “(B) If provided by the Secretary through regu-
20 lations, such term may include—

21 “(i) drugs other than systemic anti-
22 bacterial and antifungal drugs; and

23 “(ii) biological products (as such term is
24 defined in section 351 of the Public Health

1 Service Act) to the extent such products exhibit
2 antimicrobial activity.

3 “(g) RULE OF CONSTRUCTION.—Nothing in this sec-
4 tion shall be construed—

5 “(1) to alter the standards of evidence—

6 “(A) under subsection (c) or (d) of section
7 505, including the substantial evidence stand-
8 ard in section 505(d), or under section 351 of
9 the Public Health Service Act (as applicable);
10 or

11 “(B) with respect to marketing authoriza-
12 tion for devices, under section 510, 513, or 515;

13 “(2) to apply with respect to any drug, device,
14 or biological product, in any context other than—

15 “(A) an antimicrobial drug; or

16 “(B) an antimicrobial susceptibility testing
17 device that uses susceptibility test interpretive
18 criteria to characterize and report the in vitro
19 susceptibility of certain bacteria, fungi, or other
20 microorganisms to antimicrobial drugs in ac-
21 cordance with this section; or

22 “(3) unless specifically stated, to have any ef-
23 fect on authorities provided under other sections of
24 this Act, including any regulations issued under such
25 sections.”.

1 (b) CONFORMING AMENDMENTS.—

2 (1) REPEAL OF RELATED AUTHORITY.—Section
3 1111 of the Food and Drug Administration Amend-
4 ments Act of 2007 (42 U.S.C. 247d–5a; relating to
5 identification of clinically susceptible concentrations
6 of antimicrobials) is repealed.

7 (2) MISBRANDING.—Section 502 of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 352), as
9 amended by section 2121, is further amended by
10 adding at the end the following:

11 “(ee) If it is an antimicrobial drug and its labeling
12 fails to conform with the requirements under section
13 511(d).”.

14 (3) RECOGNITION OF INTERPRETIVE CRITERIA
15 AS DEVICE STANDARD.—Section 514(c)(1)(A) of the
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 360d(c)(1)(A)) is amended by inserting after “the
18 Secretary shall, by publication in the Federal Reg-
19 ister” the following: “(or, with respect to suscepti-
20 bility test interpretive criteria or standards recog-
21 nized or otherwise listed under section 511, by post-
22 ing on the Interpretive Criteria Website in accord-
23 ance with such section)”.

24 (c) REPORT TO CONGRESS.—Not later than two
25 years after the date of enactment of this Act, the Sec-

1 retary of Health and Human Services shall submit to the
2 Committee on Energy and Commerce of the House of
3 Representatives and the Committee on Health, Education,
4 Labor and Pensions of the Senate a report on the progress
5 made in implementing section 511 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 360a), as amended
7 by this section.

8 (d) REQUESTS FOR UPDATES TO INTERPRETIVE CRI-
9 TERIA WEBSITE.—Chapter 35 of title 44, United States
10 Code, shall not apply to the collection of information from
11 interested parties regarding the updating of lists under
12 paragraph (2) of subsection (b) section 511 of the Federal
13 Food, Drug, and Cosmetic Act (as amended by subsection
14 (a)) and posted on the Interpretive Criteria Website estab-
15 lished under paragraph (1) of such subsection (b).

16 (e) NO EFFECT ON HEALTH CARE PRACTICE.—
17 Nothing in this subtitle (including the amendments made
18 by this subtitle) shall be construed to restrict, in any man-
19 ner, the prescribing or administering of antibiotics or
20 other products by health care practitioners, or to limit the
21 practice of health care.

22 **SEC. 2123. ENCOURAGING THE DEVELOPMENT AND USE OF**
23 **NEW ANTIMICROBIAL DRUGS.**

24 (a) ADDITIONAL PAYMENT FOR NEW ANTI-
25 MICROBIAL DRUGS UNDER MEDICARE.—

1 (1) IN GENERAL.—Section 1886(d)(5) of the
2 Social Security Act (42 U.S.C. 1395ww(d)(5)) is
3 amended by adding at the end the following new
4 subparagraph:

5 “(M)(i)(I) Effective for discharges beginning on or
6 after October 1, 2017, the Secretary shall, after notice and
7 opportunity for public comment (in the publications re-
8 quired by subsection (e)(5) for a fiscal year or otherwise),
9 provide for additional payment to be made under this sub-
10 section in accordance with the provisions of this subpara-
11 graph with respect to discharges by eligible hospitals that
12 involve new antimicrobial drugs in the amount, subject to
13 clause (vi), provided for under section 1847A.

14 “(II) Additional payments to be made under this sub-
15 section shall be with respect to discharges involving a new
16 antimicrobial drug that occur during the four-fiscal-year
17 period beginning on which an inpatient hospital code is
18 issued with respect to the drug.

19 “(ii) For purposes of this subparagraph, the term
20 ‘new antimicrobial drug’ means a product that is approved
21 for use, or a product for which an indication is first ap-
22 proved for use, by the Food and Drug Administration on
23 or after December 1, 2014, and that the Food and Drug
24 Administration determines—

25 “(I) either—

1 “(aa) is intended to treat an infection
2 caused by, or likely to be caused by, a quali-
3 fying pathogen (as defined under section
4 505E(f) of the Federal Food, Drug, and Cos-
5 metic Act); or

6 “(bb) meets the definition of a qualified in-
7 fectious disease product under section 505E(g)
8 of the Federal Food, Drug, and Cosmetic Act;

9 “(II) is intended to treat an infection for which
10 there is an ‘unmet medical need’; and

11 “(III) is intended to treat an infection associ-
12 ated with high rates of mortality or significant pa-
13 tient morbidity, as determined in consultation with
14 the infectious disease professional community.

15 “(iii) For purposes of this subparagraph, the term
16 ‘eligible hospital’ means a hospital that participates in the
17 National Healthcare Safety Network of the Centers for
18 Disease Control and Prevention (or, to the extent a similar
19 surveillance system reporting program that includes re-
20 porting about antimicrobial drugs is determined by the
21 Secretary to be available to such hospitals, such similar
22 surveillance system as the Secretary may specify).

23 “(iv) The Secretary may only revoke a determination
24 of a product under this subparagraph as a new anti-
25 microbial drug if the Secretary finds that the request for

1 such determination contained an untrue statement of ma-
2 terial fact.

3 “(v) Not later than October 1, 2017, the Secretary
4 shall first publish in the Federal Register a list of the new
5 antimicrobial drugs. Each fiscal year thereafter, the Sec-
6 retary shall publish a list of the new antimicrobial drugs
7 for such fiscal year as part of the annual rulemaking
8 under this subsection.

9 “(vi)(I) The total of the additional payments made
10 under this subsection pursuant to this subparagraph for
11 discharges in a fiscal year (as estimated by the Secretary
12 as part of the rulemaking under this subsection for the
13 fiscal year) may not exceed the applicable percentage
14 (specified in subclause (II)) of the total program payments
15 estimated to be made under this subsection for all dis-
16 charges in such fiscal year (as calculated by the Secretary
17 as part of the rulemaking under this subsection for the
18 fiscal year). For purposes of the preceding sentence, in
19 the case that, with respect to a fiscal year, such additional
20 payments are made only with respect to discharges during
21 a portion of such fiscal year, the reference to ‘all dis-
22 charges in such fiscal year’ shall be considered a reference
23 to all discharges during such portion of such fiscal year.

1 “(II) For purposes of subclause (I), the term ‘appli-
2 cable percentage’ means, for fiscal year 2018 and each fis-
3 cal year thereafter, 0.06807 percent.

4 “(III) If the Secretary estimates before the beginning
5 of a fiscal year that the amount of the additional payments
6 under this subsection pursuant to this subparagraph for
7 the fiscal year (or portion thereof) as determined under
8 subclause (I) will exceed the limit established under such
9 subclause, the Secretary shall reduce pro rata the amount
10 of each of the additional payments under this subsection
11 pursuant to this subparagraph for such fiscal year (or por-
12 tion thereof) in order to ensure that the aggregate addi-
13 tional payments under this subsection pursuant to this
14 paragraph (as so estimated) do not exceed such limit.”.

15 (2) CONFORMING AMENDMENTS.—

16 (A) NO DUPLICATIVE NTAP PAYMENTS.—

17 Section 1886(d)(5)(K)(i) of the Social Security
18 Act (42 U.S.C. 1395ww(d)(5)(K)(i)) is amend-
19 ed by inserting “and with respect to which an
20 additional payment is not made pursuant to
21 subparagraph (M),” after “2001,”.

22 (B) ACCESS TO PRICE INFORMATION.—

23 Section 1927(b)(3)(A)(iii) of the Social Security
24 Act (42 U.S.C. 1396r-8(b)(3)(A)(iii)) is
25 amended—

1 (i) in subclause (II), by inserting “, or
2 under section 1886(d) pursuant to para-
3 graph (5)(M) of such section,” after
4 “1847A,”; and

5 (ii) in the matter following subclause
6 (III), by inserting “or section
7 1886(d)(5)(M)” after
8 “1881(b)(13)(A)(ii)”.

9 (b) STUDY AND REPORT ON REMOVING BARRIERS TO
10 DEVELOPMENT OF NEW ANTIMICROBIAL DRUGS.—

11 (1) STUDY.—The Comptroller General of the
12 United States shall conduct a study to—

13 (A) identify and examine the barriers that
14 prevent the development of new antimicrobial
15 drugs, as defined in section 1886(d)(5)(M)(iii)
16 of the Social Security Act (42 U.S.C.
17 1395ww(d)(5)(M)(iii)); and

18 (B) develop recommendations for actions
19 to be taken in order to overcome any barriers
20 identified under subparagraph (A).

21 (2) CONSIDERATION.—In conducting such
22 study, the Comptroller General shall take into ac-
23 count the perspectives of the Director of the Na-
24 tional Institutes of Health, the Commissioner of the

1 Food and Drugs, and the Director of the Centers for
2 Disease Control and Prevention.

3 (3) REPORT.—Not later than 1 year after the
4 date of the enactment of this Act, the Comptroller
5 General shall submit to Congress a report on the
6 study conducted under paragraph (1).

7 **Subtitle H—Vaccine Access,**
8 **Certainty, and Innovation**

9 **SEC. 2141. TIMELY REVIEW OF VACCINES BY THE ADVISORY**
10 **COMMITTEE ON IMMUNIZATION PRACTICES.**

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

14 “(10) ADVISORY COMMITTEE ON IMMUNIZATION
15 PRACTICES.—

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

23 “(B) EXPEDITED REVIEW PURSUANT TO
24 REQUEST BY SPONSOR OR MANUFACTURER.—If
25 the Advisory Committee does not make rec-

1 ommendations with respect to the use of a vac-
2 cine at the Advisory Committee’s first regularly
3 scheduled meeting after the licensure of the
4 vaccine or any new indication for the vaccine,
5 the Advisory Committee, at the request of the
6 sponsor of the vaccine, shall make such rec-
7 ommendations on an expedited basis.

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

17 “(D) DEFINITION.—In this paragraph, the
18 terms ‘Advisory Committee on Immunization
19 Practices’ and ‘Advisory Committee’ mean the
20 advisory committee on immunization practices
21 established by the Secretary pursuant to section
22 222, acting through the Director of the Centers
23 for Disease Control and Prevention.”.

1 **SEC. 2142. REVIEW OF PROCESSES AND CONSISTENCY OF**
2 **ACIP RECOMMENDATIONS.**

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

8 (b) CONSIDERATIONS.—The review under subsection
9 (a) shall include assessment of—

10 (1) the criteria used to evaluate new and exist-
11 ing vaccines;

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

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

21 (c) STAKEHOLDERS.—In carrying out the review
22 under subsection (a), the Director of the Centers for Dis-
23 ease Control and Prevention shall solicit input from vac-
24 cine stakeholders.

25 (d) REPORT.—Not later than 18 months after the
26 date of enactment of this Act, the Director of the Centers

1 for Disease Control and Prevention shall submit to the
2 appropriate committees of the Congress and make publicly
3 available a report on the results of the review under sub-
4 section (a), including recommendations on improving the
5 consistency of the process described in such subsection.

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

13 **SEC. 2143. MEETINGS BETWEEN CDC AND VACCINE DEVEL-**
14 **OPERS.**

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

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

20 “(A)(i) the development of a vaccine with the
21 intent to pursue licensing of the vaccine by the Food
22 and Drug Administration; or

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

25 “(B) vaccine research.

1 “(2)(A) Upon the submission of a written request for
2 a meeting by a vaccine developer, that includes a justifica-
3 tion for the meeting, the Secretary, acting through the Di-
4 rector of the Centers for Disease Control and Prevention,
5 shall convene a meeting of representatives of the vaccine
6 developer and experts from the Centers for Disease Con-
7 trol and Prevention in immunization programs, epidemi-
8 ology, and other relevant areas at which the Director (or
9 the Director’s designee), for the purpose of informing the
10 vaccine developer’s understanding of public health needs
11 and priorities, shall provide the perspectives of the Centers
12 for Disease Control and Prevention and other relevant
13 Federal agencies regarding—

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

17 “(ii) potential implications of such perspectives
18 for the vaccine developer’s vaccine research and de-
19 velopment planning.

20 “(B) In addition to the representatives specified in
21 subparagraph (A), the Secretary may, with the agreement
22 of the vaccine developer requesting a meeting under such
23 subparagraph, include in such meeting representatives
24 of—

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

1 “(ii) the National Vaccine Program.

2 “(C) The Secretary shall convene a meeting re-
3 requested under subparagraph (A) not later than 120 days
4 after receipt of the request for the meeting.

5 “(3)(A) Upon the submission of a written request by
6 a vaccine developer, the Secretary, acting through the Di-
7 rector of the Centers for Disease Control and Prevention,
8 shall provide to the vaccine developer any age-based or
9 other demographically assessed disease epidemiological
10 analyses or data that—

11 “(i) are specified in the request;

12 “(ii) have been published;

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

15 “(iv) are not a trade secret or commercial or fi-
16 nancial information that is privileged or confidential
17 and subject to section 552(b)(4) of title 5, United
18 States Code, or section 1905 of title 18, United
19 States Code; and

20 “(v) do not contain individually identifiable in-
21 formation.

22 “(B) The Secretary shall provide analyses requested
23 by a vaccine manufacturer under subparagraph (A) not
24 later than 120calendar days after receipt of the request
25 for the analyses.

1 “(4) The Secretary shall promptly notify a vaccine
2 developer if—

3 “(A) the Secretary becomes aware of any
4 change to information that was—

5 “(i) shared by the Secretary with the vac-
6 cine developer during a meeting under para-
7 graph (2); or

8 “(ii) provided by the Secretary to the vac-
9 cine developer in one or more analyses under
10 paragraph (3); and

11 “(B) the change may have implications for the
12 vaccine developer’s vaccine research and develop-
13 ment.”.

14 **Subtitle I—Orphan Product Exten-**
15 **sions Now; Incentives for Cer-**
16 **tain Products for Limited Popu-**
17 **lations**

18 **SEC. 2151. EXTENSION OF EXCLUSIVITY PERIODS FOR A**
19 **DRUG APPROVED FOR A NEW INDICATION**
20 **FOR A RARE DISEASE OR CONDITION.**

21 (a) IN GENERAL.—Chapter V of the Federal Food,
22 Drug, and Cosmetic Act, as amended by section 2063, is
23 further amended by inserting after section 505F of such
24 Act the following:

1 **“SEC. 505G. EXTENSION OF EXCLUSIVITY PERIODS FOR A**
2 **DRUG APPROVED FOR A NEW INDICATION**
3 **FOR A RARE DISEASE OR CONDITION.**

4 “(a) DESIGNATION.—

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

10 “(A) prior to approval of an application or
11 supplemental application for the new indication,
12 the drug was approved or licensed for mar-
13 keting under section 505(c) of this Act or sec-
14 tion 351(a) of the Public Health Service Act,
15 but was not so approved or licensed for the new
16 indication;

17 “(B)(i) the sponsor of the approved or li-
18 censed drug files an application or a supple-
19 mental application for approval of the new indi-
20 cation for use of the drug to prevent, diagnose,
21 or treat the rare disease or condition; and

22 “(ii) the Secretary approves the application
23 or supplemental application; and

24 “(C) the application or supplemental appli-
25 cation for the new indication contains the con-
26 sent of the applicant to notice being given by

1 the Secretary under paragraph (4) respecting
2 the designation of the drug.

3 “(2) REVOCATION OF DESIGNATION.—

4 “(A) IN GENERAL.—Except as provided in
5 subparagraph (B), a designation under this
6 subsection shall not be revoked for any reason.

7 “(B) EXCEPTION.—The Secretary may re-
8 voke a designation of a drug under paragraph
9 (1) if the Secretary finds that the application or
10 supplemental application resulting in such des-
11 ignation contained an untrue statement of ma-
12 terial fact.

13 “(3) NOTIFICATION PRIOR TO DISCONTINUANCE
14 OF PRODUCTION FOR SOLELY COMMERCIAL REA-
15 SONS.—A designation of a drug under paragraph (1)
16 shall be subject to the condition that the sponsor of
17 the drug will notify the Secretary of any discontinu-
18 ance of the production of the drug for solely com-
19 mercial reasons at least one year before such dis-
20 continuance.

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

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

4 “(1)(A) the 4-, 5-, and 7 ½-year periods de-
5 scribed in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii)
6 of section 505, the 3-year periods described in
7 clauses (iii) and (iv) of subsection (c)(3)(E) and
8 clauses (iii) and (iv) of subsection (j)(5)(F) of sec-
9 tion 505, and the 7-year period described in section
10 527, as applicable, shall be extended by 6 months;
11 or

12 “(B) the 4- and 12-year periods described in
13 subparagraphs (A) and (B) of section 351(k)(7) of
14 the Public Health Service Act and the 7-year period
15 described in section 527, as applicable, shall be ex-
16 tended by 6 months; and

17 “(2)(A) if the drug is the subject of a listed
18 patent for which a certification has been submitted
19 under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of
20 section 505 or a listed patent for which a certifi-
21 cation has been submitted under subsections
22 (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,
23 the period during which an application may not be
24 approved under section 505(c)(3) or section
25 505(j)(5)(B) shall be extended by a period of 6

1 months after the date the patent expires (including
2 any patent extensions); or

3 “(B) if the drug is the subject of a listed patent
4 for which a certification has been submitted under
5 subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of sec-
6 tion 505, and in the patent infringement litigation
7 resulting from the certification the court determines
8 that the patent is valid and would be infringed, the
9 period during which an application may not be ap-
10 proved 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).

14 “(c) RELATION TO PEDIATRIC AND QUALIFIED IN-
15 FECTIOUS DISEASE PRODUCT EXCLUSIVITY.—Any exten-
16 sion under subsection (b) of a period shall be in addition
17 to any extension of the periods under sections 505A and
18 505E of this Act and section 351(m) of the Public Health
19 Service Act, as applicable, with respect to the drug.

20 “(d) LIMITATIONS.—The extension described in sub-
21 section (b) shall not apply if the drug designated under
22 subsection (a)(1) has previously received an extension by
23 operation of subsection (b).

1 “(e) DEFINITION.—In this section, the term ‘rare
2 disease or condition’ has the meaning given to such term
3 in section 526(a)(2).”.

4 (b) APPLICATION.—Section 505G of the Federal
5 Food, Drug, and Cosmetic Act, as added by subsection
6 (a), applies only with respect to a drug for which an appli-
7 cation or supplemental application described in subsection
8 (a)(1)(B)(i) of such section 505G is first approved under
9 section 505(c) of such Act (21 U.S.C. 355(c)) or section
10 351(a) of the Public Health Service Act (42 U.S.C.
11 262(a)) on or after the date of the enactment of this Act.

12 (c) CONFORMING AMENDMENTS.—

13 (1) RELATION TO PEDIATRIC EXCLUSIVITY FOR
14 DRUGS.—Section 505A of the Federal Food, Drug,
15 and Cosmetic Act (21 U.S.C. 355a) is amended—

16 (A) in subsection (b), by adding at the end
17 the following:

18 “(3) RELATION TO EXCLUSIVITY FOR A DRUG
19 APPROVED FOR A NEW INDICATION FOR A RARE DIS-
20 EASE OR CONDITION.—Notwithstanding the ref-
21 erences in subsection (b)(1) to the lengths of the ex-
22 clusivity periods after application of pediatric exclu-
23 sivity, the 6-month extensions described in sub-
24 section (b)(1) shall be in addition to any extensions
25 under section 505G.”; and

1 (B) in subsection (c), by adding at the end
2 the following:

3 “(3) RELATION TO EXCLUSIVITY FOR A DRUG
4 APPROVED FOR A NEW INDICATION FOR A RARE DIS-
5 EASE OR CONDITION.—Notwithstanding the ref-
6 erences in subsection (c)(1) to the lengths of the ex-
7 clusivity periods after application of pediatric exclu-
8 sivity, the 6-month extensions described in sub-
9 section (c)(1) shall be in addition to any extensions
10 under section 505G.”.

