

## COMMITTEE PRINT

[SHOWING THE TEXT OF THE BILL AS FAVORABLY FORWARDED BY THE  
SUBCOMMITTEE ON HEALTH ON MAY 14, 2015]

114TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

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

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### IN THE HOUSE OF REPRESENTATIVES

Mr. UPTON (for himself, Ms. DEGETTE, Mr. PITTS, Mr. PALLONE, and Mr.  
GENE GREEN of Texas) introduced the following bill; which was referred  
to the Committee on \_\_\_\_\_

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## A BILL

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

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

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

4       (a) SHORT TITLE.—This Act may be cited as the  
5       “21st Century Cures Act”.

6       (b) TABLE OF CONTENTS.—The table of contents for  
7       this Act is as follows:

Sec. 1. Short title; table of contents.

## TITLE I—DISCOVERY

### Subtitle A—National Institutes of Health Funding

Sec. 1001. National Institutes of Health reauthorization.

Sec. 1002. NIH Innovation Fund.

### Subtitle B—National Institutes of Health Planning and Administration

Sec. 1021. NIH research strategic plan.

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

Sec. 1023. Biomedical research working group.

Sec. 1024. Exemption for the National Institutes of Health from the Paperwork Reduction Act requirements.

Sec. 1025. NIH travel.

Sec. 1026. Other transactions authority.

Sec. 1027. NCATS phase IIB restriction.

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

### Subtitle C—Supporting Young Emerging Scientists

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

Sec. 1042. Report.

### Subtitle D—Capstone Grant Program

Sec. 1061. Capstone award.

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

Sec. 1081. National Pediatric Research Network.

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

Sec. 1083. Appropriate age groupings in clinical research.

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

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

Sec. 1102. Standardization of data in Clinical Trial Registry Data Bank on eligibility for clinical trials.

### Subtitle G—Facilitating Collaborative Research

Sec. 1121. Clinical Trial Data System.

Sec. 1122. National neurological diseases surveillance system.

Sec. 1123. Data on natural history of diseases.

Sec. 1124. Accessing, sharing, and using health data for research purposes.

### Subtitle H—Council for 21st Century Cures

Sec. 1141. Council for 21st Century Cures.

## TITLE II—DEVELOPMENT

### Subtitle A—Patient-Focused Drug Development

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

Subtitle B—Qualification and Use of Drug Development Tools

Sec. 2021. Qualification of drug development tools.

Sec. 2022. Accelerated approval development plan.

Subtitle C—FDA Advancement of Precision Medicine

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

Subtitle D—Modern Trial Design and Evidence Development

Sec. 2061. Broader application of Bayesian statistics and adaptive trial designs.

Sec. 2062. Utilizing evidence from clinical experience.

Sec. 2063. Streamlined data review program.

Subtitle E—Expediting Patient Access

Sec. 2081. Sense of Congress.

Sec. 2082. Expanded access policy.

Sec. 2083. Finalizing draft guidance on expanded access.

Subtitle F—Facilitating Responsible Manufacturer Communications

Sec. 2101. Facilitating dissemination of health care economic information.

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

Subtitle G—Antibiotic Drug Development

Sec. 2121. Approval of certain drugs for use in a limited population of patients.

Sec. 2122. Susceptibility test interpretive criteria for microorganisms.

Sec. 2123. Encouraging the development and responsible use of new antimicrobial drugs.

Subtitle H—Vaccine Access, Certainty, and Innovation

Sec. 2141. Timely review of vaccines by the Advisory Committee on Immunization Practices.

Sec. 2142. Review of processes and consistency of ACIP recommendations.

Sec. 2143. Meetings between CDC and vaccine developers.

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

Sec. 2151. Extension of exclusivity periods for a drug approved for a new indication for a rare disease or condition.

Sec. 2152. Reauthorization of rare pediatric disease priority review voucher incentive program.

Subtitle J—Domestic Manufacturing and Export Efficiencies

Sec. 2161. Grants for studying the process of continuous drug manufacturing.

Sec. 2162. Re-exportation among members of the European Economic Area.

Subtitle K—Enhancing Combination Products Review

Sec. 2181. Enhancing combination products review.

Subtitle L—Priority Review for Breakthrough Devices

Sec. 2201. Priority review for breakthrough devices.

Subtitle M—Medical Device Regulatory Process Improvements

Sec. 2221. Third-party quality system assessment.

Sec. 2222. Valid scientific evidence.

Sec. 2223. Training and oversight in least burdensome appropriate means concept.

Sec. 2224. Recognition of standards.

Sec. 2225. Easing regulatory burden with respect to certain class I and class II devices.

Sec. 2226. Advisory committee process.

Sec. 2227. Humanitarian device exemption application.

Sec. 2228. CLIA waiver study design guidance for in vitro diagnostics.

Subtitle N—Sensible Oversight for Technology Which Advances Regulatory Efficiency

Sec. 2241. Health software.

Sec. 2242. Applicability and inapplicability of regulation.

Sec. 2243. Exclusion from definition of device.

Subtitle O—Streamlining Clinical Trials

Sec. 2261. Protection of human subjects in research; applicability of rules.

Sec. 2262. Use of non-local institutional review boards for review of investigational device exemptions and human device exemptions.

Sec. 2263. Alteration or waiver of informed consent for clinical investigations.

Subtitle P—Improving Scientific Expertise and Outreach at FDA

Sec. 2281. Silvio O. Conte Senior Biomedical Research Service.

Sec. 2282. Enabling FDA scientific engagement.

Sec. 2283. Reagan-Udall Foundation for the Food and Drug Administration.

Sec. 2284. Collection of certain voluntary information exempted from Paperwork Reduction Act.

TITLE III—DELIVERY

Subtitle A—Interoperability

Sec. 3001. Ensuring interoperability.

Subtitle B—Telehealth

Sec. 3021. Telehealth services under the Medicare program.

Subtitle C—Encouraging Continuing Medical Education for Physicians

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

Subtitle D—Disposable Medical Technologies

Sec. 3061. Treatment of certain items and devices.

## Subtitle E—Local Coverage Decision Reforms

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

## Subtitle F—Medicare Pharmaceutical and Technology Ombudsman

Sec. 3101. Medicare pharmaceutical and technology ombudsman.

## Subtitle G—Medicare Site-of-Service Price Transparency

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

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

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

1                   **TITLE I—DISCOVERY**  
2                   **Subtitle A—National Institutes of**  
3                   **Health Funding**  
4   **SEC. 1001. NATIONAL INSTITUTES OF HEALTH REAUTHOR-**  
5                   **IZATION.**

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

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

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

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

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

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

1                   “(F) \$34,851,000,000 for fiscal year  
2                   2018.”.

3 **SEC. 1002. NIH INNOVATION FUND.**

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

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

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

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

12           “(25) shall, with respect to funds appropriated  
13       under section 402A(e) to the NIH Innovation Fund,  
14       allocate such funds to the national research insti-  
15       tutes and national centers for conducting and sup-  
16       porting innovation fund initiatives identified under  
17       paragraph (3) of such section.”.

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

20           (1) by redesignating subsection (e) as sub-  
21       section (f); and

22           (2) by inserting after subsection (d) the fol-  
23       lowing new subsection:

24       “(e) NIH INNOVATION FUND.—

1           “(1) ESTABLISHMENT.—For the purpose of al-  
2           locations under section 402(b)(25), there is estab-  
3           lished a fund to be known as the NIH Innovation  
4           Fund. The Director of NIH shall, with respect to  
5           funds appropriated to the NIH Innovation Fund, al-  
6           locate such funds to support biomedical research  
7           through the funding of basic, translational, and clin-  
8           ical research.

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

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

20           “(B) MAINTAINING BASE APPROPRIATIONS  
21           LEVEL.—The amounts appropriated by sub-  
22           paragraph (A) for a fiscal year shall not be  
23           available for obligation or expenditure unless  
24           and until the total amount of funds made avail-  
25           able to the National Institutes of Health for

1           such fiscal year, without regard to this sub-  
2           section, are not less than the total amount of  
3           funds made available to the National Institutes  
4           of Health for fiscal year 2016.

5           “(C) ALLOCATION OF AMOUNTS.—Of the  
6           amounts made available from the NIH Innova-  
7           tion Fund for allocations under section  
8           402(b)(25) for a fiscal year—

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

12                  “(ii) not less than 35 percent of such  
13                  amounts remaining after subtracting the  
14                  allocation for the Accelerating Advance-  
15                  ment Program shall be for research under  
16                  paragraph (3)(B);

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

22                  “(iv) not more than 10 percent of  
23                  such amounts (without subtracting the al-  
24                  location for the Accelerating Advancement  
25                  Program) shall be for intramural research.



1 “(D) INAPPLICABILITY OF CERTAIN PROVI-  
2 SIONS.—Amounts in the NIH Innovation Fund  
3 shall not be subject to—

4 “(i) any transfer authority of the Sec-  
5 retary or the Director of NIH under sec-  
6 tion 241, subsection (c), subsection (d), or  
7 any other provision of law (other than sec-  
8 tion 402(b)(25) and this subsection); or

9 “(ii) the Nonrecurring expenses fund  
10 under section 223 of division G of the Con-  
11 solidated Appropriations Act, 2008 (42  
12 U.S.C. 3514a).

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

17 “(A) Research in which—

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

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

22 “(B) Research in which—

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

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

3 “(C) Research to be carried out by an  
4 early stage investigator (as defined in para-  
5 graph (7)).

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

9 “(E) The Accelerating Advancement Pro-  
10 gram under paragraph (5).

11 “(F) Development and implementation of  
12 the strategic plan under paragraph (6).

13 “(4) COORDINATION.—In funding programs  
14 and activities through the NIH Innovation Fund,  
15 the Secretary, acting through the Director of NIH,  
16 shall—

17 “(A) ensure coordination among the na-  
18 tional research institutes, the national centers,  
19 and other departments, agencies, and offices of  
20 the Federal Government; and

21 “(B) minimize unnecessary duplication.

22 “(5) ACCELERATING ADVANCEMENT PRO-  
23 GRAM.—The Director of NIH shall establish a pro-  
24 gram, to be known as the Accelerating Advancement  
25 Program, under which—

1           “(A) the Director of NIH partners with  
2           national research institutes and national centers  
3           to accomplish important biomedical research ob-  
4           jectives; and

5           “(B) for every \$1 made available by the  
6           Director of NIH to a national research institute  
7           or national center for a research project, the in-  
8           stitute or center makes \$1 available for such  
9           project from funds that are not derived from  
10          the NIH Innovation Fund.

11          “(6) STRATEGIC PLAN.—

12           “(A) IN GENERAL.—The Director of NIH  
13           shall ensure that scientifically based strategic  
14           planning is implemented in support of research  
15           priorities, including through development, use,  
16           and updating of a research strategic plan  
17           that—

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

23                   “(ii) identifies areas, to be known as  
24                   strategic focus areas, in which the re-  
25                   sources of the NIH Innovation Fund can

1 contribute to the goals of expanding knowl-  
2 edge to address, and find more effective  
3 treatments for, unmet medical needs in the  
4 United States, including the areas of—

5 “(I) biomarkers;

6 “(II) precision medicine;

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

14 “(IV) antibiotics;

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

17 “(iv) ensures that basic research re-  
18 mains a priority.

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

23 “(7) DEFINITION.—In this subsection, the term  
24 ‘early stage investigator’ means an investigator  
25 who—

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

3 “(B) has never been awarded, or has been  
4 awarded only once, a substantial, competing  
5 grant by the National Institutes of Health for  
6 independent research; and

7 “(C) is within 10 years of having com-  
8 pleted—

9 “(i) the investigator’s terminal degree;  
10 or

11 “(ii) a medical residency (or the  
12 equivalent).”.

13 **Subtitle B—National Institutes of**  
14 **Health Planning and Adminis-**  
15 **tration**

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

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

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

21 “(5) shall ensure that scientifically based stra-  
22 tegic planning is implemented in support of research  
23 priorities as determined by the agencies of the Na-  
24 tional Institutes of Health, including through devel-

1       opment, use, and updating of the research strategic  
2       plan under subsection (m);” and

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

4       “(m) RESEARCH STRATEGIC PLAN.—

5               “(1) FIVE-YEAR PLANS FOR BIOMEDICAL RE-  
6       SEARCH STRATEGY.—

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

13              “(B) ENTITIES DESCRIBED.—The entities  
14       described in this subparagraph are the directors  
15       of the national research institutes and national  
16       centers, researchers, patient advocacy groups,  
17       and industry leaders.

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

21              “(A) to identify research opportunities;  
22       and

23              “(B) to develop individual strategic plans  
24       for the research activities of each of the na-

1           tional research institutes and national centers  
2           that—

3                     “(i) have a common template; and

4                     “(ii) identify strategic focus areas in  
5                     which the resources of the national re-  
6                     search institutes and national centers can  
7                     best contribute to the goal of expanding  
8                     knowledge on human health in the United  
9                     States through biomedical research.

10           “(3) CONTENTS OF PLANS.—

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

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

15                     “(I) considers the return on in-  
16                     vestment to the United States public  
17                     through the investments of the Na-  
18                     tional Institutes of Health in bio-  
19                     medical research; and

20                     “(II) contributes to expanding  
21                     knowledge to improve the United  
22                     States public’s health through bio-  
23                     medical research; and

24                     “(ii) include overarching and trans-  
25                     National Institutes of Health strategic

1 focus areas, to be known as Mission Pri-  
2 ority Focus Areas, which best serve the  
3 goals of preventing or eliminating the bur-  
4 den of a disease or condition and scientif-  
5 ically merit enhanced and focused research  
6 over the next 5 years.

7 “(B) RARE AND PEDIATRIC DISEASES AND  
8 CONDITIONS.—In developing and maintaining a  
9 strategic plan under this subsection, the Direc-  
10 tor of NIH shall ensure that rare and pediatric  
11 diseases and conditions remain a priority.

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

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

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

21 “(5) REVIEW; UPDATES.—

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



1 progress reviews for each strategic focus area  
2 identified under paragraph (2)(B).

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

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

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

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

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

22 “(a) APPOINTMENT; TERMS.—

23 “(1) APPOINTMENT.—The Director of the Na-  
24 tional Cancer Institute shall be appointed by the  
25 President and the directors of the other national re-

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

6 “(2) TERMS.—

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

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

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

20 “(D) VACANCIES.—If the office of a direc-  
21 tor of a national research institute or national  
22 center becomes vacant before the end of such  
23 director’s term, the director appointed to fill the  
24 vacancy shall be appointed for a 5-year term  
25 starting on the date of such appointment.

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

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

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

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

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

1 “(B) shall take into consideration—

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

6 “(ii) whether other agencies are funding  
7 programs or projects to accomplish the same  
8 goal.”.

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

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

19 (2) submit a report to the Congress on the re-  
20 sults of such study, including recommendations on  
21 how to prevent such duplication.

22 **[SEC. 1023. BIOMEDICAL RESEARCH WORKING GROUP.]**

23 **[(a) ESTABLISHMENT.—There is established a work-**  
24 **ing group to be known as the “Biomedical Research Work-**  
25 **ing Group”].]**

1       **[(b) DUTIES.—**The Biomedical Research Working  
2 Group shall—**]**

3           **[(1)** provide recommendations to the Director  
4 of the National Institutes of Health to reduce ad-  
5 ministrative burdens of researchers funded by the  
6 National Institutes of Health, including with respect  
7 to the extent to which (and how) grant proposals,  
8 grant review, and management should be restruc-  
9 tured, streamlined, and simplified;**]**

10          **[(2)** evaluate and provide recommendations on  
11 the extent to which it is required for Congress to  
12 provide any statutory authority to implement any  
13 recommendation proposed pursuant to paragraph  
14 (1); and**]**

15          **[(3)** prepare a plan, including timeframes, for  
16 implementing recommendations proposed pursuant  
17 to paragraph (1) for which congressional action is  
18 not required.**]**

19       **[(c) MEMBERSHIP.—**The Secretary shall appoint the  
20 members of the Biomedical Research Working Group. The  
21 Biomedical Research Working Group shall be composed  
22 of—**]**

23           **[(1)** non-Federal members from the extramural  
24 community;**]**

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

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

6       【(d) IMPLEMENTATION OF MEASURES TO REDUCE  
7       ADMINISTRATIVE BURDENS.—The Director of the Na-  
8       tional Institutes of Health, taking into account the rec-  
9       ommendations, evaluations, and plan described in sub-  
10      section (b), shall implement measures to reduce the ad-  
11      ministrative burdens of researchers funded by the Na-  
12      tional Institutes of Health.】

13      【(e) REPORTS.—】

14           【(1) REPORT BY WORKING GROUP ON REC-  
15      OMMENDATIONS AND PLAN.—Not later than one  
16      year after the date of the enactment of this Act, the  
17      Biomedical Research Working Group shall submit to  
18      Congress a report including the recommendations,  
19      evaluations, and plan described in subsection (b).】

20           【(2) REPORT BY DIRECTOR OF NIH ON IMPLE-  
21      MENTATION OF MEASURES TO REDUCE ADMINISTRA-  
22      TIVE BURDENS.—The Director of the National Insti-  
23      tutes of Health shall submit to Congress a report on  
24      the extent to which the Director has implemented  
25      measures pursuant to subsection (d).】

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

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

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

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

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

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

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

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

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

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

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

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

1 “(C) OTHER TRANSACTIONS AUTHORITY.—

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

22 “(e) AVAILABILITY OF APPROPRIATIONS.—Amounts  
23 appropriated for a fiscal year for contracts under sub-  
24 section (a) are authorized to remain available until the ex-

1   piration of the second fiscal year beginning after the fiscal  
2   year for which the amounts were appropriated.”.

3       (b) UPDATE OF OTHER LOAN REPAYMENT PRO-  
4   GRAMS.—

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

9           (A) in subsection (a), by striking  
10       “\$35,000” and inserting “\$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          (2) LOAN REPAYMENT PROGRAM FOR RE-  
18       SEARCH WITH RESPECT TO ACQUIRED IMMUNE DE-  
19       FICIENCY SYNDROME.—Section 487A(a) of such Act  
20       (42 U.S.C. 288–1(a)) is amended—

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

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

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

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

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

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

16 (4) LOAN REPAYMENT PROGRAM FOR RE-  
17 SEARCH GENERALLY.—Section 487C(a)(1) of such  
18 Act (42 U.S.C. 288–3(a)(1)) 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 paragraph in the same manner

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

3 (5) LOAN REPAYMENT PROGRAM REGARDING  
4 CLINICAL RESEARCHERS FROM DISADVANTAGED  
5 BACKGROUNDS.—Section 487E(a)(1) of such Act  
6 (42 U.S.C. 288–5(a)(1)) is amended—

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

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

15 (6) LOAN REPAYMENT PROGRAM REGARDING  
16 CLINICAL RESEARCHERS.—Section 487F(a) of such  
17 Act (42 U.S.C. 288–5a(a)), as added by section 205  
18 of Public Law 106–505, 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 (7) PEDIATRIC RESEARCH LOAN REPAYMENT  
4 PROGRAM.—Section 487F of such Act (42 U.S.C.  
5 288–6, as added by section 1002(b) of Public Law  
6 106–310, is amended—

7 (A) in subsection (a)(1), by striking  
8 “\$35,000” and inserting “\$50,000”;

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

16 (C) by redesignating such section as sec-  
17 tion 487G.

18 **SEC. 1042. REPORT.**

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

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

3   **SEC. 1061. CAPSTONE AWARD.**

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

7   **“SEC. 490. CAPSTONE AWARD.**

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

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

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

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

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

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

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

7 (1) in paragraph (1)—

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

18 (B) by striking subparagraph (B);

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

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



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

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

7           It is the sense of Congress that—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25          (a) **STANDARDIZATION.**—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

22 (d) REPORTS.—

23 (1) REPORT TO SECRETARY AND CONGRESS.—  
24 Not later than 6 years after the date on which the  
25 pilot program is established under subsection (a),

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

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

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

9 (2) GAO INTERIM AND FINAL REPORT.—

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

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

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

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

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

6 (B) TIMING.—The Secretary shall submit  
7 the first report under subparagraph (A) not  
8 later than 3 years after the date on which the  
9 pilot program established under subsection (a)  
10 and the second such report at the end of the 7-  
11 year period referred to in such subsection.

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

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

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

21 (e) DEFINITIONS.—In this section:

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

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

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

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

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

20 (A) that was—

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

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

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

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

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

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

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

23 Part P of title III of the Public Health Service Act  
24 (42 U.S.C. 280g et seq.) is amended by adding at the end  
25 the following:

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

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

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

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

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

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

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

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

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

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

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

10              “(C) diagnosis and progression markers;

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

14              “(A) the epidemiology of the diseases;

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

16              “(C) the prevention of the diseases;

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

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

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

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

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

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

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

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

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

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

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

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

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



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

7           “(2) to State and local agencies.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 “In this part:

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

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

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

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

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

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

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

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

1           “(C) a business associate that has entered  
2           into a contract under section 164.504(e) of part  
3           164 for the purpose of data aggregation (as de-  
4           fined in such section 164.501 of part 164); and  
5           “(2) the Secretary shall further revise or clarify  
6           the Rule so that the limitation specified by section  
7           164.506(e)(4) of part 164 does not apply to disclo-  
8           sures that are described by subsection (a).

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

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

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

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

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

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

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

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

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

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

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



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

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

7 “(2) either—

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

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

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

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

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

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

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

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

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

14 **“SEC. 281. ESTABLISHMENT.**

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

1   **“SEC. 281A. PURPOSE.**

2           “The purpose of the Council is to accelerate the dis-  
3   covery, development, and delivery in the United States of  
4   innovative cures, treatments, and preventive measures for  
5   patients.

6   **“SEC. 281B. DUTIES.**

7           “For the purpose described in section 281A, the  
8   Council shall—

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

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

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

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

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

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

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

6           “(8) propose recommendations that will facili-  
7           tate precompetitive collaboration;

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

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

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

16          “(a) BOARD OF DIRECTORS.—

17                  “(1) ESTABLISHMENT.—

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

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

4                   “(i) The Director of the National In-  
5                   stitutes of Health.

6                   “(ii) The Commissioner of Food and  
7                   Drugs.

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

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

14                  “(C) APPOINTED MEMBERS.—The ap-  
15                  pointed members of the Board shall consist of  
16                  17 individuals, of whom—

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

21                  “(I) 4 of whom shall be rep-  
22                  resentatives of the biopharmaceutical  
23                  industry;

1 “(II) 2 of whom shall be rep-  
2 resentatives of the medical device in-  
3 dustry; and

4 “(III) 2 of whom shall be rep-  
5 resentatives of the information and  
6 digital technology industry; and

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

10 “(I) 2 of whom shall be rep-  
11 resentatives of academic researchers;

12 “(II) 3 of whom shall be rep-  
13 resentative of patients;

14 “(III) 2 of whom shall be rep-  
15 resentatives of health care providers;  
16 and

17 “(IV) 2 of whom shall be rep-  
18 resentatives of health care plans and  
19 insurers.

20 “(D) CHAIR.—The Chair of the Board  
21 shall be selected by the members of the Board  
22 by majority vote from among the members of  
23 the Board.

24 “(2) TERMS AND VACANCIES.—

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

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

6                   “(i) shall not affect the power of the  
7                   remaining members to execute the duties  
8                   of the Board; and

9                   “(ii) shall be filled by appointment by  
10                  the appointed members described in para-  
11                  graph (1)(C) by majority vote.

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

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

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

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

3                   “(i) the officers, employees, agents,  
4                   and contractors of the Council; and

5                   “(ii) the members of any committees  
6                   of the Council;

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

10           “(D) establish specific duties of the Execu-  
11           tive Director.

12           “(4) MEETINGS.—

13                   “(A) IN GENERAL.—the Board of Direc-  
14                   tors shall—

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

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

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

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



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

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

7                   “(1) the Comptroller General of the United  
8           States shall appoint the appointed members of the  
9           Board of Directors under subsection (a)(1)(C); and  
10                   “(2) the ex officio members of the Board of Di-  
11           rectors under subsection (a)(1)(B) shall serve as  
12           incorporators and shall take whatever actions are  
13           necessary to incorporate the Council.

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

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

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

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

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

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

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

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

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

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

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

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

1 **“SEC. 281F. FUNDING.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18          (b) GUIDANCE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3           (3) WORKSHOPS.—

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

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

15               (i) patients;

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 “(a) PROCESS FOR QUALIFICATION.—

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

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

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

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

16 “(ii) the Secretary shall accept or decline  
17 to accept the qualification plan; and

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

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

24 “(iii) if the Secretary accepts such quali-  
25 fication package for review, conduct such review  
26 in accordance with this section.

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

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

17                  “(B) PRIORITIZATION OF QUALIFICATION  
18                  REVIEW.—The Secretary may prioritize the re-  
19                  view of a full qualification package submitted  
20                  under the process described in paragraph (1)  
21                  with respect to a drug development tool, based  
22                  on factors determined appropriate by the Sec-  
23                  retary, including—

24                          “(i) as applicable, the severity, rarity,  
25                          or prevalence of the disease or condition

1           targeted by the drug development tool and  
2           the availability or lack of alternative treat-  
3           ments for such disease or condition; and

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

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

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

23                 “(A) conduct a comprehensive review of a  
24                 full qualification package accepted under para-  
25                 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 (2).

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 a determination to  
15          qualify a drug development tool under subpara-  
16          graph (A), the requestor involved shall be  
17          granted a request for a meeting with the Sec-  
18          retary to discuss the basis of the Secretary’s de-  
19          cision to rescind or modify the determination  
20          before the effective date of the rescission or  
21          modification.

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 quarterly 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; and

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.

14 “(B) The Secretary’s formal written deter-  
15 minations in response to such qualification sub-  
16 missions.

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

20 “(D) Summary reviews that document con-  
21 clusions and recommendations for determina-  
22 tions to qualify drug development tools under  
23 subsection (a).



1           “(E) A comprehensive list of all drug de-  
2           velopment tools qualified under subsection (c)  
3           or used in the labeling of drugs.

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

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

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

23               “(1) to alter the standards of evidence under  
24               subsection (c) or (d) of section 505, including the  
25               substantial evidence standard in such subsection (d),

1 or under section 351 of the Public Health Service  
2 Act (as applicable); or

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

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

12 “(f) DEFINITIONS.—In this section:

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

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

21 “(2) BIOMEDICAL RESEARCH CONSORTIA.—The  
22 term ‘biomedical research consortia’ means public-  
23 private partnerships of government agencies, institu-  
24 tions of higher education (as defined in section  
25 101(a) of the Higher Education Act of 1965 (20

1 U.S.C. 1001)), patient advocacy groups, industry  
2 representatives, clinical and scientific experts, and  
3 other relevant entities and individuals.

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

9 “(B) Such term includes a patient-reported out-  
10 come.

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

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

18 “(A) a biomarker;

19 “(B) a clinical outcome assessment; and

20 “(C) any other method, material, or meas-  
21 ure that the Secretary determines aids drug de-  
22 velopment and regulatory review for purposes of  
23 this section.

24 “(6) PATIENT-REPORTED OUTCOME.—The term  
25 ‘patient-reported outcome’ means a measurement

1 based on a report from a patient regarding the sta-  
2 tus of the patient's health condition without amend-  
3 ment or interpretation of the patient's report by a  
4 clinician or any other person.