11 (2) RELATION TO EXCLUSIVITY FOR NEW
12 QUALIFIED INFECTIOUS DISEASE PRODUCTS THAT
13 ARE DRUGS.—Subsection (b) of section 505E of the
14 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 355f) is amended—

16 (A) by amending the subsection heading to
17 read as follows: “RELATION TO PEDIATRIC EX-
18 CLUSIVITY AND EXCLUSIVITY FOR A DRUG AP-
19 PROVED FOR A NEW INDICATION FOR A RARE
20 DISEASE OR CONDITION”; and

21 (B) by striking “any extension of the pe-
22 riod under section 505A” and inserting “any
23 extension of the periods under sections 505A
24 and 505G, as applicable,”.

1 (3) RELATION TO PEDIATRIC EXCLUSIVITY FOR
2 BIOLOGICAL PRODUCTS.—Section 351(m) of the
3 Public Health Service Act (42 U.S.C. 262(m)) is
4 amended by adding at the end the following:

5 “(5) RELATION TO EXCLUSIVITY FOR A BIO-
6 LOGICAL PRODUCT APPROVED FOR A NEW INDICA-
7 TION FOR A RARE DISEASE OR CONDITION.—Not-
8 withstanding the references in paragraphs (2)(A),
9 (2)(B), (3)(A), and (3)(B) to the lengths of the ex-
10 clusivity periods after application of pediatric exclu-
11 sivity, the 6-month extensions described in such
12 paragraphs shall be in addition to any extensions
13 under section 505G.”.

14 **SEC. 2152. REAUTHORIZATION OF RARE PEDIATRIC DIS-**
15 **EASE PRIORITY REVIEW VOUCHER INCEN-**
16 **TIVE PROGRAM.**

17 (a) IN GENERAL.—Section 529 of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 360ff) is amended—

19 (1) in subsection (a)—

20 (A) in paragraph (3), by amending sub-
21 paragraph (A) to read as follows:

22 “(A) The disease is a serious or life-threat-
23 ening disease in which the serious or life-threat-
24 ening manifestations primarily affect individ-
25 uals aged from birth to 18 years, including age

1 groups often called neonates, infants, children,
2 and adolescents.”; and

3 (B) in paragraph (4)(A)—

4 (i) in subparagraph (E), by striking
5 “and”;

6 (ii) in subparagraph (F), by striking
7 the period and inserting “; and”; and

8 (iii) by adding at the end the fol-
9 lowing:

10 “(G) is for a drug or biological product for
11 which a priority review voucher has not been
12 issued under section 524 (relating to tropical
13 disease products).”; and

14 (2) in subsection (b), by striking paragraph (5)
15 and inserting the following:

16 “(5) TERMINATION OF AUTHORITY.—The Sec-
17 retary may not award any priority review vouchers
18 under paragraph (1) after December 31, 2018.”.

19 (b) GAO STUDY AND REPORT.—

20 (1) STUDY.—The Comptroller General of the
21 United States shall conduct a study on the effective-
22 ness of awarding priority review vouchers under sec-
23 tion 529 of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 360ff) in providing incentives for the
25 development of drugs that treat or prevent rare pe-

1 diatric diseases that would not otherwise have been
2 developed. In conducting such study, the Comp-
3 troller General shall examine the following:

4 (A) The indications for which each drug
5 for which a priority review voucher was award-
6 ed under such section 529 was approved under
7 section 505 of such Act (21 U.S.C. 355) or sec-
8 tion 351 of the Public Health Service Act (42
9 U.S.C. 262).

10 (B) Whether the priority review voucher
11 impacted a sponsor's decision to invest in devel-
12 oping a drug to treat or prevent a rare pedi-
13 atric disease.

14 (C) An analysis of the drugs that utilized
15 such priority review vouchers, which shall in-
16 clude—

17 (i) the indications for which such
18 drugs were approved under section 505 of
19 the Federal Food, Drug, and Cosmetic Act
20 (21 U.S.C. 355) or section 351 of the Pub-
21 lic Health Service Act (42 U.S.C. 262);

22 (ii) whether unmet medical needs were
23 addressed through the approval of such
24 drugs, including, for each such drug—

1 (I) if an alternative therapy was
2 previously available to treat the indi-
3 cation; and

4 (II) the benefit or advantage the
5 drug provided over another available
6 therapy;

7 (iii) the number of patients potentially
8 treated by such drugs;

9 (iv) the value of the priority review
10 voucher if transferred; and

11 (v) the length of time between the
12 date on which a priority review voucher
13 was awarded and the date on which it was
14 used.

15 (D) With respect to the priority review
16 voucher program under section 529 of the Fed-
17 eral Food, Drug, and Cosmetic Act (21 U.S.C.
18 360ff)—

19 (i) the resources used by, and burden
20 placed on, the Food and Drug Administra-
21 tion in implementing such program, includ-
22 ing the effect of such program on the Food
23 and Drug Administration's review of drugs
24 for which a priority review voucher was not
25 awarded or used;

1 (ii) the impact of the priority review
2 voucher program on the public health as a
3 result of the expedited review of applica-
4 tions for drugs that treat or prevent non-
5 serious indications that are generally used
6 by the broader public; and

7 (iii) alternative approaches to improv-
8 ing such program so that the program is
9 appropriately targeted towards providing
10 incentives for the development of clinically
11 important drugs that—

12 (I) prevent or treat rare pediatric
13 diseases; and

14 (II) would likely not otherwise
15 have been developed to prevent or
16 treat such diseases.

17 (2) REPORT.—Not later than December 31,
18 2017, the Comptroller General of the United States
19 shall submit to the Committee on Energy and Com-
20 merce of the House of Representatives and the Com-
21 mittee on Health, Education, Labor and Pensions of
22 the Senate a report containing the results of the
23 study of conducted under paragraph (1).

1 **Subtitle J—Domestic Manufac-**
2 **turing and Export Efficiencies**

3 **SEC. 2161. GRANTS FOR STUDYING THE PROCESS OF CON-**
4 **TINUOUS DRUG MANUFACTURING.**

5 (a) IN GENERAL.—The Commissioner of Food and
6 Drugs may award grants to institutions of higher edu-
7 cation and nonprofit organizations for the purpose of
8 studying and recommending improvements to the process
9 of continuous manufacturing of drugs and biological prod-
10 ucts and similar innovative monitoring and control tech-
11 niques.

12 (b) DEFINITIONS.—In this section:

13 (1) The term “drug” has the meaning given to
14 such term in section 201 of the Federal Food, Drug,
15 and Cosmetic Act (21 U.S.C. 321).

16 (2) The term “biological product” has the
17 meaning given to such term in section 351(i) of the
18 Public Health Service Act (42 U.S.C. 262(i)).

19 (3) The term “institution of higher education”
20 has the meaning given to such term in section 101
21 of the Higher Education Act of 1965 (20 U.S.C.
22 1001).

23 (c) AUTHORIZATION OF APPROPRIATIONS.—There is
24 authorized to be appropriated \$5,000,000 for each of fis-
25 cal years 2016 through 2020 to carry out this section.

1 **SEC. 2162. RE-EXPORTATION AMONG MEMBERS OF THE EU-**
2 **ROPEAN ECONOMIC AREA.**

3 Section 1003 of the Controlled Substances Import
4 and Export Act (21 U.S.C. 953) is amended—

5 (1) in subsection (f)—

6 (A) in paragraph (5)—

7 (i) by striking “(5)” and inserting
8 “(5)(A)”;

9 (ii) by inserting “, except that the
10 controlled substance may be exported from
11 the second country to another country that
12 is a member of the European Economic
13 Area” before the period at the end; and

14 (iii) by adding at the end the fol-
15 lowing:

16 “(B) Subsequent to any re-exportation de-
17 scribed in subparagraph (A), a controlled substance
18 may continue to be exported from any country that
19 is a member of the European Economic Area to any
20 other such country, provided that—

21 “(i) the conditions applicable with respect
22 to the first country under paragraphs (1), (2),
23 (3), (4), (6), and (7) are met by each subse-
24 quent country from which the controlled sub-
25 stance is exported pursuant to this paragraph;
26 and

1 “(ii) the conditions applicable with respect
2 to the second country under such paragraphs
3 are met by each subsequent country to which
4 the controlled substance is exported pursuant to
5 this paragraph.”; and

6 (B) in paragraph (6)—

7 (i) by striking “(6)” and inserting
8 “(6)(A)”; and

9 (ii) by adding at the end the fol-
10 lowing:

11 “(B) In the case of re-exportation among mem-
12 bers of the European Economic Area, within 30
13 days after each re-exportation, the person who ex-
14 ported the controlled substance from the United
15 States delivers to the Attorney General—

16 “(i) documentation certifying that such re-
17 exportation has occurred; and

18 “(ii) information concerning the consignee,
19 country, and product.”; and

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

21 “(g) LIMITATION.—The Attorney General shall not
22 promulgate nor enforce any regulation, subregulatory
23 guidance, or enforcement policy which impedes re-expor-
24 tation among European Economic Area countries (as pro-

1 vided in subsection (f)(5)), including by promulgating or
2 enforcing any requirement that—

3 “(1) re-exportation from the first country to the
4 second country or re-exportation from the second
5 country to another country (as such terms are used
6 in subsection (f)) occur within a specified period of
7 time; or

8 “(2) information concerning the consignee,
9 country, and product be provided prior to expor-
10 tation of the controlled substance from the United
11 States or prior to each re-exportation among mem-
12 bers of the European Economic Area.”.

13 **Subtitle K—Enhancing** 14 **Combination Products Review**

15 **SEC. 2181. ENHANCING COMBINATION PRODUCTS REVIEW.**

16 Section 503(g)(4)(C) of the Federal Food, Drug, and
17 Cosmetic Act (21 U.S.C. 353(g)(4)(C)) is amended by
18 adding at the end the following new clause:

19 “(iii) Not later than 18 months after the date
20 of the enactment of the 21st Century Cures Act, the
21 Secretary shall issue final guidance that describes
22 the responsibilities of each agency center regarding
23 its review of combination products. The Secretary
24 shall, after soliciting public comment, review and up-
25 date the guidance periodically.”.

1 **Subtitle L—Priority Review for**
2 **Breakthrough Devices**

3 **SEC. 2201. PRIORITY REVIEW FOR BREAKTHROUGH DE-**
4 **VICES.**

5 (a) IN GENERAL.—Chapter V of the Federal Food,
6 Drug, and Cosmetic Act is amended—

7 (1) in section 515(d)—

8 (A) by striking paragraph (5); and

9 (B) by redesignating paragraph (6) as
10 paragraph (5); and

11 (2) by inserting after section 515A (21 U.S.C.
12 360e–1) the following:

13 **“SEC. 515B. PRIORITY REVIEW FOR BREAKTHROUGH DE-**
14 **VICES.**

15 “(a) IN GENERAL.—In order to provide for more ef-
16 fective treatment or diagnosis of life-threatening or irre-
17 versibly debilitating human diseases or conditions, the
18 Secretary shall establish a program to provide priority re-
19 view for devices—

20 “(1) representing breakthrough technologies;

21 “(2) for which no approved alternatives exist;

22 “(3) offering significant advantages over exist-
23 ing approved or cleared alternatives, including the
24 potential to, compared to existing approved or
25 cleared alternatives, reduce or eliminate the need for

1 hospitalization, improve patient quality of life, facili-
2 tate patients' ability to manage their own care (such
3 as through self-directed personal assistance), or es-
4 tablish long-term clinical efficiencies; or

5 “(4) the availability of which is in the best in-
6 terest of patients.

7 “(b) REQUEST FOR DESIGNATION.—A sponsor of a
8 device may request that the Secretary designate the device
9 for priority review under this section. Any such request
10 for designation may be made at any time prior to the sub-
11 mission of an application under section 515(c), a petition
12 for classification under section 513(f)(2), or a notification
13 under section 510(k).

14 “(c) DESIGNATION PROCESS.—

15 “(1) IN GENERAL.—Not later than 60 calendar
16 days after the receipt of a request under subsection
17 (b), the Secretary shall determine whether the device
18 that is the subject of the request meets the criteria
19 described in subsection (a). If the Secretary deter-
20 mines that the device meets the criteria, the Sec-
21 retary shall designate the device for priority review.

22 “(2) REVIEW.—Review of a request under sub-
23 section (b) shall be undertaken by a team that is
24 composed of experienced staff and managers of the

1 Food and Drug Administration and is chaired by a
2 senior manager.

3 “(3) DESIGNATION DETERMINATION.—A deter-
4 mination approving or denying a request under sub-
5 section (b) shall be considered a significant decision
6 under section 517A and the Secretary shall provide
7 a written, substantive summary of the basis for the
8 determination in accordance with section 517A(a).

9 “(4) RECONSIDERATION.—

10 “(A) REQUEST FOR RECONSIDERATION.—
11 Any person whose request under subsection (b)
12 is denied may, within 30 days of the denial, re-
13 quest reconsideration of the denial in accord-
14 ance with section 517A(b)—

15 “(i) based upon the submission of
16 documents by such person; or

17 “(ii) based upon such documents and
18 a meeting or teleconference.

19 “(B) RESPONSE.—Reconsideration of a
20 designation determination under this paragraph
21 shall be conducted in accordance with section
22 517A(b).

23 “(5) WITHDRAWAL.—If the Secretary approves
24 a priority review designation for a device under this
25 section, the Secretary may not withdraw the des-

1 ignation based on the fact that the criteria specified
2 in subsection (a) are no longer met because of the
3 subsequent clearance or approval of another device
4 that was designated under—

5 “(A) this section; or

6 “(B) section 515(d)(5) (as in effect imme-
7 diately prior to the enactment of the 21st Cen-
8 tury Cures Act).

9 “(d) PRIORITY REVIEW.—

10 “(1) ACTIONS.—For purposes of expediting the
11 development and review of devices designated under
12 subsection (c), the Secretary shall—

13 “(A) assign a team of staff, including a
14 team leader with appropriate subject matter ex-
15 pertise and experience, for each device for
16 which a request is submitted under subsection
17 (b);

18 “(B) provide for oversight of the team by
19 senior agency personnel to facilitate the effi-
20 cient development of the device and the efficient
21 review of any submission described in sub-
22 section (b) for the device;

23 “(C) adopt an efficient process for timely
24 dispute resolution;

1 “(D) provide for interactive communication
2 with the sponsor of the device during the review
3 process;

4 “(E) expedite the Secretary’s review of
5 manufacturing and quality systems compliance,
6 as applicable;

7 “(F) disclose to the sponsor in advance the
8 topics of any consultation concerning the spon-
9 sor’s device that the Secretary intends to under-
10 take with external experts or an advisory com-
11 mittee and provide the sponsor an opportunity
12 to recommend such external experts;

13 “(G) for applications submitted under sec-
14 tion 515(c), provide for advisory committee
15 input, as the Secretary determines appropriate
16 (including in response to the request of the
17 sponsor); and

18 “(H) assign staff to be available within a
19 reasonable time to address questions by institu-
20 tional review committees concerning the condi-
21 tions and clinical testing requirements applica-
22 ble to the investigational use of the device pur-
23 suant to an exemption under section 520(g).

24 “(2) ADDITIONAL ACTIONS.—In addition to the
25 actions described in paragraph (1), for purposes of

1 expediting the development and review of devices
2 designated under subsection (c), the Secretary, in
3 collaboration with the device sponsor, may, as appro-
4 priate—

5 “(A) coordinate with the sponsor regarding
6 early agreement on a data development plan;

7 “(B) take steps to ensure that the design
8 of clinical trials is as efficient as practicable,
9 such as through adoption of shorter or smaller
10 clinical trials, application of surrogate
11 endpoints, and use of adaptive trial designs and
12 Bayesian statistics, to the extent scientifically
13 appropriate;

14 “(C) facilitate, to the extent scientifically
15 appropriate, expedited and efficient develop-
16 ment and review of the device through utiliza-
17 tion of timely postmarket data collection, with
18 regard to applications for approval under sec-
19 tion 515(c); and

20 “(D) agree to clinical protocols that the
21 Secretary will consider binding on the Secretary
22 and the sponsor, subject to—

23 “(i) changes agreed to by the sponsor
24 and the Secretary;

1 “(ii) changes that the Secretary deter-
2 mines are required to prevent an unreason-
3 able risk to the public health; or

4 “(iii) the identification of a substan-
5 tial scientific issue determined by the Sec-
6 retary to be essential to the safety or effec-
7 tiveness of the device involved.

8 “(e) PRIORITY REVIEW GUIDANCE.—

9 “(1) CONTENT.—The Secretary shall issue
10 guidance on the implementation of this section. Such
11 guidance shall include the following:

12 “(A) The process for a person to seek a
13 priority review designation.

14 “(B) A template for requests under sub-
15 section (b).

16 “(C) The criteria the Secretary will use in
17 evaluating a request for priority review.

18 “(D) The standards the Secretary will use
19 in assigning a team of staff, including team
20 leaders, to review devices designated for priority
21 review, including any training required for such
22 personnel on effective and efficient review.

23 “(2) PROCESS.—Prior to finalizing the guid-
24 ance under paragraph (1), the Secretary shall pro-
25 pose such guidance for public comment.

1 “(f) CONSTRUCTION.—

2 “(1) PURPOSE.—This section is intended to en-
3 courage the Secretary and provide the Secretary suf-
4 ficient authorities to apply efficient and flexible ap-
5 proaches to expedite the development of, and
6 prioritize the agency’s review of, devices that rep-
7 resent breakthrough technologies.

8 “(2) CONSTRUCTION.—Nothing in this section
9 shall be construed to alter the criteria and standards
10 for evaluating an application pursuant to section
11 515(c), a report and request for classification under
12 section 513(f)(2), or a report under section 510(k),
13 including the recognition of valid scientific evidence
14 as described in section 513(a)(3)(B), and consider-
15 ation of the least burdensome means of evaluating
16 device effectiveness or demonstrating substantial
17 equivalence between devices with differing techno-
18 logical characteristics, as applicable. Nothing in this
19 section alters the authority of the Secretary to act
20 on an application pursuant to section 515(d) before
21 completion of an establishment inspection, as the
22 Secretary deems appropriate.”.

23 (b) CONFORMING AMENDMENT RELATED TO DES-
24 IGNATION DETERMINATIONS.—Section 517A(a)(1) of the
25 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–

1 1(a)(1)) is amended by inserting “a request for designa-
2 tion under section 515B,” after “an application under sec-
3 tion 515,”.

4 **Subtitle M—Medical Device**
5 **Regulatory Process Improvements**

6 **SEC. 2221. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

7 (a) ESTABLISHMENT OF THIRD-PARTY QUALITY
8 SYSTEM ASSESSMENT PROGRAM.—Chapter V of the Fed-
9 eral Food, Drug, and Cosmetic Act is amended by insert-
10 ing after section 524A (21 U.S.C. 360n–1) the following
11 new section:

12 **“SEC. 524B. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

13 **“(a) ACCREDITATION AND ASSESSMENT.—**

14 **“(1) IN GENERAL; CERTIFICATION OF DEVICE**
15 **QUALITY SYSTEM.—**The Secretary shall, in accord-
16 ance with this section, establish a third-party quality
17 system assessment program—

18 **“(A) to accredit persons to assess whether**
19 **a requestor’s quality system, including its de-**
20 **sign controls, can reasonably assure the safety**
21 **and effectiveness of in-scope devices subject to**
22 **device-related changes (as defined in paragraph**
23 **(2));**

24 **“(B) under which accredited persons shall,**
25 **as applicable, certify that a requestor’s quality**

1 system meets the criteria issued under para-
2 graph (5) with respect to the in-scope devices at
3 issue; and

4 “(C) under which the Secretary shall rely
5 on such certifications for purposes of deter-
6 mining the safety and effectiveness of in-scope
7 devices subject to the device-related changes in-
8 volved, in lieu of compliance with the following
9 submission requirements:

10 “(i) A thirty-day notice (as defined in
11 paragraph (2)).

12 “(ii) A Special PMA supplement (as
13 defined in paragraph (2)).

14 “(2) DEFINITIONS.—For purposes of this sec-
15 tion—

16 “(A) the term ‘device-related changes’
17 means changes made by a requestor with re-
18 spect to in-scope devices, which are—

19 “(i) manufacturing changes subject to
20 a 30-day notice;

21 “(ii) changes that qualify for a Spe-
22 cial PMA supplement; and

23 “(iii) such other changes relating to
24 the devices or the device manufacturing

1 process as the Secretary determines appro-
2 priate;

3 “(B) the term ‘in-scope device’ means a
4 device within the scope of devices agreed to by
5 the requestor and the accredited person for pur-
6 poses of a request for certification under this
7 section;

8 “(C) the term ‘quality system’ means a
9 quality system described in section 520(f);

10 “(D) the term ‘requestor’ means a device
11 manufacturer that is seeking certification under
12 this section of a quality system used by such
13 manufacturer;

14 “(E) the term ‘Special PMA’ means a Spe-
15 cial PMA supplement under section 814.39(d)
16 of title 21, Code of Federal Regulations (or any
17 successor regulations); and

18 “(F) the term ‘thirty-day notice’ means a
19 notice described in section 515(d)(6).

20 “(3) ACCREDITATION PROCESS; ACCREDITATION
21 RENEWAL.—Except as inconsistent with this section,
22 the process and qualifications for accreditation of
23 persons and renewal of such accreditation under sec-
24 tion 704(g) shall apply with respect to accreditation

1 of persons and renewal of such accreditation under
2 this section.

3 “(4) USE OF ACCREDITED PARTIES TO CON-
4 DUCT ASSESSMENTS.—

5 “(A) INITIATION OF ASSESSMENT SERV-
6 ICES.—

7 “(i) DATE ASSESSMENTS AUTHOR-
8 IZED.—Beginning after issuance of the
9 final guidance under paragraph (5), an ac-
10 credited person may conduct an assess-
11 ment under this section.

12 “(ii) INITIATION OF ASSESSMENTS.—
13 Use of one or more accredited persons to
14 assess a requestor’s quality system under
15 this section with respect to in-scope devices
16 shall be at the initiation of the person who
17 registers and lists the devices at issue
18 under section 510.

19 “(B) COMPENSATION.—Compensation for
20 such accredited persons shall—

21 “(i) be determined by agreement be-
22 tween the accredited person and the person
23 who engages the services of the accredited
24 person; and

1 “(ii) be paid by the person who en-
2 gages such services.

3 “(C) ACCREDITED PERSON SELECTION.—
4 Each person who chooses to use an accredited
5 person to assess a requestor’s quality system,
6 as described in this section, shall select the ac-
7 credited person from a list of such persons pub-
8 lished by the Secretary in accordance with sec-
9 tion 704(g)(4).

10 “(5) GUIDANCE; CRITERIA FOR CERTIFI-
11 CATION.—

12 “(A) IN GENERAL.—The criteria for cer-
13 tification of a quality system under this section
14 shall be as specified by the Secretary in guid-
15 ance issued under this paragraph.

16 “(B) CONTENTS; CERTIFICATION CRI-
17 TERIA.—The guidance under this paragraph
18 shall include specification of—

19 “(i) evaluative criteria to be used by
20 an accredited person to assess and as ap-
21 plicable certify a requestor’s quality system
22 under this section with respect to in-scope
23 devices ; and

1 “(ii) criteria for accredited persons to
2 apply a waiver of and exemptions from the
3 certification criteria under clause (i).

4 “(C) TIMEFRAME FOR ISSUING GUID-
5 ANCE.—The Secretary shall issue under this
6 paragraph—

7 “(i) draft guidance not later than 12
8 months after the enactment of the 21st
9 Century Cures Act; and

10 “(ii) final guidance not later than 12
11 months after issuance of the draft guid-
12 ance under clause (i).

13 “(b) USE OF THIRD-PARTY ASSESSMENT.—

14 “(1) ASSESSMENT SUMMARY; CERTIFI-
15 CATION.—

16 “(A) SUBMISSION OF ASSESSMENT TO SEC-
17 RETARY.—An accredited person who assesses a
18 requestor’s quality system under subsection (a)
19 shall submit to the Secretary a summary of the
20 assessment—

21 “(i) within 30 days of the assessment;
22 and

23 “(ii) which as applicable shall in-
24 clude—

1 “(I) the accredited person’s cer-
2 tification that the requestor has satis-
3 fied the criteria issued under sub-
4 section (a)(5) for quality system cer-
5 tification with respect to the in-scope
6 devices at issue; and

7 “(II) any waivers or exemptions
8 from such criteria applied by the ac-
9 credited person.

10 “(B) TREATMENT OF ASSESSMENTS.—
11 Subject to action by the Secretary under sub-
12 paragraph (C), with respect to assessments
13 which include a certification under this sec-
14 tion—

15 “(i) the Secretary’s review of the as-
16 sessment summary shall be deemed com-
17 plete on the day that is 30 days after the
18 date on which the Secretary receives the
19 summary under subparagraph (A); and

20 “(ii) the assessment summary and
21 certification of the requestor shall be
22 deemed accepted by the Secretary on such
23 30th day.

24 “(C) ACTIONS BY SECRETARY.—

1 “(i) IN GENERAL.—Within 30 days of
2 receiving an assessment summary and cer-
3 tification under subparagraph (A), the Sec-
4 retary may, by written notice to the ac-
5 credited person submitting such assess-
6 ment certification, deem any such certifi-
7 cation to be provisional beyond such 30-
8 day period, suspended pending further re-
9 view by the Secretary, or otherwise quali-
10 fied or cancelled, based on the Secretary’s
11 determination that (as applicable)—

12 “(I) additional information is
13 needed to support such certification;

14 “(II) such assessment or certifi-
15 cation is unwarranted; or

16 “(III) such action with regard to
17 the certification is otherwise justified
18 according to such factors and criteria
19 as the Secretary finds appropriate.

20 “(ii) ACCEPTANCE OF CERTIFI-
21 CATION.—If following action by the Sec-
22 retary under clause (i) with respect to a
23 certification, the Secretary determines that
24 such certification is acceptable, the Sec-
25 retary shall issue written notice to the ap-

1 plicable accredited person indicating such
2 acceptance.

3 “(2) NOTIFICATIONS TO SECRETARY BY CER-
4 TIFIED MANUFACTURERS FOR PROGRAM EVALUA-
5 TION PURPOSES.—

6 “(A) PERIODIC NOTIFICATION FOR MANU-
7 FACTURING CHANGES OTHERWISE SUBJECT TO
8 THIRTY-DAY NOTICE.—A requestor certified
9 under this section that effectuates device-re-
10 lated changes with respect to in-scope devices,
11 without prior submission of a thirty-day notice,
12 shall provide notification to the Secretary of
13 such changes in the requestor’s next periodic
14 report under section 814.84(b) of title 21, Code
15 of Federal Regulations (or any successor regu-
16 lation). Such notification shall—

17 “(i) describe the changes made; and

18 “(ii) indicate the effective dates of
19 such changes.

20 “(B) PERIODIC NOTIFICATION FOR DE-
21 VICE-RELATED CHANGES OTHERWISE SUBJECT
22 TO SPECIAL PMA SUPPLEMENT.—A requestor
23 certified under this section that effectuates de-
24 vice-related changes with respect to in-scope de-
25 vices, without prior submission of a Special

1 PMA Supplement, shall provide notification to
2 the Secretary of such changes in the requestor's
3 next periodic report under section 814.84(b) of
4 title 21, Code of Federal Regulations (or any
5 successor regulation). Such notification shall—

6 “(i) describe the changes made, in-
7 cluding a full explanation of the basis for
8 the changes; and

9 “(ii) indicate the effective dates of
10 such changes.

11 “(C) USE OF NOTIFICATIONS FOR PRO-
12 GRAM EVALUATION PURPOSES.—Information
13 submitted to the Secretary under subpara-
14 graphs (A) and (B) shall be used by the Sec-
15 retary for purposes of the program evaluation
16 under subsection (d).

17 “(c) DURATION AND EFFECT OF CERTIFICATION.—
18 A certification under this section—

19 “(1) shall remain in effect for a period of two
20 years from the date such certification is accepted by
21 the Secretary, subject to paragraph (6);

22 “(2) may be renewed through the process de-
23 scribed in subsection (a)(3);

24 “(3) shall continue to apply with respect to de-
25 vice-related changes made during such 2-year period,

1 provided the certification remains in effect, irrespec-
2 tive of whether such certification is renewed after
3 such 2-year period;

4 “(4) shall have no effect on the need to comply
5 with applicable submission requirements specified in
6 subsection (a)(1)(C) with respect to any change per-
7 taining to in-scope devices which is not a device-re-
8 lated change under subsection (a)(2);

9 “(5) shall have no effect on the authority of the
10 Secretary to conduct an inspection or otherwise de-
11 termine the requestor’s conformance with the appli-
12 cable requirements of this Act; and

13 “(6) shall be considered to be revoked if the
14 Secretary provides written notification to the cer-
15 tified requestor that its quality system does not sat-
16 isfy the certification criteria issued under subsection
17 (a)(5) with respect to the in-scope devices at issue,
18 such that the applicable submission requirements
19 specified in subsection (a)(1)(C) must be met for
20 changes made after receipt of such written notifica-
21 tion, with respect to such devices.

22 “(d) PROGRAM EVALUATION; SUNSET.—

23 “(1) PROGRAM EVALUATION AND REPORT.—

24 “(A) EVALUATION.—The Secretary shall
25 complete an evaluation of the third-party qual-

1 ity system assessment program under this sec-
2 tion no later than January 31, 2021, based
3 on—

4 “(i) analysis of information from a
5 representative group of device manufactur-
6 ers obtained from notifications provided by
7 certified requestors under subsection
8 (b)(2); and

9 “(ii) such other available information
10 and data as the Secretary determines ap-
11 propriate.

12 “(B) REPORT.—No later than 1 year after
13 completing the evaluation under subparagraph
14 (A), the Secretary shall issue a report of the
15 evaluation’s findings on the website of the Food
16 and Drug Administration, which shall include
17 the Secretary’s recommendations with respect
18 to continuation and as applicable expansion of
19 the program under this section to include addi-
20 tional types of submissions and additional types
21 of changes beyond those identified in subsection
22 (a)(1)(C), including changes to devices cleared
23 under section 510(k). At the discretion of the
24 Secretary, the program may be expanded prior
25 to January 31, 2021.

1 “(2) SUNSET.—This section shall cease to be
2 effective October 1, 2022.

3 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-
4 tion shall be construed to limit the authority of the Sec-
5 retary to request and review the complete assessment of
6 a certified requestor under this section on a for-cause
7 basis.”.

8 (b) CONFORMING AMENDMENTS.—

9 (1) REQUIREMENTS FOR PREMARKET AP-
10 PROVAL SUPPLEMENTS.—Section 515(d)(6)(A)(i) of
11 the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 360e(d)(6)(A)(i)) is amended by inserting “,
13 subject to section 524B,” after “that affects safety
14 or effectiveness”.

15 (2) REQUIREMENTS FOR THIRTY-DAY NO-
16 TICE.—Section 515(d)(6)(A)(ii) of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C.
18 360e(d)(6)(A)(ii)) is amended by inserting “, subject
19 to section 524B,” after “the date on which the Sec-
20 retary receives the notice”.

21 **SEC. 2222. VALID SCIENTIFIC EVIDENCE.**

22 Section 513(a)(3)(B) of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 360c(a)(3)(B)) is amended—

24 (1) by redesignating clauses (i) and (ii) as sub-
25 clauses (I) and (II), respectively;

1 (2) by striking “(B) If the Secretary” and in-
2 serting “(B)(i) If the Secretary”; and

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

4 “(ii) Valid scientific evidence for purposes
5 of clause (i) may include:

6 “(I) evidence described in well-docu-
7 mented case histories, including registry
8 data, that are collected and monitored
9 under an acceptable protocol;

10 “(II) studies published in peer-re-
11 viewed journals; and

12 “(III) data collected in countries other
13 than the United States so long as such
14 data otherwise meets the criteria specified
15 in this subparagraph.

16 “(iii) In the case of a study published in
17 a peer-reviewed journal that is offered as valid
18 scientific evidence for purposes of clause (i), the
19 Secretary may request data underlying the
20 study if—

21 “(I) the Secretary, in making such re-
22 quest, complies with the requirement of
23 subparagraph (D)(ii) to consider the least
24 burdensome appropriate means of evalu-
25 ating device effectiveness or subsection

1 (i)(1)(D) to consider the least burdensome
2 means of determining substantial equiva-
3 lence, as applicable;

4 “(II) the Secretary furnishes a written
5 rationale for so requesting the underlying
6 data together with such request; and

7 “(III) if the requested underlying data
8 for such a study are unavailable, the Sec-
9 retary shall consider such study to be part
10 of the totality of the evidence with respect
11 to the device, as the Secretary determines
12 appropriate.”.

13 **SEC. 2223. TRAINING AND OVERSIGHT IN LEAST BURDEN-**
14 **SOME APPROPRIATE MEANS CONCEPT.**

15 (a) IN GENERAL.— Section 513 of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by
17 inserting after subsection (i) the following:

18 “(j) TRAINING AND OVERSIGHT IN LEAST BURDEN-
19 SOME APPROPRIATE MEANS CONCEPT.—

20 “(1) TRAINING.—Each employee of the Food
21 and Drug Administration who is involved in the re-
22 view of premarket submissions under section 515 or
23 section 510(k), including supervisors, shall receive
24 training regarding the meaning and implementation
25 of the least burdensome appropriate means concept

1 in the context of the use of that term in subsections
2 (a)(3)(D) and (i)(1)(D) of this section and in section
3 515(c)(5).

4 “(2) GUIDANCE DOCUMENTS.—

5 “(A) DRAFT UPDATED GUIDANCE.—Not
6 later than 12 months after the date of enact-
7 ment of the 21st Century Cures Act, the Sec-
8 retary shall issue a draft guidance document
9 updating the October 4, 2002, guidance docu-
10 ment entitled ‘The Least Burdensome Provision
11 of the FDA Modernization Act of 1997: Con-
12 cept and Principles; Final Guidance for FDA
13 and Industry’.

14 “(B) MEETING OF STAKEHOLDERS.—In
15 developing such draft guidance document, the
16 Secretary shall convene a meeting of stake-
17 holders to ensure a full record to support the
18 publication of such document.

19 “(3) OMBUDSMAN AUDIT.—Not later than 18
20 months after the date of issuance of final version of
21 the draft guidance under paragraph (2), the om-
22 budsman for the organizational unit of the Food and
23 Drug Administration responsible for the premarket
24 review of devices shall—

1 “(A) conduct, or have conducted, an audit
2 of the training described in paragraph (1); and
3 “(B) include in such audit interviews with
4 a representative sample of persons from indus-
5 try regarding their experience in the device pre-
6 market review process.”.

7 (b) ADDITIONAL INFORMATION REGARDING PRE-
8 MARKET APPLICATIONS.—Subsection (c) of section 515 of
9 the Federal Food, Drug, and Cosmetic Act (21 U.S. C.
10 29 360e) is amended by adding at the end the follows:

11 “(5)(A) Whenever the Secretary requests additional
12 information from an applicant regarding an application
13 under paragraph (1), the Secretary shall consider the least
14 burdensome appropriate means necessary to demonstrate
15 device safety and effectiveness, and request information
16 accordingly.

17 “(B) For purposes of subparagraph (A), the term
18 ‘necessary’ means the minimum required information that
19 would support a determination by the Secretary that an
20 application provides a reasonable assurance of the safety
21 and effectiveness of the device.

22 “(C) Nothing in this paragraph alters the standards
23 for premarket approval of a device.”.

1 **SEC. 2224. RECOGNITION OF STANDARDS.**

2 Section 514(c) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 360d(c)) is amended—

4 (1) in paragraph (1), by inserting after sub-
5 paragraph (B) the following new subparagraphs:

6 “(C)(i) Any person may submit a request
7 for recognition under subparagraph (A) of all
8 or part of an appropriate standard established
9 by a nationally or internationally recognized
10 standard organization.

11 “(ii) Not later than 60 days after the Sec-
12 retary receives such a request, the Secretary
13 shall—

14 “(I) make a determination to recog-
15 nize all, part, or none of the standard that
16 is the subject of the request; and

17 “(II) issue to the person who sub-
18 mitted such request a response in writing
19 that states the Secretary’s rationale for
20 that determination, including the scientific,
21 technical, regulatory, or other basis for
22 such determination;

23 “(iii) The Secretary shall make a response
24 issued under clause (ii)(II) publicly available, in
25 such manner as the Secretary determines ap-
26 propriate.

1 “(iv) The Secretary shall take such actions
2 as may be necessary to implement all or part of
3 a standard recognized under subclause (I), in
4 accordance with subparagraph (A).

5 “(D) The Secretary shall make publicly
6 available, in such manner as the Secretary de-
7 termines appropriate, the rationale for recogni-
8 tion under subparagraph (A) of part of a stand-
9 ard, including the scientific, technical, regu-
10 latory, or other basis for such recognition.”;
11 and

12 (2) by adding at the end the following new
13 paragraphs:

14 “(4) TRAINING ON USE OF STANDARDS.—The
15 Secretary shall provide to all employees of the Food
16 and Drug Administration who review premarket sub-
17 missions for devices periodic training on the concept
18 and use of recognized standards for purposes of
19 meeting a premarket submission requirement or
20 other applicable requirement under this Act, includ-
21 ing standards relevant to an employee’s area of de-
22 vice review.

23 “(5) GUIDANCE.—

24 “(A) DRAFT GUIDANCE.—The Secretary
25 shall publish guidance identifying the principles

1 for recognizing standards under this section. In
2 publishing such guidance, the Secretary shall
3 consider the experience with, and reliance on, a
4 standard by other Federal regulatory authori-
5 ties and the device industry, and whether rec-
6 ognition of a standard will promote harmoni-
7 zation among regulatory authorities in the regu-
8 lation of devices.

9 “(B) TIMING.—The Secretary shall pub-
10 lish—

11 “(i) draft guidance under subpara-
12 graph (A) not later than 12 months after
13 the date of the enactment of the 21st Cen-
14 tury Cures Act; and

15 “(ii) final guidance not later than 12
16 months of the close of the public comment
17 period for the draft guidance under clause
18 (i).”.

19 **SEC. 2225. EASING REGULATORY BURDEN WITH RESPECT**
20 **TO CERTAIN CLASS I AND CLASS II DEVICES.**

21 (a) CLASS I DEVICES.—Section 510(l) of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is
23 amended—

1 (1) by striking “A report under subsection (k)”
2 and inserting “(1) A report under subsection (k)”;
3 and

4 (2) by adding at the end the following new
5 paragraph:

6 “(2) Not later than 120 days after the date of the
7 enactment of the 21st Century Cures Act, the Secretary
8 shall identify, through publication in the Federal Register,
9 any type of class I device that the Secretary determines
10 no longer requires a report under subsection (k) to provide
11 reasonable assurance of safety and effectiveness. Upon
12 such publication—

13 “(A) each type of class I device so identified
14 shall be exempt from the requirement for a report
15 under subsection (k); and

16 “(B) the classification regulation applicable to
17 each such type of device shall be deemed amended
18 to incorporate such exemption.”.

19 (b) CLASS II DEVICES.—Section 510(m) of the Fed-
20 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360(m))
21 is amended—

22 (1) by striking paragraph (1) and inserting the
23 following new paragraph:

24 “(1) The Secretary shall—

1 “(A) not later than 60 days after the date of
2 the enactment of the 21st Century Cures Act—

3 “(i) publish in the Federal Register a no-
4 tice that contains a list of each type of class II
5 device that the Secretary determines no longer
6 requires a report under subsection (k) to pro-
7 vide reasonable assurance of safety and effec-
8 tiveness; and

9 “(ii) provide for a period of not less than
10 60 days for public comment beginning on the
11 date of the publication of such notice; and

12 “(B) not later than 180 days after the date of
13 the enactment of 21st Century Cures Act, publish in
14 the Federal Register a list representing the Sec-
15 retary’s final determination with respect to the de-
16 vices contained in the list published under subpara-
17 graph (A).”;

18 (2) in paragraph (2)—

19 (A) by striking “1 day after the date of
20 publication of a list under this subsection,” and
21 inserting “1 day after the date of publication of
22 the final list under paragraph (1)(B),”; and

23 (B) by striking “30-day period” and in-
24 serting “60-day period”; and

1 (3) by adding at the end the following new
2 paragraph:

3 “(3) Upon the publication of the final list under para-
4 graph (1)(B)—

5 “(A) each type of class II device so listed shall
6 be exempt from the requirement for a report under
7 subsection (k); and

8 “(B) the classification regulation applicable to
9 each such type of device shall be deemed amended
10 to incorporate such exemption.”.