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

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

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

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

23 “(B) is reasonably likely to predict clinical  
24 benefit and could be used to support the accel-

1           erated approval of a drug or biological product  
2           in accordance with section 506(c).”.

3       (d) GUIDANCE.—

4           (1) IN GENERAL.—The Secretary of Health and  
5       Human Services shall, in consultation with bio-  
6       medical research consortia (as defined in subsection  
7       (e) of section 507 the Federal Food, Drug, and Cos-  
8       metic Act (as added by subsection (c))) and other  
9       interested parties through a collaborative public  
10      process, issue guidance to implement such section  
11      507 that—

12           (A) provides a conceptual framework de-  
13      scribing appropriate standards and scientific  
14      approaches to support the development of bio-  
15      markers delineated under the taxonomy estab-  
16      lished under paragraph (3);

17           (B) makes recommendations for dem-  
18      onstrating that a surrogate endpoint is reason-  
19      ably likely to predict clinical benefit for the pur-  
20      pose of supporting the accelerated approval of  
21      a drug under section 506(c) of the Federal  
22      Food, Drug, and Cosmetic Act (21 U.S.C.  
23      356(c));

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

1 (i) specifies the requirements that en-  
2 tities seeking to qualify a drug develop-  
3 ment tool under such section shall observe  
4 when engaging in such process;

5 (ii) specifies reasonable timeframes  
6 for the Secretary's review of letters, quali-  
7 fication plans, or full qualification pack-  
8 ages submitted under such process; and

9 (iii) establishes a process by which  
10 such entities or the Secretary may consult  
11 with biomedical research consortia and  
12 other individuals and entities with expert  
13 knowledge and insights that may assist the  
14 Secretary in the review of qualification  
15 plans and full qualification submissions  
16 under such process; and

17 (D) includes such other information as the  
18 Secretary determines appropriate.

19 (2) TIMING.—Not later than 24 months after  
20 the date of the enactment of this Act, the Secretary  
21 shall issue draft guidance on the implementation of  
22 section 507 of the Federal Food, Drug, and Cos-  
23 metic Act (as added by subsection (c)). The Sec-  
24 retary shall issue final guidance on the implementa-  
25 tion of such section not later than 6 months after

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

3 (3) TAXONOMY.—

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

12 (B) PUBLIC AVAILABILITY.—Not later  
13 than 12 months after the date of the enactment  
14 of this Act, the Secretary shall make such tax-  
15 onomy publicly available in draft form for pub-  
16 lic comment. The Secretary shall finalize the  
17 taxonomy not later than 12 months after the  
18 close of the public comment period.

19 (e) MEETING AND REPORT.—

20 (1) MEETING.—Not later than 12 months after  
21 the date of the enactment of this Act, the Secretary  
22 of Health and Human Services shall convene a pub-  
23 lic meeting to describe and solicit public input re-  
24 garding the qualification process under section 507

1 of the Federal Food, Drug, and Cosmetic Act, as  
2 added by subsection (c).

3 (2) REPORT.—Not later than 5 years after the  
4 date of the enactment of this Act, the Secretary  
5 shall make publicly available on the Internet website  
6 of the Food and Drug Administration a report. Such  
7 report shall include, with respect to the qualification  
8 process under section 507 of the Federal Food,  
9 Drug, and Cosmetic Act, as added by subsection (c),  
10 information on—

11 (A) the number of requests submitted, as  
12 a letter of intent, for qualification of a drug de-  
13 velopment tool (as defined in subsection (e) of  
14 such section);

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

20 (C) the number of such requests for which  
21 the Secretary utilized external scientific experts  
22 in the development of a qualification plan or re-  
23 view of a full qualification package; and



1 (D) the number of qualification plans and  
2 full qualification packages, respectively, sub-  
3 mitted to the Secretary; and

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

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

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

13 “(g) ACCELERATED APPROVAL DEVELOPMENT  
14 PLAN.—

15 “(1) IN GENERAL.—In the case of a drug deter-  
16 mined to be eligible for accelerated approval under  
17 subsection (c), at any time after the submission of  
18 an application for the investigation of the drug  
19 under section 505(i) of this Act or section 351(a)(3)  
20 of the Public Health Service Act, the sponsor of  
21 such drug may voluntarily request agreement by the  
22 Secretary to an accelerated approval development  
23 plan with respect to a surrogate endpoint to be used  
24 to study the drug.

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

3           “(A) the surrogate endpoint to be assessed  
4       under the plan;

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

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

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

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

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

22          “(4) SPONSOR CONSULTATION.—If the Sec-  
23      retary requires the modification or termination of an  
24      accelerated approval development plan under para-  
25      graph (3), the sponsor shall be granted a request for

1 a meeting to discuss the basis of the Secretary’s de-  
2 cision before the effective date of the modification or  
3 termination.

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

10 “(A) is reasonably likely to predict clinical  
11 benefit; and

12 “(B) is intended to be the basis of the ac-  
13 celerated approval of a drug under subsection  
14 (c).”.

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

18 (1) by striking “(f) AWARENESS EFFORTS” and  
19 inserting “(e) AWARENESS EFFORTS”; and

20 (2) by striking “(e) CONSTRUCTION” and in-  
21 serting “(f) CONSTRUCTION”.

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

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

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

9             **“Subchapter J—Precision Medicine**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 “(2) as appropriate under section 506, consider  
21 the application for approval of such precision drug  
22 or biological product to be eligible for expedited re-  
23 view, including under section 506(c) (relating to ac-  
24 celerated approval).”.

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

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

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

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

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

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

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

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

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

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

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

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

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

23 (D) recommended analysis methodologies.

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



1 the Secretary shall consult with stakeholders, includ-  
2 ing representatives of regulated industry, academia,  
3 patient advocacy organizations, and disease research  
4 foundations, through a public meeting to be held not  
5 later than 1 year after the date of enactment of this  
6 Act.

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

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

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

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

18 Chapter V of the Federal Food, Drug, and Cosmetic  
19 Act, as amended by section 2021, is further amended by  
20 inserting after section 505E of such Act (21 U.S.C. 355f)  
21 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 potential  
14 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 EX-**  
2 **PERIENCE THROUGH TARGETED EXTEN-**  
3 **SIONS 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**  
14 **demonstrations to utilize data captured through**  
15 **the Sentinel System surveillance infrastructure**  
16 **authorized under section 505(k) for purposes**  
17 **of, 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 by the Food and Drug Ad-  
14                  ministration, 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 related to assessing or re-  
20                   assessing the safety of such sponsor’s drug  
21                   or drugs;】

22                   **【“(ii) providing adequate notice of the**  
23                   findings related to analyses described in  
24                   clause (i) and an opportunity for the spon-

1 sor of such drug or drugs to comment on  
2 such findings; and】

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

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

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

20 【“(B) deem safety surveillance performed  
21 at the request of the Food and Drug Adminis-  
22 tration or under such jurisdiction by a sponsor  
23 with responsibility for a drug approved under  
24 this section or section 351 of the Public Health  
25 Services Act using the Sentinel System surveil-



1           lance infrastructure authorized under section  
2           505(k), including use of analytic tools and  
3           querying capabilities developed to implement  
4           the active postmarket surveillance system de-  
5           scribed in this section, public health activities  
6           as described in section 164.512(b)(1)(iii) of title  
7           45, Code of Federal Regulations (or any suc-  
8           cessor regulation) and exempted as a public  
9           health activity as described in section  
10          46.101(b)(5) of title 46, Code of Federal Regu-  
11          lations (or any successor regulation).】

12        【“(c) AUTHORIZATION OF APPROPRIATIONS.—There  
13   are authorized to be appropriated to carry out this section  
14   【\$\_\_\_\_\_】 for each of fiscal years 2016 through  
15   2019.”.】

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

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

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

22       “(a) IN GENERAL.—The Secretary shall establish a  
23   streamlined data review program under which a holder of  
24   an approved application submitted under section  
25   505(b)(1) or under section 351(a) of the Public Health

1 Service Act may, to support the approval or licensure (as  
2 applicable) of the use of the drug that is the subject of  
3 such approved application for a new qualified indication,  
4 submit qualified data summaries.

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

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

15 “(2) the supplemental application is for ap-  
16 proval or licensure (as applicable) under such section  
17 505(c) or 351(a) of the use of the drug for a new  
18 qualified indication under such section 505(c) or  
19 351(a);

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

1 “(4) the supplemental application incorporates  
2 or supplements the data submitted in the application  
3 for approval or licensure referred to in paragraph  
4 (1); and

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

8 “(c) DEFINITIONS.—In this section:

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

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

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

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

21 (b) GUIDANCE; REGULATIONS.—The Commissioner  
22 of Food and Drugs—

23 (1) shall—

24 (A) issue final guidance for implementation  
25 of the streamlined data review program estab-

1           lished under section 505H of the Federal Food,  
2           Drug, and Cosmetic Act, as added by sub-  
3           section (a), not later than 24 months after the  
4           date of enactment of this Act; and

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

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

## 13           **Subtitle E—Expediting Patient** 14                   **Access**

### 15   **SEC. 2081. SENSE OF CONGRESS.**

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

1 505 of such Act (21 U.S.C. 355), including the substantial  
2 evidence standard under subsection (d) of such section or  
3 under section 351(a) of the Public Health Service Act (42  
4 U.S.C. 262(a)).

5 **SEC. 2082. EXPANDED ACCESS POLICY.**

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

8 (1) by redesignating subsections (d) and (e) as  
9 subsections (e) and (f), respectively; and

10 (2) by inserting after subsection (c) the fol-  
11 lowing new subsection:

12 “(d) EXPANDED ACCESS POLICY REQUIRED FOR IN-  
13 VESTIGATIONAL DRUGS.—

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

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

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

7                   “(B) procedures for making such requests;

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

10                   “(D) the length of time the sponsor antici-  
11                   pates will be necessary to acknowledge receipt  
12                   of such requests.

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

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

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

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

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

9   **SEC. 2083. FINALIZING DRAFT GUIDANCE ON EXPANDED**  
10           **ACCESS.**

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 “(IV) such other confirmatory evi-  
2 dence as the Secretary determines appro-  
3 priate to approve the drug.

4 “(2) FORMAL MEETINGS.—

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

17 “(i) An early consultation meeting.

18 “(ii) An assessment meeting.

19 “(iii) A postapproval meeting.

20 “(B) NO ALTERING OF GOALS.—Nothing  
21 in this paragraph shall be construed to alter  
22 agreed upon goals and procedures identified in  
23 the letters described in section 101(b) of the  
24 Prescription Drug User Fee Amendments of  
25 2012.

1           “(C) BREAKTHROUGH THERAPIES.—In the  
2           case of a drug designated as a breakthrough  
3           therapy under section 506(a), the sponsor of  
4           such drug may elect to utilize meetings pro-  
5           vided under such section with respect to such  
6           drug in lieu of meetings described in subpara-  
7           graph (A).

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

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

1           “(5) TERMINATION OF REQUIREMENTS OR CON-  
2           DITIONS.—If a drug is approved in accordance with  
3           this subsection for an indication in a limited popu-  
4           lation of patients and is subsequently approved or li-  
5           censed under this section or section 351 of the Pub-  
6           lic Health Service Act, other than in accordance with  
7           this subsection, for—

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

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

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

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

4           “(B) designation and treatment of the  
5           drug as a breakthrough therapy under section  
6           506(a);

7           “(C) designation and treatment of the  
8           drug as a fast track product under section  
9           506(b); or

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

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

14               “(A) to alter the standards of evidence  
15               under subsection (c) or (d) (including the sub-  
16               stantial evidence standard in subsection (d));

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

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

24               “(D) to restrict in any manner, the pre-  
25               scribing of antibiotics or other products by



1 health care providers, or to limit or restrict the  
2 practice of health care, including the pre-  
3 scribing of such products by physicians for pa-  
4 tients.

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

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

12 “(A) EARLY CONSULTATION MEETING.—  
13 The term ‘early consultation meeting’ means a  
14 pre-investigational new drug meeting or an end-  
15 of-phase 1 meeting that—

16 “(i) is conducted to review and reach  
17 a written agreement—

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

23 “(II) which, as appropriate, may  
24 include agreement on the design and  
25 size of necessary preclinical and clin-

1                   ical studies early in the development  
2                   process, including clinical trials whose  
3                   data are intended to form the primary  
4                   basis for an effectiveness claim; and  
5                   “(ii) provides an opportunity to dis-  
6                   cuss expectations of the Secretary regard-  
7                   ing studies or other information that the  
8                   Secretary deems appropriate for purposes  
9                   of applying paragraph (5), relating to the  
10                  termination of labeling requirements or  
11                  postmarketing conditions.

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

21               “(C) POSTAPPROVAL MEETING.—The term  
22               ‘postapproval meeting’ means a meeting fol-  
23               lowing initial approval or licensure of the drug  
24               for use in a limited population, to discuss any  
25               issues identified by the Secretary or the sponsor

1           regarding postapproval commitments or expan-  
2           sion of approved uses.”.

3       (c) GUIDANCE.—Not later than 18 months after the  
4   date of enactment of this Act, the Secretary of Health and  
5   Human Services, acting through the Commissioner of  
6   Food and Drugs, shall issue draft guidance describing cri-  
7   teria, process, and other general considerations for dem-  
8   onstrating the safety and effectiveness of antibacterial and  
9   antifungal drugs to be approved for use in a limited popu-  
10   lation in accordance with section 505(z) of the Federal  
11   Food, Drug, and Cosmetic Act, as added by subsection  
12   (b).

13       (d) CONFORMING AMENDMENTS.—

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

17               (A) by striking “(j)” and inserting  
18               “(j)(1)”;

19               (B) by inserting “505(z),” after “505(p),”;  
20               and

21               (C) by adding at the end the following new  
22               paragraph:

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

1           “(A) references to an antibacterial or antifungal  
2           drug that is intended to treat a serious or life-  
3           threatening infection shall be construed to refer to  
4           a biological product intended to treat a serious or  
5           life-threatening bacterial or fungal infection; and

6           “(B) references to approval of a drug under  
7           section 505(c) of such Act shall be construed to  
8           refer to a licensure of a biological product under  
9           subsection (a) of this section.”.

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

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

18           (e) EVALUATION.—

19           (1) ASSESSMENT.—Not later than 48 months  
20           after the date of enactment of this Act, the Sec-  
21           retary of Health and Human Services shall publish  
22           for public comment an assessment of the program  
23           established under section 505(z) of the Federal  
24           Food, Drug, and Cosmetic Act, as added by sub-  
25           section (b). Such assessment shall determine if the

1       limited-use pathway established under such section  
2       505(z) has improved or is likely to improve patient  
3       access to novel antibacterial or antifungal treat-  
4       ments and assess how the pathway could be ex-  
5       panded to cover products for serious or life-threat-  
6       ening diseases or conditions beyond bacterial and  
7       fungal infections.

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

18      (f) EXPANSION OF PROGRAM.—If the Secretary of  
19      Health and Human Services determines, based on the as-  
20      sessment under subsection (e)(1), evaluation of the assess-  
21      ment, and any other relevant information, that the public  
22      health would benefit from expansion of the limited-use  
23      pathway established under section 505(z) of the Federal  
24      Food, Drug, and Cosmetic Act (as added by subsection  
25      (b)) beyond the drugs approved in accordance with such

1 section, the Secretary may expand such limited-use path-  
2 way in accordance with such a determination. The ap-  
3 proval of any drugs under any such expansion shall be  
4 subject to the considerations and requirements described  
5 in such section 505 for purposes of expansion to other se-  
6 rious or life-threatening diseases or conditions.

7 (g) MONITORING.—The Public Health Service Act is  
8 amended by inserting after section 317T (42 U.S.C.  
9 247b–22) the following:

10 **“SEC. 317U. MONITORING ANTIBACTERIAL AND**  
11 **ANTIFUNGAL DRUG USE AND RESISTANCE.**

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

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

18 “(2) changes in bacterial and fungal resistance  
19 to drugs.

20 “(b) PUBLIC AVAILABILITY OF DATA.—The Sec-  
21 retary shall make summaries of the data derived from  
22 monitoring under this section publicly available for the  
23 purposes of—

1 “(1) improving the monitoring of important  
2 trends in antibacterial and antifungal resistance;  
3 and

4 “(2) ensuring appropriate stewardship of anti-  
5 bacterial and antifungal drugs, including those re-  
6 ceiving approval or licensure for a limited population  
7 pursuant to section 505(z) of the Federal Food,  
8 Drug, and Cosmetic Act.”.

9 **SEC. 2122. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA**  
10 **FOR MICROORGANISMS.**

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

14 **“SEC. 511. IDENTIFYING AND UPDATING SUSCEPTIBILITY**  
15 **TEST INTERPRETIVE CRITERIA FOR MICRO-**  
16 **ORGANISMS.**

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

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

21 “(A) clearance or premarket approval of  
22 antimicrobial susceptibility testing devices uti-  
23 lizing updated, recognized susceptibility test in-  
24 terpretive criteria to characterize the in vitro  
25 susceptibility of particular bacteria, fungi, or

1 other microorganisms to antimicrobial drugs;  
2 and

3 “(B) providing public notice of the avail-  
4 ability of recognized interpretive criteria to  
5 meet premarket submission requirements or  
6 other requirements under this Act for anti-  
7 microbial susceptibility testing devices.

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

11 “(A) if such criteria are available on the  
12 date of approval of the drug under section 505  
13 of this Act or licensure of the drug under sec-  
14 tion 351 of the Public Health Service Act (as  
15 applicable), upon such approval or licensure; or

16 “(B) if such criteria are unavailable on  
17 such date, on the date on which such criteria  
18 are available for such drug.

19 “(3) BASES FOR INITIAL IDENTIFICATION.—  
20 The Secretary shall identify appropriate suscepti-  
21 bility test interpretive criteria under paragraph (2),  
22 based on the Secretary’s review of, to the extent  
23 available and relevant—



1           “(A) preclinical and clinical data, including  
2           pharmacokinetic, pharmacodynamic, and epide-  
3           miological data;

4           “(B) Bayesian and pharmacometric statis-  
5           tical methodologies; and

6           “(C) such other evidence and information  
7           as the Secretary considers appropriate.

8           “(b) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA  
9           WEBSITE.—

10           “(1) IN GENERAL.—Not later than 1 year after  
11           the date of the enactment of the 21st Century Cures  
12           Act, the Secretary shall establish, and maintain  
13           thereafter, on the website of the Food and Drug Ad-  
14           ministration, a dedicated website that contains a list  
15           of any appropriate new or updated susceptibility test  
16           interpretive criteria standards in accordance with  
17           paragraph (2) (referred to in this section as the ‘In-  
18           terpretive Criteria Website’).

19           “(2) LISTING OF SUSCEPTIBILITY TEST INTER-  
20           PRETIVE CRITERIA STANDARDS.—

21           “(A) IN GENERAL.—The list described in  
22           paragraph (1) shall consist of any new or up-  
23           dated susceptibility test interpretive criteria  
24           standards that are—

1 “(i) established by a nationally or  
2 internationally recognized standard devel-  
3 opment organization that—

4 “(I) establishes and maintains  
5 procedures to address potential con-  
6 flicts of interest and ensure trans-  
7 parent decisionmaking;

8 “(II) holds open meetings to en-  
9 sure that there is an opportunity for  
10 public input by interested parties, and  
11 establishes and maintains processes to  
12 ensure that such input is considered  
13 in decisionmaking; and

14 “(III) permits its standards to be  
15 made publicly available, through the  
16 National Library of Medicine or an-  
17 other similar source acceptable to the  
18 Secretary; and

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

21 “(B) OTHER LIST.—The Interpretive Cri-  
22 teria Website shall, in addition to the list de-  
23 scribed in subparagraph (A), include a list of  
24 interpretive criteria, if any, that the Secretary  
25 has determined to be appropriate with respect

1           to legally marketed antimicrobial drugs,  
2           where—

3                   “(i) the Secretary does not recognize,  
4                   in whole or in part, an interpretive criteria  
5                   standard described under subparagraph  
6                   (A) otherwise applicable to such a drug;

7                   “(ii) the Secretary withdraws under  
8                   subsection (c)(1)(B) recognition of a  
9                   standard, in whole or in part, otherwise  
10                  applicable to such a drug;

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

19                  “(iv) because the characteristics of  
20                  such a drug differ from other drugs with  
21                  the same active ingredient, the interpretive  
22                  criteria with respect to such drug—

23                           “(I) differ from otherwise appli-  
24                           cable interpretive criteria included in  
25                           a standard listed under subparagraph

1 (A) or interpretive criteria otherwise  
2 listed under this subparagraph; and

3 “(II) are determined to be appro-  
4 priate for the drug.

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

8 “(i) A statement that—

9 “(I) the website provides infor-  
10 mation about the susceptibility of bac-  
11 teria, fungi, or other microorganisms  
12 to a certain drug (or drugs); and

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

21 “(ii) A statement that directs health  
22 care practitioners to consult the approved  
23 product labeling for specific drugs to deter-  
24 mine the uses for which the Food and

1 Drug Administration has approved the  
2 product.

3 “(iii) Any other statement that the  
4 Secretary determines appropriate to ade-  
5 quately convey the limitations of the data  
6 supporting susceptibility test interpretive  
7 criteria standard listed on the website.

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

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

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

1       “(c) RECOGNITION OF SUSCEPTIBILITY TEST INTER-  
2       PRETIVE CRITERIA FROM STANDARD DEVELOPMENT OR-  
3       GANIZATIONS.—

4               “(1) IN GENERAL.—Beginning on the date of  
5       the establishment of the Interpretive Criteria  
6       Website, and at least every 6 months thereafter, the  
7       Secretary shall—

8               “(A) evaluate any appropriate new or up-  
9       dated susceptibility test interpretive criteria  
10       standards established by a nationally or inter-  
11       nationally recognized standard development or-  
12       ganization described in subsection (b)(2)(A)(i);  
13       and

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

16               “(i) withdrawing recognition of any  
17       different susceptibility test interpretive cri-  
18       teria standard, in whole or in part;

19               “(ii) recognizing the new or updated  
20       standards;

21               “(iii) recognizing one or more parts of  
22       the new or updated interpretive criteria  
23       specified in such a standard and declining  
24       to recognize the remainder of such stand-  
25       ard; and

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

3 “(2) BASES FOR UPDATING INTERPRETIVE CRI-  
4 TERIA STANDARDS.—In evaluating new or updated  
5 susceptibility test interpretive criteria standards  
6 under paragraph (1)(A), the Secretary may con-  
7 sider—

8 “(A) the Secretary’s determination that  
9 such a standard is not applicable to a particular  
10 drug because the characteristics of the drug dif-  
11 fer from other drugs with the same active in-  
12 gredient;

13 “(B) information provided by interested  
14 third parties, including public comment on the  
15 annual compilation of notices published under  
16 paragraph (3);

17 “(C) any bases used to identify suscepti-  
18 bility test interpretive criteria under subsection  
19 (a)(2); and

20 “(D) such other information or factors as  
21 the Secretary determines appropriate.

22 “(3) ANNUAL COMPILATION OF NOTICES.—  
23 Each year, the Secretary shall compile the notices  
24 published under paragraph (1)(B) and publish such  
25 compilation in the Federal Register and provide for

1 public comment. If the Secretary receives comments,  
2 the Secretary will review such comments and, if the  
3 Secretary determines appropriate, update pursuant  
4 to this subsection susceptibility test interpretive cri-  
5 teria standards—

6 “(A) recognized by the Secretary under  
7 this subsection; or

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

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

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

23 “(d) ANTIMICROBIAL DRUG LABELING.—

24 “(1) DRUGS MARKETED PRIOR TO ESTABLISH-  
25 MENT OF INTERPRETIVE CRITERIA WEBSITE.—With



1       respect to an antimicrobial drug lawfully introduced  
2       or delivered for introduction into interstate com-  
3       merce for commercial distribution before the estab-  
4       lishment of the Interpretive Criteria Website, a hold-  
5       er of an approved application under section 505 or  
6       section 351 of the Public Health Service Act, as ap-  
7       plicable, for each such drug—

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

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

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

1 criteria and related information, a reference to such  
2 Website.

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

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

13 “(2) CONDITIONS APPLICABLE TO ANTI-  
14 MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—  
15 The conditions specified in this paragraph are the  
16 following:

17 “(A) The device is used to make a deter-  
18 mination of susceptibility using susceptibility  
19 test interpretive criteria that are—

20 “(i) included in a standard recognized  
21 by the Secretary under subsection (c); or

22 “(ii) otherwise listed on the Interpre-  
23 tive Criteria Website under subsection  
24 (b)(2).

1           “(B) The labeling of such device promi-  
2           nently and conspicuously—

3           “(i) includes a statement that—

4                   “(I) the device provides informa-  
5                   tion about the susceptibility of bac-  
6                   teria and fungi to certain drugs; and

7                   “(II) the safety and efficacy of  
8                   such drugs in treating clinical infec-  
9                   tions due to such bacteria or fungi  
10                  may not have been established in ade-  
11                  quate and well-controlled clinical trials  
12                  and the clinical significance of such  
13                  susceptibility information in those in-  
14                  stances is unknown;

15                  “(ii) includes a statement directing  
16                  health care practitioners to consult the ap-  
17                  proved labeling for drugs tested using such  
18                  a device, to determine the uses for which  
19                  the Food and Drug Administration has ap-  
20                  proved such drugs; and

21                  “(iii) includes any other statement the  
22                  Secretary determines appropriate to ade-  
23                  quately convey the limitations of the data  
24                  supporting the interpretive criteria de-  
25                  scribed in subparagraph (A).

1 “(f) DEFINITIONS.—In this section:

2 “(1) The term ‘antimicrobial susceptibility test-  
3 ing device’ means a device that utilizes susceptibility  
4 test interpretive criteria to determine and report the  
5 in vitro susceptibility of certain microorganisms to a  
6 drug (or drugs).

7 “(2) The term ‘qualified infectious disease  
8 product’ means a qualified infectious disease product  
9 designated under section 505E(d).

10 “(3) The term ‘susceptibility test interpretive  
11 criteria’ means—

12 “(A) one or more specific numerical values  
13 which characterize the susceptibility of bacteria  
14 or other microorganisms to the drug tested; and

15 “(B) related categorizations of such sus-  
16 ceptibility, including categorization of the drug  
17 as susceptible, intermediate, resistant, or such  
18 other term as the Secretary determines appro-  
19 priate.

20 “(4)(A) The term ‘antimicrobial drug’ means,  
21 subject to subparagraph (B), a systemic anti-  
22 bacterial or antifungal drug that—

23 “(i) is intended for human use in the treat-  
24 ment of a disease or condition caused by a bac-  
25 terium or fungus;

1 “(ii) may include a qualified infectious dis-  
2 ease product designated under section 505E(d);  
3 and

4 “(iii) is subject to section 503(b)(1).

5 “(B) If provided by the Secretary through regu-  
6 lations, such term may include—

7 “(i) drugs other than systemic anti-  
8 bacterial and antifungal drugs; and

9 “(ii) biological products (as such term is  
10 defined in section 351 of the Public Health  
11 Service Act) to the extent such products exhibit  
12 antimicrobial activity.

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

15 “(1) to alter the standards of evidence—

16 “(A) under subsection (c) or (d) of section  
17 505, including the substantial evidence stand-  
18 ard in section 505(d), or under section 351 of  
19 the Public Health Service Act (as applicable);  
20 or

21 “(B) with respect to marketing authoriza-  
22 tion for devices, under section 510, 513, or 515;

23 “(2) to apply with respect to any drug, device,  
24 or biological product, in any context other than—

1           “(A) the use of such drug or product as an  
2           antimicrobial drug; or

3           “(B) the use of an antimicrobial suscepti-  
4           bility testing device to characterize and report  
5           the in vitro susceptibility of certain bacteria,  
6           fungi, or other microorganisms to antimicrobial  
7           drugs in accordance with this section; or

8           “(3) unless specifically stated, to have any ef-  
9           fect on authorities provided under other sections of  
10          this Act, including any regulations issued under such  
11          sections.”.

12       (b) CONFORMING AMENDMENTS.—

13           (1) REPEAL OF RELATED AUTHORITY.—Section  
14          1111 of the Food and Drug Administration Amend-  
15          ments Act of 2007 (42 U.S.C. 247d–5a; relating to  
16          identification of clinically susceptible concentrations  
17          of antimicrobials) is repealed.

18           (2) MISBRANDING.—Section 502 of the Federal  
19          Food, Drug, and Cosmetic Act (21 U.S.C. 352), as  
20          amended by section 2121, is further amended by  
21          adding at the end the following:

22          “(ee) If it is an antimicrobial drug and its labeling  
23          fails to conform with the requirements under section  
24          511(d).”.

1           (3) RECOGNITION OF INTERPRETIVE CRITERIA  
2       AS DEVICE STANDARD.—Section 514(c)(1)(A) of the  
3       Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
4       360d(c)(1)(A)) is amended by inserting after “the  
5       Secretary shall, by publication in the Federal Reg-  
6       ister” the following: “(or, with respect to suscepti-  
7       bility test interpretive criteria or standards recog-  
8       nized or otherwise listed under section 511, by post-  
9       ing on the Interpretive Criteria Website in accord-  
10      ance with such section)”.

11      (c) REPORT TO CONGRESS.—Not later than two  
12      years after the date of enactment of this Act, the Sec-  
13      retary of Health and Human Services shall submit to the  
14      Committee on Energy and Commerce of the House of  
15      Representatives and the Committee on Health, Education,  
16      Labor and Pensions of the Senate a report on the progress  
17      made in implementing section 511 of the Federal Food,  
18      Drug, and Cosmetic Act (21 U.S.C. 360a), as amended  
19      by this section.

20      (d) REQUESTS FOR UPDATES TO INTERPRETIVE CRI-  
21      TERIA WEBSITE.—Chapter 35 of title 44, United States  
22      Code, shall not apply to the collection of information from  
23      interested parties regarding the updating of lists under  
24      paragraph (2) of subsection (b) section 511 of the Federal  
25      Food, Drug, and Cosmetic Act (as amended by subsection

1 (a)) and posted on the Interpretive Criteria Website estab-  
2 lished under paragraph (1) of such subsection (b).

3 (e) NO EFFECT ON HEALTH CARE PRACTICE.—  
4 Nothing in this subtitle (including the amendments made  
5 by this subtitle) shall be construed to restrict, in any man-  
6 ner, the prescribing or administering of antibiotics or  
7 other products by health care practitioners, or to limit the  
8 practice of health care.

9 **[SEC. 2123. ENCOURAGING THE DEVELOPMENT AND RE-**  
10 **SPONSIBLE USE OF NEW ANTIMICROBIAL**  
11 **DRUGS.]**

12 **[(a) ADDITIONAL PAYMENT FOR NEW ANTI-**  
13 **MICROBIAL DRUGS UNDER MEDICARE.—**Section  
14 1886(d)(5) of the Social Security Act (42 U.S.C.  
15 1395ww(d)(5)) is amended by adding at the end the fol-  
16 lowing new subparagraph:]

17 **["(M)(i) Effective for discharges beginning**  
18 **on or after October 1, 2015, the Secretary**  
19 **shall, after notice and opportunity for public**  
20 **comment (in the publications required by sub-**  
21 **section (e)(5) for a fiscal year or otherwise),**  
22 **recognize the costs of new antimicrobial drugs**  
23 **under the payment system established under**  
24 **this subparagraph.]**



1           【“(ii) Pursuant to clause (i), the Secretary  
2           shall provide for additional payment to be made  
3           under this subsection with respect to discharges  
4           involving new antimicrobial drugs in the  
5           amount provided for under section 1847A for  
6           drugs and biological products that are described  
7           in section 1842(o)(1)(C).】

8           【“(iii) For purposes of this subparagraph,  
9           the term ‘new antimicrobial drug’ means a  
10          product that is approved for use, or a product  
11          for which an indication is first approved for  
12          use, by the Food and Drug Administration on  
13          or after January 1, 2015, and—】

14          【“(I)(aa) is intended to treat an in-  
15          fection caused by, or likely to be caused by,  
16          a qualifying pathogen (as defined under  
17          section 505E(f) of the Federal Food,  
18          Drug, and Cosmetic Act); or】

19          【“(bb) meets the definition of a quali-  
20          fied infectious disease product under sec-  
21          tion 505E(g) of the Federal Food, Drug,  
22          and Cosmetic Act;】

23          【“(II) for which there is an ‘unmet  
24          medical need’ as determined by the Food  
25          and Drug Administration;】

1           【“(III) which is associated with high  
2           rates of mortality or significant patient  
3           morbidity, as determined by the Secretary,  
4           in consultation with the Director of the  
5           Centers for Disease Control and Preven-  
6           tion and the infectious disease professional  
7           community; and】

8           【“(IV) is used in facilities that par-  
9           ticipate in the National Healthcare Safety  
10          Network of the Centers for Disease Con-  
11          trol and Prevention (or, to the extent a  
12          similar reporting program relating to anti-  
13          microbial drugs is determined by the Sec-  
14          retary to be available to such facilities,  
15          such similar reporting program as the Sec-  
16          retary may specify).】

17          【“(iv)(I) The manufacturer or sponsor of a  
18          drug may request the Secretary to designate a  
19          drug as a new antimicrobial drug at any time  
20          before or after the submission of an application  
21          under section 505(b) of the Federal Food,  
22          Drug, and Cosmetic Act or section 351(a) of  
23          the Public Health Service Act for such drug.  
24          The Secretary shall, not later than 60 days  
25          after the submission of such a request, deter-

1 mine whether the drug is a new antimicrobial  
2 drug.】

3 【“(II) Except as provided in subclause  
4 (III), a designation under this subsection shall  
5 not be withdrawn for any reason.”】

6 【“(III) The Secretary may revoke a des-  
7 ignation of a drug as a new antimicrobial drug  
8 product if the Secretary finds that the request  
9 for such designation contained an untrue state-  
10 ment of material fact.”】

11 【“(v) Not later than July 1, 2015, the  
12 Secretary shall first publish in the Federal Reg-  
13 ister a list of the new antimicrobial drugs.”】

14 【(b) STUDY AND REPORT ON REMOVING BARRIERS  
15 TO DEVELOPMENT OF NEW ANTIMICROBIAL DRUGS.—】

16 【(1) STUDY.—The Comptroller General of the  
17 United States shall, in consultation with the Direc-  
18 tor of the National Institutes of Health, the Com-  
19 missioner of Food and Drugs, and the Director of  
20 the Centers for Disease Control and Prevention, con-  
21 duct a study to—】

22 【(A) identify and examine the barriers  
23 that prevent the development of new anti-  
24 microbial drugs, as defined in section

1 1886(d)(5)(M)(iii) of the Social Security Act  
2 (42 U.S.C. 1395ww(d)(5)(M)(iii)); and】

3 【(B) develop recommendations for actions  
4 to be taken in order to overcome any barriers  
5 identified under subparagraph (A).】

6 【(2) REPORT.—Not later than 1 year after the  
7 date of the enactment of this Act, the Comptroller  
8 General shall submit to Congress a report on the  
9 study conducted under paragraph (1).】

10 **Subtitle H—Vaccine Access,**  
11 **Certainty, and Innovation**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6           “(B) vaccine research.

7           “(2)(A) Upon the submission of a written request for  
8           a meeting by a vaccine developer, that includes a justifica-  
9           tion for the meeting, the Secretary, acting through the Di-  
10          rector of the Centers for Disease Control and Prevention,  
11          shall convene a meeting of representatives of the vaccine  
12          developer and experts from the Centers for Disease Con-  
13          trol and Prevention in immunization programs, epidemi-  
14          ology, and other relevant areas at which the Director (or  
15          the Director’s designee), for the purpose of informing the  
16          vaccine developer’s understanding of public health needs  
17          and priorities, shall provide the perspectives of the Centers  
18          for Disease Control and Prevention and other relevant  
19          Federal agencies regarding—

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

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



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

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

7 “(ii) the National Vaccine Program.

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

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

17 “(i) are specified in the request;

18 “(ii) have been published;

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

21 “(iv) are not a trade secret or commercial or fi-  
22 nancial information that is privileged or confidential  
23 and subject to section 552(b)(4) of title 5, United  
24 States Code, or section 1905 of title 18, United  
25 States Code; and

1           “(v) do not contain individually identifiable in-  
2           formation.

3           “(B) The Secretary shall provide analyses requested  
4           by a vaccine manufacturer under subparagraph (A) not  
5           later than 90 calendar days after receipt of the request  
6           for the analyses.

7           “(4) The Secretary shall promptly notify a vaccine  
8           developer if—

9           “(A) the Secretary becomes aware of any  
10          change to information that was—

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

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

17           “(B) the change may have implications for the  
18           vaccine developer’s vaccine research and develop-  
19           ment.”.

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

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

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

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

15 “(a) DESIGNATION.—

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

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

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

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

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

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

15 “(2) REVOCATION OF DESIGNATION.—

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

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

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

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

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

15               “(1)(A) the 4-, 5-, and 7 ½-year periods de-  
16               scribed in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii)  
17               of section 505, the 3-year periods described in  
18               clauses (iii) and (iv) of subsection (c)(3)(E) and  
19               clauses (iii) and (iv) of subsection (j)(5)(F) of sec-  
20               tion 505, and the 7-year period described in section  
21               527, as applicable, shall be extended by 6 months;  
22               or

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

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

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

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

1       “(c) RELATION TO PEDIATRIC AND QUALIFIED IN-  
2       FECTIONOUS DISEASE PRODUCT EXCLUSIVITY.—Any exten-  
3       sion under subsection (b) of a period shall be in addition  
4       to any extension of the periods under sections 505A and  
5       505E of this Act and section 351(m) of the Public Health  
6       Service Act, as applicable, with respect to the drug.

7       “(d) LIMITATIONS.—The extension described in sub-  
8       section (b) shall not apply if the drug designated under  
9       subsection (a)(1) has previously received an extension by  
10      operation of subsection (b).

11      “(e) REGULATIONS.—

12           “(1) IN GENERAL.—Not later than 2 years  
13      after the date of enactment of this section, the Sec-  
14      retary shall adopt final regulations implementing  
15      this section.

16           “(2) PROCEDURE.—In promulgating a regula-  
17      tion implementing this section, the Secretary shall—

18                   “(A) issue a notice of proposed rulemaking  
19                   that includes the proposed regulation;

20                   “(B) provide a period of not less than 60  
21                   days for comments on the proposed regulation;  
22                   and

23                   “(C) publish the final regulation not less  
24                   than 30 days before the effective date of the  
25                   regulation.

1           “(3) RESTRICTIONS.—Notwithstanding any  
2       other provision of law, the Secretary shall promul-  
3       gate regulations implementing this section only as  
4       described in paragraph (2), except that the Sec-  
5       retary may issue interim guidance for sponsors seek-  
6       ing to submit an application or supplemental appli-  
7       cation described in subsection (a) prior to the pro-  
8       mulgation of such regulations.

9           “(4) DESIGNATION PRIOR TO REGULATIONS.—  
10      The Secretary shall designate drugs under sub-  
11      section (a) prior to the promulgation of regulations  
12      under this subsection, if such drugs meet the criteria  
13      described in subsection (a).

14      “(f) DEFINITION.—In this section, the term ‘rare dis-  
15      ease or condition’ has the meaning given to such term in  
16      section 526(a)(2).”.

17      (b) APPLICATION.—Section 505G of the Federal  
18      Food, Drug, and Cosmetic Act, as added by subsection  
19      (a), applies only with respect to a drug for which an appli-  
20      cation or supplemental application described in subsection  
21      (a)(1)(B)(i) of such section 505G is first approved under  
22      section 505(c) of such Act (21 U.S.C. 355(c)) or section  
23      351(a) of the Public Health Service Act (42 U.S.C.  
24      262(a)) on or after the date of the enactment of this Act.

25      (c) CONFORMING AMENDMENTS.—



1           (1) RELATION TO PEDIATRIC EXCLUSIVITY FOR  
2       DRUGS.—Section 505A of the Federal Food, Drug,  
3       and Cosmetic Act (21 U.S.C. 355a) is amended—

4           (A) in subsection (b), by adding at the end  
5       the following:

6           “(3) RELATION TO EXCLUSIVITY FOR A DRUG  
7       APPROVED FOR A NEW INDICATION FOR A RARE DIS-  
8       EASE OR CONDITION.—Notwithstanding the ref-  
9       erences in subsection (b)(1) to the lengths of the ex-  
10      clusivity periods after application of pediatric exclu-  
11      sivity, the 6-month extensions described in sub-  
12      section (b)(1) shall be in addition to any extensions  
13      under section 505G.”; and

14          (B) in subsection (c), by adding at the end  
15      the following:

16          “(3) RELATION TO EXCLUSIVITY FOR A DRUG  
17      APPROVED FOR A NEW INDICATION FOR A RARE DIS-  
18      EASE OR CONDITION.—Notwithstanding the ref-  
19      erences in subsection (c)(1) to the lengths of the ex-  
20      clusivity periods after application of pediatric exclu-  
21      sivity, the 6-month extensions described in sub-  
22      section (c)(1) shall be in addition to any extensions  
23      under section 505G.”.

24          (2) RELATION TO EXCLUSIVITY FOR NEW  
25      QUALIFIED INFECTIOUS DISEASE PRODUCTS THAT

1 ARE DRUGS.—Subsection (b) of section 505E of the  
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
3 355f) is amended—

4 (A) by amending the subsection heading to  
5 read as follows: “RELATION TO PEDIATRIC EX-  
6 CLUSIVITY AND EXCLUSIVITY FOR A DRUG AP-  
7 PROVED FOR A NEW INDICATION FOR A RARE  
8 DISEASE OR CONDITION”; and

9 (B) by striking “any extension of the pe-  
10 riod under section 505A” and inserting “any  
11 extension of the periods under sections 505A  
12 and 505G, as applicable,”.

13 (3) RELATION TO PEDIATRIC EXCLUSIVITY FOR  
14 BIOLOGICAL PRODUCTS.—Section 351(m) of the  
15 Public Health Service Act (42 U.S.C. 262(m)) is  
16 amended by adding at the end the following:

17 “(5) RELATION TO EXCLUSIVITY FOR A BIO-  
18 LOGICAL PRODUCT APPROVED FOR A NEW INDICA-  
19 TION FOR A RARE DISEASE OR CONDITION.—Not-  
20 withstanding the references in paragraphs (2)(A),  
21 (2)(B), (3)(A), and (3)(B) to the lengths of the ex-  
22 clusivity periods after application of pediatric exclu-  
23 sivity, the 6-month extensions described in such  
24 paragraphs shall be in addition to any extensions  
25 under section 505G.”.

1 **[SEC. 2152. REAUTHORIZATION OF RARE PEDIATRIC DIS-**  
2 **EASE PRIORITY REVIEW VOUCHER INCEN-**  
3 **TIVE PROGRAM.**

4 Section 529 of the Federal Food, Drug, and Cosmetic  
5 Act (21 U.S.C. 360ff) is amended—

6 **[(1) in subsection (a)—]**

7 **[(A) in paragraph (3), by amending sub-**  
8 **paragraph (A) to read as follows:]**

9 **["(A) The disease is a serious and life-**  
10 **threatening disease in which the serious and**  
11 **life-threatening manifestations primarily affect**  
12 **individuals aged from birth to 18 years, includ-**  
13 **ing age groups often called neonates, infants,**  
14 **children, and adolescents.”; and]**

15 **[(B) in paragraph (4)(A)—]**

16 **[(i) in subparagraph (E), by striking**  
17 **“and”;]**

18 **[(ii) in subparagraph (F), by striking**  
19 **the period and inserting “; and”; and]**

20 **[(iii) by adding at the end the fol-**  
21 **lowing:]**

22 **["(G) is for a drug or biological product**  
23 **for which a priority review voucher has not been**  
24 **issued under section 524 (relating to tropical**  
25 **disease products).”; and]**

1           【(2) in subsection (b), by striking paragraph  
2           (5) and inserting the following:】

3           【“(5) TERMINATION OF AUTHORITY.—The Sec-  
4           retary may not award any priority review vouchers  
5           under paragraph (1) after June 30, 2022.”.】

6       **Subtitle    J—Domestic    Manufac-**  
7       **turing and Export Efficiencies**

8       **SEC. 2161. GRANTS FOR STUDYING THE PROCESS OF CON-**  
9       **TINUOUS DRUG MANUFACTURING.**

10       (a) IN GENERAL.—The Commissioner of Food and  
11       Drugs may award grants to institutions of higher edu-  
12       cation and nonprofit organizations for the purpose of  
13       studying and recommending improvements to the process  
14       of continuous manufacturing of drugs and biological prod-  
15       ucts and similar innovative monitoring and control tech-  
16       niques.

17       (b) DEFINITIONS.—In this section:

18           (1) The term “drug” has the meaning given to  
19           such term in section 201 of the Federal Food, Drug,  
20           and Cosmetic Act (21 U.S.C. 321).

21           (2) The term “biological product” has the  
22           meaning given to such term in section 351(i) of the  
23           Public Health Service Act (42 U.S.C. 262(i)).

24           (3) The term “institution of higher education”  
25           has the meaning given to such term in section 101

1 of the Higher Education Act of 1965 (20 U.S.C.  
2 1001).

3 (c) AUTHORIZATION OF APPROPRIATIONS.—There is  
4 authorized to be appropriated \$5,000,000 for each of fis-  
5 cal years 2016 through 2020 to carry out this section.

6 **SEC. 2162. RE-EXPORTATION AMONG MEMBERS OF THE EU-**  
7 **ROPEAN ECONOMIC AREA.**

8 Section 1003(f) of the Controlled Substances Import  
9 and Export Act (21 U.S.C. 953(f)) is amended—

10 (1) in paragraph (5)—

11 (A) by striking “(5)” and inserting  
12 “(5)(A)”;

13 (B) by inserting “, except that the con-  
14 trolled substance may be exported from the sec-  
15 ond country to another country that is a mem-  
16 ber of the European Economic Area” before the  
17 period at the end; and

18 (C) by adding at the end the following:

19 “(B) Subsequent to any re-exportation de-  
20 scribed in subparagraph (A), a controlled substance  
21 may continue to be exported from any country that  
22 is a member of the European Economic Area to any  
23 other such country, provided that—

24 “(i) the conditions applicable with respect  
25 to the first country under paragraphs (1), (2),

1           (3), (4), (6), and (7) are met by each subse-  
2           quent country from which the controlled sub-  
3           stance is exported pursuant to this paragraph;  
4           and

5           “(ii) the conditions applicable with respect  
6           to the second country under such paragraphs  
7           are met by each subsequent country to which  
8           the controlled substance is exported pursuant to  
9           this paragraph.”; and

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

11          “(g) LIMITATION.—The Attorney General shall not  
12          promulgate nor enforce any regulation, subregulatory  
13          guidance, or enforcement policy which impedes re-expor-  
14          tation among European Economic Area countries (as pro-  
15          vided in subsection (f)(5)), including by promulgating or  
16          enforcing any requirement that—

17               “(1) re-exportation from the first country to the  
18          second country or re-exportation from the second  
19          country to another country (as such terms are used  
20          in subsection (f)) occur within a specified period of  
21          time; or

22               “(2) information concerning the consignee,  
23          country, and product be provided prior to expor-  
24          tation of the controlled substance from the United  
25          States.”.

1                   **Subtitle K—Enhancing**  
2                   **Combination Products Review**

3   **SEC. 2181. ENHANCING COMBINATION PRODUCTS REVIEW.**

4           Section 503(g)(4)(C) of the Federal Food, Drug, and  
5   Cosmetic Act (21 U.S.C. 353(g)(4)(C)) is amended by  
6   adding at the end the following new clause:

7                   “(iii) Not later than 18 months after the date  
8           of the enactment of the 21st Century Cures Act, the  
9           Secretary shall issue final guidance that describes  
10          the responsibilities of each agency center regarding  
11          its review of combination products. The Secretary  
12          shall, after soliciting public comment, review and up-  
13          date the guidance periodically.”.

14                   **Subtitle L—Priority Review for**  
15                   **Breakthrough Devices**

16   **SEC. 2201. PRIORITY REVIEW FOR BREAKTHROUGH DE-**  
17                   **VICES.**

18          (a) IN GENERAL.—Chapter V of the Federal Food,  
19   Drug, and Cosmetic Act is amended—

20                   (1) in section 515(d)—

21                           (A) by striking paragraph (5); and

22                           (B) by redesignating paragraph (6) as  
23          paragraph (5); and

24                   (2) by inserting after section 515A (21 U.S.C.  
25          360e–1) the following:

1 **“SEC. 515B. PRIORITY REVIEW FOR BREAKTHROUGH DE-**  
2 **VICES.**

3 “(a) IN GENERAL.—In order to provide for more ef-  
4 fective treatment or diagnosis of life-threatening or irre-  
5 versibly debilitating human diseases or conditions, the  
6 Secretary shall establish a program to provide priority re-  
7 view for devices—

8 “(1) representing breakthrough technologies;

9 “(2) for which no approved alternatives exist;

10 “(3) offering significant advantages over exist-  
11 ing approved or cleared alternatives, including the  
12 potential to, compared to existing approved or  
13 cleared alternatives, reduce or eliminate the need for  
14 hospitalization, improve patient quality of life, facili-  
15 tate patients’ ability to manage their own care (such  
16 as through self-directed personal assistance), or es-  
17 tablish long-term clinical efficiencies; or

18 “(4) the availability of which is in the best in-  
19 terest of patients.

20 “(b) REQUEST FOR DESIGNATION.—A sponsor of a  
21 device may request that the Secretary designate the device  
22 for priority review under this section. Any such request  
23 for designation may be made at any time prior to the sub-  
24 mission of an application under section 515(c), a petition  
25 for classification under section 513(f)(2), or a notification  
26 under section 510(k).



1 “(c) DESIGNATION PROCESS.—

2 “(1) IN GENERAL.—Not later than 60 calendar  
3 days after the receipt of a request under subsection  
4 (b), the Secretary shall determine whether the device  
5 that is the subject of the request meets the criteria  
6 described in subsection (a). If the Secretary deter-  
7 mines that the device meets the criteria, the Sec-  
8 retary shall designate the device for priority review.

9 “(2) REVIEW.—Review of a request under sub-  
10 section (b) shall be undertaken by a team that is  
11 composed of experienced staff and managers of the  
12 Food and Drug Administration and is chaired by a  
13 senior manager.

14 “(3) DESIGNATION DETERMINATION.—A deter-  
15 mination approving or denying a request under sub-  
16 section (b) shall be considered a significant decision  
17 under section 517A and the Secretary shall provide  
18 a written, substantive summary of the basis for the  
19 determination in accordance with section 517A(a).

20 “(4) RECONSIDERATION.—

21 “(A) REQUEST FOR RECONSIDERATION.—

22 Any person whose request under subsection (b)  
23 is denied may, within 30 days of the denial, re-  
24 quest reconsideration of the denial in accord-  
25 ance with section 517A(b)—

1 “(i) based upon the submission of  
2 documents by such person; or

3 “(ii) based upon such documents and  
4 a meeting or teleconference.

5 “(B) RESPONSE.—Reconsideration of a  
6 designation determination under this paragraph  
7 shall be conducted in accordance with section  
8 517A(b).

9 “(5) WITHDRAWAL.—If the Secretary approves  
10 a priority review designation for a device under this  
11 section, the Secretary may not withdraw the des-  
12 ignation based on the fact that the criteria specified  
13 in subsection (a) are no longer met because of the  
14 subsequent clearance or approval of another device  
15 that was designated under—

16 “(A) this section; or

17 “(B) section 515(d)(5) (as in effect imme-  
18 diately prior to the enactment of the 21st Cen-  
19 tury Cures Act).

20 “(d) PRIORITY REVIEW.—

21 “(1) ACTIONS.—For purposes of expediting the  
22 development and review of devices designated under  
23 subsection (c), the Secretary shall—

24 “(A) assign a team of staff, including a  
25 team leader with appropriate subject matter ex-

1           pertise and experience, for each device for  
2           which a request is submitted under subsection  
3           (b);

4           “(B) provide for oversight of the team by  
5           senior agency personnel to facilitate the effi-  
6           cient development of the device and the efficient  
7           review of any submission described in sub-  
8           section (b) for the device;

9           “(C) adopt an efficient process for timely  
10          dispute resolution;

11          “(D) provide for interactive communication  
12          with the sponsor of the device during the review  
13          process;

14          “(E) expedite the Secretary’s review of  
15          manufacturing and quality systems compliance,  
16          as applicable;

17          “(F) disclose to the sponsor in advance the  
18          topics of any consultation concerning the spon-  
19          sor’s device that the Secretary intends to under-  
20          take with external experts or an advisory com-  
21          mittee and provide the sponsor an opportunity  
22          to recommend such external experts;

23          “(G) for applications submitted under sec-  
24          tion 515(c), provide for advisory committee  
25          input, as the Secretary determines appropriate

1 (including in response to the request of the  
2 sponsor); and

3 “(H) assign staff to be available within a  
4 reasonable time to address questions by institu-  
5 tional review committees concerning the condi-  
6 tions and clinical testing requirements applica-  
7 ble to the investigational use of the device pur-  
8 suant to an exemption under section 520(g).

9 “(2) ADDITIONAL ACTIONS.—In addition to the  
10 actions described in paragraph (1), for purposes of  
11 expediting the development and review of devices  
12 designated under subsection (c), the Secretary, in  
13 collaboration with the device sponsor, may, as appro-  
14 priate—

15 “(A) coordinate with the sponsor regarding  
16 early agreement on a data development plan;

17 “(B) take steps to ensure that the design  
18 of clinical trials is as efficient as practicable,  
19 such as through adoption of shorter or smaller  
20 clinical trials, application of surrogate  
21 endpoints, and use of adaptive trial designs and  
22 Bayesian statistics, to the extent scientifically  
23 appropriate;

24 “(C) facilitate, to the extent scientifically  
25 appropriate, expedited and efficient develop-

1           ment and review of the device through utiliza-  
2           tion of timely postmarket data collection, with  
3           regard to applications for approval under sec-  
4           tion 515(c); and

5           “(D) agree to clinical protocols that the  
6           Secretary will consider binding on the Secretary  
7           and the sponsor, subject to—

8                   “(i) changes agreed to by the sponsor  
9                   and the Secretary;

10                   “(ii) changes that the Secretary deter-  
11                   mines are required to prevent an unreason-  
12                   able risk to the public health; or

13                   “(iii) the identification of a substan-  
14                   tial scientific issue determined by the Sec-  
15                   retary to be essential to the safety or effec-  
16                   tiveness of the device involved.