11 **SEC. 2226. ADVISORY COMMITTEE PROCESS.**

12 (a) CLASSIFICATION PANELS.—Paragraph (5) of sec-
13 tion 513(b) of the Federal Food, Drug, and Cosmetic Act
14 (21 U.S.C. 360c(b)) is amended—

15 (1) by striking “(5)” and inserting “(5)(A)”;
16 and

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

18 “(B) When a device is specifically the sub-
19 ject of review by a classification panel, the Sec-
20 retary shall—

21 “(i) ensure that adequate expertise is
22 represented on the classification panel to
23 assess—

24 “(I) the disease or condition
25 which the device is intended to cure,

1 treat, mitigate, prevent, or diagnose;
2 and

3 “(II) the technology of the de-
4 vice; and

5 “(ii) as part of the process to ensure
6 adequate expertise under clause (i), give
7 due consideration to the recommendations
8 of the person whose premarket submission
9 is subject to panel review on the expertise
10 needed among the voting members of the
11 panel.

12 “(C) For review by a classification panel of
13 a premarket submission for a device, the Sec-
14 retary shall—

15 “(i) provide an opportunity for the
16 person whose premarket submission is sub-
17 ject to panel review to provide rec-
18 ommendations on the expertise needed
19 among the voting members of the panel;
20 and

21 “(ii) give due consideration to such
22 recommendations and ensure that adequate
23 expertise is represented on advisory panels
24 to assess—

1 “(I) the disease or condition for
2 which the device is intended to cure,
3 treat, mitigate, prevent, or diagnose;
4 and

5 “(II) the technology of the de-
6 vice.

7 “(D) For purposes of subparagraph
8 (B)(ii), the term ‘adequate expertise’ means
9 that the membership of the classification panel
10 reviewing a premarket submission includes—

11 “(i) two or more voting members, with
12 a specialty or other expertise clinically rel-
13 evant to the device under review; and

14 “(ii) at least one voting member who
15 is knowledgeable about the technology of
16 the device.”.

17 (b) PANEL REVIEW PROCESS.—Section 513(b)(6) of
18 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 360c(b)(6)) is amended—

20 (1) in subparagraph (A)(iii), by inserting before
21 the period at the end “, including by designating a
22 representative who will be provided a time during
23 the panel meeting to address the panel individually
24 (or accompanied by experts selected by such rep-
25 resentative) for the purpose of correcting

1 misstatements of fact or providing clarifying infor-
2 mation, subject to the discretion of panel chair-
3 person.”.

4 (2) by striking subparagraph (B) and inserting
5 the following new subparagraph:

6 “(B)(i) Any meeting of a classification
7 panel for a device that is specifically the subject
8 of review shall—

9 “(I) provide adequate time for initial
10 presentations by the person whose device is
11 specifically the subject of a classification
12 panel review and by the Secretary; and

13 “(II) encourage free and open partici-
14 pation by all interested persons.

15 “(ii) Following the initial presentations de-
16 scribed in clause (i), the panel may—

17 “(I) pose questions to a designated
18 representative described in subparagraph
19 (A)(iii); and

20 “(II) consider the responses to such
21 questions in the panel’s review of the de-
22 vice that is specifically the subject of re-
23 view by the classification panel.”.

1 **SEC. 2227. HUMANITARIAN DEVICE EXEMPTION APPLICA-**
2 **TION.**

3 (a) IN GENERAL.—Section 520(m) of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amend-
5 ed—

6 (1) in paragraph (1) by striking “fewer than
7 4,000” and inserting “not more than 8,000”;

8 (2) in paragraph (2)(A) by striking “fewer than
9 4,000” and inserting “not more than 8,000”; and

10 (3) in paragraph (6)(A)(ii), by striking “4,000”
11 and inserting “8,000”

12 (b) GUIDANCE DOCUMENT ON PROBABLE BEN-
13 EFIT.—Not later than 18 months after the date of enact-
14 ment of this Act, the Secretary of Health and Human
15 Services, acting through the Commissioner of Food and
16 Drugs, shall publish a draft guidance document that de-
17 fines the criteria for establishing “probable benefit” as
18 that term is used in section 520(m)(2)(C) of the Federal
19 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)(C)).

20 **SEC. 2228. CLIA WAIVER STUDY DESIGN GUIDANCE FOR IN**
21 **VITRO DIAGNOSTICS.**

22 (a) DRAFT REVISED GUIDANCE.—Not later than 12
23 months after the date of the enactment of this Act, the
24 Secretary of Health and Human Services shall publish a
25 draft guidance that—

1 (1) revises section V “Demonstrating Insignifi-
2 cant Risk of an Erroneous Result—‘Accuracy’” of
3 the guidance entitled “Recommendations for Clinical
4 Laboratory Improvement Amendments of 1988
5 (CLIA) Waiver Applications for Manufacturers of In
6 Vitro Diagnostic Devices” and dated January 30,
7 2008; and

8 (2) includes guidance on the appropriate use of
9 comparable performance between a waived user and
10 a moderately complex laboratory user to dem-
11 onstrate accuracy.

12 (b) FINAL REVISED GUIDANCE.—The Secretary of
13 Health and Human Services shall finalize the draft guid-
14 ance published under subsection (a) not later than 12
15 months after the comment period for such draft guidance
16 closes.

17 **Subtitle N—Sensible Oversight for**
18 **Technology Which Advances**
19 **Regulatory Efficiency**

20 **SEC. 2241. HEALTH SOFTWARE.**

21 Section 201 of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 321) is amended by adding at the end the
23 following:

24 “(ss)(1) The term ‘health software’ means software
25 that does not, through use of an in vitro diagnostic device

1 or signal acquisition system, acquire, process, or analyze
2 an image or physiological signal, is not an accessory, is
3 not an integral part of a device necessary to support the
4 use of the device, is not used in the manufacture and
5 transfusion of blood and blood components to assist in the
6 prevention of disease in humans, and—

7 “(A) is intended for use for administrative
8 or operational support or the processing and
9 maintenance of financial records;

10 “(B) is intended for use in clinical, labora-
11 tory, or administrative workflow and related
12 recordkeeping;

13 “(C)(i) is intended for use solely in the
14 transfer, aggregation, conversion (in accordance
15 with a present specification), storage, manage-
16 ment, retrieval, or transmission of data or in-
17 formation;

18 “(ii) utilizes a connectivity software plat-
19 form, electronic or electrical hardware, or a
20 physical communications infrastructure; and

21 “(iii) is not intended for use—

22 “(I) in active patient monitoring; or

23 “(II) in controlling or altering the
24 functions or parameters of a device that is
25 connected to such software;

1 “(D) is intended for use to organize and
2 present information for health or wellness edu-
3 cation or for use in maintaining a healthy life-
4 style, including medication adherence and
5 health management tools;

6 “(E) is intended for use to analyze infor-
7 mation to provide general health information
8 that does not include patient-specific rec-
9 ommended options to consider in the preven-
10 tion, diagnosis, treatment, cure, or mitigation of
11 a particular disease or condition; or

12 “(F) is intended for use to analyze infor-
13 mation to provide patient-specific recommended
14 options to consider in the prevention, diagnosis,
15 treatment, cure, or mitigation of a particular
16 disease or condition.

17 “(2) The term ‘accessory’ means a product that—

18 “(A) is intended for use with one or more par-
19 ent devices;

20 “(B) is intended to support, supplement, or
21 augment the performance of one or more parent de-
22 vices; and

23 “(C) shall be classified by the Secretary—

24 “(i) according to its intended use; and

1 “(ii) independently of any classification of
2 any parent device with which it is used.”.

3 **SEC. 2242. APPLICABILITY AND INAPPLICABILITY OF REGU-**
4 **LATION.**

5 Subchapter A of chapter V of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
7 ed by adding at the end the following:

8 **“SEC. 524B. HEALTH SOFTWARE.**

9 “(a) INAPPLICABILITY OF REGULATION TO HEALTH
10 SOFTWARE.—Except as provided in subsection (b), health
11 software shall not be subject to regulation under this Act.

12 “(b) EXCEPTION.—

13 “(1) IN GENERAL.—Subsection (a) shall not
14 apply with respect to a software product—

15 “(A) of a type described in subparagraph
16 (F) of section 201(ss)(1); and

17 “(B) that the Secretary determines poses a
18 significant risk to patient safety.

19 “(2) CONSIDERATIONS.—In making a deter-
20 mination under subparagraph (B) of paragraph (1)
21 with respect to a product to which such paragraph
22 applies, the Secretary shall consider the following:

23 “(A) The likelihood and severity of patient
24 harm if the product were to not perform as in-
25 tended.

1 “(B) The extent to which the product is
2 intended to support the clinical judgment of a
3 medical professional.

4 “(C) Whether there is a reasonable oppor-
5 tunity for a medical professional to review the
6 basis of the information or treatment rec-
7 ommendation provided by the product.

8 “(D) The intended user and user environ-
9 ment, such as whether a medical professional
10 will use a software product of a type described
11 in subparagraph (F) of section 201(ss)(1).

12 “(c) DELEGATION.—The Secretary shall delegate pri-
13 mary jurisdiction for regulating a software product deter-
14 mined under subsection (b) to be subject to regulation
15 under this Act to the center at the Food and Drug Admin-
16 istration charged with regulating devices.

17 “(d) REGULATION OF SOFTWARE.—

18 “(1) IN GENERAL.—The Secretary shall review
19 existing regulations and guidance regarding the reg-
20 ulation of software under this Act. The Secretary
21 may implement a new framework for the regulation
22 of software and shall, as appropriate, modify such
23 regulations and guidance or issue new regulations or
24 guidance.

1 “(2) ISSUANCE BY ORDER.—Notwithstanding
2 subchapter II of chapter 5 of title 5, United States
3 Code, the Secretary may modify or issue regulations
4 for the regulation of software under this Act by ad-
5 ministrative order published in the Federal Register
6 following the publication of a proposed order.

7 “(3) AREAS UNDER REVIEW.—The review of ex-
8 isting regulations and guidance under paragraph (1)
9 may include review of the following areas:

10 “(A) Classification of software.

11 “(B) Standards for development of soft-
12 ware.

13 “(C) Standards for validation and
14 verification of software.

15 “(D) Review of software.

16 “(E) Modifications to software.

17 “(F) Manufacturing of software.

18 “(G) Quality systems for software.

19 “(H) Labeling requirements for software.

20 “(I) Postmarketing requirements for re-
21 porting of adverse events.

22 “(4) PROCESS FOR ISSUING PROPOSED REGU-
23 LATIONS, ADMINISTRATIVE ORDER, AND GUID-
24 ANCE.—Not later than 18 months after the date of
25 enactment of this section, the Secretary shall consult

1 with external stakeholders (including patients, indus-
2 try, health care providers, academia, and govern-
3 ment) to gather input before issuing regulations, an
4 administrative order, and guidance under this sub-
5 section.

6 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-
7 tion shall be construed as providing the Secretary with the
8 authority to regulate under this Act any health software
9 product of the type described in subparagraph (F) of sec-
10 tion 201(ss)(1) unless and until the Secretary has made
11 a determination described in subsection (b)(1)(B) with re-
12 spect to such product.”.

13 **SEC. 2243. EXCLUSION FROM DEFINITION OF DEVICE.**

14 Section 201(h) of the Federal Food, Drug, and Cos-
15 metic Act (21 U.S.C. 321) is amended—

16 (1) in subparagraph (2), by striking “or” after
17 “or other animals,”;

18 (2) in subparagraph (3), by striking “and” and
19 inserting “or”; and

20 (3) by inserting after subparagraph (3) the fol-
21 lowing:

22 “(4) is not health software (other than software
23 determined to be a risk to patient safety under sec-
24 tion 524B(b)), and”.

1 **Subtitle O—Streamlining Clinical**
2 **Trials**

3 **SEC. 2261. PROTECTION OF HUMAN SUBJECTS IN RE-**
4 **SEARCH; APPLICABILITY OF RULES.**

5 (a) IN GENERAL.—In order to simplify and facilitate
6 compliance by researchers with applicable regulations for
7 protection of human subjects in research, the Secretary
8 of Health and Human Services shall, to the extent possible
9 and consistent with other statutory provisions, harmonize
10 differences between the HHS Human Subject Regulations
11 and the FDA Human Subject Regulations in accordance
12 with subsection (b).

13 (b) AVOIDING REGULATORY DUPLICATION AND UN-
14 NECESSARY DELAYS.—

15 (1) IN GENERAL.—The Secretary shall—

16 (A) make such modifications to the provi-
17 sions of the HHS Human Subject Regulations
18 and the vulnerable-populations rules as may be
19 necessary—

20 (i) to reduce regulatory duplication
21 and unnecessary delays;

22 (ii) to modernize such provisions in
23 the context of multisite and cooperative re-
24 search projects; and

1 (iii) to incorporate local consider-
2 ations, community values, and mechanisms
3 to protect vulnerable populations; and

4 (B) ensure that human subject research
5 that is subject to the HHS Human Subject
6 Regulations or to the FDA Human Subject
7 Regulations may—

8 (i) use joint or shared review;

9 (ii) rely upon the review of—

10 (I) an independent institutional
11 review board; or

12 (II) an institutional review board
13 of an entity other than the sponsor of
14 the research; or

15 (iii) use similar arrangements to avoid
16 duplication of effort.

17 (2) REGULATIONS AND GUIDANCE.—Not later
18 than 12 months after the date of enactment of this
19 Act, the Secretary, acting through the relevant agen-
20 cies and offices of the Department of Health and
21 Human Services, including the Office for Human
22 Research Protections and relevant agencies and of-
23 fices of the Food and Drug Administration, shall
24 issue such regulations and guidance and take such
25 other actions as may be necessary to implement this

1 section and help facilitate the broader use of single,
2 central, or lead institutional review boards. Such
3 regulations and guidance shall include clarification
4 of requirements and policies relating to the fol-
5 lowing:

6 (A) Arrangements to avoid duplication de-
7 scribed in paragraph (1)(A)(i), including—

8 (i) delineating the roles of institu-
9 tional review boards in multisite or cooper-
10 ative, multisite studies where one or more
11 local institutional review boards are relied
12 upon, or similar arrangements are used;

13 (ii) the risks and benefits to human
14 subjects;

15 (iii) standardization of informed con-
16 sent and other processes and legal docu-
17 ments; and

18 (iv) incorporating community values
19 through the use of local institutional re-
20 view boards while continuing to use central
21 or lead institutional review boards.

22 (B) Concerns about regulatory and legal li-
23 ability contributing to decisions by the sponsors
24 of research to rely on local institutional review
25 boards for multisite research.

1 (3) CONSULTATION.—In issuing regulations or
2 guidance pursuant to paragraph (2), the Secretary
3 shall consult with stakeholders (including research-
4 ers, academic organizations, hospitals, institutional
5 research boards, pharmaceutical, biotechnology and
6 medical device developers, clinical research organiza-
7 tions, patient groups, and others).

8 (c) TIMING.—The Secretary shall complete the har-
9 monization described in subsection (a) not later than 36
10 months after the date of enactment of this Act.

11 (d) PROGRESS REPORT.—Not later than 24 months
12 after the date of enactment of this Act, the Secretary shall
13 submit to Congress a report on the progress made towards
14 completing such harmonization.

15 (d) DEFINITIONS.—

16 (1) HUMAN SUBJECT REGULATIONS.—In this
17 section:

18 (A) FDA HUMAN SUBJECT REGULA-
19 TIONS.—The term “FDA Human Subject Reg-
20 ulations” means the provisions of parts 50, 56,
21 312, and 812 of title 21, Code of Federal Regu-
22 lations (or any successor regulations).

23 (B) HHS HUMAN SUBJECT REGULA-
24 TIONS.—The term “HHS Human Subject Reg-
25 ulations” subject to clause (ii), means the provi-

1 sions of subpart A of part 46 of title 45, Code
2 of Federal Regulations (or any successor regu-
3 lations).

4 (C) VULNERABLE-POPULATIONS RULES.—
5 The term “vulnerable-populations rules”—

6 (i) subject to clause (ii), means the
7 provisions of subparts B through D of
8 such part 46 (or any successor regula-
9 tions); or

10 (ii) as applicable to the human sub-
11 jects involved in research described in sub-
12 paragraph (B), means the provisions appli-
13 cable to vulnerable populations under part
14 56 of such title 21 (or any successor regu-
15 lations) and subpart D of part 50 of such
16 title 21 (or any successor regulations).

17 (2) HUMAN SUBJECT RESEARCH.—

18 (A) Except as provided in subparagraph
19 (B), the term “human subject research” means
20 research, as defined in subpart A of part 46 of
21 title 45, Code of Federal Regulations (or any
22 successor regulations), that involves a human
23 subject, as defined in such subpart A (or any
24 successor regulations); and

1 (B) In the case of an investigation that is
2 subject to the provisions of part 50 of title 21,
3 Code of Federal Regulations (or any successor
4 regulations), the term “human subject” has the
5 meaning given such term in such part 50, and
6 the term “human subject research” means a
7 clinical investigation as defined in such part 50.

8 (3) OTHER DEFINITIONS.—In this section:

9 (A) INSTITUTIONAL REVIEW BOARD.—The
10 term “institutional review board” has the mean-
11 ing that applies to the term “institutional re-
12 view board” under the HHS Human Subject
13 Regulations.

14 (B) LEAD INSTITUTIONAL REVIEW
15 BOARD.—The term “lead institutional review
16 board” means an institutional review board that
17 otherwise meets the requirements of the HHS
18 Human Subject Regulations and enters into a
19 written agreement with an institution, another
20 institutional review board, a sponsor, or a prin-
21 cipal investigator to approve and oversee human
22 subject research that is conducted at multiple
23 locations. References to an institutional review
24 board include an institutional review board that

1 serves a single institution as well as a lead in-
2 stitutional review board.

3 **SEC. 2262. USE OF NON-LOCAL INSTITUTIONAL REVIEW**
4 **BOARDS FOR REVIEW OF INVESTIGATIONAL**
5 **DEVICE EXEMPTIONS AND HUMAN DEVICE**
6 **EXEMPTIONS.**

7 (a) IN GENERAL.—Section 520 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 360(j)) is amended—

9 (1) in subsection (g)(3)—

10 (A) by striking “local” each place it ap-
11 pears; and

12 (B) in subparagraph (A)(i), by striking
13 “which has been”; and

14 (2) in subsection (m)(4)—

15 (A) by striking “local” each place it ap-
16 pears; and

17 (B) by striking subparagraph (A) and in-
18 serting the following new subparagraph:

19 “(A) in facilities in which clinical testing of de-
20 vices is supervised by an institutional review com-
21 mittee established in accordance with the regulations
22 of the Secretary, and”.

23 (b) REGULATIONS.—Not later than 12 months after
24 the date of the enactment of this Act, the Secretary of
25 Health and Human Services shall revise or issue such reg-

1 ulations or guidance as may be necessary to carry out the
2 amendments made by subsection (a).

3 **SEC. 2263. ALTERATION OR WAIVER OF INFORMED CON-**
4 **SENT FOR CLINICAL INVESTIGATIONS.**

5 (a) DEVICES.—Section 520(g)(3) of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(3)) is
7 amended—

8 (1) in subparagraph (D), by striking “except
9 where subject to such conditions as the Secretary
10 may prescribe, the investigator” and inserting the
11 following: “except where, subject to such conditions
12 as the Secretary may prescribe—

13 “(i) the proposed clinical testing poses
14 no more than minimal risk to the human
15 subject and includes appropriate safe-
16 guards to protect the rights, safety, and
17 welfare of the human subject; or

18 “(ii) the investigator”; and

19 (2) in the matter following subparagraph (D),
20 by striking “subparagraph (D)” and inserting “sub-
21 paragraph (D)(ii)”.

22 (b) DRUGS.—Section 505(i)(4) of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) is amended
24 by striking “except where it is not feasible or it is contrary
25 to the best interests of such human beings” and inserting

1 “except where it is not feasible, it is contrary to the best
2 interests of such human beings, or the proposed clinical
3 testing poses no more than minimal risk to such human
4 beings and includes appropriate safeguards as prescribed
5 to protect the rights, safety, and welfare of such human
6 beings”.

7 **Subtitle P—Improving Scientific**
8 **Expertise and Outreach at FDA**

9 **SEC. 2281. SILVIO O. CONTE SENIOR BIOMEDICAL RE-**
10 **SEARCH SERVICE.**

11 (a) **HIRING AND RETENTION AUTHORITY.**—Section
12 228 of the Public Health Service Act (42 U.S.C. 237) is
13 amended—

14 (1) in the section heading, by inserting “AND
15 BIOMEDICAL PRODUCT ASSESSMENT” after “RE-
16 SEARCH”;

17 (2) in subsection (a)(1), by striking “Silvio O.
18 Conte Senior Biomedical Research Service, not to
19 exceed 500 members” and inserting “Silvio O. Conte
20 Senior Biomedical Research and Biomedical Product
21 Assessment Service (in this section referred to as the
22 ‘Service’), the purpose of which is to recruit and re-
23 tain competitive and qualified scientific and tech-
24 nical experts outstanding in the field of biomedical

1 research, clinical research evaluation, and biomedical
2 product assessment”;

3 (3) by amending subsection (a)(2) to read as
4 follows:

5 “(2) The authority established in paragraph (1) may
6 not be construed to require the Secretary to reduce the
7 number of employees serving under any other employment
8 system in order to offset the number of members serving
9 in the Service.”;

10 (4) in subsection (b)—

11 (A) in the matter preceding paragraph (1),
12 by striking “or clinical research evaluation” and
13 inserting “, clinical research evaluation or bio-
14 medical product assessment” after “evalua-
15 tion”; and

16 (B) in paragraph (1), by inserting “or a
17 master’s level degree in engineering,
18 bioinformatics, or a related or emerging field,”
19 after the comma;

20 (5) in subsection (d), by striking “and shall not
21 exceed the rate payable for level I of the Executive
22 Schedule unless approved by the President under
23 section 5377(d)(2) of title 5, United States Code”
24 and inserting “and shall not exceed the rate payable
25 for the President”;

1 (6) by striking subsection (e); and

2 (7) by redesignating subsections (f) and (g) as
3 subsections (e) and (f), respectively.

4 (b) REPORT.—Not later than 3 years after the date
5 of the enactment of this Act, the Secretary of Health and
6 Human Services shall submit, and publish on the website
7 of the Department of Health and Human Services a report
8 on the implementation of the amendments made by sub-
9 section (a), including whether the amendments have im-
10 proved the ability of the Food and Drug Administration
11 to hire and retain qualified experts to fulfill obligations
12 specified under user fee agreements.

13 **SEC. 2282. ENABLING FDA SCIENTIFIC ENGAGEMENT.**

14 It is the sense of Congress that participation in or
15 sponsorship of scientific conferences and meetings is es-
16 sential to the mission of the Food and Drug Administra-
17 tion.

18 **SEC. 2283. REAGAN-UDALL FOUNDATION FOR THE FOOD**
19 **AND DRUG ADMINISTRATION.**

20 (a) BOARD OF DIRECTORS.—

21 (1) COMPOSITION AND SIZE.—Section
22 770(d)(1)(C) of the Federal Food, Drug, and Cos-
23 metic Act (21 U.S.C. 379dd(d)(1)(C)) is amended—

24 (A) by redesignating clause (ii) as clause
25 (iii);

1 (B) by inserting after clause (i) the fol-
2 lowing:

3 “(ii) ADDITIONAL MEMBERS.—The
4 Board, through amendments to the bylaws
5 of the Foundation, may provide that the
6 number of voting members of the Board
7 shall be a number (to be specified in such
8 amendment) greater than 14. Any Board
9 positions that are established by any such
10 amendment shall be appointed (by majority
11 vote) by the individuals who, as of the date
12 of such amendment, are voting members of
13 the Board and persons so appointed may
14 represent any of the categories specified in
15 subclauses (I) through (V) of clause (i), so
16 long as no more than 30 percent of the
17 total voting members of the Board (includ-
18 ing members whose positions are estab-
19 lished by such amendment) are representa-
20 tives of the general pharmaceutical, device,
21 food, cosmetic, and biotechnology indus-
22 tries.”; and

23 (C) in clause (iii)(I), as redesignated by
24 subparagraph (A), by striking “The ex officio
25 members shall ensure” and inserting “The ex

1 officio members, acting pursuant to clause (i),
2 and the Board, acting pursuant to clause (ii),
3 shall ensure”.

4 (2) FEDERAL EMPLOYEES ALLOWED TO SERVE
5 ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C)
6 of the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 379dd(d)(1)(C)), as redesignated by para-
8 graph (1)(A), is amended by adding at the end the
9 following: “For purposes of this section, the term
10 ‘employee of the Federal Government’ does not in-
11 clude a ‘special Government employee’, as that term
12 is defined in section 202(a) of title 18, United
13 States Code.”.

14 (3) STAGGERED TERMS.—Subparagraph (A) of
15 section 770(d)(3) of the Federal Food, Drug, and
16 Cosmetic Act (21 U.S.C. 379dd(d)(3)) is amended
17 to read as follows:

18 “(A) TERM.—The term of office of each
19 member of the Board appointed under para-
20 graph (1)(C)(i), and the term of office of any
21 member of the Board whose position is estab-
22 lished pursuant to paragraph (1)(C)(ii), shall be
23 4 years, except that—

24 “(i) the terms of offices for the mem-
25 bers of the Board initially appointed under

1 paragraph (1)(C)(i) shall expire on a stag-
2 gered basis as determined by the ex officio
3 members; and

4 “(ii) the terms of office for the per-
5 sons initially appointed to positions estab-
6 lished pursuant to paragraph (1)(C)(ii)
7 may be made to expire on a staggered
8 basis, as determined by the individuals
9 who, as of the date of the amendment es-
10 tablishing such positions, are members of
11 the Board.”.

12 (b) EXECUTIVE DIRECTOR COMPENSATION.—Section
13 770(g)(2) of the Federal Food, Drug, and Cosmetic Act
14 (21 U.S.C. 379dd(g)(2)) is amended by striking “but shall
15 not be greater than the compensation of the Commis-
16 sioner”.

17 (c) SEPARATION OF FUNDS.—Section 770(m) of the
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 379dd(m)) is amended by striking “are held in separate
20 accounts from funds received from entities under sub-
21 section (i)” and inserting “are managed as individual pro-
22 grammatic funds under subsection (i), according to best
23 accounting practices”.

1 **SEC. 2284. COLLECTION OF CERTAIN VOLUNTARY INFOR-**
2 **MATION EXEMPTED FROM PAPERWORK RE-**
3 **DUCTION ACT.**

4 Chapter VII of the Federal Food, Drug, and Cos-
5 metic Act is amended by inserting after section 708 of
6 such Act (21 U.S.C. 379) the following:

7 **“SEC. 708A. COLLECTION OF CERTAIN VOLUNTARY INFOR-**
8 **MATION EXEMPTED FROM PAPERWORK RE-**
9 **DUCTION ACT.**

10 “Chapter 35 of title 44, United States Code, shall
11 not apply to the collection from patients, industry, aca-
12 demia, and other stakeholders, of voluntary information
13 such as through voluntary surveys or questionnaires, initi-
14 ated by the Secretary.”.

15 **TITLE III—DELIVERY**
16 **Subtitle A—Interoperability**

17 **SEC. 3001. ENSURING INTEROPERABILITY OF HEALTH IN-**
18 **FORMATION TECHNOLOGY.**

19 (a) INTEROPERABILITY STANDARDS.—

20 (1) IN GENERAL.—Subtitle A of title XXX of
21 the Public Health Service Act (42 U.S.C. 300jj–11
22 et seq.) is amended by adding at the end the fol-
23 lowing new section:

1 **“SEC. 3010. ENSURING INTEROPERABILITY OF HEALTH IN-**
2 **FORMATION TECHNOLOGY.**

3 “(a) INTEROPERABILITY.—In order for health infor-
4 mation technology to be considered interoperable, such
5 technology must satisfy the following criteria:

6 “(1) SECURE TRANSFER.—The technology al-
7 lows the secure transfer of the entirety of a patient’s
8 data from any and all health information technology
9 for authorized use under applicable law.

10 “(2) COMPLETE ACCESS TO HEALTH DATA.—
11 The technology allows access to the entirety of a pa-
12 tient’s available data for authorized use under appli-
13 cable law without special effort, as defined by rec-
14 ommendations adopted in accordance with this sec-
15 tion, by the requestor of such data unless such data
16 is not disclosable under applicable law.

17 “(3) NO INFORMATION BLOCKING.—The tech-
18 nology is not configured, set up, or implemented to
19 engage in information blocking, as defined in section
20 3010A(f).

21 “(b) CATEGORIES FOR INTEROPERABILITY STAND-
22 ARDS.—The categories described in this subsection, with
23 respect to standards for determining if health information
24 technology is interoperable, consistent with the criteria de-
25 scribed in subsection (a), include the following categories
26 of standards:

1 “(1) Standards with respect to vocabulary and
2 terminology.

3 “(2) Standards with respect to content and
4 structure.

5 “(3) Standards with respect to transport of in-
6 formation.

7 “(4) Security standards.

8 “(5) Service standards.”.

9 (2) GUIDANCE.—Not later than January 1,
10 2017, the Secretary of Health and Human Services,
11 through the National Coordinator of the Office of
12 the National Coordinator for Health Information
13 Technology, shall issue guidance with respect to the
14 implementation of section 3010 of the Public Health
15 Service Act, as added by paragraph (1), including
16 with respect to defining and providing examples of
17 authorized use of health information technology, as
18 described in such section.

19 (b) IMPROVEMENTS TO RECOMMENDATION PROC-
20 ESS.—

21 (1) HIT POLICY COMMITTEE TO INCORPORATE
22 POLICIES FOR UPDATES TO INTEROPERABILITY
23 STANDARDS.—Section 3002 of the Public Health
24 Service Act (42 U.S.C. 300jj–12) is amended—

25 (A) in subsection (a)—

1 (i) by striking “National Coordinator”
2 and inserting “Secretary, in consultation
3 with the National Coordinator,”; and

4 (ii) by adding at the end the following
5 new sentence: “The HIT Policy Committee
6 is authorized only to provide policy and
7 priority recommendations to the Secretary
8 and not authorized to otherwise affect the
9 development or modification of any stand-
10 ard, implementation specification, or cer-
11 tification criterion under this title.”; and
12 (B) in subsection (b)(2)—

13 (i) in subparagraph (A), in the first
14 sentence—

15 (I) by striking “The HIT Policy
16 Committee” and inserting “Subject to
17 subparagraph (D), the HIT Policy
18 Committee”; and

19 (II) by inserting “(including the
20 areas in which modifications and addi-
21 tions to interoperability standards
22 under section 3010 are needed for the
23 electronic exchange and use of health
24 information for purposes of adoption
25 of such modifications and additions

1 under section 3004)” after “section
2 3004”.

3 (ii) by adding at the end the following
4 new subparagraph:

5 “(D) SPECIAL RULE RELATED TO INTER-
6 OPERABILITY.—Any recommendation made by
7 the HIT Policy Committee on or after the date
8 of the enactment of this subparagraph with re-
9 spect to interoperability of health information
10 technology shall be consistent with the criteria
11 described in subsection (a) of section 3010.”.

12 (2) SUNSET OF HIT STANDARDS COMMITTEE.—
13 Section 3003 of the Public Health Service Act (42
14 U.S.C. 300jj–13) is amended by adding at the end
15 the following new subsection:

16 “(f) TERMINATION.—The HIT Standards Committee
17 shall terminate on the date that is 90 days after the date
18 of the enactment of this subsection.”.

19 (3) STANDARDS DEVELOPMENT ORGANIZA-
20 TIONS.—Title XXX of the Public Health Service Act
21 is amended by inserting after section 3003 the fol-
22 lowing new section:

1 **“SEC. 3003A. RECOMMENDATIONS FOR STANDARDS**
2 **THROUGH CONTRACT WITH STANDARDS DE-**
3 **VELOPMENT ORGANIZATIONS.**

4 “(a) CONTRACT.—

5 “(1) IN GENERAL.—For purposes of activities
6 conducted under this title, the Secretary shall enter
7 into contracts with health care standards develop-
8 ment organizations accredited by the American Na-
9 tional Standards Institute to carry out the duties de-
10 scribed in subsection (b), as applicable.

11 “(2) TIMING FOR FIRST CONTRACT.—As soon
12 as practicable after the date of the enactment of this
13 section, the Secretary shall enter into the first con-
14 tract under paragraph (1).

15 “(3) PERIOD OF CONTRACT.—Each contract
16 under paragraph (1) shall be for a period deter-
17 mined necessary by the Secretary, in consultation
18 with the National Coordinator, to carry out the ap-
19 plicable duties described in subsection (b).

20 “(4) APPROPRIATE ORGANIZATIONS.—The Sec-
21 retary shall ensure the most appropriate organiza-
22 tions described in paragraph (1) are selected for
23 each contract under paragraph (1).

24 “(b) DUTIES.—

1 “(1) INITIAL CONTRACT.—Under the initial
2 contract under subsection (a)(1), the standards de-
3 velopment organizations—

4 “(A) shall provide to the Secretary, in con-
5 sultation with the National Coordinator, for
6 adoption under section 3004, recommendations,
7 in accordance with section 3010, for interoper-
8 ability standards consistent with the criteria de-
9 scribed in subsection (a) of such section and
10 with respect to the categories described in sub-
11 section (b)(1) of such section; and

12 “(B) may provide to the Secretary, in con-
13 sultation with the National Coordinator, rec-
14 ommendations described in paragraph (2).

15 “(2) SUBSEQUENT CONTRACTS.—Under each
16 subsequent contract, the organizations shall provide
17 to the Secretary, in consultation with the National
18 Coordinator, for adoption under section 3004 rec-
19 ommendations for any standards (including inter-
20 operability criteria), implementation specifications,
21 and certification criteria (and modifications, includ-
22 ing additions to such standards, specifications, and
23 criteria), which are in accordance with the policies
24 and priorities developed by the Secretary, in con-
25 sultation with the National Coordinator.

1 “(c) MODIFICATIONS AND SUBSEQUENT CON-
2 TRACTS.—

3 “(1) IN GENERAL.—The Secretary, in consulta-
4 tion with the National Coordinator, shall periodically
5 conduct hearings to evaluate and review the stand-
6 ards, implementation specification, and certification
7 criteria adopted under section 3004 for purposes of
8 determining if modifications, including any addi-
9 tions, are needed with respect to such standards,
10 specifications, and criteria.

11 “(2) CONTRACT TRIGGER.—Based on the needs
12 for standards, implementation specifications, and
13 certification criteria (and modifications, including
14 additions to such standards, specifications, and cri-
15 teria) under this title, as determined by the Sec-
16 retary, in consultation with the National Coordi-
17 nator, the Secretary shall, as needed, enter into con-
18 tracts under subsection (a) in addition to the initial
19 contract.

20 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
21 is authorized to be appropriated \$10,000,000 for contracts
22 under subsection (a), to remain available until expended.”.

23 (4) MODIFICATIONS TO ROLE OF ONCHIT.—
24 Section 3001(c)(1)(A) of the Public Health Service
25 Act (42 U.S.C. 300jj–11(c)(1)(A)) is amended by in-

1 serting “for recommendations made before the date
2 of the enactment of the 21st Century Cures Act,”
3 before “review and determine”.

4 (c) ADOPTION.—Section 3004 of the Public Health
5 Service Act (42 U.S.C. 300jj–14) is amended—

6 (1) in subsection (a)—

7 (A) in paragraph (1), by inserting after
8 “section 3001(c)” the following: “(or, subject to
9 subsection (c), in the case of a standard, speci-
10 fication, or criterion recommended on or after
11 the date of the enactment of the 21st Century
12 Cures Act, after the date of submission of the
13 recommendation to the Secretary under section
14 3003A)”; and

15 (B) in paragraph (2), by striking “and the
16 HIT Standards Committee”;

17 (2) in subsection (b), by adding at the end the
18 following new paragraph:

19 “(4) LIMITATION.—The Secretary may not
20 adopt any standards, implementation specifications,
21 or certification criteria under this subsection or sub-
22 section (a) that are inconsistent with or duplicative
23 of an interoperability standard adopted under this
24 section, in accordance with section 3010. In the case
25 of a standard, specification, or criterion that has

1 been adopted under this section and is inconsistent
2 or duplicative of such an interoperability standard
3 that is subsequently adopted under this section, such
4 interoperability standard shall supercede such other
5 standard, specification, or criterion and such other
6 standard, specification, or criterion shall no longer
7 be considered adopted under this section beginning
8 on the date that such interoperability standard be-
9 comes effective.”; and

10 (3) by adding at the end the following new sub-
11 sections:

12 “(c) ADOPTION OF INITIAL INTEROPERABILITY
13 STANDARDS.—Notwithstanding the previous subsections
14 of this section, the following shall apply in the case of the
15 initial set of interoperability standards recommended
16 under section 3003A:

17 “(1) REVIEW OF STANDARDS.—Not later than
18 90 days after the date of receipt of recommendations
19 for such interoperability standards, the Secretary, in
20 consultation with the National Coordinator and rep-
21 resentatives of other relevant Federal agencies, shall
22 jointly review such standards and shall determine
23 whether or not to propose adoption of such stand-
24 ards.

1 “(2) DETERMINATION TO ADOPT.—If the Sec-
2 retary determines—

3 “(A) to propose adoption of such stand-
4 ards, the Secretary shall, by regulation under
5 section 553 of title 5, United States Code, de-
6 termine whether or not to adopt such stand-
7 ards; or

8 “(B) not to propose adoption of such
9 standards, the Secretary shall notify the Na-
10 tional Coordinator and the standards develop-
11 ment organizations under section 3003A in
12 writing of such determination and the reasons
13 for not proposing the adoption of the rec-
14 ommendation for such standards.

15 “(3) PUBLICATION.—The Secretary shall pro-
16 vide for publication in the Federal Register of all de-
17 terminations made by the Secretary under para-
18 graph (1).

19 “(4) APPLICATION.—Any standard adopted
20 under this subsection shall be effective 12 months
21 after the date of publication of the determination to
22 adopt such standard.

23 “(c) RULES FOR ADOPTION.—In the case of a stand-
24 ard (including interoperability standard), implementation
25 specification, or certification criteria adopted under this

1 section on or after the date of the enactment of the 21st
2 Century Cures Act, the following shall apply:

3 “(1) IN GENERAL.—Except as provided in para-
4 graph (2), any such standard (including interoper-
5 ability standard), implementation specification, or
6 certification criteria shall be a standard, specifica-
7 tion, or criterion that has been recommended by the
8 standards development organizations with which the
9 Secretary has entered into a contract under section
10 3003A.

11 “(2) SPECIAL RULE IF NO STANDARD, SPECI-
12 FICATION, OR CRITERION RECOMMENDED.—If no
13 standard is recommended under paragraph (1)—

14 “(A) in the case of interoperability stand-
15 ards, relating to a category described in section
16 3010(b)—

17 “(i) paragraph (1) shall not apply;
18 and

19 “(ii) paragraph (4) shall apply; or

20 “(B) in the case of any other standard, im-
21 plementation specification, or certification cri-
22 teria, relating to a policy or priority to carry
23 out this title, as determined by the Secretary,
24 in consultation with the National Coordinator—

1 “(i) paragraph (1) shall not apply;

2 and

3 “(ii) paragraph (4) shall apply.

4 “(3) EFFECTIVE DATE.—Any standard, imple-
5 mentation specification, or certification criterion
6 adopted under this section shall be effective 12
7 months after the date of publication of the final rule
8 to adopt such standard, implementation specifica-
9 tion, or certification criteria.

10 “(4) ASSISTANCE TO THE SECRETARY.—In
11 complying with the requirements of this subsection,
12 the Secretary shall rely on the recommendations of
13 the National Committee on Vital and Health Statis-
14 tics established under section 306(k), and shall con-
15 sult with appropriate Federal and State agencies
16 and private organizations. The Secretary shall pub-
17 lish in the Federal Register any recommendation of
18 the National Committee on Vital and Health Statis-
19 tics regarding the adoption of a standard implemen-
20 tation specification, or certification criterion under
21 this section. Any standard, implementation specifica-
22 tion, or certification criterion adopted pursuant to
23 this paragraph shall be promulgated in accordance
24 with the rulemaking procedures of subchapter III of
25 chapter 5 of title 5, United States Code.”.

1 (d) REPORTS AND NOTIFICATIONS.—Section 3010 of
2 the Public Health Service Act, as added by subsection (a),
3 is amended by adding at the end the following new sub-
4 section:

5 “(c) DISSEMINATION OF INFORMATION.—

6 “(1) INITIAL SUMMARY REPORT.—Not later
7 than July 1, 2017, the Secretary, after consultation
8 with relevant stakeholders, shall submit to Congress
9 and provide for publication in the Federal Register
10 and the posting on the Internet website of the Office
11 of the National Coordinator for Health Information
12 Technology of a report on the following:

13 “(A) The initial set of interoperability
14 standards adopted under section 3004(c).

15 “(B) The strategies for achieving wide-
16 spread interoperability.

17 “(C) An overview of the extent to which
18 electronic health records and health information
19 technology offered as of such date satisfy such
20 initial set.

21 “(D) Any barriers that are preventing
22 widespread interoperability.

23 “(E) The plan and milestones, including
24 specific steps, to achieve widespread interoper-
25 ability.

1 “(2) FOLLOW-UP DETERMINATION AND REPORT
2 ON WIDESPREAD INTEROPERABILITY.—Not later
3 than December 31, 2019, the Secretary shall provide
4 for publication in the Federal Register and the post-
5 ing on the Internet website of the Office of the Na-
6 tional Coordinator for Health Information Tech-
7 nology of the following:

8 “(A) A determination by the Secretary
9 whether the goal of widespread interoperability
10 has been achieved.