17       “(e) PRIORITY REVIEW GUIDANCE.—

18           “(1) CONTENT.—The Secretary shall issue  
19           guidance on the implementation of this section. Such  
20           guidance shall include the following:

21                   “(A) The process for a person to seek a  
22                   priority review designation.

23                   “(B) A template for requests under sub-  
24                   section (b).

1           “(C) The criteria the Secretary will use in  
2           evaluating a request for priority review.

3           “(D) The standards the Secretary will use  
4           in assigning a team of staff, including team  
5           leaders, to review devices designated for priority  
6           review, including any training required for such  
7           personnel on effective and efficient review.

8           “(2) PROCESS.—Prior to finalizing the guid-  
9           ance under paragraph (1), the Secretary shall pro-  
10          pose such guidance for public comment.

11          “(f) CONSTRUCTION.—

12           “(1) PURPOSE.—This section is intended to en-  
13          courage the Secretary and provide the Secretary suf-  
14          ficient authorities to apply efficient and flexible ap-  
15          proaches to expedite the development of, and  
16          prioritize the agency’s review of, devices that rep-  
17          resent breakthrough technologies.

18           “(2) CONSTRUCTION.—Nothing in this section  
19          shall be construed to alter the criteria and standards  
20          for evaluating an application pursuant to section  
21          515(c), a report and request for classification under  
22          section 513(f)(2), or a report under section 510(k),  
23          including the recognition of valid scientific evidence  
24          as described in section 513(a)(3)(B), and consider-  
25          ation of the least burdensome means of evaluating

1 device effectiveness or demonstrating substantial  
2 equivalence between devices with differing techno-  
3 logical characteristics, as applicable. Nothing in this  
4 section alters the authority of the Secretary to act  
5 on an application pursuant to section 515(d) before  
6 completion of an establishment inspection, as the  
7 Secretary deems appropriate.”.

8 (b) CONFORMING AMENDMENT RELATED TO DES-  
9 IGNATION DETERMINATIONS.—Section 517A(a)(1) of the  
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–  
11 1(a)(1)) is amended by inserting “a request for designa-  
12 tion under section 515B,” after “an application under sec-  
13 tion 515,”.

## 14 **Subtitle M—Medical Device**

## 15 **Regulatory Process Improvements**

### 16 **SEC. 2221. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

17 (a) ESTABLISHMENT OF THIRD-PARTY QUALITY  
18 SYSTEM ASSESSMENT PROGRAM.—Chapter V of the Fed-  
19 eral Food, Drug, and Cosmetic Act is amended by insert-  
20 ing after section 524A (21 U.S.C. 360n–1) the following  
21 new section:

#### 22 **“SEC. 524B. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

23 **“(a) ACCREDITATION AND ASSESSMENT.—**

24 **“(1) IN GENERAL; CERTIFICATION OF DEVICE**  
25 **QUALITY SYSTEM.—The Secretary shall, in accord-**

1       ance with this section, establish a third-party quality  
2       system assessment program—

3               “(A) to accredit persons to assess whether  
4               a requestor’s quality system, including its de-  
5               sign controls, can reasonably assure the safety  
6               and effectiveness of in-scope devices subject to  
7               device-related changes (as defined in paragraph  
8               (2));

9               “(B) under which accredited persons shall,  
10              as applicable, certify that a requestor’s quality  
11              system meets the criteria issued under para-  
12              graph (5) with respect to the in-scope devices at  
13              issue; and

14              “(C) under which the Secretary shall rely  
15              on such certifications for purposes of deter-  
16              mining the safety and effectiveness of in-scope  
17              devices subject to the device-related changes in-  
18              volved, in lieu of compliance with the following  
19              submission requirements:

20                      “(i) A thirty-day notice (as defined in  
21                      paragraph (2)).

22                      “(ii) A Special PMA supplement (as  
23                      defined in paragraph (2)).

24              “(2) DEFINITIONS.—For purposes of this sec-  
25       tion—



1           “(A) the term ‘device-related changes’  
2 means changes made by a requestor with re-  
3 spect to in-scope devices, which are—

4                   “(i) manufacturing changes subject to  
5 a 30-day notice;

6                   “(ii) changes that qualify for a Spe-  
7 cial PMA supplement; and

8                   “(iii) such other changes relating to  
9 the devices or the device manufacturing  
10 process as the Secretary determines appro-  
11 priate;

12           “(B) the term ‘in-scope device’ means a  
13 device within the scope of devices agreed to by  
14 the requestor and the accredited person for pur-  
15 poses of a request for certification under this  
16 section;

17           “(C) the term ‘quality system’ means a  
18 quality system described in section 520(f);

19           “(D) the term ‘requestor’ means a device  
20 manufacturer that is seeking certification under  
21 this section of a quality system used by such  
22 manufacturer;

23           “(E) the term ‘Special PMA’ means a Spe-  
24 cial PMA supplement under section 814.39(d)

1 of title 21, Code of Federal Regulations (or any  
2 successor regulations); and

3 “(F) the term ‘thirty-day notice’ means a  
4 notice described in section 515(d)(6).

5 “(3) ACCREDITATION PROCESS; ACCREDITATION  
6 RENEWAL.—Except as inconsistent with this section,  
7 the process and qualifications for accreditation of  
8 persons and renewal of such accreditation under sec-  
9 tion 704(g) shall apply with respect to accreditation  
10 of persons and renewal of such accreditation under  
11 this section.

12 “(4) USE OF ACCREDITED PARTIES TO CON-  
13 DUCT ASSESSMENTS.—

14 “(A) INITIATION OF ASSESSMENT SERV-  
15 ICES.—

16 “(i) DATE ASSESSMENTS AUTHOR-  
17 IZED.—Beginning after issuance of the  
18 final guidance under paragraph (5), an ac-  
19 credited person may conduct an assess-  
20 ment under this section.

21 “(ii) INITIATION OF ASSESSMENTS.—  
22 Use of one or more accredited persons to  
23 assess a requestor’s quality system under  
24 this section with respect to in-scope devices  
25 shall be at the initiation of the person who

1 registers and lists the devices at issue  
2 under section 510.

3 “(B) COMPENSATION.—Compensation for  
4 such accredited persons shall—

5 “(i) be determined by agreement be-  
6 tween the accredited person and the person  
7 who engages the services of the accredited  
8 person; and

9 “(ii) be paid by the person who en-  
10 gages such services.

11 “(C) ACCREDITED PERSON SELECTION.—  
12 Each person who chooses to use an accredited  
13 person to assess a requestor’s quality system,  
14 as described in this section, shall select the ac-  
15 credited person from a list of such persons pub-  
16 lished by the Secretary in accordance with sec-  
17 tion 704(g)(4).

18 “(5) GUIDANCE; CRITERIA FOR CERTIFI-  
19 CATION.—

20 “(A) IN GENERAL.—The criteria for cer-  
21 tification of a quality system under this section  
22 shall be as specified by the Secretary in guid-  
23 ance issued under this paragraph.

1           “(B) CONTENTS; CERTIFICATION CRI-  
2           TERIA.—The guidance under this paragraph  
3           shall include specification of—

4                   “(i) evaluative criteria to be used by  
5                   an accredited person to assess and as ap-  
6                   plicable certify a requestor’s quality system  
7                   under this section with respect to in-scope  
8                   devices ; and

9                   “(ii) criteria for accredited persons to  
10                  apply a waiver of and exemptions from the  
11                  certification criteria under clause (i).

12           “(C) TIMEFRAME FOR ISSUING GUID-  
13           ANCE.—The Secretary shall issue under this  
14           paragraph—

15                   “(i) draft guidance not later than 12  
16                   months after the enactment of the 21st  
17                   Century Cures Act; and

18                   “(ii) final guidance not later than 12  
19                   months after issuance of the draft guid-  
20                   ance under clause (i).

21           “(b) USE OF THIRD-PARTY ASSESSMENT.—

22                   “(1) ASSESSMENT SUMMARY; CERTIFI-  
23           CATION.—

24                   “(A) SUBMISSION OF ASSESSMENT TO SEC-  
25           RETARY.—An accredited person who assesses a

1 requestor's quality system under subsection (a)  
2 shall submit to the Secretary a summary of the  
3 assessment—

4 “(i) within 30 days of the assessment;  
5 and

6 “(ii) which as applicable shall in-  
7 clude—

8 “(I) the accredited person's cer-  
9 tification that the requestor has satis-  
10 fied the criteria issued under sub-  
11 section (a)(5) for quality system cer-  
12 tification with respect to the in-scope  
13 devices at issue; and

14 “(II) any waivers or exemptions  
15 from such criteria applied by the ac-  
16 credited person.

17 “(B) TREATMENT OF ASSESSMENTS.—  
18 Subject to action by the Secretary under sub-  
19 paragraph (C), with respect to assessments  
20 which include a certification under this sec-  
21 tion—

22 “(i) the Secretary's review of the as-  
23 sessment summary shall be deemed com-  
24 plete on the day that is 30 days after the

1 date on which the Secretary receives the  
2 summary under subparagraph (A); and

3 “(ii) the assessment summary and  
4 certification of the requestor shall be  
5 deemed accepted by the Secretary on such  
6 30th day.

7 “(C) ACTIONS BY SECRETARY.—

8 “(i) IN GENERAL.—Within 30 days of  
9 receiving an assessment summary and cer-  
10 tification under subparagraph (A), the Sec-  
11 retary may, by written notice to the ac-  
12 credited person submitting such assess-  
13 ment certification, deem any such certifi-  
14 cation to be provisional beyond such 30-  
15 day period, suspended pending further re-  
16 view by the Secretary, or otherwise quali-  
17 fied or cancelled, based on the Secretary’s  
18 determination that (as applicable)—

19 “(I) additional information is  
20 needed to support such certification;

21 “(II) such assessment or certifi-  
22 cation is unwarranted; or

23 “(III) such action with regard to  
24 the certification is otherwise justified

1 according to such factors and criteria  
2 as the Secretary finds appropriate.

3 “(ii) ACCEPTANCE OF CERTIFI-  
4 CATION.—If following action by the Sec-  
5 retary under clause (i) with respect to a  
6 certification, the Secretary determines that  
7 such certification is acceptable, the Sec-  
8 retary shall issue written notice to the ap-  
9 plicable accredited person indicating such  
10 acceptance.

11 “(2) NOTIFICATIONS TO SECRETARY BY CER-  
12 TIFIED MANUFACTURERS FOR PROGRAM EVALUA-  
13 TION PURPOSES.—

14 “(A) PERIODIC NOTIFICATION FOR MANU-  
15 FACTURING CHANGES OTHERWISE SUBJECT TO  
16 THIRTY-DAY NOTICE.—A requestor certified  
17 under this section that effectuates device-re-  
18 lated changes with respect to in-scope devices,  
19 without prior submission of a thirty-day notice,  
20 shall provide notification to the Secretary of  
21 such changes in the requestor’s next periodic  
22 report under section 814.84(b) of title 21, Code  
23 of Federal Regulations (or any successor regu-  
24 lation). Such notification shall—

25 “(i) describe the changes made; and

1 “(ii) indicate the effective dates of  
2 such changes.

3 “(B) PERIODIC NOTIFICATION FOR DE-  
4 VICE-RELATED CHANGES OTHERWISE SUBJECT  
5 TO SPECIAL PMA SUPPLEMENT.—A requestor  
6 certified under this section that effectuates de-  
7 vice-related changes with respect to in-scope de-  
8 vices, without prior submission of a Special  
9 PMA Supplement, shall provide notification to  
10 the Secretary of such changes in the requestor’s  
11 next periodic report under section 814.84(b) of  
12 title 21, Code of Federal Regulations (or any  
13 successor regulation). Such notification shall—

14 “(i) describe the changes made, in-  
15 cluding a full explanation of the basis for  
16 the changes; and

17 “(ii) indicate the effective dates of  
18 such changes.

19 “(C) USE OF NOTIFICATIONS FOR PRO-  
20 GRAM EVALUATION PURPOSES.—Information  
21 submitted to the Secretary under subpara-  
22 graphs (A) and (B) shall be used by the Sec-  
23 retary for purposes of the program evaluation  
24 under subsection (d).



1 “(c) DURATION AND EFFECT OF CERTIFICATION.—

2 A certification under this section—

3 “(1) shall remain in effect for a period of two  
4 years from the date such certification is accepted by  
5 the Secretary, subject to paragraph (6);

6 “(2) may be renewed through the process de-  
7 scribed in subsection (a)(3);

8 “(3) shall continue to apply with respect to de-  
9 vice-related changes made during such 2-year period,  
10 provided the certification remains in effect, irrespec-  
11 tive of whether such certification is renewed after  
12 such 2-year period;

13 “(4) shall have no effect on the need to comply  
14 with applicable submission requirements specified in  
15 subsection (a)(1)(C) with respect to any change per-  
16 taining to in-scope devices which is not a device-re-  
17 lated change under subsection (a)(2);

18 “(5) shall have no effect on the authority of the  
19 Secretary to conduct an inspection or otherwise de-  
20 termine the requestor’s conformance with the appli-  
21 cable requirements of this Act; and

22 “(6) shall be considered to be revoked if the  
23 Secretary provides written notification to the cer-  
24 tified requestor that its quality system does not sat-  
25 isfy the certification criteria issued under subsection

1 (a)(5) with respect to the in-scope devices at issue,  
2 such that the applicable submission requirements  
3 specified in subsection (a)(1)(C) must be met for  
4 changes made after receipt of such written notifica-  
5 tion, with respect to such devices.

6 “(d) PROGRAM EVALUATION; SUNSET.—

7 “(1) PROGRAM EVALUATION AND REPORT.—

8 “(A) EVALUATION.—The Secretary shall  
9 complete an evaluation of the third-party qual-  
10 ity system assessment program under this sec-  
11 tion no later than January 31, 2021, based  
12 on—

13 “(i) analysis of information from a  
14 representative group of device manufactur-  
15 ers obtained from notifications provided by  
16 certified requestors under subsection  
17 (b)(2); and

18 “(ii) such other available information  
19 and data as the Secretary determines ap-  
20 propriate.

21 “(B) REPORT.—No later than 1 year after  
22 completing the evaluation under subparagraph  
23 (A), the Secretary shall issue a report of the  
24 evaluation’s findings on the website of the Food  
25 and Drug Administration, which shall include

1 the Secretary's recommendations with respect  
2 to continuation and as applicable expansion of  
3 the program under this section to include addi-  
4 tional types of submissions and additional types  
5 of changes beyond those identified in subsection  
6 (a)(1)(C), including changes to devices cleared  
7 under section 510(k). At the discretion of the  
8 Secretary, the program may be expanded prior  
9 to January 31, 2021.

10 “(2) SUNSET.—This section shall cease to be  
11 effective October 1, 2022.

12 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-  
13 tion shall be construed to limit the authority of the Sec-  
14 retary to request and review the complete assessment of  
15 a certified requestor under this section on a for-cause  
16 basis.”.

17 (b) CONFORMING AMENDMENTS.—

18 (1) REQUIREMENTS FOR PREMARKET AP-  
19 PROVAL SUPPLEMENTS.—Section 515(d)(6)(A)(i) of  
20 the Federal Food, Drug, and Cosmetic Act (21  
21 U.S.C. 360e(d)(6)(A)(i)) is amended by inserting “,  
22 subject to section 524B,” after “that affects safety  
23 or effectiveness”.

24 (2) REQUIREMENTS FOR THIRTY-DAY NO-  
25 TICE.—Section 515(d)(6)(A)(ii) of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C.  
2 360e(d)(6)(A)(ii)) is amended by inserting “, subject  
3 to section 524B,” after “the date on which the Sec-  
4 retary receives the notice”.

5 **SEC. 2222. VALID SCIENTIFIC EVIDENCE.**

6 Section 513(a)(3)(B) of the Federal Food, Drug, and  
7 Cosmetic Act (21 U.S.C. 360c(a)(3)(B)) is amended—

8 (1) by redesignating clauses (i) and (ii) as sub-  
9 clauses (I) and (II), respectively;

10 (2) by striking “(B) If the Secretary” and in-  
11 serting “(B)(i) If the Secretary”; and

12 (3) by adding at the end the following:

13 “(ii) Valid scientific evidence for purposes  
14 of clause (i) may include:

15 “(I) evidence described in well-docu-  
16 mented case histories, including registry  
17 data, that are collected and monitored  
18 under an acceptable protocol;

19 “(II) studies published in peer-re-  
20 viewed journals; and

21 “(III) data collected in countries other  
22 than the United States so long as such  
23 data otherwise meets the criteria specified  
24 in this subparagraph.

1           “(iii) In the case of a study published in  
2           a peer-reviewed journal that is offered as valid  
3           scientific evidence for purposes of clause (i), the  
4           Secretary may request data underlying the  
5           study if—

6                   “(I) the Secretary, in making such re-  
7                   quest, complies with the requirement of  
8                   subparagraph (D)(ii) to consider the least  
9                   burdensome appropriate means of evalu-  
10                  ating device effectiveness or subsection  
11                  (i)(1)(D) to consider the least burdensome  
12                  means of determining substantial equiva-  
13                  lence, as applicable;

14                   “(II) the Secretary furnishes a written  
15                   rationale for so requesting the underlying  
16                   data together with such request; and

17                   “(III) if the requested underlying data  
18                   for such a study are unavailable, the Sec-  
19                   retary shall consider such study to be part  
20                   of the totality of the evidence with respect  
21                   to the device, as the Secretary determines  
22                   appropriate.”.

1 **SEC. 2223. TRAINING AND OVERSIGHT IN LEAST BURDEN-**  
2 **SOME APPROPRIATE MEANS CONCEPT.**

3 (a) IN GENERAL.— Section 513 of the Federal Food,  
4 Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by  
5 inserting after subsection (i) the following:

6 “(j) TRAINING AND OVERSIGHT IN LEAST BURDEN-  
7 SOME APPROPRIATE MEANS CONCEPT.—

8 “(1) TRAINING.—Each employee of the Food  
9 and Drug Administration who is involved in the re-  
10 view of premarket submissions under section 515 or  
11 section 510(k), including supervisors, shall receive  
12 training regarding the meaning and implementation  
13 of the least burdensome appropriate means concept  
14 in the context of the use of that term in subsections  
15 (a)(3)(D) and (i)(1)(D) of this section and in section  
16 515(c)(5).

17 “(2) GUIDANCE DOCUMENTS.—

18 “(A) DRAFT UPDATED GUIDANCE.—Not  
19 later than 12 months after the date of enact-  
20 ment of the 21st Century Cures Act, the Sec-  
21 retary shall issue a draft guidance document  
22 updating the October 4, 2002, guidance docu-  
23 ment entitled ‘The Least Burdensome Provision  
24 of the FDA Modernization Act of 1997: Con-  
25 cept and Principles; Final Guidance for FDA  
26 and Industry’.

1           “(B) MEETING OF STAKEHOLDERS.—In  
2           developing such draft guidance document, the  
3           Secretary shall convene a meeting of stake-  
4           holders to ensure a full record to support the  
5           publication of such document.

6           “(3) OMBUDSMAN AUDIT.—Not later than 18  
7           months after the date of issuance of final version of  
8           the draft guidance under paragraph (2), the om-  
9           budsman for the organizational unit of the Food and  
10          Drug Administration responsible for the premarket  
11          review of devices shall—

12           “(A) conduct, or have conducted, an audit  
13           of the training described in paragraph (1); and

14           “(B) include in such audit interviews with  
15           a representative sample of persons from indus-  
16           try regarding their experience in the device pre-  
17           market review process.”.

18          (b) ADDITIONAL INFORMATION REGARDING PRE-  
19          MARKET APPLICATIONS.—Subsection (c) of section 515 of  
20          the Federal Food, Drug, and Cosmetic Act (21 U.S. C.  
21          29 360e) is amended by adding at the end the follows:

22           “(5)(A) Whenever the Secretary requests additional  
23           information from an applicant regarding an application  
24           under paragraph (1), the Secretary shall consider the least  
25           burdensome appropriate means necessary to demonstrate

1 device safety and effectiveness, and request information  
2 accordingly.

3 “(B) For purposes of subparagraph (A), the term  
4 ‘necessary’ means the minimum required information that  
5 would support a determination by the Secretary that an  
6 application provides a reasonable assurance of the safety  
7 and effectiveness of the device.

8 “(C) Nothing in this paragraph alters the standards  
9 for premarket approval of a device.”.

10 **SEC. 2224. RECOGNITION OF STANDARDS.**

11 Section 514(c) of the Federal Food, Drug, and Cos-  
12 metic Act (21 U.S.C. 360d(c)) is amended—

13 (1) in paragraph (1), by inserting after sub-  
14 paragraph (B) the following new subparagraphs:

15 “(C)(i) Any person may submit a request  
16 for recognition under subparagraph (A) of all  
17 or part of an appropriate standard established  
18 by a nationally or internationally recognized  
19 standard organization.

20 “(ii) Not later than 60 days after the Sec-  
21 retary receives such a request, the Secretary  
22 shall—

23 “(I) make a determination to recog-  
24 nize all, part, or none of the standard that  
25 is the subject of the request; and



1 “(II) issue to the person who sub-  
2 mitted such request a respond in writing  
3 that states the Secretary’s rationale for  
4 that determination, including the scientific,  
5 technical, regulatory, or other basis for  
6 such determination;

7 “(iii) The Secretary make a response  
8 issued under clause (ii)(II) publicly available, in  
9 such manner as the Secretary determines ap-  
10 propriate.

11 “(iv) The Secretary shall take such actions  
12 as may be necessary to implement all or part of  
13 a standard recognized under subclause (I), in  
14 accordance with subparagraph (A).

15 “(D) The Secretary shall make publicly  
16 available, in such manner as the Secretary de-  
17 termines appropriate, the rationale for recogni-  
18 tion under subparagraph (A) of part of a stand-  
19 ard, including the scientific, technical, regu-  
20 latory, or other basis for such recognition.”;  
21 and

22 (2) by adding at the end the following new  
23 paragraphs:

24 “(4) TRAINING ON USE OF STANDARDS.—The  
25 Secretary shall provide to all employees of the Food

1 and Drug Administration who review premarket sub-  
2 missions for devices periodic training on the concept  
3 and use of recognized standards for purposes of  
4 meeting a premarket submission requirement or  
5 other applicable requirement under this Act, includ-  
6 ing standards relevant to an employee's area of de-  
7 vice review.

8 “(5) GUIDANCE.—

9 “(A) DRAFT GUIDANCE.—The Secretary  
10 shall publish guidance identifying the principles  
11 for recognizing standards under this section. In  
12 publishing such guidance, the Secretary shall  
13 consider the experience with, and reliance on, a  
14 standard by other Federal regulatory authori-  
15 ties and the device industry, and whether rec-  
16 ognition of a standard will promote harmoni-  
17 zation among regulatory authorities in the regu-  
18 lation of devices.

19 “(B) TIMING.—The Secretary shall pub-  
20 lish—

21 “(i) draft guidance under subpara-  
22 graph (A) not later than 12 months after  
23 the date of the enactment of the 21st Cen-  
24 tury Cures Act; and

1 “(ii) final guidance not later than 12  
2 months of the close of the public comment  
3 period for the draft guidance under clause  
4 (i).”.

5 **SEC. 2225. EASING REGULATORY BURDEN WITH RESPECT**  
6 **TO CERTAIN CLASS I AND CLASS II DEVICES.**

7 (a) CLASS I DEVICES.—Section 510(l) of the Federal  
8 Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is  
9 amended—

10 (1) by striking “A report under subsection (k)”  
11 and inserting “(1) A report under subsection (k)”;  
12 and

13 (2) by adding at the end the following new  
14 paragraph:

15 “(2) Not later than 120 days after the date of the  
16 enactment of the 21st Century Cures Act, the Secretary  
17 shall identify, through publication in the Federal Register,  
18 any type of class I device that the Secretary determines  
19 no longer requires a report under subsection (k) to provide  
20 reasonable assurance of safety and effectiveness. Upon  
21 such publication—

22 “(A) each type of class I device so identified  
23 shall be exempt from the requirement for a report  
24 under subsection (k); and

1 “(B) the classification regulation applicable to  
2 each such type of device shall be deemed amended  
3 to incorporate such exemption.”.

4 (b) CLASS II DEVICES.—Section 510(m) of the Fed-  
5 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360(m))  
6 is amended—

7 (1) by striking paragraph (1) and inserting the  
8 following new paragraph:

9 “(1) The Secretary shall—

10 “(A) not later than 60 days after the date of  
11 the enactment of the 21st Century Cures Act—

12 “(i) publish in the Federal Register a no-  
13 tice that contains a list of each type of class II  
14 device that the Secretary determines no longer  
15 requires a report under subsection (k) to pro-  
16 vide reasonable assurance of safety and effec-  
17 tiveness; and

18 “(ii) provide for a period of not less than  
19 60 days for public comment beginning on the  
20 date of the publication of such notice; and

21 “(B) not later than 180 days after the date of  
22 the enactment of 21st Century Cures Act, publish in  
23 the Federal Register a list representing the Sec-  
24 retary’s final determination with respect to the de-

1       vices contained in the list published under subpara-  
2       graph (A).”;

3               (2) in paragraph (2)—

4                       (A) by striking “1 day after the date of  
5                       publication of a list under this subsection,” and  
6                       inserting “1 day after the date of publication of  
7                       the final list under paragraph (1)(B),”; and

8                       (B) by striking “30-day period” and in-  
9                       serting “60-day period”; and

10               (3) by adding at the end the following new  
11       paragraph:

12       “(3) Upon the publication of the final list under para-  
13       graph (1)(B)—

14                       “(A) each type of class II device so listed shall  
15                       be exempt from the requirement for a report under  
16                       subsection (k); and

17                       “(B) the classification regulation applicable to  
18                       each such type of device shall be deemed amended  
19                       to incorporate such exemption.”.

20       **SEC. 2226. ADVISORY COMMITTEE PROCESS.**

21       (a) CLASSIFICATION PANELS.—Paragraph (5) of sec-  
22       tion 513(b) of the Federal Food, Drug, and Cosmetic Act  
23       (21 U.S.C. 360c(b)) is amended—

24                       (1) by striking “(5)” and inserting “(5)(A)”;  
25       and

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

2 “(B) For review by a classification panel of  
3 a premarket submission for a device, the Sec-  
4 retary shall—

5 “(i) provide an opportunity for the  
6 person whose premarket submission is sub-  
7 ject to panel review to provide rec-  
8 ommendations on the expertise needed  
9 among the voting members of the panel;  
10 and

11 “(ii) give due consideration to such  
12 recommendations and ensure that adequate  
13 expertise is represented on advisory panels  
14 to assess—

15 “(I) the disease or condition for  
16 which the device is intended to cure,  
17 treat, mitigate, prevent, or diagnose;  
18 and

19 “(II) the technology of the de-  
20 vice.

21 “(C) For purposes of subparagraph (B)(ii),  
22 the term ‘adequate expertise’ means that the  
23 membership of the classification panel reviewing  
24 a premarket submission includes—

1 “(i) two or more voting members, with  
2 a specialty or other expertise clinically rel-  
3 evant to the device under review; and

4 “(ii) at least one voting member who  
5 is knowledgeable about the technology of  
6 the device.”.