11 “(B) A list identifying the vendors of, or
12 other entities offering, qualified electronic
13 health records, which categorizes such entities,
14 with respect to such records, as in compliance
15 or not in compliance with the certification cri-
16 teria described in section 3001(c)(5)(B)(ii) and
17 with the requirements under clause (i) of sec-
18 tion 3001(c)(5)(C) (including with the terms of
19 the attestation and other requirements under
20 such clause).

21 “(C) Actions that may be taken by entities
22 identified under subparagraph (B) as not being
23 in compliance with such criteria and require-
24 ments in order for such entities to become in
25 compliance with such criteria and requirements.

1 “(D) Penalties described in section
2 3010A(d) to which entities, with respect to such
3 qualified electronic health records, beginning
4 January 1, 2019, are subject if such technology
5 and entities are not in compliance with the cer-
6 tification criteria described in section
7 3001(c)(5)(B)(ii) and with the requirements
8 under clause (i) of section 3001(c)(5)(C), re-
9 spectively.

10 “(3) ONGOING PUBLICATION OF RECOMMENDA-
11 TIONS.—The Secretary shall provide for publication
12 in the Federal Register and the posting on the
13 Internet website of the Office of the National Coor-
14 dinator for Health Information Technology of all
15 recommendations made under this section.”.

16 (e) CERTIFICATION AND OTHER ENFORCEMENT
17 PROVISIONS.—

18 (1) CERTIFICATION OF QUALIFIED ELECTRONIC
19 HEALTH RECORDS.—

20 (A) IN GENERAL.—Section 3007(b) of the
21 Public Health Service Act (42 U.S.C. 300jj–
22 17(b)) is amended by striking “under section
23 3001(c)(3) to be in compliance with” and all
24 that follows through the period at the end and
25 inserting “under section 3001(c)(3)—

1 “(1) for certifications made before January 1,
2 2018, to be in compliance with applicable standards
3 adopted under subsections (a) and (b) of section
4 3004; and

5 “(2) for certifications made on or after January
6 1, 2018, to be in compliance with applicable stand-
7 ards adopted under subsections (a) and (b) of sec-
8 tion 3004 and to be interoperable in accordance with
9 section 3010, including by being in compliance with
10 interoperability standards adopted under section
11 3004.”.

12 (B) REQUIREMENTS OF SECRETARY.—Sec-
13 tion 3001(c)(5) of the Public Health Service
14 Act (42 U.S.C. 300jj–11(c)(5)) is amended—

15 (i) by amending subparagraph (B) of
16 such section to read as follows:

17 “(B) CERTIFICATION CRITERIA DE-
18 SCRIBED.—In this title, the term ‘certification
19 criteria’ means, with respect to qualified elec-
20 tronic health records—

21 “(i) for certifications made before
22 January 1, 2018, criteria to establish that
23 the records meet standards and implemen-
24 tation specifications adopted under sub-

1 sections (a) and (b) of section 3004 for
2 qualified electronic health records; and

3 “(ii) for certifications made on or
4 after January 1, 2018, criteria described
5 in clause (i) and criteria to establish that
6 the records are interoperable, in accord-
7 ance with section 3010, including by being
8 in compliance with interoperability stand-
9 ards adopted under section 3004.”; and

10 (ii) by adding at the end the following
11 new subparagraph:

12 “(C) ENFORCEMENT;
13 DECERTIFICATIONS.—

14 “(i) REQUIREMENTS.—Under any
15 program kept or recognized under subpara-
16 graph (A), the Secretary shall ensure that
17 any vendor of or other entity offering
18 qualified electronic health records seeking
19 a certification of such records under such
20 program on or after January 1, 2018,
21 shall, as a condition of certification (and
22 maintenance of certification) of such a
23 record under such program—

24 “(I) provide to the Secretary an
25 attestation—

1 “(aa) that the entity, unless
2 for a legitimate purpose specified
3 by the Secretary, has not taken
4 any action, including through any
5 financial, administrative, or tech-
6 nological barrier, which the entity
7 knows or should know (as defined
8 in section 1128A(i)(7) of the So-
9 cial Security Act), is to limit or
10 restrict the exchange of informa-
11 tion or to prevent or
12 disincentivize widespread inter-
13 operability between any providers
14 using such records or other
15 health information technology in
16 connection with such record;

17 “(bb) on the pricing infor-
18 mation described in clause (v) for
19 purposes of the portal created
20 under paragraph (9), that such
21 information will be available on a
22 public Web site of such entity
23 and in marketing materials, com-
24 munications statements, and
25 other assertions of such entity re-

1 lated to such record, and that the
2 entity will voluntarily provide
3 such information to customers
4 prior to providing any qualified
5 electronic health records or re-
6 lated product or service (includ-
7 ing subsequent updates, add-ons,
8 or additional products or services
9 to be provided during the course
10 of an on-going contract), prospec-
11 tive customers (such as persons
12 who request or receive a
13 quotation, estimate, or other
14 similar marketing or promotional
15 material), and other persons who
16 request such information;

17 “(cc) that the software with
18 respect to such records have pub-
19 lished application programming
20 interfaces for medical records
21 data, search and indexing, se-
22 mantic harmonization and vocab-
23 ulary translation, and user inter-
24 face applications;

1 “(dd) that the entity has
2 successfully tested the use of the
3 record in the type of setting in
4 which it would be marketed;

5 “(ee) the entity has in place
6 implementation guidelines for
7 such record that support inter-
8 operability, consistent with sec-
9 tion 3010; and

10 “(ff) that the entity has in
11 place data sharing programs or
12 capabilities based on common
13 data elements through applica-
14 tion programming interfaces
15 without the requirement for ven-
16 dor-specific interfaces;

17 “(II) publish application pro-
18 gramming interfaces and associated
19 documentation, with respect to such
20 records, for medical records data,
21 search and indexing, semantic harmo-
22 nization and vocabulary translation,
23 and user interface applications; and

24 “(III) demonstrate to the satis-
25 faction of the Secretary that data

1 from such records is able to be ex-
2 changed through the use of applica-
3 tion programming interfaces and used
4 in a manner that allows for exchange
5 and everyday use, as authorized under
6 applicable law, of such record.

7 “(ii) DECERTIFICATION.—Under any
8 program kept or recognized under subpara-
9 graph (A), the Secretary shall ensure that
10 beginning January 1, 2019, any qualified
11 electronic health records that do not sat-
12 isfy the certification criteria described in
13 section 3001(c)(5)(B)(ii) or with respect to
14 which the vendor or other entity described
15 in clause (i) does not satisfy the require-
16 ments under such clause (or is determined
17 to be in violation of the terms of the attes-
18 tation or other requirements under such
19 clause) shall no longer be considered as
20 certified under such program.

21 “(iii) ANNUAL PUBLICATION.—For
22 2019 and each subsequent year, the Sec-
23 retary shall post on the public Internet
24 website of the Department of Health and
25 Human Services a list of any vendors of or

1 other entities offering qualified electronic
2 health records with respect to which cer-
3 tification has been withdrawn under clause
4 (ii) during such year.

5 “(iv) PERIODIC REVIEW.—The Sec-
6 retary shall periodically review and confirm
7 that vendors of and other entities offering
8 qualified electronic health records have
9 publicly published application program-
10 ming interfaces and associated documenta-
11 tion as required by clause (i)(II) for pur-
12 poses of certification and maintaining cer-
13 tification under any program kept or rec-
14 ognized under subparagraph (A).

15 “(v) PRICING INFORMATION.—For
16 purposes of clause (i)(I)(bb), the pricing
17 information described in this clause, with
18 respect to a vendor of or other entity offer-
19 ing a qualified electronic health record, is
20 the following:

21 “(I) Additional types of costs or
22 fees (whether fixed, recurring, trans-
23 action based, or otherwise) imposed by
24 the entity (or any third-party from
25 whom the entity purchases, licenses,

1 or obtains any technology, products,
2 or services in connection with the
3 qualified electronic health record) to
4 purchase, license, implement, main-
5 tain, upgrade, use, or otherwise enable
6 and support the use of capabilities to
7 which such record is to be certified
8 under this section; or in connection
9 with any data generated in the course
10 of using any capability to which the
11 record is to be so certified.

12 “(II) Limitations, whether by
13 contract or otherwise, on the use of
14 any capability to which the record is
15 to be certified under this section for
16 any purpose within the scope of the
17 record’s certification; or in connection
18 with any data generated in the course
19 of using any capability to which the
20 record is to be certified under this
21 section.

22 “(III) Limitations, including
23 technical or practical limitations of
24 technology or its capabilities, that
25 could prevent or impair the successful

1 implementation, configuration,
2 customization, maintenance, support,
3 or use of any capabilities to which the
4 record is to be certified under this
5 section; or that could prevent or limit
6 the use, exchange, or portability of
7 any data generated in the course of
8 using any capability to which the
9 record is to be so certified.”.

10 (2) ADDITIONAL ENFORCEMENT PROVISIONS
11 UNDER THE PUBLIC HEALTH SERVICE ACT.—Sub-
12 title A of title XXX of the Public Health Service Act
13 (42 U.S.C. 300jj–11 et seq.), as amended by sub-
14 section (a)(1), is further amended by adding at the
15 end the following new section:

16 **“SEC. 3010A. ENFORCEMENT MECHANISMS.**

17 “(a) INSPECTOR GENERAL AUTHORITY.—The In-
18 spector General of the Department of Health and Human
19 Services shall have the authority to investigate claims of—

20 “(1) vendors of, or other entities offering, quali-
21 fied electronic health records—

22 “(A) being in violation of an attestation
23 made under section 3001(c)(5)(C)(i)(I), with
24 respect to the use of such records by a health

1 care provider under a specified meaningful use
2 incentive program; and

3 “(B) having engaged in information block-
4 ing (as defined in subsection (f)), unless for a
5 legitimate purpose specified by the Secretary,
6 with respect to the use of such records by a
7 health care provider under such a program;

8 “(2) health care providers, with respect to the
9 use of such records under a specified meaningful use
10 incentive program, having, unless for a legitimate
11 purpose specified by the Secretary, engaged in infor-
12 mation blocking (as so defined);

13 “(3) health information system providers de-
14 scribed in subsection (b) having engaged in informa-
15 tion blocking (as so defined), unless for a legitimate
16 purpose specified by the Secretary, with respect to
17 the use of such records under a specified meaningful
18 use incentive program; and

19 “(4) vendors of, or other entities offering,
20 health information technology (other than technology
21 described in paragraph (1)), health care providers,
22 with respect to the use of such technology, and
23 health information system providers, with respect to
24 such technology, unless for a legitimate purpose

1 specified by the Secretary, having engaged in infor-
2 mation blocking (as so defined).

3 “(b) HEALTH INFORMATION SYSTEM PROVIDERS.—
4 The Inspector General of the Department of Health and
5 Human Services shall, in coordination with the Federal
6 Trade Commission, ensure that health information system
7 providers (such as operators of health information ex-
8 changes and other systems that facilitate the exchange of
9 information) investigate claims of information blocking,
10 with respect to the use of such records under a specified
11 meaningful use incentive program.

12 “(c) INFORMATION SHARING PROVISIONS.—

13 “(1) IN GENERAL.—The National Coordinator
14 may serve as a technical consultant to the Inspector
15 General of the Department of Health and Human
16 Services and the Federal Trade Commission for pur-
17 poses of carrying out this section. As such technical
18 consultant, the National Coordinator may, notwith-
19 standing any other provision of law, share informa-
20 tion related to claims or investigations under sub-
21 section (a) or (b) with the Inspector General and
22 Federal Trade Commission for purposes of such in-
23 vestigations.

24 “(2) PROTECTION FROM DISCLOSURE OF IN-
25 FORMATION.—Any information shared by the Na-

1 tional Coordinator under paragraph (1) shall not be
2 subject to the provisions of section 552 of title 5,
3 United States Code (commonly referred to as the
4 Freedom of Information Act). Any information ac-
5 quired pursuant to paragraph (1) shall be held in
6 confidence and shall not be disclosed to any person
7 except as may be necessary to carry out the pur-
8 poses of subsection (a).

9 “(3) NON-APPLICATION OF PAPERWORK REDUC-
10 TION ACT.—Chapter 35 of title 44, United States
11 Code (commonly referred to as the Paperwork Re-
12 duction Act of 1995) shall not apply to the National
13 Coordinator or to the Office of the National Coordi-
14 nator for Health Information Technology with re-
15 spect to the collection of complaints relating to
16 claims described in subsection (a).

17 “(d) PENALTY.—Any person or entity determined to
18 have committed an act described in paragraph (1), (2),
19 or (3) of subsection (a), in connection with a specified
20 meaningful use incentive program, shall be subject to a
21 civil monetary penalty of not more than \$10,000 for each
22 such act. The provisions of section 1128A (other than sub-
23 sections (a) and (b)) shall apply to a civil money penalty
24 applied under this subsection in the same manner as they

1 apply to a civil money penalty or proceeding under section
2 1128A(a).

3 “(e) SPECIFIED MEANINGFUL USE INCENTIVE PRO-
4 GRAM.—For purposes of this section, the term ‘specified
5 meaningful use incentive program’ includes the following:

6 “(1) The incentive payments under subsection
7 (o) of section 1848 of the Social Security Act (42
8 U.S.C. 1395w–4) and adjustments under subsection
9 (a)(7) of such section.

10 “(2) The incentive payments under subsection
11 (n) of section 1848 of such Act (42 U.S.C. 1395ww)
12 and adjustments under subsection (b)(3)(B) of such
13 section.

14 “(3) The incentive payments and adjustments
15 made under subsections (l) and (m) of section 1853
16 of such Act (42 U.S.C. 1395w–23).

17 “(4) The incentive payment under paragraph
18 (3) of section 1814(l) of such Act (42 U.S.C.
19 1395f(l)) and adjustment under paragraph (4) of
20 such section.

21 “(5) The shared savings program under section
22 1899 of such Act (42 U.S.C. 1395jjj).

23 “(6) The payments to Medicaid providers de-
24 scribed in section 1903(t) of such Act (42 U.S.C.
25 1396b(t)).

1 “(f) INFORMATION BLOCKING.—

2 “(1) IN GENERAL.—For purposes of this sec-
3 tion and section 3010, the term ‘information block-
4 ing’ means, with respect to the use of qualified elec-
5 tronic health records or other health information
6 technology under a specified meaningful use incen-
7 tive program, business, technical, and organizational
8 practices, including practices described in paragraph
9 (2), that—

10 “(A) prevent or materially discourage the
11 exchange of electronic health information;

12 “(B) the actor knows or should know (as
13 defined in section 1128A(i)(7) of the Social Se-
14 curity Act) is likely to interfere with the ex-
15 change or use of electronic health information;
16 and

17 “(C) do not serve to protect patient safety,
18 maintain the privacy and security of individ-
19 uals’ health information or promote competition
20 and consumer welfare.

21 “(2) PRACTICES DESCRIBED.—For purposes of
22 paragraph (1), the practices described in this para-
23 graph are the following:

24 “(A) Contract terms, policies, or other
25 business or organizational practices that restrict

1 individuals' access to their electronic health in-
2 formation or restrict the exchange or use of
3 that information for treatment and other per-
4 mitted purposes.

5 “(B) Charging prices or fees (such as for
6 data exchange, portability, and interfaces) that
7 make exchanging and using electronic health in-
8 formation cost prohibitive.

9 “(C) Developing or implementing health
10 information technology in non-standard ways
11 that are likely to substantially increase the
12 costs, complexity, or burden of sharing elec-
13 tronic health information, especially in cases in
14 which relevant interoperability standards or
15 methods to measure interoperability have been
16 adopted by the Secretary.

17 “(D) Developing or implementing health
18 information technology in ways that are likely
19 to lock in users or electronic health information,
20 such as not allowing for the full export of data;
21 lead to fraud, waste, or abuse; or impede inno-
22 vations and advancements in health information
23 exchange and health information technology-en-
24 abled care delivery.

1 “(g) TREATMENT OF VENDORS WITH RESPECT TO
2 PATIENT SAFETY ORGANIZATIONS.—In applying part C
3 of title IX—

4 “(1) vendors shall be treated as a provider (as
5 defined in section 921) for purposes of reporting re-
6 quirements under such part, to the extent that such
7 reports are related to attestation requirements under
8 section 3001(c)(5)(C)(i)(I);

9 “(2) claims of information blocking described in
10 subsection (a) shall be treated as a patient safety ac-
11 tivity under such part for purposes of reporting re-
12 quirements under such part; and

13 “(3) health care providers that are not mem-
14 bers of patient safety organizations shall be treated
15 in the same manner as health care providers that
16 are such members for purposes of such reporting re-
17 quirements with respect to claims of information
18 blocking described in subsection (a).”.

19 (3) ONCHIT.—

20 (A) PORTAL.—Section 3001(c) of the Pub-
21 lic Health Service Act (42 U.S.C. 300jj–11(c))
22 is amended by adding at the end the following
23 new paragraph:

24 “(9) PORTAL.—Not later than January 1,
25 2019, the National Coordinator shall create a portal

1 to make the information described in paragraph
2 (5)(C)(I)(i)(bb) available to the public in a manner
3 that allows for comparison of price information
4 among health information technology products and
5 that aids in making informed decisions for pur-
6 chasing such a product.”.

7 (B) INFORMATION BLOCKING.—Not later
8 than 12 months after the date of the enactment
9 of this Act, the National Coordinator shall,
10 through rulemaking, implement the provisions
11 of this section, and amendments made by this
12 section, relating to information blocking.

13 (C) HIPAA.—Not later than January 1,
14 2017, the National Coordinator shall publish
15 guidance to clarify the relationship of the
16 HIPAA privacy and security law, as defined in
17 section 3009(a)(2) of the Public Health Service
18 Act (42 U.S.C. 300jj–19(a)(2)) as such provi-
19 sions relate to information blocking (as defined
20 in section 3010A(f) of such Act, as added by
21 paragraph (2), including examples of how such
22 provisions may result in information blocking.

23 (4) DEMONSTRATION REQUIRED FOR MEANING-
24 FUL EHR USE INCENTIVES UNDER MEDICARE.—

25 (A) INCENTIVES FOR PROFESSIONALS.—

1 (i) IN GENERAL.—Section
2 1848(o)(2)(C) of the Social Security Act
3 (42 U.S.C. 1395w–4(o)(2)(C)) is amended
4 by adding at the end the following new
5 clause:”.

6 “(iii) INTEROPERABILITY.—With re-
7 spect to EHR reporting periods for pay-
8 ment years beginning with 2018, the
9 means described in clause (i) specified by
10 the Secretary shall include a demonstra-
11 tion, through means such as an attesta-
12 tion, that the professional has not taken
13 any action described in subsection (a)(2) of
14 section 3010A of the Public Health Service
15 Act with respect to which the professional,
16 with respect to the use of any certified
17 EHR technology.”.

18 (ii) HARDSHIP EXEMPTION IN CASE
19 OF DECERTIFIED EHR.—Subparagraph (B)
20 of section 1848(a)(7) of the Social Security
21 Act (42 U.S.C. 1395w–4(a)(7)(B)) is
22 amended to read as follows:

23 “(B) SIGNIFICANT HARDSHIP EXCEP-
24 TION.—

1 “(i) IN GENERAL.—The Secretary
2 may, on a case-by-case basis, exempt an el-
3 igible professional from the application of
4 the payment adjustment under subpara-
5 graph (A) if the Secretary determines, sub-
6 ject to annual renewal, that compliance
7 with the requirement for being a meaning-
8 ful EHR user would result in a significant
9 hardship, such as in the case of an eligible
10 professional who practices in a rural area
11 without sufficient Internet access.

12 “(ii) DECERTIFICATION.—

13 “(I) IN GENERAL.—The Sec-
14 retary may, on a case-by-case basis,
15 exempt an eligible professional from
16 the application of the payment adjust-
17 ment under subparagraph (A) if the
18 Secretary determines that such pro-
19 fessional was determined to not be a
20 meaningful EHR user because the
21 qualified electronic health record used
22 by such professional was decertified
23 under section 3001(c)(5)(C) of the
24 Public Health Service Act. An exemp-
25 tion under the previous sentence may

1 be applied to an eligible professional
2 only, subject to subclause (II), during
3 the first payment year with respect to
4 the first EHR reporting period to
5 which such decertification applies.

6 “(II) DURATION.—

7 “(aa) IN GENERAL.—In no
8 case shall an exemption by rea-
9 son of this clause be for a period
10 of less than 12 months.

11 “(bb) EXTENSION.—An ex-
12 emption under this clause may be
13 extended for a period of an addi-
14 tional 12 months subject to the
15 limitation described in clause (ii).

16 “(iii) LIMITATION.—Subject to clause
17 (ii)(II)(aa), in no case may an eligible pro-
18 fessional be granted an exemption under
19 this subparagraph for more than 5 years.”.

20 (B) INCENTIVES FOR HOSPITALS.—

21 (i) IN GENERAL.—Section 1886(o)(1)
22 of the Social Security Act (42 U.S.C.
23 1395ww(o)(1)) is amended—

24 (I) in subparagraph (A), by in-
25 serting before the period at the end

1 the following: “and, for performance
2 periods for fiscal year 2018 or a sub-
3 sequent fiscal year, that provide a
4 demonstration described in subpara-
5 graph (D) to the Secretary”; and

6 (II) by adding at the end the fol-
7 lowing new subparagraph:

8 “(D) DEMONSTRATION DESCRIBED.—The
9 demonstration described in this subparagraph is
10 a demonstration, through means such as an at-
11 testation, that the hospital has not taken any
12 action described in subsection (a)(2) of section
13 3010A of the Public Health Service Act with
14 respect to which the hospital, with respect to
15 the 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 record
18 used by such hospital was decertified
19 under section 3001(c)(5)(C) of the
20 Public Health Service Act. An exemp-
21 tion under the previous sentence may
22 be applied to a subsection (d) hospital
23 only, subject to items (cc) and (dd),
24 during the first payment year with re-
25 spect to the first EHR reporting pe-

1 riod to which such decertification ap-
2 plies.

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) An exemption under item
7 (bb) may be extended for a period of
8 an additional 12 months subject to
9 the limitation described in item (ee).

10 “(ee) Subject to item (cc), in no
11 case may a hospital be granted an ex-
12 emption under this subclause for more
13 than 5 years.”.

14 (C) DEMONSTRATION REQUIRED FOR
15 MEANINGFUL EHR USE INCENTIVES UNDER
16 MEDICAID.—Section 1903(t)(2) of the Social
17 Security Act (42 U.S.C. 1396b(t)(2)) is amend-
18 ed by adding at the end the following: “An eli-
19 gible professional shall not qualify as a Med-
20 icaid provider under this subsection, with re-
21 spect to a year beginning with 2018, unless
22 such provider demonstrates to the Secretary,
23 through means such as an attestation, that the
24 provider has not taken any action described in
25 subsection (a)(2) of section 3010A of the Public

1 Health Service Act with respect to which the
2 provider knows or should know (as defined in
3 section 1128A(i)(7) of the Social Security Act)
4 about, with respect to the use of any certified
5 EHR technology.”.

6 (f) DEFINITIONS.—

7 (1) CERTIFIED EHR TECHNOLOGY.—Paragraph
8 (1) of section 3000 of the Public Health Service Act
9 (42 U.S.C. 300jj) is amended to read as follows:

10 “(1) CERTIFIED EHR TECHNOLOGY.—The term
11 ‘certified EHR technology’ means a qualified elec-
12 tronic health record that is certified pursuant to sec-
13 tion 3001(c)(5) as meeting the certification criteria
14 defined in subparagraph (B) of such section that are
15 applicable to the type of record involved (as deter-
16 mined by the Secretary, such as an ambulatory elec-
17 tronic health record for office-based physicians or an
18 inpatient hospital electronic health record for hos-
19 pitals) including, beginning January 1, 2018, with
20 respect to which the vendor or other entity offering
21 such technology is in compliance with the require-
22 ments under section 3001(c)(5)(C)(i).”.

23 (2) WIDESPREAD INTEROPERABILITY.—Section
24 3000 of the Public Health Service Act (42 U.S.C.

1 300jj) is amended by adding at the end the following
2 new paragraph:

3 “(15) WIDESPREAD INTEROPERABILITY.—The
4 term ‘widespread interoperability’ means that, on a
5 nationwide basis—

6 “(A) health information technology are
7 interoperable, in accordance with section 3010,
8 including as measured by the methods adopted
9 under such section; and

10 “(B) such records are employed by mean-
11 ingful EHR users under the specified meaning-
12 ful use incentive programs (as defined in sec-
13 tion 3010A(e)) and other clinicians and health
14 care providers.”.

15 (g) CONFORMING AMENDMENTS.—

16 (1) VOLUNTARY USE OF STANDARDS.—Section
17 3006 of the Public Health Service Act (42 U.S.C.
18 300jj–16) is amended—

19 (A) in subsection (a)(1), by inserting “in-
20 cluding an interoperability standard adopted
21 under section 3004” after “section 3004”.

22 (B) in subsection (b), by inserting “includ-
23 ing the interoperability standards adopted
24 under section 3004” after “section 3004”.

1 (2) HIPAA PRIVACY AND SECURITY LAW DEFINITION CORRECTION.—Section 3009(a)(2)(A) of the
2 Public Health Service Act (42 U.S.C. 300jj–
3 19(a)(2)(A)) is amended by striking “title IV” and
4 inserting “title XIII”.

6 (3) COORDINATION OF FEDERAL ACTIVITIES.—
7 Section 13111 of the HITECH Act is amended—

8 (A) in subsection (a), by inserting before
9 the period at the end the following: “(and, be-
10 ginning on January 1, 2018, that are also
11 interoperable under section 3010 of such Act,
12 including by being in compliance with interoper-
13 ability standards adopted under section 3004 of
14 such Act)”;

15 (B) in subsection (b), by inserting “(and,
16 beginning on January 1, 2018, including an
17 interoperability standard adopted under section
18 3004 of such Act)” before “the President”.

19 (4) APPLICATION TO PRIVATE ENTITIES.—Sec-
20 tion 13112 of the HITECH Act is amended by in-
21 serting before the period at the end the following
22 “(and, beginning on January 1, 2018, that are also
23 interoperable under section 3010 of such Act, in-
24 cluding by being in compliance with interoperability
25 standards adopted under section 3004 of such Act)”.

1 (5) COORDINATION WITH RECOMMENDATIONS
2 FOR ACHIEVING WIDESPREAD EHR INTEROPER-
3 ABILITY.—Section 106 of the Medicare Access and
4 CHIP Reauthorization Act of 2015 (Public Law
5 114–10) is amended by striking subsection (b).”.

6 (h) PATIENT EMPOWERMENT.—It is the sense of
7 Congress that—

8 (1) patients have the right to the entirety of the
9 health information of such patient, including such
10 information contained in an electronic health record
11 of such patient;

12 (2) such right extends to both structured and
13 unstructured data; and

14 (3) to further facilitate patient ownership over
15 health information of such patient—

16 (A) health care providers should not have
17 the ability to deny a patient’s request for access
18 to the entirety of such health information of
19 such patient; and

20 (B) health care providers do not need the
21 consent of their patients to share personal
22 health information of such patients with other
23 covered entities, in compliance with the HIPAA
24 privacy regulations promulgated pursuant to
25 section 264(c) of the Health Insurance Port-

1 ability and Accountability Act of 1996 for the
2 purposes of supporting patient care, except in
3 situations where consent is specifically required
4 under such regulations, such as in cases related
5 to the psychiatric records of the patient.

6 **Subtitle B—Telehealth**

7 **SEC. 3021. TELEHEALTH SERVICES UNDER THE MEDICARE**
8 **PROGRAM.**

9 (a) PROVISION OF INFORMATION BY CENTERS FOR
10 MEDICARE & MEDICAID SERVICES.—Not later than one
11 year after the date of the enactment of this Act, the Ad-
12 ministrator of the Centers for Medicare & Medicaid Serv-
13 ices shall provide to the committees of jurisdiction of the
14 House of Representatives and the Senate information on
15 the following:

16 (1) The populations of Medicare beneficiaries,
17 such as those who are dually eligible for the Medi-
18 care program under title XVIII of the Social Secu-
19 rity Act and the Medicaid program under title XIX
20 of such Act and those with chronic conditions, whose
21 care may be improved most in terms of quality and
22 efficiency by the expansion, in a manner that meets
23 or exceeds the existing in-person standard of care
24 under the Medicare program under title XVIII of

1 such Act, of telehealth services under section
2 1834(m)(4) of such Act (42 U.S.C. 1395m(m)(4)).

3 (2) Activities by the Center for Medicare and
4 Medicaid Innovation which examine the use of tele-
5 health services in models, projects, or initiatives
6 funded through section 1115A of the Social Security
7 Act (42 U.S.C. 1315a).

8 (3) The types of high volume procedures codes
9 or diagnoses under such title XVIII which might be
10 suitable to the furnishing of services via telehealth.

11 (4) Barriers that might prevent the expansion
12 of telehealth services under section 1834(m)(4) of
13 the Social Security Act (42 U.S.C. 1395m(m)(4))
14 beyond such services that are in effect as of the date
15 of the enactment of this Act.

16 (b) PROVISION OF INFORMATION BY MEDPAC.—Not
17 later than one year after the date of the enactment of this
18 Act, the Medicare Payment Advisory Commission estab-
19 lished under section 1805 of the Social Security Act (42
20 U.S.C. 1395b–6) shall, using data from the Medicare Ad-
21 vantage program under part C of title XVIII of such Act,
22 provide information to the committees of jurisdiction of
23 the House of Representatives and the Senate that identi-
24 fies—

25 (1) services—

1 (A) for which payment could not be made,
2 as of the date of the enactment of this Act,
3 under the fee-for-service program under parts A
4 and B of such title by reason of any limitation
5 imposed under section 1834(m) of such Act (42
6 U.S.C. 1395m(m)); and

7 (B) that are services that are rec-
8 ommended by the Commission to be included as
9 telehealth services for which payment may be
10 made under the fee-for-service program under
11 parts A and B of such title; and

12 (2) barriers to furnishing telehealth services for
13 which payment may be made under such title XVIII
14 and solutions to address such barriers.

15 (c) SENSE OF CONGRESS.—It is the sense of Con-
16 gress that—

17 (1) States should collaborate, through the use
18 of State health board compacts or other mecha-
19 nisms, to create common licensure requirements
20 services in order to facilitate multistate practices
21 and allow for health care providers to provide such
22 services across State lines;

23 (2) health care providers should be appro-
24 priately licensed in the physical location where the
25 patient is receiving services;

1 (3) eligible originating sites should be expanded
2 beyond those originating sites described in section
3 1834(m)(4)(C) of the Social Security Act (42 U.S.C.
4 1395m(m)(4)(C)); and

5 (4) any expansion of telehealth services under
6 the Medicare program should—

7 (A) recognize that telemedicine is the deliv-
8 ery of safe, effective, quality health care serv-
9 ices, by a health care provider, using technology
10 as the mode of care delivery;

11 (B) meet or exceed the conditions of cov-
12 erage and payment with respect to the Medicare
13 program under title XVIII unless specifically
14 address in subsequent statute, of such Act if
15 the service were furnished in person, including
16 standards of care; and

17 (C) involve clinically appropriate means to
18 furnish such services.

1 **Subtitle C—Encouraging Con-**
2 **tinuing Medical Education for**
3 **Physicians**

4 **SEC. 3041. EXEMPTING FROM MANUFACTURER TRANS-**
5 **PARENCY REPORTING CERTAIN TRANSFERS**
6 **USED FOR EDUCATIONAL PURPOSES.**

7 (a) IN GENERAL.—Section 1128G(e)(10)(B) of the
8 Social Security Act (42 U.S.C. 1320a–7h(e)(10)(B)) is
9 amended—

10 (1) in clause (iii), by inserting “, including
11 peer-reviewed journals, journal reprints, journal sup-
12 plements, medical conference reports, and medical
13 textbooks” after “patient use”; and

14 (2) by adding at the end the following new
15 clause:

16 “(xiii) In the case of a covered recipi-
17 ent who is a physician, an indirect pay-
18 ment or transfer of value to the covered re-
19 cipient—

20 “(I) for speaking at, or preparing
21 educational materials for, an edu-
22 cational event for physicians or other
23 health care professionals that does not
24 commercially promote a covered drug,

1 device, biological, or medical supply;
2 or

3 “(II) that serves the sole purpose
4 of providing the covered recipient with
5 medical education, such as by pro-
6 viding the covered recipient with the
7 tuition required to attend an edu-
8 cational event or with materials pro-
9 vided to physicians at an educational
10 event.”.

11 (b) EFFECTIVE DATE.—The amendments made by
12 this section shall apply with respect to transfers of value
13 made on or after the date of the enactment of this Act.

14 **Subtitle D—Disposable Medical**
15 **Technologies**

16 **SEC. 3061. TREATMENT OF CERTAIN ITEMS AND DEVICES.**

17 (a) PAYMENT FOR DURABLE MEDICAL ITEMS
18 (DMI).—

19 (1) IN GENERAL.—Section 1861(s)(2) of the
20 Social Security Act (42 U.S.C. 1395x(s)(2)) is
21 amended—

22 (A) in subparagraph (EE), by striking
23 “and” at the end;

24 (B) in subparagraph (FF), by inserting
25 “and” at the end; and

1 (C) by adding at the end the following new
2 subparagraph:

3 “(GG) a durable medical item that administers
4 a drug described in section 1927(k)(2)(C) that
5 would otherwise be self-administered multiple times
6 per day and includes a disposable component and at
7 least one component that can withstand repeated
8 use, and supplies used in conjunction with such item
9 (including the drug administered by such item);”.

10 (2) PAYMENT.—

11 (A) PAYMENT AMOUNT FOR DMI.—Section
12 1834 of the Social Security Act (42 U.S.C.
13 1395m) is amended by adding at the end the
14 following new subsection:

15 “(r) PAYMENT METHODOLOGY FOR DURABLE MED-
16 ICAL ITEMS (DMI).—The Secretary shall establish a pay-
17 ment methodology for a durable medical item described
18 in section 1861(s)(2)(GG) and supplies used in conjunc-
19 tion with such item (other than a drug administered by
20 such item) such that the estimated average total payment
21 per individual for such items and supplies does not exceed
22 the estimated average total payment per individual that
23 would otherwise be made (taking into account the applica-
24 tion of section 1847) for the durable medical equipment
25 for which it is a substitute and for supplies used in con-

1 junction with such equipment (other than such a drug)
2 as determined appropriate by the Secretary.”.

3 (B) PAYMENT FOR DRUG.—Section
4 1842(o)(1)(D) of the Social Security Act (42
5 U.S.C. 1395u(o)(1)(D)) is amended—

6 (i) in clause (i), by inserting “or
7 drugs administered by a durable medical
8 item covered under section 1861(s)(2)(GG)
9 on or after January 1, 2017,” after “after
10 January 1, 2004,”; and

11 (ii) in clause (ii), by striking “infu-
12 sion”.

13 (C) COMPETITIVE ACQUISITION.—Section
14 1847(a)(2) of the Social Security Act (42
15 U.S.C. 1395w–3(a)(2)) is amended by adding
16 at the end the following new subparagraph:

17 “(D) DURABLE MEDICAL ITEM.—A dura-
18 ble medical item and supplies used in conjunc-
19 tion with such item, described in section
20 1861(s)(2)(GG).”.

21 (3) CONFORMING AMENDMENT.—Section
22 1833(a)(1) of the Social Security Act (42 U.S.C.
23 1395l(a)(1)) is amended—

24 (A) by striking “and” before “(Z)”;

1 (B) by inserting before the semicolon at
2 the end the following: “, and (AA) with respect
3 to durable medical items described in section
4 1861(s)(2)(GG), the amount paid shall be equal
5 to 80 percent of the lesser of the actual charge
6 or the amount determined under section
7 1834(r)”.

8 (4) EFFECTIVE DATE.—The amendments made
9 by this subsection shall apply to items furnished on
10 or after January 1, 2017.

11 (b) PAYMENT FOR CERTAIN DISPOSABLE DE-
12 VICES.—

13 (1) IN GENERAL.—Section 1834 of the Social
14 Security Act (42 U.S.C. 1395m), as amended by
15 subsection (a)(2), is further amended by adding at
16 the end the following new subsection:

17 “(s) PAYMENT FOR CERTAIN DISPOSABLE DE-
18 VICES.—

19 “(1) IN GENERAL.—The Secretary shall make
20 separate payment in the amount established under
21 paragraph (3) to a home health agency for a device
22 described in paragraph (2) when furnished to an in-
23 dividual who receives home health services for which
24 payment is made under section 1895(b).

1 “(2) DEVICE DESCRIBED.—For purposes of
2 paragraph (1), a device described in this paragraph
3 is a disposable device for which, as of January 1,
4 2015, there is—

5 “(A) a Level I Healthcare Common Proce-
6 dure Coding System (HCPCS) code for which
7 the description for a professional service in-
8 cludes the furnishing of such device; and

9 “(B) a separate Level I HCPCS code for
10 a professional service that uses durable medical
11 equipment instead of such device.

12 “(3) PAYMENT AMOUNT.—The Secretary shall
13 establish the separate payment amount for such a
14 device such that such amount does not exceed the
15 payment that would be made for the HCPCS code
16 described in paragraph (2)(A) under section 1833(t)
17 (relating to payment for covered OPD services).”.

18 (2) CONFORMING AMENDMENT.—Section
19 1861(m)(5) of the Social Security Act (42 U.S.C.
20 1395x(m)(5)) is amended by inserting “and devices
21 described in section 1834(s)(2)” after “durable med-
22 ical equipment”.

23 (3) EFFECTIVE DATE.—The amendments made
24 by this subsection shall apply to devices furnished on
25 or after January 1, 2017.

Subtitle E—Local Coverage Decision Reforms

SEC. 3081. IMPROVEMENTS IN THE MEDICARE LOCAL COV- ERAGE DETERMINATION (LCD) PROCESS.

(a) IN GENERAL.—Section 1862(l)(5) of the Social Security Act (42 U.S.C. 1395y(l)(5)) is amended by adding at the end the following new subparagraph:

“(D) LOCAL COVERAGE DETERMINATIONS.—The Secretary shall require each medicare administrative contractor that develops a local coverage determination to make available on the website of such contractor and in the coverage database on the Medicare website, at least 45 days before the effective date of such determination, the following information:

“(i) Such determination in its entirety.

“(ii) Where and when the proposed determination was first made public.

“(iii) Links to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.

“(iv) A summary of evidence that was considered by the contractor during the de-

1 velopment of such determination and a list
2 of the sources of such evidence.

3 “(v) An explanation of the rationale
4 that supports such determination.”.

5 (b) EFFECTIVE DATE.—The amendment made by
6 subsection (a) shall apply with respect to local coverage
7 determinations that are proposed or revised on or after
8 the date that is 180 days after the date of the enactment
9 of this Act.

10 **Subtitle F—Medicare Pharma-**
11 **ceutical and Technology Om-**
12 **budsman**

13 **SEC. 3101. MEDICARE PHARMACEUTICAL AND TECH-**
14 **NOLOGY OMBUDSMAN.**

15 Section 1808(c) of the Social Security Act (42 U.S.C.
16 1395b–9(c)) is amended by adding at the end the fol-
17 lowing new paragraph:

18 “(4) PHARMACEUTICAL AND TECHNOLOGY OM-
19 BUDSMAN.—Not later than 12 months after the date
20 of the enactment of this paragraph, the Secretary
21 shall provide for a pharmaceutical and technology
22 ombudsman within the Centers for Medicare & Med-
23 icaid Services who shall receive and respond to com-
24 plaints, grievances, and requests that—

1 “(A) are from entities that manufacture
2 pharmaceutical, biotechnology, medical device,
3 or diagnostic products that are covered or for
4 which coverage is being sought under this title;
5 and

6 “(B) regard coverage, coding, or payment
7 under this title for such products.”.

8 **Subtitle G—Medicare Site-of-**
9 **Service Price Transparency**

10 **SEC. 3121. MEDICARE SITE-OF-SERVICE PRICE TRANS-**
11 **PARENCY.**

12 Section 1834 of the Social Security Act (42 U.S.C.
13 1395m) is amended by adding at the end the following
14 new subsection:

15 “(r) SITE-OF-SERVICE PRICE TRANSPARENCY.—

16 “(1) IN GENERAL.—In order to facilitate price
17 transparency with respect to items and services for
18 which payment may be made either to a hospital
19 outpatient department or to an ambulatory surgery
20 center under this title, the Secretary shall, for 2017
21 and each year thereafter, make available to the pub-
22 lic via a searchable website, with respect to an ap-
23 propriate number of such items and services—

24 “(A) the estimated payment amount for
25 such items and services under the outpatient

1 department fee schedule under subsection (t) of
2 section 1833 and the ambulatory surgical cen-
3 ter payment system under subsection (i) of such
4 section; and

5 “(B) the estimated amount of beneficiary
6 liability applicable to such an item or service.

7 “(2) CALCULATION OF ESTIMATED BENE-
8 FICIARY LIABILITY.—For purposes of paragraph
9 (1)(B), the estimated amount of beneficiary liability,
10 with respect to an item or service, is the amount for
11 such item or service for which an individual who
12 does not have coverage under a medicare supple-
13 mental policy certified under section 1882 or any
14 other supplemental insurance coverage is respon-
15 sible.