7 (b) PANEL REVIEW PROCESS.—Section 513(b)(6) of  
8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
9 360c(b)(6)) is amended—

10 (1) in subparagraph (A)(iii), by inserting before  
11 the period at the end “, including by designating a  
12 representative who will be provided a time during  
13 the panel meeting to address the panel individually  
14 (or accompanied by experts selected by such rep-  
15 resentative) for the purpose of correcting  
16 misstatements of fact or providing clarifying infor-  
17 mation, subject to the discretion of panel chair-  
18 person.”.

19 (2) by striking subparagraph (B) and inserting  
20 the following new subparagraph:

21 “(B)(i) Any meeting of a classification  
22 panel with respect to the review of a premarket  
23 submission for a device shall—

24 “(I) provide adequate time for initial  
25 presentations by the person whose pre-

1 market submission is specifically the sub-  
2 ject of such review and by the Secretary;  
3 and

4 “(II) encourage free and open partici-  
5 pation by all interested persons.

6 “(ii) Following the initial presentations de-  
7 scribed in clause (i), the panel may—

8 “(I) pose questions to a designated  
9 representative described in subparagraph  
10 (A)(iii); and

11 “(II) consider the responses to such  
12 questions in the panel’s review of the pre-  
13 market submission.”.

14 **SEC. 2227. HUMANITARIAN DEVICE EXEMPTION APPLICA-**  
15 **TION.**

16 (a) IN GENERAL.—Section 520(m) of the Federal  
17 Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amend-  
18 ed—

19 (1) in paragraph (1) by striking “fewer than  
20 4,000” and inserting “not more than 8,000”;

21 (2) in paragraph (2)(A) by striking “fewer than  
22 4,000” and inserting “not more than 8,000”; and

23 (3) in paragraph (6)(A)(ii), by striking “4,000”  
24 and inserting “8,000”



1 (b) GUIDANCE DOCUMENT ON PROBABLE BEN-  
2 EFIT.—Not later than 18 months after the date of enact-  
3 ment of this Act, the Secretary of Health and Human  
4 Services, acting through the Commissioner of Food and  
5 Drugs, shall publish a draft guidance document that de-  
6 fines the criteria for establishing “probable benefit” as  
7 that term is used in section 520(m)(2)(C) of the Federal  
8 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)(C)).

9 **SEC. 2228. CLIA WAIVER STUDY DESIGN GUIDANCE FOR IN**  
10 **VITRO DIAGNOSTICS.**

11 (a) DRAFT REVISED GUIDANCE.—Not later than 12  
12 months after the date of the enactment of this Act, the  
13 Secretary of Health and Human Services shall publish a  
14 draft guidance that—

15 (1) revises section V “Demonstrating Insignifi-  
16 cant Risk of an Erroneous Result—‘Accuracy’” of  
17 the guidance entitled “Recommendations for Clinical  
18 Laboratory Improvement Amendments of 1988  
19 (CLIA) Waiver Applications for Manufacturers of In  
20 Vitro Diagnostic Devices” and dated January 30,  
21 2008; and

22 (2) includes guidance on the appropriate use of  
23 comparable performance between a waived user and  
24 a moderately complex laboratory user to dem-  
25 onstrate accuracy.

1 (b) FINAL REVISED GUIDANCE.—The Secretary of  
2 Health and Human Services shall finalize the draft guid-  
3 ance published under subsection (a) not later than 12  
4 months after the comment period for such draft guidance  
5 closes.

6 **Subtitle N—Sensible Oversight for**  
7 **Technology Which Advances**  
8 **Regulatory Efficiency**

9 **SEC. 2241. HEALTH SOFTWARE.**

10 Section 201 of the Federal Food, Drug, and Cosmetic  
11 Act (21 U.S.C. 321) is amended by adding at the end the  
12 following:

13 “(ss)(1) The term ‘health software’ means software  
14 that does not, through use of an in vitro diagnostic device  
15 or signal acquisition system, acquire, process, or analyze  
16 an image or physiological signal, is not an accessory, is  
17 not an integral part of a device necessary to support the  
18 use of the device, and—

19 “(A) is intended for use for administrative  
20 or operational support or the processing and  
21 maintenance of financial records;

22 “(B) is intended for use in clinical, labora-  
23 tory, or administrative workflow and related  
24 recordkeeping;

1           “(C)(i) is intended for use solely in the  
2           transfer, aggregation, conversion (in accordance  
3           with a present specification), storage, manage-  
4           ment, retrieval, or transmission of data or in-  
5           formation;

6           “(ii) utilizes a connectivity software plat-  
7           form, electronic or electrical hardware, or a  
8           physical communications infrastructure; and

9           “(iii) is not intended for use—

10           “(I) in active patient monitoring; or

11           “(II) in controlling or altering the  
12           functions or parameters of a device that is  
13           connected to such software;

14           “(D) is intended for use to organize and  
15           present information for health or wellness edu-  
16           cation or for use in maintaining a healthy life-  
17           style, including medication adherence and  
18           health management tools;

19           “(E) is intended for use to analyze infor-  
20           mation to provide general health information  
21           that does not include patient-specific rec-  
22           ommended options to consider in the preven-  
23           tion, diagnosis, treatment, cure, or mitigation of  
24           a particular disease or condition; or

1 “(F) is intended for use to analyze infor-  
2 mation to provide patient-specific recommended  
3 options to consider in the prevention, diagnosis,  
4 treatment, cure, or mitigation of a particular  
5 disease or condition.

6 “(2) The term ‘accessory’ means a product that—

7 “(A) is intended for use with one or more par-  
8 ent devices;

9 “(B) is intended to support, supplement, or  
10 augment the performance of one or more parent de-  
11 vices; and

12 “(C) shall be classified by the Secretary—

13 “(i) according to its intended use; and

14 “(ii) independently of any classification of  
15 any parent device with which it is used.”.

16 **SEC. 2242. APPLICABILITY AND INAPPLICABILITY OF REGU-**  
17 **LATION.**

18 Subchapter A of chapter V of the Federal Food,  
19 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-  
20 ed by adding at the end the following:

21 **“SEC. 524B. HEALTH SOFTWARE.**

22 “(a) INAPPLICABILITY OF REGULATION TO HEALTH  
23 SOFTWARE.—Subject to subsection (b), health software  
24 shall not be subject to regulation under this Act.

1       “(b) EXCEPTION.—Subsection (a) shall not apply in  
2 the case of a software product of a type described in sub-  
3 paragraph (F) of section 201(ss)(1) that the Secretary de-  
4 termines poses a significant risk to patient safety. In mak-  
5 ing such a determination for such product, the Secretary  
6 shall consider the following:

7           “(1) The likelihood and severity of patient  
8 harm if the product were to not perform as in-  
9 tended.

10          “(2) The extent to which the product is in-  
11 tended to support the clinical judgment of a medical  
12 professional.

13          “(3) Whether there is a reasonable opportunity  
14 for a medical professional to review the basis of the  
15 information or treatment recommendation provided  
16 by the product.

17          “(4) The intended use of the product, including  
18 the intended user and user environment, such as  
19 whether a medical professional will use a software  
20 product of a type described in subparagraph (F) of  
21 section 201(ss)(1).

22       “(c) DELEGATION.—The Secretary shall delegate pri-  
23 mary jurisdiction for regulating a software product deter-  
24 mined under subsection (b) to be subject to regulation

1 under this Act to the center at the Food and Drug Admin-  
2 istration charged with regulating devices.

3 “(d) REGULATION OF SOFTWARE.—

4 “(1) IN GENERAL.—The Secretary shall review  
5 existing regulations and guidance regarding the reg-  
6 ulation of software under this Act. The Secretary  
7 may implement a new framework for the regulation  
8 of software and shall, as appropriate, modify such  
9 regulations and guidance or issue new regulations or  
10 guidance.

11 “(2) ISSUANCE BY ORDER.—Notwithstanding  
12 subchapter II of chapter 5 of title 5, United States  
13 Code, the Secretary may modify or issue regulations  
14 for the regulation of software under this Act by ad-  
15 ministrative order published in the Federal Register  
16 following the publication of a proposed order.

17 “(3) AREAS UNDER REVIEW.—The review of ex-  
18 isting regulations and guidance under paragraph (1)  
19 may include review of the following areas:

20 “(A) Classification of software.

21 “(B) Standards for development of soft-  
22 ware.

23 “(C) Standards for validation and  
24 verification of software.

25 “(D) Review of software.

1 “(E) Modifications to software.

2 “(F) Manufacturing of software.

3 “(G) Quality systems for software.

4 “(H) Labeling requirements for software.

5 “(I) Postmarketing requirements for re-  
6 porting of adverse events.

7 “(4) PROCESS FOR ISSUING PROPOSED REGU-  
8 LATIONS, ADMINISTRATIVE ORDER, AND GUID-  
9 ANCE.—Not later than 18 months after the date of  
10 enactment of this section, the Secretary shall consult  
11 with external stakeholders (including patients, indus-  
12 try, health care providers, academia, and govern-  
13 ment) to gather input before issuing regulations, an  
14 administrative order, and guidance under this sub-  
15 section.”.

16 **SEC. 2243. EXCLUSION FROM DEFINITION OF DEVICE.**

17 Section 201(h) of the Federal Food, Drug, and Cos-  
18 metic Act (21 U.S.C. 321) is amended—

19 (1) in subparagraph (2), by striking “or” after  
20 “or other animals,”;

21 (2) in subparagraph (3), by striking “and” and  
22 inserting “or”; and

23 (3) by inserting after subparagraph (3) the fol-  
24 lowing:

1 “(4) is not health software (other than software  
2 determined to be a risk to patient safety under sec-  
3 tion 524B(b)), and”.

## 4 **Subtitle O—Streamlining Clinical** 5 **Trials**

### 6 **[SEC. 2261. PROTECTION OF HUMAN SUBJECTS IN RE-** 7 **SEARCH; APPLICABILITY OF RULES.**

8 Part H of title IV of the Public Health Service Act  
9 (42 U.S.C. 289 et seq.) is amended by inserting after sec-  
10 tion 491 the following section:】

### 11 **[“SEC. 491A. PROTECTION OF HUMAN SUBJECTS IN RE-** 12 **SEARCH; APPLICABILITY OF RULES.**

#### 13 **[“(a) PROTECTION OF HUMAN SUBJECTS.—】**

14 **[“(1) IN GENERAL.—All human subject re-**  
15 **search described in paragraph (2)(A) shall be con-**  
16 **ducted in accordance with the HHS Human Subject**  
17 **Regulations, and as applicable to the human sub-**  
18 **jects involved in such research, with the vulnerable-**  
19 **populations rules.】**

#### 20 **[“(2) APPLICABILITY.—】**

21 **[“(A) IN GENERAL.—This section applies**  
22 **to human subject research that is—】**

23 **[“(i) conducted or supported by the**  
24 **Department of Health and Human Serv-**  
25 **ices; or】**



1                   【“(ii) otherwise subject to regulation  
2                   by the Department under a provision of  
3                   Federal law (other than this section).】

4                   【“(B) OTHER FEDERAL DEPARTMENTS  
5                   AND AGENCIES.—The Secretary shall make  
6                   available assistance to any Federal department  
7                   or agency seeking—】

8                   【“(i) to improve the regulation or  
9                   oversight of human subject research; or】

10                  【“(ii) to apply the HHS Human Sub-  
11                  ject Regulations or the vulnerable-popu-  
12                  lations rules to human subject research  
13                  that is conducted, supported, or regulated  
14                  by such department or agency.】

15                  【“(b) HHS HUMAN SUBJECT REGULATIONS; OTHER  
16                  DEFINITIONS.—】

17                  【“(1) HHS HUMAN SUBJECT REGULATIONS;  
18                  VULNERABLE-POPULATIONS RULES.—For purposes  
19                  of this section:】

20                  【“(A) The term ‘HHS Human Subject  
21                  Regulations’—】

22                  【“(i) subject to clause (ii), means the  
23                  provisions of subpart A of part 46 of title  
24                  45, Code of Federal Regulations (or any  
25                  successor regulations); or】

1                   【“(ii) in the case of human subject re-  
2                   search that is subject to the Federal Food,  
3                   Drug, and Cosmetic Act or to section 351  
4                   of this Act, means the provisions of parts  
5                   50, 56, 312, and 812 of title 21, Code of  
6                   Federal Regulations (or any successor reg-  
7                   ulations).】

8                   【“(B) The term ‘vulnerable-populations  
9                   rules’—】

10                  【“(i) subject to clause (ii), means the  
11                  provisions of subparts B through D of  
12                  such part 46 (or any successor regula-  
13                  tions); or】

14                  【“(ii) as applicable to the human sub-  
15                  jects involved in research described in sub-  
16                  paragraph (A), means the provisions appli-  
17                  cable to vulnerable populations under part  
18                  56 of such title 21 (or any successor regu-  
19                  lations) and subpart D of part 50 of such  
20                  title 21 (or any successor regulations).】

21                  【“(2) HUMAN SUBJECT RESEARCH.—For pur-  
22                  poses of this section:】

23                  【“(A) Except as provided in subparagraph  
24                  (B), the term ‘human subject research’ means  
25                  research, as defined in subpart A of part 46 of

1 title 45, Code of Federal Regulations (or any  
2 successor regulations), that involves a human  
3 subject, as defined in such subpart A (or any  
4 successor regulations).】

5 【“(B) In the case of an investigation that  
6 is subject to the provisions of part 50 of title  
7 21, Code of Federal Regulations (or any suc-  
8 cessor regulations), the term ‘human subject’  
9 has the meaning given such term in such part  
10 50, and the term ‘human subject research’  
11 means a clinical investigation as defined in such  
12 part 50.】

13 【“(3) OTHER DEFINITIONS.—For purposes of  
14 this section:】

15 【“(A) The term ‘institutional review  
16 board’ has the meaning that applies to the term  
17 ‘institutional review board’ under the HHS  
18 Human Subject Regulations.】

19 【“(B) The term ‘lead institutional review  
20 board’ means an institutional review board that  
21 otherwise meets the requirements of the HHS  
22 Human Subject Regulations and enters into a  
23 written agreement with an institution, another  
24 institutional review board, a sponsor, or a prin-  
25 cipal investigator to approve and oversee human

1 subject research that is conducted at multiple  
2 locations. References to an institutional review  
3 board include an institutional review board that  
4 serves a single institution as well as a lead in-  
5 stitutional review board.】

6 【“(c) SCOPE OF AUTHORITY OF SECRETARY.—】

7 【“(1) IN GENERAL.—The HHS Human Subject  
8 Regulations (including provisions regarding exemp-  
9 tions) and the vulnerable-populations rules, as in ef-  
10 fect on the day before the date of the enactment of  
11 the 21st Century Cures Act, continue to be in effect  
12 on and after such date, subject to paragraph (2).】

13 【“(2) MODIFICATIONS.—】

14 【“(A) COMPLIANCE WITH LAW.—Promptly  
15 after the date of the enactment of the Act re-  
16 ferred to in paragraph (1), the Secretary shall  
17 promulgate regulations to make such modifica-  
18 tions to the provisions of the HHS Human  
19 Subject Regulations as may be necessary to en-  
20 sure that such provisions implement, and do not  
21 conflict with, this section.】

22 【“(B) OTHER MODIFICATIONS.—This sec-  
23 tion may not be construed as affecting the au-  
24 thority of the Secretary to modify the provisions  
25 of the HHS Human Subject Regulations or the

1 vulnerable-populations rules, except to the ex-  
2 tent that any such modification is in conflict  
3 with this section. Any such modification shall  
4 be made by regulation or guidance, as applica-  
5 ble.】

6 【“(d) AVOIDING REGULATORY DUPLICATION AND  
7 UNNECESSARY DELAYS.—】

8 【“(1) IN GENERAL.—The Secretary shall—】

9 【“(A) make such modifications to the pro-  
10 visions of the HHS Human Subject Regulations  
11 and the vulnerable-populations rules as may be  
12 necessary—】

13 【“(i) to reduce regulatory duplication  
14 and unnecessary delays;】

15 【“(ii) to modernize such provisions in  
16 the context of multisite and cooperative re-  
17 search projects;】

18 【“(iii) to incorporate local consider-  
19 ations, community values, and mechanisms  
20 to protect vulnerable populations; and】

21 【“(iv) to ensure that human subject  
22 research that is subject to the Federal  
23 Food, Drug, and Cosmetic Act or to sec-  
24 tion 351 of this Act, and is therefore sub-  
25 ject to parts 50, 56, 312, and 812 of title

1                   21, Code of Federal Regulations (or any  
2                   successor regulations), is not subject to  
3                   subpart A of part 46 of title 45, Code of  
4                   Federal Regulations (or any successor reg-  
5                   ulations); and】

6                   【“(B) ensure that human subject research  
7                   that is described in subparagraph (A)(iv), or is  
8                   cooperative research as such term is defined in  
9                   section 46.114 of title 45, Code of Federal Reg-  
10                  ulations (or any successor regulations), may—  
11                  】

12                   【“(i) use joint or shared review;】

13                   【“(ii) rely upon the review of—】

14                   【“(I) an independent institu-  
15                   tional review board; or】

16                   【“(II) an institutional review  
17                   board of an entity other than the  
18                   sponsor of the research; or】

19                   【“(iii) use similar arrangements to  
20                   avoid duplication of effort.】

21                  【“(2) REGULATIONS AND GUIDANCE.—Not  
22                  later than 12 months after the date of enactment of  
23                  the 21st Century Cures Act, the Secretary, acting  
24                  through the relevant agencies and offices of the De-  
25                  partment of Health and Human Services, including

1 the Office for Human Research Protections and rel-  
2 evant agencies and offices of the Food and Drug Ad-  
3 ministration, shall issue such regulations and guid-  
4 ance and take such other actions as may be nec-  
5 essary to implement this subsection. Such regula-  
6 tions and guidance shall include clarification of re-  
7 quirements and policies relating to the following:】

8 【“(A) Arrangements to avoid duplication  
9 described in paragraph (1)(C), including—】

10 【“(i) delineating the roles of institu-  
11 tional review boards in multisite or cooper-  
12 ative, multisite studies where one or more  
13 local institutional review boards are relied  
14 upon, or similar arrangements are used;】

15 【“(ii) the risks and benefits to human  
16 subjects;】

17 【“(iii) standardization of informed  
18 consent and other processes and legal doc-  
19 uments; and】

20 【“(iv) incorporating community values  
21 through the use of local institutional re-  
22 view boards while continuing to use central  
23 or lead institutional review boards.】

24 【“(B) Concerns about regulatory and legal  
25 liability contributing to decisions by the spon-

1           sors of research to rely on local institutional re-  
2           view boards for multisite research.】

3           【“(3) CONSULTATION.—In issuing regulations  
4           or guidance pursuant to paragraph (2), the Sec-  
5           retary shall consult with stakeholders (including re-  
6           searchers, academic organizations, hospitals, institu-  
7           tional research boards, pharmaceutical, bio-  
8           technology and medical device developers, clinical re-  
9           search organizations, patient groups, and others).”】

10 **SEC. 2262. USE OF NON-LOCAL INSTITUTIONAL REVIEW**  
11 **BOARDS FOR REVIEW OF INVESTIGATIONAL**  
12 **DEVICE EXEMPTIONS AND HUMAN DEVICE**  
13 **EXEMPTIONS.**

14       (a) IN GENERAL.—Section 520 of the Federal Food,  
15 Drug, and Cosmetic Act (21 U.S.C. 360(j)) is amended—

16           (1) in subsection (g)(3)—

17               (A) by striking “local” each place it ap-  
18           pears; and

19               (B) in subparagraph (A)(i), by striking  
20           “which has been”; and

21           (2) in subsection (m)(4)—

22               (A) by striking “local” each place it ap-  
23           pears; and

24               (B) by striking subparagraph (A) and in-  
25           serting the following new subparagraph:



1           “(A) in facilities in which clinical testing of de-  
2           vices is supervised by an institutional review com-  
3           mittee established in accordance with the regulations  
4           of the Secretary, and”.

5           (b) REGULATIONS.—Not later than 12 months after  
6           the date of the enactment of this Act, the Secretary of  
7           Health and Human Services shall revise or issue such reg-  
8           ulations or guidance as may be necessary to carry out the  
9           amendments made by subsection (a).

10   **SEC. 2263. ALTERATION OR WAIVER OF INFORMED CON-**  
11           **SENT FOR CLINICAL INVESTIGATIONS.**

12           (a) DEVICES.—Section 520(g)(3) of the Federal  
13           Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(3)) is  
14           amended—

15                   (1) in subparagraph (D), by striking “except  
16           where subject to such conditions as the Secretary  
17           may prescribe, the investigator” and inserting the  
18           following: “except where, subject to such conditions  
19           as the Secretary may prescribe—

20                           “(i) the proposed clinical testing poses  
21                           no more than minimal risk to the human  
22                           subject and includes appropriate safe-  
23                           guards to protect the rights, safety, and  
24                           welfare of the human subject; or

25                           “(ii) the investigator”; and

1 (2) in the matter following subparagraph (D),  
2 by striking “subparagraph (D)” and inserting “sub-  
3 paragraph (D)(ii)”.

4 (b) DRUGS.—Section 505(i)(4) of the Federal Food,  
5 Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) is amended  
6 by striking “except where it is not feasible or it is contrary  
7 to the best interests of such human beings” and inserting  
8 “except where it is not feasible, it is contrary to the best  
9 interests of such human beings, or the proposed clinical  
10 testing poses no more than minimal risk to such human  
11 beings and includes appropriate safeguards as prescribed  
12 to protect the rights, safety, and welfare of such human  
13 beings”.

14 **Subtitle P—Improving Scientific**  
15 **Expertise and Outreach at FDA**

16 **SEC. 2281. SILVIO O. CONTE SENIOR BIOMEDICAL RE-**  
17 **SEARCH SERVICE.**

18 (a) HIRING AND RETENTION AUTHORITY.—Section  
19 228 of the Public Health Service Act (42 U.S.C. 237) is  
20 amended—

21 (1) in the section heading, by inserting “AND  
22 BIOMEDICAL PRODUCT ASSESSMENT” after “RE-  
23 SEARCH”;

24 (2) in subsection (a)(1), by striking “Silvio O.  
25 Conte Senior Biomedical Research Service, not to

1       exceed 500 members” and inserting “Silvio O. Conte  
2       Senior Biomedical Research and Biomedical Product  
3       Assessment Service (in this section referred to as the  
4       ‘Service’), the purpose of which is to recruit and re-  
5       tain competitive and qualified scientific and tech-  
6       nical experts outstanding in the field of biomedical  
7       research, clinical research evaluation, and biomedical  
8       product assessment”;

9               (3) by amending subsection (a)(2) to read as  
10      follows:

11      “(2) The authority established in paragraph (1) may  
12      not be construed to require the Secretary to reduce the  
13      number of employees serving under any other employment  
14      system in order to offset the number of members serving  
15      in the Service.”;

16              (4) in subsection (b)—

17              (A) in the matter preceding paragraph (1),  
18              by striking “or clinical research evaluation” and  
19              inserting “, clinical research evaluation or bio-  
20              medical product assessment” after “evalua-  
21              tion”; and

22              (B) in paragraph (1), by inserting “or a  
23              master’s level degree in engineering,  
24              bioinformatics, or a related or emerging field,”  
25              after the comma;

1           (5) in subsection (d), by striking “and shall not  
2       exceed the rate payable for level I of the Executive  
3       Schedule unless approved by the President under  
4       section 5377(d)(2) of title 5, United States Code”  
5       and inserting “and shall not exceed the rate payable  
6       for the President”;

7           (6) by striking subsection (e); and

8           (7) by redesignating subsections (f) and (g) as  
9       subsections (e) and (f), respectively.

10       (b) **REPORT.**—Not later than 3 years after the date  
11   of the enactment of this Act, the Secretary of Health and  
12   Human Services shall submit, and publish on the website  
13   of the Department of Health and Human Services a report  
14   on the implementation of the amendments made by sub-  
15   section (a), including whether the amendments have im-  
16   proved the ability of the Food and Drug Administration  
17   to hire and retain qualified experts to fulfill obligations  
18   specified under user fee agreements.

19   **SEC. 2282. ENABLING FDA SCIENTIFIC ENGAGEMENT.**

20       It is the sense of Congress that participation in or  
21   sponsorship of scientific conferences and meetings is es-  
22   sential to the mission of the Food and Drug Administra-  
23   tion.

1 **SEC. 2283. REAGAN-UDALL FOUNDATION FOR THE FOOD**  
2 **AND DRUG ADMINISTRATION.**

3 (a) BOARD OF DIRECTORS.—

4 (1) COMPOSITION AND SIZE.—Section  
5 770(d)(1)(C) of the Federal Food, Drug, and Cos-  
6 metic Act (21 U.S.C. 379dd(d)(1)(C)) is amended—

7 (A) by redesignating clause (ii) as clause  
8 (iii);

9 (B) by inserting after clause (i) the fol-  
10 lowing:

11 “(ii) ADDITIONAL MEMBERS.—The  
12 Board, through amendments to the bylaws  
13 of the Foundation, may provide that the  
14 number of voting members of the Board  
15 shall be a number (to be specified in such  
16 amendment) greater than 14. Any Board  
17 positions that are established by any such  
18 amendment shall be appointed (by majority  
19 vote) by the individuals who, as of the date  
20 of such amendment, are voting members of  
21 the Board and persons so appointed may  
22 represent any of the categories specified in  
23 subclauses (I) through (V) of clause (i), so  
24 long as no more than 30 percent of the  
25 total voting members of the Board (includ-  
26 ing members whose positions are estab-

1           lished by such amendment) are representa-  
2           tives of the general pharmaceutical, device,  
3           food, cosmetic, and biotechnology indus-  
4           tries.”; and

5           (C) in clause (iii)(I), as redesignated by  
6           subparagraph (A), by striking “The ex officio  
7           members shall ensure” and inserting “The ex  
8           officio members, acting pursuant to clause (i),  
9           and the Board, acting pursuant to clause (ii),  
10          shall ensure”.

11          (2) FEDERAL EMPLOYEES ALLOWED TO SERVE  
12          ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C)  
13          of the Federal Food, Drug, and Cosmetic Act (21  
14          U.S.C. 379dd(d)(1)(C)), as redesignated by para-  
15          graph (1)(A), is amended by adding at the end the  
16          following: “For purposes of this section, the term  
17          ‘employee of the Federal Government’ does not in-  
18          clude a ‘special Government employee’, as that term  
19          is defined in section 202(a) of title 18, United  
20          States Code.”.

21          (3) STAGGERED TERMS.—Subparagraph (A) of  
22          section 770(d)(3) of the Federal Food, Drug, and  
23          Cosmetic Act (21 U.S.C. 379dd(d)(3)) is amended  
24          to read as follows:

1           “(A) TERM.—The term of office of each  
2           member of the Board appointed under para-  
3           graph (1)(C)(i), and the term of office of any  
4           member of the Board whose position is estab-  
5           lished pursuant to paragraph (1)(C)(ii), shall be  
6           4 years, except that—

7                   “(i) the terms of offices for the mem-  
8           bers of the Board initially appointed under  
9           paragraph (1)(C)(i) shall expire on a stag-  
10          gered basis as determined by the ex officio  
11          members; and

12                   “(ii) the terms of office for the per-  
13          sons initially appointed to positions estab-  
14          lished pursuant to paragraph (1)(C)(ii)  
15          may be made to expire on a staggered  
16          basis, as determined by the individuals  
17          who, as of the date of the amendment es-  
18          tablishing such positions, are members of  
19          the Board.”.