16 “(3) IMPLEMENTATION.—In carrying out this
17 subsection, the Secretary—

18 “(A) shall include in the notice described
19 in section 1804(a) a notification of the avail-
20 ability of the estimated amounts made available
21 under paragraph (1); and

22 “(B) may utilize existing mechanisms, such
23 as the portion of the website of the Centers for
24 Medicare & Medicaid Services on which infor-
25 mation comparing physician performance is

1 posted (commonly referred to as the Physician
2 Compare website), to make available such esti-
3 mated amounts under such paragraph.

4 “(4) FUNDING.—For purposes of implementing
5 this subsection, the Secretary shall provide for the
6 transfer, from the Supplemental Medical Insurance
7 Trust Fund under section 1841 to the Centers for
8 Medicare & Medicaid Services Program Management
9 Account, of \$6,000,000 for fiscal year 2015, to re-
10 main available until expended.”.

11 **Subtitle H—Medicare Part D Pa-**
12 **tient Safety and Drug Abuse**
13 **Prevention**

14 **SEC. 3141. PROGRAMS TO PREVENT PRESCRIPTION DRUG**
15 **ABUSE UNDER MEDICARE PARTS C AND D.**

16 (a) DRUG MANAGEMENT PROGRAM FOR AT-RISK
17 BENEFICIARIES.—

18 (1) IN GENERAL.—Section 1860D–4(c) of the
19 Social Security Act (42 U.S.C. 1395w–10(c)) is
20 amended by adding at the end the following:

21 “(5) DRUG MANAGEMENT PROGRAM FOR AT-
22 RISK BENEFICIARIES.—

23 “(A) AUTHORITY TO ESTABLISH.—A PDP
24 sponsor may establish a drug management pro-
25 gram for at-risk beneficiaries under which, sub-

1 ject to subparagraph (B), the PDP sponsor
2 may, in the case of an at-risk beneficiary for
3 prescription drug abuse who is an enrollee in a
4 prescription drug plan of such PDP sponsor,
5 limit such beneficiary's access to coverage for
6 frequently abused drugs under such plan to fre-
7 quently abused drugs that are prescribed for
8 such beneficiary by one or more prescribers se-
9 lected under subparagraph (D), and dispensed
10 for such beneficiary by one or more pharmacies
11 selected under such subparagraph.

12 “(B) REQUIREMENT FOR NOTICES.—

13 “(i) IN GENERAL.—A PDP sponsor
14 may not limit the access of an at-risk ben-
15 eficiary for prescription drug abuse to cov-
16 erage for frequently abused drugs under a
17 prescription drug plan until such spon-
18 sor—

19 “(I) provides to the beneficiary
20 an initial notice described in clause
21 (ii) and a second notice described in
22 clause (iii); and

23 “(II) verifies with the providers
24 of the beneficiary that the beneficiary

1 is an at-risk beneficiary for prescrip-
2 tion drug abuse.

3 “(ii) INITIAL NOTICE.—An initial no-
4 tice described in this clause is a notice that
5 provides to the beneficiary—

6 “(I) notice that the PDP sponsor
7 has identified the beneficiary as po-
8 tentially being an at-risk beneficiary
9 for prescription drug abuse;

10 “(II) information describing all
11 State and Federal public health re-
12 sources that are designed to address
13 prescription drug abuse to which the
14 beneficiary has access, including men-
15 tal health services and other coun-
16 seling services;

17 “(III) notice of, and information
18 about, the right of the beneficiary to
19 appeal such identification under sub-
20 section (h) and the option of an auto-
21 matic escalation to external review;

22 “(IV) a request for the bene-
23 ficiary to submit to the PDP sponsor
24 preferences for which prescribers and
25 pharmacies the beneficiary would pre-

1 fer the PDP sponsor to select under
2 subparagraph (D) in the case that the
3 beneficiary is identified as an at-risk
4 beneficiary for prescription drug
5 abuse as described in clause (iii)(I);

6 “(V) an explanation of the mean-
7 ing and consequences of the identi-
8 fication of the beneficiary as poten-
9 tially being an at-risk beneficiary for
10 prescription drug abuse, including an
11 explanation of the drug management
12 program established by the PDP
13 sponsor pursuant to subparagraph
14 (A);

15 “(VI) clear instructions that ex-
16 plain how the beneficiary can contact
17 the PDP sponsor in order to submit
18 to the PDP sponsor the preferences
19 described in subclause (IV) and any
20 other communications relating to the
21 drug management program for at-risk
22 beneficiaries established by the PDP
23 sponsor; and

24 “(VII) contact information for
25 other organizations that can provide

1 the beneficiary with assistance regard-
2 ing such drug management program
3 (similar to the information provided
4 by the Secretary in other standardized
5 notices provided to part D eligible in-
6 dividuals enrolled in prescription drug
7 plans under this part).

8 “(iii) SECOND NOTICE.—A second no-
9 tice described in this clause is a notice that
10 provides to the beneficiary notice—

11 “(I) that the PDP sponsor has
12 identified the beneficiary as an at-risk
13 beneficiary for prescription drug
14 abuse;

15 “(II) that such beneficiary is
16 subject to the requirements of the
17 drug management program for at-risk
18 beneficiaries established by such PDP
19 sponsor for such plan;

20 “(III) of the prescriber (or pre-
21 scribers) and pharmacy s(or phar-
22 macies) elected for such individual
23 under subparagraph (D);

24 “(IV) of, and information about,
25 the beneficiary’s right to appeal such

1 identification under subsection (h)
2 and the option of an automatic esca-
3 lation to external review;

4 “(V) that the beneficiary can, in
5 the case that the beneficiary has not
6 previously submitted to the PDP
7 sponsor preferences for which pre-
8 scribers and pharmacies the bene-
9 ficiary would prefer the PDP sponsor
10 select under subparagraph (D), sub-
11 mit such preferences to the PDP
12 sponsor; and

13 “(VI) that includes clear instruc-
14 tions that explain how the beneficiary
15 can contact the PDP sponsor.

16 “(iv) TIMING OF NOTICES.—

17 “(I) IN GENERAL.—Subject to
18 subclause (II), a second notice de-
19 scribed in clause (iii) shall be provided
20 to the beneficiary on a date that is
21 not less than 60 days after an initial
22 notice described in clause (ii) is pro-
23 vided to the beneficiary.

24 “(II) EXCEPTION.—In the case
25 that the PDP sponsor, in conjunction

1 with the Secretary, determines that
2 concerns identified through rule-
3 making by the Secretary regarding
4 the health or safety of the beneficiary
5 or regarding significant drug diversion
6 activities require the PDP sponsor to
7 provide a second notice described in
8 clause (iii) to the beneficiary on a
9 date that is earlier than the date de-
10 scribed in subclause (II), the PDP
11 sponsor may provide such second no-
12 tice on such earlier date.

13 “(C) AT-RISK BENEFICIARY FOR PRE-
14SCRIPTION DRUG ABUSE.—

15 “(i) IN GENERAL.—For purposes of
16 this paragraph, the term ‘at-risk bene-
17 ficiary for prescription drug abuse’ means
18 a part D eligible individual who is not an
19 exempted individual described in clause (ii)
20 and—

21 “(I) who is identified through the
22 use of clinical guidelines developed by
23 the Secretary in consultation with
24 PDP sponsors and other stakeholders

1 described in section 3141(f)(2)(A) of
2 the 21st Century Cures Act; or

3 “(II) with respect to whom the
4 PDP sponsor of a prescription drug
5 plan, upon enrolling such individual in
6 such plan, received notice from the
7 Secretary that such individual was
8 identified under this paragraph to be
9 an at-risk beneficiary for prescription
10 drug abuse under the prescription
11 drug plan in which such individual
12 was most recently previously enrolled
13 and such identification has not been
14 terminated under subparagraph (F).

15 “(ii) EXEMPTED INDIVIDUAL DE-
16 SCRIBED.—An exempted individual de-
17 scribed in this clause is an individual
18 who—

19 “(I) receives hospice care under
20 this title;

21 “(II) is a resident of a long-term
22 care facility, of an intermediate care
23 facility for the mentally retarded, or
24 of another facility for which fre-
25 quently abused drugs are dispensed

1 for residents through a contract with
2 a single pharmacy; or

3 “(III) the Secretary elects to
4 treat as an exempted individual for
5 purposes of clause (i).

6 “(D) SELECTION OF PRESCRIBERS AND
7 PHARMACIES.—

8 “(i) IN GENERAL.—With respect to
9 each at-risk beneficiary for prescription
10 drug abuse enrolled in a prescription drug
11 plan offered by such sponsor, a PDP spon-
12 sor shall, based on the preferences sub-
13 mitted to the PDP sponsor by the bene-
14 ficiary pursuant to clauses (ii)(IV) and
15 (iii)(V) of subparagraph (B), select—

16 “(I) one or more individuals who
17 are authorized to prescribe frequently
18 abused drugs (referred to in this
19 paragraph as ‘prescribers’) who may
20 write prescriptions for such drugs for
21 such beneficiary; and

22 “(II) one or more pharmacies
23 that may dispense such drugs to such
24 beneficiary.

1 “(ii) REASONABLE ACCESS.—In mak-
2 ing the selections under this subpara-
3 graph—

4 “(I) a PDP sponsor shall ensure
5 that the beneficiary continues to have
6 reasonable access to drugs described
7 in subparagraph (G), taking into ac-
8 count geographic location, beneficiary
9 preference, impact on cost-sharing,
10 and reasonable travel time; or

11 “(II) a PDP sponsor shall ensure
12 such access to prescribers and phar-
13 macies in the case of individuals with
14 multiple residences and in the case of
15 natural disasters and similar emer-
16 gency situations.

17 “(iii) BENEFICIARY PREFERENCES.—

18 “(I) IN GENERAL.—If an at-risk
19 beneficiary for prescription drug
20 abuse submits preferences for which
21 in-network prescribers and pharmacies
22 the beneficiary would prefer the PDP
23 sponsor select in response to a notice
24 under subparagraph (B), the PDP
25 sponsor shall—

1 “(aa) review such pref-
2 erences;

3 “(bb) select or change the
4 selection of prescribers and phar-
5 macies for the beneficiary based
6 on such preferences; and

7 “(cc) inform the beneficiary
8 of such selection or change of se-
9 lection.

10 “(II) EXCEPTION.—In the case
11 that the PDP sponsor determines that
12 a change to the selection of prescriber
13 or pharmacy under item (bb) by the
14 PDP sponsor is contributing or would
15 contribute to prescription drug abuse
16 or drug diversion by the beneficiary,
17 the PDP sponsor may change the se-
18 lection of prescriber or pharmacy for
19 the beneficiary without regard to the
20 preferences of the beneficiary de-
21 scribed in subclause (I).

22 “(iv) CONFIRMATION.—Before select-
23 ing a prescriber (or prescribers) or phar-
24 macy (or pharmacies) under this subpara-
25 graph, a PDP sponsor must request and

1 receive confirmation from such a prescriber
2 or pharmacy acknowledging and accepting
3 that the beneficiary involved is in the drug
4 management program for at-risk bene-
5 ficiaries.

6 “(E) TERMINATIONS AND APPEALS.—The
7 identification of an individual as an at-risk ben-
8 eficiary for prescription drug abuse under this
9 paragraph, a coverage determination made
10 under a drug management program for at-risk
11 beneficiaries, and the selection of prescriber or
12 pharmacy under subparagraph (D) with respect
13 to such individual shall be subject to reconsider-
14 ation and appeal under subsection (h) and the
15 option of an automatic escalation to external re-
16 view to the extent provided by the Secretary.

17 “(F) TERMINATION OF IDENTIFICATION.—

18 “(i) IN GENERAL.—The Secretary
19 shall develop standards for the termination
20 of identification of an individual as an at-
21 risk beneficiary for prescription drug abuse
22 under this paragraph. Under such stand-
23 ards such identification shall terminate as
24 of the earlier of—

1 “(I) the date the individual dem-
2 onstrates that the individual is no
3 longer likely, in the absence of the re-
4 strictions under this paragraph, to be
5 an at-risk beneficiary for prescription
6 drug abuse described in subparagraph
7 (C)(i); or

8 “(II) the end of such maximum
9 period of identification as the Sec-
10 retary may specify.

11 “(ii) RULE OF CONSTRUCTION.—
12 Nothing in clause (i) shall be construed as
13 preventing a plan from identifying an indi-
14 vidual as an at-risk beneficiary for pre-
15 scription drug abuse under subparagraph
16 (C)(i) after such termination on the basis
17 of additional information on drug use oc-
18 curring after the date of notice of such ter-
19 mination.

20 “(G) FREQUENTLY ABUSED DRUG.—For
21 purposes of this subsection, the term ‘frequently
22 abused drug’ means a drug that is a controlled
23 substance that the Secretary determines to be
24 frequently abused or diverted.

1 “(H) DATA DISCLOSURE.—In the case of
2 an at-risk beneficiary for prescription drug
3 abuse whose access to coverage for frequently
4 abused drugs under a prescription drug plan
5 has been limited by a PDP sponsor under this
6 paragraph, such PDP sponsor shall disclose
7 data, including any necessary individually iden-
8 tifiable health information, in a form and man-
9 ner specified by the Secretary, about the deci-
10 sion to impose such limitations and the limita-
11 tions imposed by the sponsor under this part.

12 “(I) EDUCATION.—The Secretary shall
13 provide education to enrollees in prescription
14 drug plans of PDP sponsors and providers re-
15 garding the drug management program for at-
16 risk beneficiaries described in this paragraph,
17 including education—

18 “(i) provided by medicare administra-
19 tive contractors through the improper pay-
20 ment outreach and education program de-
21 scribed in section 1874A(h); and

22 “(ii) through current education efforts
23 (such as State health insurance assistance
24 programs described in subsection (a)(1)(A)
25 of section 119 of the Medicare Improve-

1 ments for Patients and Providers Act of
2 2008 (42 U.S.C. 1395b–3 note)) and ma-
3 terials directed toward such enrollees.

4 “(J) APPLICATION UNDER MA–PD
5 PLANS.—Pursuant to section 1860D—21(c)(1),
6 the provisions of this paragraph apply under
7 part D to MA organizations offering MA–PD
8 plans to MA eligible individuals in the same
9 manner as such provisions apply under this
10 part to a PDP sponsor offering a prescription
11 drug plan to a part D eligible individual.”.

12 (2) INFORMATION FOR CONSUMERS.—Section
13 1860D–4(a)(1)(B) of the Social Security Act (42
14 U.S.C. 1395w–104(a)(1)(B)) is amended by adding
15 at the end the following:

16 “(v) The drug management program
17 for at-risk beneficiaries under subsection
18 (c)(5).”.

19 (b) UTILIZATION MANAGEMENT PROGRAMS.—Sec-
20 tion 1860D–4(c) of the Social Security Act (42 U.S.C.
21 1395w–104(c)), as amended by subsection (a)(1), is fur-
22 ther amended—

23 (1) in paragraph (1), by inserting after sub-
24 paragraph (D) the following new subparagraph:

1 “(E) A utilization management tool to pre-
2 vent drug abuse (as described in paragraph
3 (6)(A)).”; and
4 (2) by adding at the end the following new
5 paragraph:

6 “(6) UTILIZATION MANAGEMENT TOOL TO PRE-
7 VENT DRUG ABUSE.—

8 “(A) IN GENERAL.—A tool described in
9 this paragraph is any of the following:

10 “(i) A utilization tool designed to pre-
11 vent the abuse of frequently abused drugs
12 by individuals and to prevent the diversion
13 of such drugs at pharmacies.

14 “(ii) Retrospective utilization review
15 to identify—

16 “(I) individuals that receive fre-
17 quently abused drugs at a frequency
18 or in amounts that are not clinically
19 appropriate; and

20 “(II) providers of services or sup-
21 pliers that may facilitate the abuse or
22 diversion of frequently abused drugs
23 by beneficiaries.

24 “(iii) Consultation with the contractor
25 described in subparagraph (B) to verify if

1 an individual enrolling in a prescription
2 drug plan offered by a PDP sponsor has
3 been previously identified by another PDP
4 sponsor as an individual described in
5 clause (ii)(I).

6 “(B) REPORTING.—A PDP sponsor offer-
7 ing a prescription drug plan (and an MA orga-
8 nization offering an MA–PD plan) in a State
9 shall submit to the Secretary and the Medicare
10 drug integrity contractor with which the Sec-
11 retary has entered into a contract under section
12 1893 with respect to such State a report, on a
13 monthly basis, containing information on—

14 “(i) any provider of services or sup-
15 plier described in subparagraph (A)(ii)(II)
16 that is identified by such plan sponsor (or
17 organization) during the 30-day period be-
18 fore such report is submitted; and

19 “(ii) the name and prescription
20 records of individuals described in para-
21 graph (5)(C).”.

22 (c) EXPANDING ACTIVITIES OF MEDICARE DRUG IN-
23 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-
12 PD plans, and physicians with respect to an indi-
13 vidual in order for such contractors to provide infor-
14 mation relevant to the determination of whether
15 such individual is an at-risk beneficiary for prescrip-
16 tion drug abuse, as defined in section 1860D-
17 4(c)(5)(C).

18 “(2) REQUIREMENT FOR ACKNOWLEDGMENT
19 OF REFERRALS.—If a PDP sponsor or MA organiza-
20 tion refers information to a contractor described in
21 paragraph (1) in order for such contractor to assist
22 in the determination described in such paragraph,
23 the contractor shall—

24 “(A) acknowledge to the sponsor or organi-
25 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) SENSE OF CONGRESS REGARDING USE OF TECH-
17 NOLOGY TOOLS TO COMBAT FRAUD.—It is the sense of
18 Congress that MA organizations and PDP sponsors
19 should consider using e-prescribing and other health infor-
20 mation technology tools to support combating fraud under
21 MA–PD plans and prescription drug plans under parts C
22 and D of the Medicare program.

23 (f) EFFECTIVE DATE.—

24 (1) IN GENERAL.—The amendments made by
25 this section shall apply to prescription drug plans

1 (and MA–PD plans) for plan years beginning more
2 than 1 year after the date of the enactment of this
3 Act.

4 (2) STAKEHOLDER MEETINGS PRIOR TO EFFEC-
5 TIVE DATE.—

6 (A) IN GENERAL.—Not later than January
7 1, 2016, the Secretary of Health and Human
8 Services shall convene stakeholders, including
9 individuals entitled to benefits under part A of
10 title XVIII of the Social Security Act or en-
11 rolled under part B of such title of such Act,
12 advocacy groups representing such individuals,
13 physicians, pharmacists, and other clinicians,
14 retail pharmacies, plan sponsors, entities dele-
15 gated by plan sponsors, and biopharmaceutical
16 manufacturers for input regarding the topics
17 described in subparagraph (B).

18 (B) TOPICS DESCRIBED.—The topics de-
19 scribed in this subparagraph are the topics of—

20 (i) the impact on cost-sharing and en-
21 suring accessibility to prescription drugs
22 for enrollees in prescription drug plans of
23 PDP sponsors, and enrollees in MA–PD
24 plans, who are at-risk beneficiaries for pre-
25 scription drug abuse (as defined in sub-

1 paragraph (C) of paragraph (5) of section
2 1860D–4(c) of the Social Security Act (42
3 U.S.C. 1395w–104(c));

4 (ii) the use of an expedited appeals
5 process under which such an enrollee may
6 appeal an identification of such enrollee as
7 an at-risk beneficiary for prescription drug
8 abuse under such paragraph (similar to the
9 processes established under the Medicare
10 Advantage program under part C of title
11 XVIII of the Social Security Act that allow
12 an automatic escalation to external review
13 of claims submitted under such part);

14 (iii) the types of enrollees that should
15 be treated as exempted individuals, as de-
16 scribed in subparagraph (C)(ii) of such
17 paragraph;

18 (iv) the manner in which terms and
19 definitions in such paragraph should be ap-
20 plied, such as the use of clinical appro-
21 priateness in determining whether an en-
22 rollee is an at-risk beneficiary for prescrip-
23 tion drug abuse as defined in subpara-
24 graph (C) of such paragraph;

1 (v) the information to be included in
2 the notices described in subparagraph (B)
3 of such paragraph and the standardization
4 of such notices; and

5 (vi) with respect to a PDP sponsor
6 (or Medicare Advantage organization) that
7 establishes a drug management program
8 for at-risk beneficiaries under such para-
9 graph, the responsibilities of such PDP
10 sponsor (or organization) with respect to
11 the implementation of such program.

12 (g) RULEMAKING.—The Secretary of Health and
13 Human Services shall promulgate regulations based on the
14 input gathered pursuant to subsection (f)(2)(A).