20          (b) EXECUTIVE DIRECTOR COMPENSATION.—Section  
21          770(g)(2) of the Federal Food, Drug, and Cosmetic Act  
22          (21 U.S.C. 379dd(g)(2)) is amended by striking “but shall  
23          not be greater than the compensation of the Commis-  
24          sioner”.

1 (c) SEPARATION OF FUNDS.—Section 770(m) of the  
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
3 379dd(m)) is amended by striking “are held in separate  
4 accounts from funds received from entities under sub-  
5 section (i)” and inserting “are managed as individual pro-  
6 grammatic funds under subsection (i), according to best  
7 accounting practices”.

8 **SEC. 2284. COLLECTION OF CERTAIN VOLUNTARY INFOR-**  
9 **MATION EXEMPTED FROM PAPERWORK RE-**  
10 **DUCTION ACT.**

11 Chapter VII of the Federal Food, Drug, and Cos-  
12 metic Act is amended by inserting after section 708 of  
13 such Act (21 U.S.C. 379) the following:

14 **“SEC. 708A. COLLECTION OF CERTAIN VOLUNTARY INFOR-**  
15 **MATION EXEMPTED FROM PAPERWORK RE-**  
16 **DUCTION ACT.**

17 “Chapter 35 of title 44, United States Code, shall  
18 not apply to the collection from patients, industry, aca-  
19 demia, and other stakeholders, of voluntary information  
20 such as through voluntary surveys or questionnaires, initi-  
21 ated by the Secretary.”.



1                   **TITLE III—DELIVERY**  
2                   **Subtitle A—Interoperability**

3   **SEC. 3001. ENSURING INTEROPERABILITY.**

4           (a) DEVELOPMENT OF AND RECOMMENDATIONS FOR  
5   METHODS TO MEASURE INTEROPERABILITY.—Subtitle A  
6   of title XXX of the Public Health Service Act (42 U.S.C.  
7   300jj–11 et seq.) is amended by adding at the end the  
8   following new section:

9   **“SEC. 3010. ENSURING INTEROPERABILITY OF [QUALIFIED**  
10                   **ELECTRONIC HEALTH RECORDS]/[HEALTH**  
11                   **INFORMATION TECHNOLOGY].**

12           “(a) INTEROPERABILITY.—In order for [qualified  
13   electronic health record]/[health information technology]  
14   to be considered interoperable, such [record]/[tech-  
15   nology] must satisfy the following criteria:

16                   “(1) SECURE TRANSFER.—The [record]/[tech-  
17   nology] allows the secure transfer of the entirety of  
18   a patient’s data from any and all [qualified elec-  
19   tronic health records]/[health information tech-  
20   nology] for [authorized use].

21                   “(2) COMPLETE ACCESS TO HEALTH DATA.—  
22   The [record]/[technology] allows access to the en-  
23   tirety of a patient’s data for [authorized use] with-  
24   out special effort, as defined by recommendations  
25   adopted in accordance with this section, by the re-

1       questor of such data unless such data is not  
2       disclosable under applicable law.

3           “(3) NO INFORMATION BLOCKING.—The  
4       **【record】/【technology】** is not **【configured, set up, or**  
5       **implemented】** to engage in information blocking, as  
6       defined in section 3010A(f).

7           “(b) DETERMINING METHODS BY WHICH TO MEAS-  
8       URE IF **【QUALIFIED ELECTRONIC HEALTH RECORDS】/**  
9       **【HEALTH INFORMATION TECHNOLOGY】【ARE】/【IS】**  
10      INTEROPERABLE.—

11          “(1) IN GENERAL.—The Secretary shall adopt,  
12      in accordance with this section and section  
13      3004(c)—

14           “(A) methods by which to measure if  
15      **【qualified electronic health records】/【health in-**  
16      **formation technology】** satisfy the criteria de-  
17      scribed in subsection (a); and

18           “(B) as appropriate, modifications (includ-  
19      ing additions) to such methods, that are in ac-  
20      cordance with the policies developed by the HIT  
21      Policy Committee under section 3002(b)(2)(A)  
22      with respect to such methods.

23          “(2) RULES FOR ADOPTION.—

24           “(A) IN GENERAL.—Except as provided in  
25      subparagraph (B), any method adopted under

1 section 3004(c) or modification to such a meth-  
2 od adopted under subsection (c)(2)(B)(ii), pur-  
3 suant to this subsection, shall be a method that  
4 has been recommended by the Charter Organi-  
5 zation established under subsection (c).

6 “(B) SPECIAL RULES.—

7 “(i) DIFFERENT METHODS.—The  
8 Secretary may adopt a method that is dif-  
9 ferent from any method recommended  
10 under subsection (c) by the Charter Orga-  
11 nization, if—

12 “(I) the different method will  
13 substantially reduce administrative  
14 costs to health care providers and  
15 health plans compared to the alter-  
16 natives; and

17 “(II) the method is promulgated  
18 in accordance with the rulemaking  
19 procedures of subchapter III of chap-  
20 ter 5 of title 5, United States Code.

21 “(ii) NO METHOD BY CHARTER ORGA-  
22 NIZATION.—If the Charter Organization  
23 under subsection (c) has not recommended  
24 any method relating to the criteria de-  
25 scribed in subsection (a)—

1 “(I) subparagraph (A) shall not  
2 apply; and

3 “(II) paragraph (3) shall apply.

4 “(C) CONSULTATION REQUIREMENT.—

5 “(i) IN GENERAL.—The Secretary, in  
6 complying with paragraph (3), may not  
7 adopt under this subsection a method that  
8 has not been recommended by the Charter  
9 Organization under subsection (c) unless  
10 the Secretary consulted with each of the  
11 organizations described in clause (ii) before  
12 adopting the method.

13 “(ii) ORGANIZATIONS DESCRIBED.—  
14 The organizations referred to in clause (i)  
15 are each of the health care standards de-  
16 velopment organizations accredited by the  
17 American National Standards Institute.

18 “(D) EFFECTIVE DATE.—Any method  
19 adopted under clause (i) or (ii) of paragraph  
20 (2)(B) shall be effective 12 months after the  
21 date of publication of the final rule to adopt  
22 such method.

23 “(3) ASSISTANCE TO THE SECRETARY.—In  
24 complying with the requirements of this subsection,  
25 the Secretary shall rely on the recommendations of

1 the National Committee on Vital and Health Statis-  
2 tics established under section 306(k) of the Public  
3 Health Service Act (42 U.S.C. 242k(k)), and shall  
4 consult with appropriate Federal and State agencies  
5 and private organizations. The Secretary shall pub-  
6 lish in the Federal Register any recommendation of  
7 the National Committee on Vital and Health Statis-  
8 tics regarding the adoption of a method under this  
9 subsection. Any method adopted pursuant to this  
10 paragraph shall be promulgated in accordance with  
11 the rulemaking procedures of subchapter III of  
12 chapter 5 of title 5, United States Code.

13 “(4) APPLICATION TO MODIFICATION OF METH-  
14 ODS.—Paragraphs (2) and (3) shall apply to a modi-  
15 fication to a method (including an addition to a  
16 method) adopted pursuant to paragraph (1)(B) in  
17 the same manner as such paragraphs apply to an  
18 initial method adopted pursuant to paragraph  
19 (1)(A).

20 “(c) CHARTER ORGANIZATION.—

21 “(1) ESTABLISHMENT.—Not later than 180  
22 days after the date of the enactment of this section,  
23 the Secretary shall seek to enter into a contract with  
24 health care standards development organizations ac-  
25 credited by the American National Standards Insti-

1       tute to establish a committee to be known as the  
2       ‘Charter Organization’. Under such contract, the  
3       Charter Organization shall provide to the HIT  
4       Standards Committee for adoption under this sec-  
5       tion and section 3004(c), as applicable, rec-  
6       ommendations, in accordance with this section, for  
7       methods in which to measure if ~~qualified electronic~~  
8       health records~~]/[health information technology]~~ sat-  
9       isfy the criteria described in subsection (a) and  
10      modifications to such methods, which are in accord-  
11      ance with the policies developed by the HIT Policy  
12      Committee under section 3002(b)(2)(A) with respect  
13      to such methods.

14           “(2) RECOMMENDATIONS.—

15               “(A) INITIAL METHODS.—Not later than  
16               one year after the date of the enactment of this  
17               section, the Charter Organization shall submit  
18               to the HIT Standards Committee recommenda-  
19               tions for an initial set of methods described in  
20               paragraph (1).

21               “(B) MODIFICATIONS AND ADDITIONS.—

22                   “(i) EVALUATIONS AND REPORTS.—

23                       “(I) HEARINGS.—Not later than  
24                       3 years after the date of the enact-  
25                       ment of this section, and not less than

1 biennially thereafter, the Secretary,  
2 acting through the Charter Organiza-  
3 tion, shall conduct hearings to evalu-  
4 ate and review the methods adopted  
5 under section 3004(c) and subsection  
6 (b)(2)(B).

7 “(II) REPORT.—Not later than  
8 five years after the date of the enact-  
9 ment of this section, and not less than  
10 biennially thereafter, the Charter Or-  
11 ganization shall provide recommenda-  
12 tions to the HIT Standards Com-  
13 mittee for updating and improving  
14 such methods, in accordance with the  
15 policies developed by the HIT Policy  
16 Committee under section  
17 3002(b)(2)(A) with respect to such  
18 methods.

19 “(ii) INTERIM FINAL RULEMAKING.—

20 “(I) IN GENERAL.—Subject to  
21 subclause (III) and subsection  
22 (b)(2)(B) and notwithstanding section  
23 3004, any recommendations submitted  
24 by the Charter Organization under  
25 clause (i)(II) shall be adopted by the

1 Secretary through promulgation of an  
2 interim final rule not later than 90  
3 days after receipt by the Secretary of  
4 the organization's submission from  
5 the HIT Standards Committee.

6 “(II) PUBLIC COMMENT.—The  
7 Secretary shall accept and consider  
8 public comments on any interim final  
9 rule published under this clause for  
10 60 days after the date of such publi-  
11 cation.

12 “(III) AUTHORITY NOT TO  
13 ADOPT.—The Secretary, after the pe-  
14 riod of public comment described in  
15 subclause (II), may determine not to  
16 adopt a recommendation to amend an  
17 adopted method. Not later than 90  
18 days after the date of such determina-  
19 tion, the Secretary shall publish in the  
20 Federal Register the reason for such  
21 determination not to adopt such rec-  
22 ommendation.

23 “(IV) EFFECTIVE DATE.—The  
24 effective date of any amendment to  
25 existing methods that is adopted



1 through an interim final rule pub-  
2 lished under this paragraph shall be  
3 12 months following the close of the  
4 public comment period described in  
5 subclause (II).

6 “(3) MEMBERSHIP.—The Charter Organization  
7 shall consist of one representative from each of the  
8 health care standards development organizations ac-  
9 credited by the American National Standards Insti-  
10 tute.

11 “(4) AUTHORIZATION OF APPROPRIATIONS.—  
12 There is authorized to be appropriated \$10,000,000  
13 for a contract with the Charter Organization entered  
14 into under paragraph (1), to remain available until  
15 expended.

16 “(d) HARMONIZATION.—In carrying out this section,  
17 the Secretary shall recognize methods, with respect to  
18 interoperability of **【qualified electronic health records】**/  
19 **【health information technology】**, from an entity or enti-  
20 ties for the purpose of harmonizing or updating methods  
21 in order to achieve uniform and consistent implementation  
22 of the methods.

23 “(e) PILOT TESTING OF METHODS.—In the develop-  
24 ment, harmonization, or recognition of methods under this  
25 section, the Secretary shall, as appropriate, provide for the

1 testing of such methods by the National Institute for  
2 Standards and Technology under section 13201(a) of the  
3 Health Information Technology for Economic and Clinical  
4 Health Act.

5 “(f) CONSISTENCY.—The methods recommended  
6 under this section shall be consistent with the standards  
7 for information transactions and data elements adopted  
8 pursuant to section 1173 of the Social Security Act.”.

9 (b) MODIFICATIONS TO HIT POLICY COMMITTEE TO  
10 INCORPORATE POLICIES FOR UPDATES TO INTEROPER-  
11 ABILITY METHODS.—Section 3002(b)(2) of the Public  
12 Health Service Act (42 U.S.C. 300jj–12(b)(2)) is amend-  
13 ed—

14 (1) in subparagraph (A), in the first sentence—

15 (A) by striking “The HIT Policy Com-  
16 mittee” and inserting “Subject to subparagraph  
17 (D), the HIT Policy Committee”;

18 (B) by inserting “(and the areas in which  
19 modifications and additions to methods to  
20 measure if **qualified electronic health records**)/  
21 **health information** satisfy the criteria de-  
22 scribed in subsection (a) of section 3010 are  
23 needed for the electronic exchange and use of  
24 health information for purposes of adoption of  
25 such modifications and additions under sub-

1 section (c)(2)(B) of such section)” after “sec-  
2 tion 3004”; and

3 (C) by striking “such standards, specifica-  
4 tions, and certification criteria” and inserting  
5 “such standards, specifications, certification cri-  
6 teria, and methods”; and

7 (2) by adding at the end the following new sub-  
8 paragraph:

9 “(D) SPECIAL RULE RELATED TO INTER-  
10 OPERABILITY.—Any recommendation made by  
11 the HIT Policy Committee on or after the date  
12 of the enactment of this subparagraph with re-  
13 spect to interoperability of **qualified electronic**  
14 **health records**/**health information tech-**  
15 **nology** shall be consistent with the criteria de-  
16 scribed in subsection (a) of section 3010.”.

17 (c) MODIFICATIONS TO HIT STANDARDS COM-  
18 MITTEE TO INCORPORATE INTEROPERABILITY REC-  
19 OMMENDATIONS.—Section 3003 of the Public Health  
20 Service Act (42 U.S.C. 300jj–13) is amended—

21 (1) in subsection (a), by inserting before the pe-  
22 riod at the end the following: “and, in accordance  
23 with subsection (b)(1)(E), to submit to the Secretary  
24 methods in which to measure if **qualified electronic**  
25 **health records**/**health information technology** sat-

1 isfy the criteria described in subsection (a) of section  
2 3010 (and modifications to such methods) that are  
3 recommended to the HIT Standards Committee  
4 under subsection (c) of such section for adoption  
5 under section 3004(c)”; and

6 (2) in subsection (b)(1), by adding at the end  
7 the following new subparagraph:

8 “(E) METHODS TO MEASURE INTEROPER-  
9 ABILITY.—The HIT Standards Committee shall  
10 submit to the Secretary, in accordance with sec-  
11 tion 3010, recommendations submitted by the  
12 Charter Organization under subsection (c) of  
13 such section (along with comments by the HIT  
14 Standards Committee with respect to such rec-  
15 ommendations) for methods in which to meas-  
16 ure if **【qualified electronic health records】**/  
17 **【health information technology】** satisfy the cri-  
18 teria described in subsection (a) of such section  
19 (and for modifications to such methods) for  
20 adoption by the Secretary under section  
21 3004(c). To the extent that any such rec-  
22 ommendation submitted to the Secretary for  
23 such adoption is inconsistent with or duplicative  
24 of a recommendation under subparagraph (A),  
25 the recommendation under this subparagraph

1           shall supercede the recommendation under sub-  
2           paragraph (A).”.

3           (d) ADOPTION.—Section 3004 of the Public Health  
4 Service Act (42 U.S.C. 300jj–14) is amended—

5           (1) in subsection (b), by adding at the end the  
6           following new paragraph:

7           “(4) LIMITATION.—The Secretary may not  
8           adopt any standards, implementation specifications,  
9           or certification criteria under this subsection or sub-  
10          section (a) that are inconsistent with or duplicative  
11          of a method adopted under subsection (c) or section  
12          3010. In the case of a standard, specification, or cri-  
13          terion that has been adopted under this section and  
14          is inconsistent or duplicative of a method that is  
15          subsequently adopted under subsection (c) or section  
16          3010, such method shall supercede such standard,  
17          specification, or criterion and such standard, speci-  
18          fication, or criterion shall no longer be considered  
19          adopted under this section beginning on the date  
20          that such method becomes effective.”; and

21          (2) by adding at the end the following new sub-  
22          section:

23          “(c) ADOPTION OF METHODS TO MEASURE INTER-  
24          OPERABILITY.—

1           “(1) REVIEW OF METHODS.—Not later than 90  
2       days after the date of receipt of recommendations  
3       for methods, the Secretary, in consultation with the  
4       National Coordinator and representatives of other  
5       relevant Federal agencies, shall jointly review such  
6       methods and shall determine whether or not to pro-  
7       pose adoption of such methods.

8           “(2) DETERMINATION TO ADOPT.—If the Sec-  
9       retary determines—

10           “(A) to propose adoption of such methods,  
11       the Secretary shall, by regulation under section  
12       553 of title 5, United States Code, determine  
13       whether or not to adopt such methods; or

14           “(B) not to propose adoption of such  
15       methods, the Secretary shall notify the National  
16       Coordinator and the HIT Standards Committee  
17       and Charter Organization under section  
18       3010(c) in writing of such determination and  
19       the reasons for not proposing the adoption of  
20       the recommendation for such methods.

21           “(3) PUBLICATION.—The Secretary shall pro-  
22       vide for publication in the Federal Register of all de-  
23       terminations made by the Secretary under para-  
24       graph (1).

1           “(4) APPLICATION.—Any method adopted  
2           under this subsection shall be effective 12 months  
3           after the date of publication of the determination to  
4           adopt such method.”.

5           (e) REPORTS AND NOTIFICATIONS.—Section 3010 of  
6           the Public Health Service Act, as added by subsection (a),  
7           is amended by adding at the end the following new sub-  
8           section:

9           “(g) DISSEMINATION OF INFORMATION.—

10           “(1) INITIAL SUMMARY REPORT.—Not later  
11           than July 1, 2016, the Secretary, after consultation  
12           with relevant stakeholders, shall submit to Congress  
13           and provide for publication in the Federal Register  
14           and the posting on the Internet website of the Office  
15           of the National Coordinator for Health Information  
16           Technology of a report on the following:

17           “(A) The initial set of methods adopted  
18           under this section and section 3004(c).

19           “(B) The strategies for achieving wide-  
20           spread interoperability.

21           “(C) An overview of the extent to which  
22           **【qualified electronic health records】/【health in-**  
23           **formation technology】** offered as of such date  
24           satisfy such initial set.

1           “(D) Any barriers that are preventing  
2           widespread interoperability.

3           “(E) The plan and milestones, including  
4           specific steps, to achieve widespread interoper-  
5           ability.

6           “(2) FOLLOW-UP DETERMINATION AND REPORT  
7           ON WIDESPREAD INTEROPERABILITY.—Not later  
8           than **【December 31, 2017】**, the Secretary shall pro-  
9           vide for publication in the Federal Register and the  
10          posting on the Internet website of the Office of the  
11          National Coordinator for Health Information Tech-  
12          nology of the following:

13           “(A) A determination by the Secretary  
14           whether the goal of widespread interoperability  
15           has been achieved.

16           “(B) A list identifying the vendors of, or  
17           other entities offering, **【qualified electronic**  
18           **health records】/【health information tech-**  
19           **nology】**, which categorizes such entities, with  
20           respect to such records, as in compliance or not  
21           in compliance with the certification criteria de-  
22           scribed in section 3001(c)(5)(B)(ii) and with  
23           the requirements under clause (i) of section  
24           3001(c)(5)(C) (including with the terms of the



1           attestation and other requirements under such  
2           clause).

3           “(C) Actions that may be taken by entities  
4           identified under subparagraph (B) as not being  
5           in compliance with such criteria and require-  
6           ments in order for such entities to become in  
7           compliance with such criteria and requirements.

8           “(D) Penalties described in section  
9           3010A(b) to which entities, with respect to such  
10          **【qualified electronic health records】/【health in-**  
11          **formation technology】**, beginning January 1,  
12          2019, are subject if such technology and enti-  
13          ties are not in compliance with the certification  
14          criteria described in section 3001(c)(5)(B)(ii)  
15          and with the requirements under clause (i) of  
16          section 3001(c)(5)(C), respectively.

17          “(3) ONGOING PUBLICATION OF RECOMMENDA-  
18          TIONS.—The Secretary shall provide for publication  
19          in the Federal Register and the posting on the  
20          Internet website of the Office of the National Coor-  
21          dinator for Health Information Technology of all  
22          recommendations made under this section.”.

23          (f) CERTIFICATION AND OTHER ENFORCEMENT PRO-  
24          VISIONS.—

1           (1) CERTIFICATION OF **【QUALIFIED ELEC-**  
2           **TRONIC HEALTH RECORD】/【HEALTH INFORMATION】**  
3           TECHNOLOGY.—

4           (A) IN GENERAL.—Section 3007(b) of the  
5           Public Health Service Act (42 U.S.C. 300jj–  
6           17(b)) is amended by striking “under section  
7           3001(c)(3) to be in compliance with” and all  
8           that follows through the period at the end and  
9           inserting “under section 3001(c)(3)—

10          “(1) for certifications made before January 1,  
11          2018, to be in compliance with applicable standards  
12          adopted under subsections (a) and (b) of section  
13          3004; and

14          “(2) for certifications made on or after January  
15          1, 2018, to be in compliance with applicable stand-  
16          ards adopted under subsections (a) and (b) of sec-  
17          tion 3004 and to be interoperable in accordance with  
18          section 3010, including as measured by the methods  
19          adopted under such section and methods adopted  
20          under subsection (c) of section 3004.”.

21               (B) REQUIREMENTS OF SECRETARY.—Sec-  
22               tion 3001(c)(5) of the Public Health Service  
23               Act (42 U.S.C. 300jj–11(c)(5)) is amended—

24                       (i) by amending subparagraph (B) of  
25                       such section to read as follows:

1           “(B)    CERTIFICATION    CRITERIA    DE-  
2           SCRIBED.—In this title, the term ‘certification  
3           criteria’ means, with respect to **【qualified elec-**  
4           **tronic health records】**—

5                   “(i) for certifications made before  
6                   January 1, 2018, criteria to establish that  
7                   the technology meets standards and imple-  
8                   mentation specifications adopted under  
9                   subsections (a) and (b) of section 3004 for  
10                  **【qualified electronic health records】/**  
11                  **【health information technology】**; and

12                   “(ii) for certifications made on or  
13                   after January 1, 2018, criteria described  
14                   in clause (i) and criteria to establish that  
15                   the technology is interoperable, in accord-  
16                   ance with section 3010, including as meas-  
17                   ured by the methods adopted under such  
18                   section and the methods adopted under  
19                   subsection (c) of section 3004.”; and

20                   (ii) by adding at the end the following  
21                   new subparagraph:

22                   “(C)                               ENFORCEMENT;  
23           DECERTIFICATIONS.—

24                   “(i)    REQUIREMENTS.—Under    any  
25                   program kept or recognized under subpara-

1 graph (A), the Secretary shall ensure that  
2 any vendor of or other entity offering  
3 **【qualified electronic health records】**/  
4 **【health information technology】** seeking a  
5 certification of such records under such  
6 program on or after January 1, 2018,  
7 shall, as a condition of certification (and  
8 maintenance of certification) of such  
9 records under such program—

10 “(I) provide to the Secretary an  
11 attestation—

12 “(aa) that the entity, unless  
13 for a legitimate purpose specified  
14 by the Secretary, has not taken  
15 any action, including through any  
16 financial, administrative, or tech-  
17 nological barrier, which the entity  
18 **【knows or should know (as de-  
19 fined in section 1128A(i)(7) of  
20 the Social Security Act)】**, is to  
21 limit or restrict the exchange of  
22 information or to prevent or  
23 disincentivize widespread inter-  
24 operability between any providers  
25 using such records or other

1           [qualified     electronic     health  
2           records]/[health     information  
3           technology] in connection with  
4           such records;

5                   “(bb) on the pricing infor-  
6                   mation on data transmission and  
7                   other services affiliated with the  
8                   use of [qualified electronic health  
9                   records]/[health     information  
10                  technology];

11                   “(cc) that the software with  
12                   respect to such records have pub-  
13                   lished application programming  
14                   interfaces for medical records  
15                   data, search and indexing, se-  
16                   mantic harmonization and vocab-  
17                   ulary translation, and user inter-  
18                   face applications; and

19                   “(dd) that the entity has in  
20                   place data sharing programs or  
21                   capabilities based on common  
22                   data elements through applica-  
23                   tion programming interfaces  
24                   without the requirement for spe-

1                   cial middleware or vendor-specific  
2                   interfaces;

3                   “(II) publish application pro-  
4                   gramming interfaces and associated  
5                   documentation, with respect to such  
6                   records, for medical records data,  
7                   search and indexing, semantic harmo-  
8                   nization and vocabulary translation,  
9                   and user interface applications; and

10                  “(III) demonstrate to the satis-  
11                  faction of the Secretary that data  
12                  from such records is able to be ex-  
13                  changed through the use of applica-  
14                  tion programming interfaces and used  
15                  in a manner that allows for exchange  
16                  and everyday use of such **【records】/**  
17                  **【technology】** by **【authorized users】**.

18                  “(ii) DECERTIFICATION.—Under any  
19                  program kept or recognized under subpara-  
20                  graph (A), the Secretary shall ensure that  
21                  beginning January 1, 2019, any **【qualified**  
22                  **electronic health record】/【health informa-**  
23                  **tion technology】** that does not satisfy the  
24                  certification criteria described in section  
25                  3001(c)(5)(B)(ii) or with respect to which

1 the vendor or other entity described in  
2 clause (i) does not satisfy the requirements  
3 under such clause (or is determined to be  
4 in violation of the terms of the attestation  
5 or other requirements under such clause)  
6 shall no longer be considered as certified  
7 under such program.

8 “(iii) ANNUAL PUBLICATION.—For  
9 2019 and each subsequent year, the Sec-  
10 retary shall post on the public Internet  
11 website of the Department of Health and  
12 Human Services a list of any vendors of or  
13 other entities offering [qualified electronic  
14 health records]/[health information tech-  
15 nology] with respect to which certification  
16 has been withdrawn under clause (ii) dur-  
17 ing such year.

18 “(iv) PERIODIC REVIEW.—The Sec-  
19 retary shall periodically review and confirm  
20 that vendors of and other entities offering  
21 [qualified electronic health records]/  
22 [health information technology] have pub-  
23 licly published application programming  
24 interfaces and associated documentation as  
25 required by clause (i)(II) for purposes of

1 certification and maintaining certification  
2 under any program kept or recognized  
3 under subparagraph (A).”.

4 (2) ADDITIONAL ENFORCEMENT PROVISIONS  
5 UNDER THE PUBLIC HEALTH SERVICE ACT.—Sub-  
6 title A of title XXX of the Public Health Service Act  
7 (42 U.S.C. 300jj–11 et seq.), as amended by sub-  
8 section (a)(1), is further amended by adding at the  
9 end the following new section:

10 **“SEC. 3010A. ENFORCEMENT MECHANISMS.**

11 “(a) INSPECTOR GENERAL AUTHORITY.—The In-  
12 spector General of the Department of Health and Human  
13 Services shall have the authority to investigate claims of—

14 “(1) vendors of, or other entities offering,  
15 **【qualified electronic health records】**—

16 “(A) being in violation of an attestation  
17 made under section 3001(c)(5)(C)(i)(I), with  
18 respect to the use of such **【records】** by a health  
19 care provider under a specified Medicare incen-  
20 tive program; and

21 “(B) having engaged in information block-  
22 ing (as defined in subsection (f)), unless for a  
23 legitimate purpose specified by the Secretary,  
24 with respect to the use of such **【records】** by a  
25 health care provider under such a program;



1           “(2) health care providers, with respect to the  
2           use of such **【records】** under a specified Medicare in-  
3           centive program, having, unless for a legitimate pur-  
4           pose specified by the Secretary, engaged in informa-  
5           tion blocking (as so defined); and

6           “(3) health information system providers de-  
7           scribed in subsection (b) having engaged in informa-  
8           tion blocking (as so defined), unless for a legitimate  
9           purpose specified by the Secretary, with respect to  
10          the use of such **【records】** under a specified Medi-  
11          care incentive program.

12          “(b) HEALTH INFORMATION SYSTEM PROVIDERS.—  
13          The Inspector General of the Department of Health and  
14          Human Services shall, in coordination with the Federal  
15          Trade Commission, ensure that health information system  
16          providers (such as operators of health information ex-  
17          changes and other systems that facilitate the exchange of  
18          information between **【qualified electronic health records】**)  
19          investigate claims of information blocking, with respect to  
20          the use of such records under a specified Medicare incen-  
21          tive program.

22          “(c) INFORMATION SHARING PROVISIONS.—

23                 “(1) IN GENERAL.—The National Coordinator  
24                 may serve as a technical consultant to the Inspector  
25                 General of the Department of Health and Human

1 Services and the Federal Trade Commission for pur-  
2 poses of carrying out this section. As such technical  
3 consultant, the National Coordinator may, notwith-  
4 standing any other provision of law, share informa-  
5 tion related to claims or investigations under sub-  
6 section (a) or (b) with the Inspector General and  
7 Federal Trade Commission for purposes of such in-  
8 vestigations.

9 “(2) PROTECTION FROM DISCLOSURE OF IN-  
10 FORMATION.—Any information shared by the Na-  
11 tional Coordinator under paragraph (1) shall not be  
12 subject to the provisions of section 552 of title 5,  
13 United States Code (commonly referred to as the  
14 Freedom of Information Act). Any information ac-  
15 quired pursuant to paragraph (1) shall be held in  
16 confidence and shall not be disclosed to any person  
17 except as may be necessary to carry out the pur-  
18 poses of subsection (a).

19 “(3) NONAPPLICATION OF PAPERWORK REDUC-  
20 TION ACT.—Chapter 35 of title 44, United States  
21 Code (commonly referred to as the Paperwork Re-  
22 duction Act of 1995) shall not apply to the National  
23 Coordinator or to the Office of the National Coordi-  
24 nator for Health Information Technology with re-

1       spect to the collection of complaints relating to  
2       claims described in subsection (a).

3       “(d) PENALTY.—Any person or entity determined to  
4       have committed an act described in subsection (a), in con-  
5       nection with a specified Medicare incentive program, shall  
6       be subject to the provisions of sections 1128, 1128A, and  
7       1128B in the same manner as a person or entity deter-  
8       mined to have committed an act described in such respec-  
9       tive section. The provisions of section 1128A (other than  
10      subsections (a) and (b)) shall apply to a civil money pen-  
11      alty applied under this subsection in the same manner as  
12      they apply to a civil money penalty or proceeding under  
13      section 1128A(a).

14      “(e) SPECIFIED MEDICARE INCENTIVE PROGRAM.—  
15      For purposes of this section, the term ‘specified Medicare  
16      incentive program’ includes the following:

17           “(1) The incentive payments under subsection  
18           (o) of section 1848 of the Social Security Act (42  
19           U.S.C. 1395w–4) and adjustments under subsection  
20           (a)(7) of such section.

21           “(2) The incentive payments under subsection  
22           (n) of section 1848 of such Act (42 U.S.C. 1395ww)  
23           and adjustments under subsection (b)(3)(B) of such  
24           section.

1           “(3) The incentive payments and adjustments  
2           made under subsections (l) and (m) of section 1853  
3           of such Act (42 U.S.C. 1395w–23).

4           “(4) The incentive payment under paragraph  
5           (3) of section 1814(l) of such Act (42 U.S.C.  
6           1395f(l)) and adjustment under paragraph (4) of  
7           such section.

8           “(5) The shared savings program under section  
9           1899 of the Social Security Act (42 U.S.C. 1395jjj).  
10          “(f) INFORMATION BLOCKING.—

11           “(1) IN GENERAL.—For purposes of this sec-  
12           tion and section 3010, the term ‘information block-  
13           ing’ means, with respect to the use of [qualified  
14           electronic health records] under a specified Medicare  
15           incentive program, business, technical, and organiza-  
16           tional practices, including practices described in  
17           paragraph (2), that—

18           “(A) interfere with the exchange of elec-  
19           tronic health information;

20           “(B) the actor [knows or should know (as  
21           defined in section 1128A(i)(7) of the Social Se-  
22           curity Act)] is likely to interfere with the ex-  
23           change or use of electronic health information;  
24           and

1           “(C) do not serve to protect patient safety,  
2           maintain the privacy and security of individ-  
3           uals’ health information or promote competition  
4           and consumer welfare.

5           “(2) PRACTICES DESCRIBED.—For purposes of  
6           paragraph (1), the practices described in this para-  
7           graph are the following:

8           “(A) Contract terms, policies, or other  
9           business or organizational practices that restrict  
10          individuals’ access to their electronic health in-  
11          formation or restrict the exchange or use of  
12          that information for treatment and other per-  
13          mitted purposes.

14          “(B) Charging prices or fees (such as for  
15          data exchange, portability, and interfaces) that  
16          make exchanging and using electronic health in-  
17          formation cost prohibitive.

18          “(C) Developing or implementing health  
19          information technology in nonstandard ways  
20          that are likely to substantially increase the  
21          costs, complexity, or burden of sharing elec-  
22          tronic health information, especially in cases in  
23          which relevant interoperability standards or  
24          methods to measure interoperability have been  
25          adopted by the Secretary.

1           “(D) Developing or implementing health  
2           information technology in ways that are likely  
3           to lock in users or electronic health information,  
4           such as not allowing for the full export of data;  
5           lead to fraud, waste, or abuse; or impede inno-  
6           vations and advancements in health information  
7           exchange and health information technology-en-  
8           abled care delivery.

9           “(g) TREATMENT OF VENDORS WITH RESPECT TO  
10          PATIENT SAFETY ORGANIZATIONS.—In applying part C  
11          of title IX—

12           “(1) vendors shall be treated as a provider (as  
13           defined in section 921) for purposes of reporting re-  
14           quirements under such part, to the extent that such  
15           reports are related to attestation requirements under  
16           section 3001(c)(5)(C)(i)(I);

17           “(2) claims of information blocking described in  
18           subsection (a) shall be treated as a patient safety ac-  
19           tivity under such part for purposes of reporting re-  
20           quirements under such part; and

21           “(3) health care providers that are not mem-  
22           bers of patient safety organizations shall be treated  
23           in the same manner as health care providers that  
24           are such members for purposes of such reporting re-

1        requirements with respect to claims of information  
2        blocking described in subsection (a).”.

3            (3) DEMONSTRATION REQUIRED FOR MEANING-  
4        FUL EHR USE INCENTIVES UNDER MEDICARE.—

5            (A) INCENTIVES FOR PROFESSIONALS.—

6                    (i)        IN        GENERAL.—Section  
7        1848(o)(2)(C) of the Social Security Act  
8        (42 U.S.C. 1395w–4(o)(2)(C)) is amended  
9        by adding at the end the following new  
10       clause:

11                   “(iii) INTEROPERABILITY.—With re-  
12       spect to EHR reporting periods for pay-  
13       ment years beginning with 2018, the  
14       means described in clause (i) specified by  
15       the Secretary shall include a demonstra-  
16       tion, through means such as an attesta-  
17       tion, that the professional has not taken  
18       any action described in subsection (a)(2) of  
19       section 3010A of the Public Health Service  
20       Act with respect to which the professional  
21       **【**knows or should know (as defined in sec-  
22       tion 1128A(i)(7)) about**】**, with respect to  
23       the use of any certified EHR technology.”.

24                   (ii) HARDSHIP EXEMPTION IN CASE  
25       OF DECERTIFIED EHR.—Subparagraph (B)

1 of section 1848(a)(7) of the Social Security  
2 Act (42 U.S.C. 1395w-4(a)(7)(B)) is  
3 amended to read as follows:

4 “(B) SIGNIFICANT HARDSHIP EXCEP-  
5 TION.—

6 “(i) IN GENERAL.—The Secretary  
7 may, on a case-by-case basis, exempt an el-  
8 igible professional from the application of  
9 the payment adjustment under subpara-  
10 graph (A) if the Secretary determines, sub-  
11 ject to annual renewal, that compliance  
12 with the requirement for being a meaning-  
13 ful EHR user would result in a significant  
14 hardship, such as in the case of an eligible  
15 professional who practices in a rural area  
16 without sufficient Internet access.

17 “(ii) DECERTIFICATION.—

18 “(I) IN GENERAL.—The Sec-  
19 retary may, on a case-by-case basis,  
20 exempt an eligible professional from  
21 the application of the payment adjust-  
22 ment under subparagraph (A) if the  
23 Secretary determines that such pro-  
24 fessional was determined to not be a  
25 meaningful EHR user because the



1           **【qualified electronic health record】/**  
2           **【health information technology】** used  
3           by such professional was decertified  
4           under section 3001(c)(5)(C) of the  
5           Public Health Service Act. An exemp-  
6           tion under the previous sentence may  
7           be applied to an eligible professional  
8           only during the first year with respect  
9           to which such decertification applies.

10                   “(II) DURATION.—In no case  
11                   shall an exemption by reason of this  
12                   clause be for a period of less than 12  
13                   months.

14                   “(iii) LIMITATION.—Subject to clause  
15                   (ii)(II), in no case may an eligible profes-  
16                   sional be granted an exemption under this  
17                   subparagraph for more than 5 years.”.

18           (B) INCENTIVES FOR HOSPITALS.—

19                   (i) IN GENERAL.—Section 1886(o)(1)  
20                   of the Social Security Act (42 U.S.C.  
21                   1395ww(o)(1)) is amended—

22                   (I) in subparagraph (A), by in-  
23                   serting before the period at the end  
24                   the following: “and, for performance  
25                   periods for fiscal year 2018 or a sub-

1                   sequent fiscal year, that provide a  
2                   demonstration described in subpara-  
3                   graph (D) to the Secretary”; and

4                   (II) by adding at the end the fol-  
5                   lowing new subparagraph:

6                   “(D) DEMONSTRATION DESCRIBED.—The  
7                   demonstration described in this subparagraph is  
8                   a demonstration, through means such as an at-  
9                   testation, that the hospital has not taken any  
10                  action described in subsection (a)(2) of section  
11                  3010A of the Public Health Service Act with  
12                  respect to which the hospital **【**knows or should  
13                  know (as defined in section 1128A(i)(7) of the  
14                  Social Security Act) about**】**, with respect to the  
15                  use of any **【**certified EHR technology**】**.”.

16                  (ii) HARDSHIP EXEMPTION IN CASE  
17                  OF DECERTIFIED EHR.—Subclause (II) of  
18                  section 1886(b)(3)(B)(ix) of the Social Se-  
19                  curity            Act            (42            U.S.C.  
20                  1395ww(b)(3)(B)(ix)) is amended to read  
21                  as follows:

22                  “(II)(aa) The Secretary may, on  
23                  a case-by-case basis, exempt a sub-  
24                  section (d) hospital from the applica-  
25                  tion of subclause (I) with respect to a

1           fiscal year if the Secretary deter-  
2           mines, subject to annual renewal, that  
3           requiring such hospital to be a mean-  
4           ingful EHR user during such fiscal  
5           year would result in a significant  
6           hardship, such as in the case of a hos-  
7           pital in a rural area without sufficient  
8           Internet access.

9           “(bb) The Secretary may, on a  
10          case-by-case basis, exempt a sub-  
11          section (d) hospital from the applica-  
12          tion of subclause (I) with respect to a  
13          fiscal year if the Secretary deter-  
14          mines, subject to annual renewal, that  
15          such hospital was determined to not  
16          be a meaningful EHR user because  
17          the [qualified electronic health  
18          record]/[health information tech-  
19          nology] used by such hospital was de-  
20          certified under section 3001(c)(5)(C)  
21          of the Public Health Service Act. An  
22          exemption under the previous sentence  
23          may be applied to a subsection (d)  
24          hospital only during the first fiscal

1 year with respect to which such decer-  
2 tification applies.

3 “(cc) In no case shall an exemp-  
4 tion by reason of item (bb) be for a  
5 period of less than 12 months.

6 “(dd) Subject to item (cc), in no  
7 case may a hospital be granted an ex-  
8 emption under this subclause for more  
9 than 5 years.”.

10 (C) DEMONSTRATION REQUIRED FOR  
11 MEANINGFUL EHR USE INCENTIVES UNDER  
12 MEDICAID.—Section 1903(t)(2) of the Social  
13 Security Act (42 U.S.C. 1396b(t)(2)) is amend-  
14 ed by adding at the end the following: “An eli-  
15 gible professional shall not qualify as a Med-  
16 icaid provider under this subsection, with re-  
17 spect to a year beginning with 2018, unless  
18 such provider demonstrates to the Secretary,  
19 through means such as an attestation, that the  
20 provider has not taken any action described in  
21 subsection (a)(2) of section 3010A of the Public  
22 Health Service Act with respect to which the  
23 provider **■**knows or should know (as defined in  
24 section 1128A(i)(7) of the Social Security Act)

1           about**】**, with respect to the use of any certified  
2           EHR technology.”.

3       (g) DEFINITIONS.—

4           (1) CERTIFIED EHR TECHNOLOGY.—Paragraph  
5       (1) of section 3000 of the Public Health Service Act  
6       (42 U.S.C. 300jj) is amended to read as follows:

7           “(1) CERTIFIED EHR TECHNOLOGY.—The term  
8       ‘certified EHR technology’ means a **【**qualified elec-  
9       tronic health record**】** that is certified pursuant to  
10      section 3001(c)(5) as meeting the certification cri-  
11      teria defined in subparagraph (B) of such section  
12      that are applicable to the type of record involved (as  
13      determined by the Secretary, such as an ambulatory  
14      electronic health record for office-based physicians  
15      or an inpatient hospital electronic health record for  
16      hospitals) and, beginning January 1, 2018, with re-  
17      spect to which the vendor or other entity offering  
18      such technology is in compliance with the require-  
19      ments under section 3001(c)(5)(C)(i).”.

20          (2) WIDESPREAD INTEROPERABILITY.—Section  
21      3000 of the Public Health Service Act (42 U.S.C.  
22      300jj) is amended by adding at the end the following  
23      new paragraph:

1           “(15) WIDESPREAD INTEROPERABILITY.—The  
2           term ‘widespread interoperability’ means that, on a  
3           nationwide basis—

4                   “(A) **【qualified electronic health records】**/  
5                   **【health information technology】** are interoper-  
6                   able, in accordance with section 3010, including  
7                   as measured by the methods adopted under  
8                   such section; and

9                   “(B) such records are employed by mean-  
10                  ingful EHR users under the specified Medicare  
11                  incentive programs (as defined in section  
12                  3010A(e)) and other clinicians and health care  
13                  providers.”.

14          (h) CONFORMING AMENDMENTS.—

15                  (1) VOLUNTARY USE OF STANDARDS.—Section  
16                  3006 of the Public Health Service Act (42 U.S.C.  
17                  300jj–16) is amended—

18                          (A) in subsection (a)—

19                                  (i) in paragraph (1), by inserting “or  
20                                  a method adopted under section 3010 or  
21                                  3004(c)” after “section 3004”; and

22                                  (ii) in paragraph (2), by striking “or  
23                                  implementation specification” and insert-  
24                                  ing “implementation specification, or meth-  
25                                  od”; and

1 (B) in subsection (b), by inserting “or the  
2 methods adopted under section 3010 and  
3 3004(c)” after “section 3004”.

4 (2) HIPAA PRIVACY AND SECURITY LAW DEFINITION CORRECTION.—Section 3009(a)(2)(A) of the  
5 Public Health Service Act (42 U.S.C. 300jj–  
6 19(a)(2)(A)) is amended by striking “title IV” and  
7 inserting “title XIII”.  
8

9 (3) COORDINATION OF FEDERAL ACTIVITIES.—  
10 Section 13111 of the HITECH Act is amended—

11 (A) in subsection (a), by inserting before  
12 the period at the end the following: “(and, be-  
13 ginning on January 1, 2018, that are also  
14 interoperable under section 3010 of such Act,  
15 including as measured by the methods adopted  
16 under such section and section 3004(c) of such  
17 Act)”;

18 (B) in subsection (b)—

19 (i) by inserting “(and, beginning on  
20 January 1, 2018, a method adopted under  
21 section 3010 of such Act or section  
22 3004(c) of such Act)” before “the Presi-  
23 dent”;

24 (ii) by inserting “(or method)” before  
25 “, respectively”.

1           (4) APPLICATION TO PRIVATE ENTITIES.—Sec-  
2           tion 13112 of the HITECH Act is amended by in-  
3           serting before the period at the end the following  
4           “(and, beginning on January 1, 2018, that are also  
5           interoperable under section 3010 of such Act, in-  
6           cluding as measured by the methods adopted under  
7           such section and under section 3004(c) of such  
8           Act)”.

9           (5) NIST TESTING.—Section 13201(a) of the  
10          HITECH Act is amended—

11                 (A) by inserting “and methods under sec-  
12                 tion 3010 of such Act” after “under such sec-  
13                 tion”; and

14                 (B) by striking each place it appears “such  
15                 standards and implementation specifications”  
16                 and inserting “such standards, implementation  
17                 specifications, and methods”.

18          (6) COORDINATION WITH RECOMMENDATIONS  
19          FOR ACHIEVING WIDESPREAD EHR INTEROPER-  
20          ABILITY.—Section 106(b)(1) of the Medicare Access  
21          and CHIP Reauthorization Act of 2015 (Public Law  
22          114–10) is amended by adding at the end the fol-  
23          lowing new subparagraph:

24                 “(E) COORDINATION.—Any recommenda-  
25                 tion submitted under subparagraph (D) shall be



1           consistent with the criteria specified under sub-  
2           section (a) of section 3010 of the Public Health  
3           Service Act.”.

4           (i) PATIENT EMPOWERMENT.—It is the sense of Con-  
5   gress that—

6           (1) patients have the right to the entirety of the  
7           health information of such patient, including such  
8           information contained in an electronic health record  
9           of such patient;

10          (2) such right extends to both structured and  
11          unstructured data; and

12          (3) to further facilitate patient ownership over  
13          health information of such patient—

14                (A) health care providers should not have  
15                the ability to deny a patient’s request for access  
16                to the entirety of such health information of  
17                such patient; and

18                (B) health care providers do not need the  
19                consent of their patients to share personal  
20                health information of such patients with other  
21                covered entities, in compliance with the HIPAA  
22                privacy regulations promulgated pursuant to  
23                section 264(c) of the Health Insurance Port-  
24                ability and Accountability Act of 1996 for the  
25                purposes of supporting patient care, except in

1 situations where consent is specifically required  
2 under such regulations, such as in cases related  
3 to the psychiatric records of the patient.

## 4 **Subtitle B—Telehealth**

### 5 **SEC. 3021. TELEHEALTH SERVICES UNDER THE MEDICARE** 6 **PROGRAM.**

7 (a) PROVISION OF INFORMATION BY CENTERS FOR  
8 MEDICARE & MEDICAID SERVICES.—Not later than one  
9 year after the date of the enactment of this Act, the Ad-  
10 ministrator of the Centers for Medicare & Medicaid Serv-  
11 ices shall provide to the committees of jurisdiction of the  
12 House of Representatives and the Senate information on  
13 the following:

14 (1) The populations of Medicare beneficiaries,  
15 such as those who are dually eligible for the Medi-  
16 care program under title XVIII of the Social Secu-  
17 rity Act and the Medicaid program under title XIX  
18 of such Act and those with chronic conditions, whose  
19 care may be improved most in terms of quality and  
20 efficiency by the expansion, in a manner that meets  
21 or exceeds the existing in-person standard of care  
22 under the Medicare program under title XVIII of  
23 such Act, of telehealth services under section  
24 1834(m)(4) of such Act (42 U.S.C. 1395m(m)(4)).

1           (2) Activities by the Center for Medicare and  
2       Medicaid Innovation which examine the use of tele-  
3       health services in models, projects, or initiatives  
4       funded through section 1115A of the Social Security  
5       Act (42 U.S.C. 1315a).

6           (3) The types of high volume procedures codes  
7       or diagnoses under such title XVIII which might be  
8       suitable to the furnishing of services via telehealth.

9           (4) Barriers that might prevent the expansion  
10      of telehealth services under section 1834(m)(4) of  
11      the Social Security Act (42 U.S.C. 1395m(m)(4))  
12      beyond such services that are in effect as of the date  
13      of the enactment of this Act.

14      (b) PROVISION OF INFORMATION BY MEDPAC.—Not  
15      later than one year after the date of the enactment of this  
16      Act, the Medicare Payment Advisory Commission estab-  
17      lished under section 1805 of the Social Security Act (42  
18      U.S.C. 1395b–6) shall, using data from the Medicare Ad-  
19      vantage program under part C of title XVIII of such Act,  
20      provide information to the committees of jurisdiction of  
21      the House of Representatives and the Senate that identi-  
22      fies—

23           (1) services—

24           (A) for which payment could not be made,  
25           as of the date of the enactment of this Act,

1 under the fee-for-service program under parts A  
2 and B of such title by reason of any limitation  
3 imposed under section 1834(m) of such Act (42  
4 U.S.C. 1395m(m)); and

5 (B) that are services that are rec-  
6 ommended by the Commission to be included as  
7 telehealth services for which payment may be  
8 made under the fee-for-service program under  
9 parts A and B of such title; and  
10 (2) barriers to furnishing telehealth services for  
11 which payment may be made under such title XVIII  
12 and solutions to address such barriers.

13 (c) SENSE OF CONGRESS.—It is the sense of Con-  
14 gress that—

15 (1) States should collaborate, through the use  
16 of State medical board compacts or other mecha-  
17 nisms, to create common licensure requirements for  
18 providing telehealth services in order to facilitate  
19 multistate practices and allow for health care pro-  
20 viders to provide such services across State lines;

21 (2) eligible originating sites should be expanded  
22 beyond those originating sites described in section  
23 1834(m)(4)(C) of the Social Security Act (42 U.S.C.  
24 1395m(m)(4)(C)); and

1           (3) any expansion of telehealth services under  
2           the Medicare program should—

3                   (A) recognize that telemedicine is the deliv-  
4                   ery of safe, effective, quality health care serv-  
5                   ices, by a health care provider, using technology  
6                   as the mode of care delivery;

7                   (B) meet or exceed the conditions of cov-  
8                   erage and payment with respect to the Medicare  
9                   program under title XVIII unless specifically  
10                  address in subsequent statute, of such Act if  
11                  the service were furnished in person, including  
12                  standards of care; and

13                  (C) involve clinically appropriate means to  
14                  furnish such services.

15 **Subtitle     C—Encouraging     Con-**  
16 **tinuing Medical Education for**  
17 **Physicians**

18 **SEC. 3041. EXEMPTING FROM MANUFACTURER TRANS-**  
19 **PARENCY REPORTING CERTAIN TRANSFERS**  
20 **USED FOR EDUCATIONAL PURPOSES.**

21           (a) IN GENERAL.—Section 1128G(e)(10)(B) of the  
22 Social Security Act (42 U.S.C. 1320a–7h(e)(10)(B)) is  
23 amended—

24                   (1) in clause (iii), by inserting “, including  
25                  peer-reviewed journals, journal reprints, journal sup-

1       plements, medical conference reports, and medical  
2       textbooks” after “patient use”; and

3           (2) by adding at the end the following new  
4       clause:

5                   “(xiii) In the case of a covered recipi-  
6                   ent who is a physician, an indirect pay-  
7                   ment or transfer of value to the covered re-  
8                   cipient—

9                           “(I) for speaking at, or preparing  
10                           educational materials for, an edu-  
11                           cational event for physicians or other  
12                           health care professionals that does not  
13                           commercially promote a covered drug,  
14                           device, biological, or medical supply;  
15                           or

16                           “(II) that serves the sole purpose  
17                           of providing the covered recipient with  
18                           medical education, such as by pro-  
19                           viding the covered recipient with the  
20                           tuition required to attend an edu-  
21                           cational event or with materials pro-  
22                           vided to physicians at an educational  
23                           event.”.

1 (b) EFFECTIVE DATE.—The amendments made by  
2 this section shall apply with respect to transfers of value  
3 made on or after the date of the enactment of this Act.

4 **Subtitle D—Disposable Medical**  
5 **Technologies**

6 **[SEC. 3061. TREATMENT OF CERTAIN ITEMS AND DEVICES.**

7 **[(a) PAYMENT FOR DURABLE MEDICAL ITEMS**  
8 **(DMI).—]**

9 **[(1) IN GENERAL.—**Section 1861(s)(2) of the  
10 Social Security Act (42 U.S.C. 1395x(s)(2)) is  
11 amended—**]**

12 **[(A) in subparagraph (EE), by striking**  
13 **“and” at the end;]**

14 **[(B) in subparagraph (FF), by adding**  
15 **“and” at the end; and]**

16 **[(C) by adding at the end the following**  
17 **new subparagraph:]**

18 **[“(GG) a durable medical item that admin-**  
19 **isters a drug described in section 1927(k)(2)(C) that**  
20 **would otherwise be self-administered multiple times**  
21 **per day and includes a disposable component and at**  
22 **least one component that can withstand repeated**  
23 **use, and supplies used in conjunction with such item**  
24 **(including the drug administered by such item);”.]**

25 **[(2) PAYMENT.—**

1                   **[(A) PAYMENT AMOUNT FOR DMI.—**Sec-  
2                   tion 1834 of the Social Security Act (42 U.S.C.  
3                   1395m) is amended by adding at the end the  
4                   following new subsection: **]**

5           **["(r) PAYMENT METHODOLOGY FOR DURABLE**  
6   MEDICAL ITEMS (DMI).—The Secretary shall establish a  
7   payment methodology for a durable medical item described  
8   in section 1861(s)(2)(GG) and supplies used in conjunc-  
9   tion with such item (other than a drug administered by  
10  such item) such that the estimated average total payment  
11  per individual for a period for such items and supplies  
12  does not exceed the estimated average total payment per  
13  individual for such period that would otherwise be made  
14  (taking into account the application of section 1847) for  
15  the durable medical equipment for which it is a substitute  
16  and for supplies used in conjunction with such equipment  
17  (other than such a drug) as determined appropriate by  
18  the Secretary.” **]**

19                   **[(B) PAYMENT FOR DRUG.—**Section  
20                   1842(o)(1)(D) of the Social Security Act (42  
21                   U.S.C. 1395u(o)(1)(D)) is amended— **]**

22                   **[(i) in clause (i), by inserting “or**  
23                   drugs administered by a durable medical  
24                   item covered under section 1861(s)(2)(GG)



1 on or after January 1, 2017,” after “after  
2 January 1, 2004,”; and】

3 【(ii) in clause (ii), by striking “infu-  
4 sion”.】

5 【(C) COMPETITIVE ACQUISITION.—Section  
6 1847(a)(2) of the Social Security Act (42  
7 U.S.C. 1395w–3(a)(2)) is amended by adding  
8 at the end the following new subparagraph:】

9 【“(D) DURABLE MEDICAL ITEM.—A dura-  
10 ble medical item and supplies used in conjunc-  
11 tion with such item, described in section  
12 1861(s)(2)(GG).”】

13 【(3) CONFORMING AMENDMENT.—Section  
14 1833(a)(1) of the Social Security Act (42 U.S.C.  
15 1395l(a)(1)) is amended—】

16 【(A) by striking “and” before “(Z)”]; and】

17 【(B) by inserting before the semicolon at  
18 the end the following: “, and (AA) with respect  
19 to durable medical items described in section  
20 1861(s)(2)(GG), the amount paid shall be equal  
21 to 80 percent of the lesser of the actual charge  
22 or the amount determined under section  
23 1834(r)”】

1           (4) EFFECTIVE DATE.—The amendments made  
2       by this subsection shall apply to items furnished on  
3       or after January 1, 2017.

4       **[(b) PAYMENT FOR CERTAIN DISPOSABLE DE-**  
5 **VICES.—]**

6           **[(1) IN GENERAL.—**Section 1834 of the Social  
7       Security Act (42 U.S.C. 1395m), as amended by  
8       subsection (a)(2), is further amended by adding at  
9       the end the following new subsection:**]**

10       **["(s) PAYMENT FOR CERTAIN DISPOSABLE DE-**  
11 **VICES.—]**

12           **["(1) IN GENERAL.—**The Secretary shall make  
13       separate payment in the amount established under  
14       paragraph (3) to a home health agency for a device  
15       described in paragraph (2) when furnished to an in-  
16       dividual who receives home health services for which  
17       payment is made under section 1895(b).**]**

18           **["(2) DEVICE DESCRIBED.—**For purposes of  
19       paragraph (1), a device described in this paragraph  
20       is a disposable device for which, as of January 1,  
21       2015, there is**—]**

22           **["(A) a Level I Healthcare Common Pro-**  
23       cedure Coding System (HCPCS) code for which  
24       the description for a professional service in-  
25       cludes the furnishing of such device; and**]**

1           【“(B) a separate Level I HCPCS code for  
2           a professional service that uses durable medical  
3           equipment instead of such device.”】

4           【“(3) PAYMENT AMOUNT.—The Secretary shall  
5           establish the separate payment amount for such a  
6           device such that such amount does not exceed the  
7           payment that would be made for the HCPCS code  
8           described in paragraph (2)(A) under section 1833(t)  
9           (relating to payment for covered OPD services).”】

10          (2)     CONFORMING     AMENDMENT.—Section  
11          1861(m)(5) of the Social Security Act (42 U.S.C.  
12          1395x(m)(5)) is amended by inserting “and devices  
13          described in section 1834(s)(2)” after “durable med-  
14          ical equipment”.

15          (3) EFFECTIVE DATE.—The amendments made  
16          by this subsection shall apply to devices furnished on  
17          or after January 1, 2017.

18                 **Subtitle E—Local Coverage**  
19                 **Decision Reforms**

20     **SEC. 3081. IMPROVEMENTS IN THE MEDICARE LOCAL COV-**  
21                 **ERAGE DETERMINATION (LCD) PROCESS.**

22          (a) IN GENERAL.—Section 1862(l)(5) of the Social  
23          Security Act (42 U.S.C. 1395y(l)(5)) is amended by add-  
24          ing at the end the following new subparagraph:

1           “(D) LOCAL COVERAGE DETERMINA-  
2           TIONS.—The Secretary shall require each medi-  
3           care administrative contractor that develops a  
4           local coverage determination to make available  
5           on the website of such contractor and in the  
6           coverage database on the Medicare website, at  
7           least 45 days before the effective date of such  
8           determination, the following information:

9                   “(i) Such determination in its en-  
10                  tirety.

11                   “(ii) Where and when the proposed  
12                  determination was first made public.

13                   “(iii) Links to the proposed deter-  
14                  mination and a response to comments sub-  
15                  mitted to the contractor with respect to  
16                  such proposed determination.

17                   “(iv) A summary of evidence that was  
18                  considered by the contractor during the de-  
19                  velopment of such determination and a list  
20                  of the sources of such evidence.

21                   “(v) An explanation of the rationale  
22                  that supports such determination.”.

23           (b) EFFECTIVE DATE.—The amendment made by  
24           subsection (a) shall apply with respect to local coverage  
25           determinations that are proposed or revised on or after

1 the date that is 180 days after the date of the enactment  
2 of this Act.

3 **Subtitle F—Medicare Pharma-**  
4 **ceutical and Technology Om-**  
5 **budsman**

6 **SEC. 3101. MEDICARE PHARMACEUTICAL AND TECH-**  
7 **NOLOGY OMBUDSMAN.**

8 Section 1808(c) of the Social Security Act (42 U.S.C.  
9 1395b–9(c)) is amended by adding at the end the fol-  
10 lowing new paragraph:

11 “(4) PHARMACEUTICAL AND TECHNOLOGY OM-  
12 BUDSMAN.—Not later than 12 months after the date  
13 of the enactment of this paragraph, the Secretary  
14 shall provide for a pharmaceutical and technology  
15 ombudsman within the Centers for Medicare & Med-  
16 icaid Services who shall receive and respond to com-  
17 plaints, grievances, and requests that—

18 “(A) are from entities that manufacture  
19 pharmaceutical, biotechnology, medical device,  
20 or diagnostic products that are covered or for  
21 which coverage is being sought under this title;  
22 and

23 “(B) regard coverage, coding, or payment  
24 under this title for such products.”.

1       **Subtitle G—Medicare Site-of-**  
2       **Service Price Transparency**

3   **SEC. 3121. MEDICARE SITE-OF-SERVICE PRICE TRANS-**  
4       **PARENCY.**

5       Section 1834 of the Social Security Act (42 U.S.C.  
6   1395m) is amended by adding at the end the following  
7   new subsection:

8       “(r) SITE-OF-SERVICE PRICE TRANSPARENCY.—

9           “(1) IN GENERAL.—In order to facilitate price  
10   transparency with respect to items and services for  
11   which payment may be made either to a hospital  
12   outpatient department or to an ambulatory surgery  
13   center under this title, the Secretary shall, for 2017  
14   and each year thereafter, make available to the pub-  
15   lic via a searchable website, with respect to an ap-  
16   propriate number of such items and services—

17           “(A) the estimated payment amount for  
18   such items and services under the outpatient  
19   department fee schedule under subsection (t) of  
20   section 1833 and the ambulatory surgical cen-  
21   ter payment system under subsection (i) of such  
22   section; and

23           “(B) the estimated amount of beneficiary  
24   liability applicable to such an item or service.

1           “(2) CALCULATION OF ESTIMATED BENE-  
2           FICIARY LIABILITY.—For purposes of paragraph  
3           (1)(B), the estimated amount of beneficiary liability,  
4           with respect to an item or service, is the amount for  
5           such item or service for which an individual who  
6           does not have coverage under a medicare supple-  
7           mental policy certified under section 1882 or any  
8           other supplemental insurance coverage is respon-  
9           sible.

10          “(3) IMPLEMENTATION.—In carrying out this  
11          subsection, the Secretary—

12                 “(A) shall include in the notice described  
13                 in section 1804(a) a notification of the avail-  
14                 ability of the estimated amounts made available  
15                 under paragraph (1); and

16                 “(B) may utilize existing mechanisms, such  
17                 as the portion of the website of the Centers for  
18                 Medicare & Medicaid Services on which infor-  
19                 mation comparing physician performance is  
20                 posted (commonly referred to as the Physician  
21                 Compare website), to make available such esti-  
22                 mated amounts under such paragraph.

23          “(4) FUNDING.—For purposes of implementing  
24          this subsection, the Secretary shall provide for the  
25          transfer, from the Supplemental Medical Insurance

1 Trust Fund under section 1841 to the Centers for  
2 Medicare & Medicaid Services Program Management  
3 Account, of \$6,000,000 for fiscal year 2015, to re-  
4 main available until expended.”.

5 **Subtitle H—Medicare Part D Pa-**  
6 **tient Safety and Drug Abuse**  
7 **Prevention**

8 **SEC. 3141. PROGRAMS TO PREVENT PRESCRIPTION DRUG**  
9 **ABUSE UNDER MEDICARE PARTS C AND D.**

10 (a) DRUG MANAGEMENT PROGRAM FOR AT-RISK  
11 BENEFICIARIES.—

12 (1) IN GENERAL.—Section 1860D–4(c) of the  
13 Social Security Act (42 U.S.C. 1395w–10(c)) is  
14 amended by adding at the end the following:

15 “(5) DRUG MANAGEMENT PROGRAM FOR AT-  
16 RISK BENEFICIARIES.—

17 “(A) AUTHORITY TO ESTABLISH.—A PDP  
18 sponsor may establish a drug management pro-  
19 gram for at-risk beneficiaries under which, sub-  
20 ject to subparagraph (B), the PDP sponsor  
21 may, in the case of an at-risk beneficiary for  
22 prescription drug abuse who is an enrollee in a  
23 prescription drug plan of such PDP sponsor,  
24 limit such beneficiary’s access to coverage for  
25 frequently abused drugs under such plan to fre-



1           quently abused drugs that are prescribed for  
2           such beneficiary by a prescriber selected under  
3           subparagraph (D), and dispensed for such bene-  
4           ficiary by a pharmacy selected under such sub-  
5           paragraph.

6           “(B) REQUIREMENT FOR NOTICES.—

7           “(i) IN GENERAL.—A PDP sponsor  
8           may not limit the access of an at-risk ben-  
9           eficiary for prescription drug abuse to cov-  
10          erage for frequently abused drugs under a  
11          prescription drug plan until such spon-  
12          sor—

13               “(I) provides to the beneficiary  
14               an initial notice described in clause  
15               (ii) and a second notice described in  
16               clause (iii); and

17               “(II) verifies with the providers  
18               of the beneficiary that the beneficiary  
19               is an at-risk beneficiary for prescrip-  
20               tion drug abuse.

21           “(ii) INITIAL NOTICE.—An initial no-  
22           tice described in this clause is a notice that  
23           provides to the beneficiary—

24               “(I) notice that the PDP sponsor  
25               has identified the beneficiary as po-

1 tentially being an at-risk beneficiary  
2 for prescription drug abuse;

3 “(II) information describing all  
4 State and Federal public health re-  
5 sources that are designed to address  
6 prescription drug abuse to which the  
7 beneficiary has access, including men-  
8 tal health services and other coun-  
9 seling services;

10 “(III) notice of, and information  
11 about, the right of the beneficiary to  
12 appeal such identification under sub-  
13 section (h) and the option of an auto-  
14 matic escalation to external review;

15 “(IV) a request for the bene-  
16 ficiary to submit to the PDP sponsor  
17 preferences for which prescribers and  
18 pharmacies the beneficiary would pre-  
19 fer the PDP sponsor to select under  
20 subparagraph (D) in the case that the  
21 beneficiary is identified as an at-risk  
22 beneficiary for prescription drug  
23 abuse as described in clause (iii)(I);

24 “(V) an explanation of the mean-  
25 ing and consequences of the identi-

1           fication of the beneficiary as poten-  
2           tially being an at-risk beneficiary for  
3           prescription drug abuse, including an  
4           explanation of the drug management  
5           program established by the PDP  
6           sponsor pursuant to subparagraph  
7           (A);

8                   “(VI) clear instructions that ex-  
9           plain how the beneficiary can contact  
10          the PDP sponsor in order to submit  
11          to the PDP sponsor the preferences  
12          described in subclause (IV) and any  
13          other communications relating to the  
14          drug management program for at-risk  
15          beneficiaries established by the PDP  
16          sponsor; and

17                   “(VII) contact information for  
18          other organizations that can provide  
19          the beneficiary with assistance regard-  
20          ing such drug management program  
21          (similar to the information provided  
22          by the Secretary in other standardized  
23          notices provided to part D eligible in-  
24          dividuals enrolled in prescription drug  
25          plans under this part).

1                   “(iii) SECOND NOTICE.—A second no-  
2                   tice described in this clause is a notice that  
3                   provides to the beneficiary notice—

4                   “(I) that the PDP sponsor has  
5                   identified the beneficiary as an at-risk  
6                   beneficiary for prescription drug  
7                   abuse;

8                   “(II) that such beneficiary is  
9                   subject to the requirements of the  
10                  drug management program for at-risk  
11                  beneficiaries established by such PDP  
12                  sponsor for such plan;

13                  “(III) of the prescriber and phar-  
14                  macy selected for such individual  
15                  under subparagraph (D);

16                  “(IV) of, and information about,  
17                  the beneficiary’s right to appeal such  
18                  identification under subsection (h)  
19                  and the option of an automatic esca-  
20                  lation to external review;

21                  “(V) that the beneficiary can, in  
22                  the case that the beneficiary has not  
23                  previously submitted to the PDP  
24                  sponsor preferences for which pre-  
25                  scribers and pharmacies the bene-

1           ficiary would prefer the PDP sponsor  
2           select under subparagraph (D), sub-  
3           mit such preferences to the PDP  
4           sponsor; and

5           “(VI) that includes clear instruc-  
6           tions that explain how the beneficiary  
7           can contact the PDP sponsor.

8           “(iv) TIMING OF NOTICES.—

9           “(I) IN GENERAL.—Subject to  
10          subclause (II), a second notice de-  
11          scribed in clause (iii) shall be provided  
12          to the beneficiary on a date that is  
13          not less than 60 days after an initial  
14          notice described in clause (ii) is pro-  
15          vided to the beneficiary.

16          “(II) EXCEPTION.—In the case  
17          that the PDP sponsor, in conjunction  
18          with the Secretary, determines that  
19          concerns identified through rule-  
20          making by the Secretary regarding  
21          the health or safety of the beneficiary  
22          or regarding significant drug diversion  
23          activities require the PDP sponsor to  
24          provide a second notice described in  
25          clause (iii) to the beneficiary on a

1 date that is earlier than the date de-  
2 scribed in subclause (II), the PDP  
3 sponsor may provide such second no-  
4 tice on such earlier date.

5 “(C) AT-RISK BENEFICIARY FOR PRE-  
6SCRIPTION DRUG ABUSE.—

7 “(i) IN GENERAL.—For purposes of  
8 this paragraph, the term ‘at-risk bene-  
9 ficiary for prescription drug abuse’ means  
10 a part D eligible individual who is not an  
11 exempted individual described in clause (ii)  
12 and—

13 “(I) who is identified through the  
14 use of clinical guidelines developed by  
15 the Secretary in consultation with  
16 PDP sponsors and other stakeholders  
17 described in section 3151(f)(2)(A) of  
18 the 21st Century Cures Act; or

19 “(II) with respect to whom the  
20 PDP sponsor of a prescription drug  
21 plan, upon enrolling such individual in  
22 such plan, received notice from the  
23 Secretary that such individual was  
24 identified under this paragraph to be  
25 an at-risk beneficiary for prescription

1 drug abuse under the prescription  
2 drug plan in which such individual  
3 was most recently previously enrolled  
4 and such identification has not been  
5 terminated under subparagraph (F).

6 “(ii) EXEMPTED INDIVIDUAL DE-  
7 SCRIBED.—An exempted individual de-  
8 scribed in this clause is an individual  
9 who—

10 “(I) an individual who receives  
11 hospice care under this title; or

12 “(II) an individual, such as an  
13 individual who is a resident of a long-  
14 term care facility, who the Secretary  
15 elects to treat as an exempted indi-  
16 vidual for purposes of clause (i).

17 “(D) SELECTION OF PRESCRIBERS.—

18 “(i) IN GENERAL.—With respect to  
19 each at-risk beneficiary for prescription  
20 drug abuse enrolled in a prescription drug  
21 plan offered by such sponsor, a PDP spon-  
22 sor shall, based on the preferences sub-  
23 mitted to the PDP sponsor by the bene-  
24 ficiary pursuant to clauses (ii)(IV) and  
25 (iii)(V) of subparagraph (B), select—

1           “(I) one or more individuals who  
2           are authorized to prescribe frequently  
3           abused drugs (referred to in this  
4           paragraph as ‘prescribers’) who may  
5           write prescriptions for such drugs for  
6           such beneficiary; and

7           “(II) one or more pharmacies  
8           that may dispense such drugs to such  
9           beneficiary.

10          “(ii) REASONABLE ACCESS.—In mak-  
11          ing the selection under this subparagraph,  
12          a PDP sponsor shall ensure that the bene-  
13          ficiary continues to have reasonable access  
14          to drugs described in subparagraph (G),  
15          taking into account geographic location,  
16          beneficiary preference, impact on cost-  
17          sharing, and reasonable travel time.

18          “(iii) BENEFICIARY PREFERENCES.—

19                 “(I) IN GENERAL.—If an at-risk  
20                 beneficiary for prescription drug  
21                 abuse submits preferences for which  
22                 in-network prescribers and pharmacies  
23                 the beneficiary would prefer the PDP  
24                 sponsor select in response to a notice



1 under subparagraph (B), the PDP  
2 sponsor shall—

3 “(aa) review such pref-  
4 erences;

5 “(bb) select or change the  
6 selection of a prescriber or phar-  
7 macy for the beneficiary based on  
8 such preferences; and

9 “(cc) inform the beneficiary  
10 of such selection or change of se-  
11 lection.

12 “(II) EXCEPTION.—In the case  
13 that the PDP sponsor determines that  
14 a change to the selection of a pre-  
15 scriber or pharmacy under item (bb)  
16 by the PDP sponsor is contributing or  
17 would contribute to prescription drug  
18 abuse or drug diversion by the bene-  
19 ficiary, the PDP sponsor may change  
20 the selection of a prescriber or phar-  
21 macy for the beneficiary without re-  
22 gard to the preferences of the bene-  
23 ficiary described in subclause (I).

24 “(iv) CONFIRMATION.—Before select-  
25 ing a prescriber or pharmacy under this

1           subparagraph, a PDP sponsor must re-  
2           quest and receive confirmation from the  
3           prescriber or pharmacy acknowledging and  
4           accepting that the beneficiary involved is in  
5           the drug management program for at-risk  
6           beneficiaries.

7           “(E) TERMINATIONS AND APPEALS.—The  
8           identification of an individual as an at-risk ben-  
9           eficiary for prescription drug abuse under this  
10          paragraph, a coverage determination made  
11          under a drug management program for at-risk  
12          beneficiaries, and the selection of a prescriber  
13          or pharmacy under subparagraph (D) with re-  
14          spect to such individual shall be subject to re-  
15          consideration and appeal under subsection (h)  
16          and the option of an automatic escalation to ex-  
17          ternal review to the extent provided by the Sec-  
18          retary.

19          “(F) TERMINATION OF IDENTIFICATION.—

20                 “(i) IN GENERAL.—The Secretary  
21                 shall develop standards for the termination  
22                 of identification of an individual as an at-  
23                 risk beneficiary for prescription drug abuse  
24                 under this paragraph. Under such stand-

1           ards such identification shall terminate as  
2           of the earlier of—

3                   “(I) the date the individual dem-  
4                   onstrates that the individual is no  
5                   longer likely, in the absence of the re-  
6                   strictions under this paragraph, to be  
7                   an at-risk beneficiary for prescription  
8                   drug abuse described in subparagraph  
9                   (C)(i); or

10                   “(II) the end of such maximum  
11                   period of identification as the Sec-  
12                   retary may specify.

13                   “(ii) RULE OF CONSTRUCTION.—  
14                   Nothing in clause (i) shall be construed as  
15                   preventing a plan from identifying an indi-  
16                   vidual as an at-risk beneficiary for pre-  
17                   scription drug abuse under subparagraph  
18                   (C)(i) after such termination on the basis  
19                   of additional information on drug use oc-  
20                   curring after the date of notice of such ter-  
21                   mination.

22                   “(G) FREQUENTLY ABUSED DRUG.—For  
23                   purposes of this subsection, the term ‘frequently  
24                   abused drug’ means a drug that is a controlled

1 substance that the Secretary determines to be  
2 frequently abused or diverted.

3 “(H) DATA DISCLOSURE.—In the case of  
4 an at-risk beneficiary for prescription drug  
5 abuse whose access to coverage for frequently  
6 abused drugs under a prescription drug plan  
7 has been limited by a PDP sponsor under this  
8 paragraph, such PDP sponsor shall disclose  
9 data, including any necessary individually iden-  
10 tifiable health information, in a form and man-  
11 ner specified by the Secretary, about the deci-  
12 sion to impose such limitations and the limita-  
13 tions imposed by the sponsor under this part.

14 “(I) EDUCATION.—The Secretary shall  
15 provide education to enrollees in prescription  
16 drug plans of PDP sponsors and providers re-  
17 garding the drug management program for at-  
18 risk beneficiaries described in this paragraph,  
19 including education—

20 “(i) provided by medicare administra-  
21 tive contractors through the improper pay-  
22 ment outreach and education program de-  
23 scribed in section 1874A(h); and

24 “(ii) through current education efforts  
25 (such as State health insurance assistance

1 programs described in subsection (a)(1)(A)  
2 of section 119 of the Medicare Improve-  
3 ments for Patients and Providers Act of  
4 2008 (42 U.S.C. 1395b–3 note)) and ma-  
5 terials directed toward such enrollees.

6 “(J) APPLICATION UNDER MA–PD  
7 PLANS.—Pursuant to section 1860D–21(c)(1),  
8 the provisions of this paragraph apply under  
9 part D to MA organizations offering MA–PD  
10 plans to MA eligible individuals in the same  
11 manner as such provisions apply under this  
12 part to a PDP sponsor offering a prescription  
13 drug plan to a part D eligible individual.”.

14 (2) INFORMATION FOR CONSUMERS.—Section  
15 1860D–4(a)(1)(B) of the Social Security Act (42  
16 U.S.C. 1395w–104(a)(1)(B)) is amended by adding  
17 at the end the following:

18 “(v) The drug management program  
19 for at-risk beneficiaries under subsection  
20 (c)(5).”.

21 (b) UTILIZATION MANAGEMENT PROGRAMS.—Sec-  
22 tion 1860D–4(c) of the Social Security Act (42 U.S.C.  
23 1395w–104(c)), as amended by subsection (a)(1), is fur-  
24 ther amended—

1           (1) in paragraph (1), by inserting after sub-  
2       paragraph (D) the following new subparagraph:

3           “(E) A utilization management tool to pre-  
4       vent drug abuse (as described in paragraph  
5       (6)(A)).”; and

6           (2) by adding at the end the following new  
7       paragraph:

8           “(6) UTILIZATION MANAGEMENT TOOL TO PRE-  
9       VENT DRUG ABUSE.—

10          “(A) IN GENERAL.—A tool described in  
11       this paragraph is any of the following:

12           “(i) A utilization tool designed to pre-  
13       vent the abuse of frequently abused drugs  
14       by individuals and to prevent the diversion  
15       of such drugs at pharmacies.

16           “(ii) Retrospective utilization review  
17       to identify—

18           “(I) individuals that receive fre-  
19       quently abused drugs at a frequency  
20       or in amounts that are not clinically  
21       appropriate; and

22           “(II) providers of services or sup-  
23       pliers that may facilitate the abuse or  
24       diversion of frequently abused drugs  
25       by beneficiaries.

1 “(iii) Consultation with the contractor  
2 described in subparagraph (B) to verify if  
3 an individual enrolling in a prescription  
4 drug plan offered by a PDP sponsor has  
5 been previously identified by another PDP  
6 sponsor as an individual described in  
7 clause (ii)(I).

8 “(B) REPORTING.—A PDP sponsor offer-  
9 ing a prescription drug plan (and an MA orga-  
10 nization offering an MA–PD plan) in a State  
11 shall submit to the Secretary and the Medicare  
12 drug integrity contractor with which the Sec-  
13 retary has entered into a contract under section  
14 1893 with respect to such State a report, on a  
15 monthly basis, containing information on—

16 “(i) any provider of services or sup-  
17 plier described in subparagraph (A)(ii)(II)  
18 that is identified by such plan sponsor (or  
19 organization) during the 30-day period be-  
20 fore such report is submitted; and

21 “(ii) the name and prescription  
22 records of individuals described in para-  
23 graph (5)(C).”.

24 (c) EXPANDING ACTIVITIES OF MEDICARE DRUG IN-  
25 TEGRITY CONTRACTORS (MEDICS).—

1           (1) IN GENERAL.—Section 1893 of the Social  
2       Security Act (42 U.S.C. 1395ddd) is amended by  
3       adding at the end the following new subsection:

4       “(j) EXPANDING ACTIVITIES OF MEDICARE DRUG  
5       INTEGRITY CONTRACTORS (MEDICs).—

6           “(1) ACCESS TO INFORMATION.—Under con-  
7       tracts entered into under this section with Medicare  
8       drug integrity contractors, the Secretary shall au-  
9       thorize such contractors to directly accept prescrip-  
10      tion and necessary medical records from entities  
11      such as pharmacies, prescription drug plans, MA-  
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 clinicians, plan sponsors, entities delegated by  
14 plan sponsors, and biopharmaceutical manufac-  
15 turers for input regarding the topics described  
16 in subparagraph (B).

17 (B) TOPICS DESCRIBED.—The topics de-  
18 scribed in this subparagraph are the topics of—

19 (i) the impact on cost-sharing and en-  
20 suring accessibility to prescription drugs  
21 for enrollees in prescription drug plans of  
22 PDP sponsors, and enrollees in MA–PD  
23 plans, who are at-risk beneficiaries for pre-  
24 scription drug abuse (as defined in sub-  
25 paragraph (C) of paragraph (5) of section

1 1860D–4(c) of the Social Security Act (42  
2 U.S.C. 1395w–104(c));

3 (ii) the use of an expedited appeals  
4 process under which such an enrollee may  
5 appeal an identification of such enrollee as  
6 an at-risk beneficiary for prescription drug  
7 abuse under such paragraph (similar to the  
8 processes established under the Medicare  
9 Advantage program under part C of title  
10 XVIII of the Social Security Act that allow  
11 an automatic escalation to external review  
12 of claims submitted under such part);

13 (iii) the types of enrollees that should  
14 be treated as exempted individuals, as de-  
15 scribed in subparagraph (C)(ii) of such  
16 paragraph;

17 (iv) the manner in which terms and  
18 definitions in such paragraph should be ap-  
19 plied, such as the use of clinical appro-  
20 priateness in determining whether an en-  
21 rollee is an at-risk beneficiary for prescrip-  
22 tion drug abuse as defined in subpara-  
23 graph (C) of such paragraph;

24 (v) the information to be included in  
25 the notices described in subparagraph (B)

1 of such paragraph and the standardization  
2 of such notices; and

3 (vi) with respect to a PDP sponsor  
4 (or Medicare Advantage organization) that  
5 establishes a drug management program  
6 for at-risk beneficiaries under such para-  
7 graph, the responsibilities of such PDP  
8 sponsor (or organization) with respect to  
9 the implementation of such program.

10 (g) RULEMAKING.—The Secretary of Health and  
11 Human Services shall promulgate regulations based on the  
12 input gathered pursuant to subsection (f)(2)(A).