

114TH CONGRESS  
1ST SESSION

# H. R. 6

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

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## IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2015

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 Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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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.

Subtitle A—National Institutes of Health Funding

- Sec. 1001. National Institutes of Health reauthorization.
- Sec. 1002. NIH Innovation Fund.

Subtitle B—National Institutes of Health Planning and Administration

- Sec. 1021. NIH research strategic plan.
- Sec. 1022. Increasing accountability at the National Institutes of Health.
- Sec. 1023. Reducing administrative burdens of researchers.
- Sec. 1024. Exemption for the National Institutes of Health from the 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 Study Network Sense of Congress.
- Sec. 1083. Appropriate age groupings in clinical research.

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

- Sec. 1101. Sharing of data generated through NIH-funded research.
- Sec. 1102. Standardization of data in Clinical Trial Registry Data Bank on eligibility for clinical trials.

Subtitle G—Facilitating Collaborative Research

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

Subtitle H—Council for 21st Century Cures

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

TITLE II—DEVELOPMENT

Subtitle A—Patient-Focused Drug Development

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

Subtitle B—Qualification and Use of Drug Development Tools

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

Subtitle C—FDA Advancement of Precision Medicine

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

Subtitle D—Modern Trial Design and Evidence Development

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

Subtitle E—Expediting Patient Access

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

Subtitle F—Facilitating Responsible Manufacturer Communications

- Sec. 2101. Facilitating dissemination of health care economic information.
- Sec. 2102. Facilitating responsible communication of scientific and medical developments.

Subtitle G—Antibiotic Drug Development

- Sec. 2121. Approval of certain drugs for use in a limited population of patients.
- Sec. 2122. Susceptibility test interpretive criteria for microorganisms.
- Sec. 2123. Encouraging the development and use of new antimicrobial drugs.

Subtitle H—Vaccine Access, Certainty, and Innovation

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

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

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

Subtitle J—Domestic Manufacturing and Export Efficiencies

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

Subtitle K—Enhancing Combination Products Review

- Sec. 2181. Enhancing combination products review.

Subtitle L—Priority Review for Breakthrough Devices

- Sec. 2201. Priority review for breakthrough devices.

Subtitle M—Medical Device Regulatory Process Improvements

- Sec. 2221. Third-party quality system assessment.
- Sec. 2222. Valid scientific evidence.
- Sec. 2223. Training and oversight in least burdensome appropriate means concept.
- Sec. 2224. Recognition of standards.
- Sec. 2225. Easing regulatory burden with respect to certain class I and class II devices.
- Sec. 2226. Advisory committee process.
- Sec. 2227. Humanitarian device exemption application.
- Sec. 2228. CLIA waiver study design guidance for in vitro diagnostics.

Subtitle N—Sensible Oversight for Technology Which Advances Regulatory Efficiency

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

Subtitle O—Streamlining Clinical Trials

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

Subtitle P—Improving Scientific Expertise and Outreach at FDA

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

TITLE III—DELIVERY

Subtitle A—Interoperability

- Sec. 3001. Ensuring interoperability of health information technology.

Subtitle B—Telehealth

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

Subtitle C—Encouraging Continuing Medical Education for Physicians

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

Subtitle D—Disposable Medical Technologies

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

Subtitle E—Local Coverage Decision Reforms

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

Subtitle F—Medicare Pharmaceutical and Technology Ombudsman

Sec. 3101. Medicare pharmaceutical and technology ombudsman.

Subtitle G—Medicare Site-of-Service Price Transparency

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

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

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

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

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

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

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

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

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

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

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

17                   and

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

1 **SEC. 1002. NIH INNOVATION FUND.**

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

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

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

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

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

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

18 (1) by redesignating subsection (e) as sub-  
19 section (f); and

20 (2) by inserting after subsection (d) the fol-  
21 lowing new subsection:

22 “(e) NIH INNOVATION FUND.—

23 “(1) ESTABLISHMENT.—For the purpose of al-  
24 locations under section 402(b)(25), there is estab-  
25 lished a fund to be known as the NIH Innovation  
26 Fund. The Director of NIH shall, with respect to

1 funds appropriated to the NIH Innovation Fund, al-  
2 locate such funds to support biomedical research  
3 through the funding of basic, translational, and clin-  
4 ical research.

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

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

16 “(B) AVAILABILITY SUBJECT TO APPRO-  
17 PRIATIONS.—Amounts in the Fund shall not be  
18 available except to the extent and in such  
19 amounts as are provided in advance in appro-  
20 priation Acts.

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

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

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

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

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

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

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



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

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

9                   “(A) Research in which—

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

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

14                   “(B) Research in which—

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

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

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

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

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

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

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

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

13          “(B) minimize unnecessary duplication.

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

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

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

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

3 “(6) STRATEGIC PLAN.—

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

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

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

22 “(I) biomarkers;

23 “(II) precision medicine;

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

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

6 “(IV) antibiotics;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8           “(m) RESEARCH STRATEGIC PLAN.—

9           “(1) FIVE-YEAR PLANS FOR BIOMEDICAL RE-  
10          SEARCH STRATEGY.—

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

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

22           “(ii) identifies areas, to be known  
23           strategic focus areas, in which the re-  
24           sources of the National Institutes of  
25           Health can best contribute to the goal of

1 expanding knowledge on human health in  
2 the United States through biomedical re-  
3 search; and

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

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

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

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

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

20 “(i) have a common template; and

21 “(ii) identify strategic focus areas in  
22 which the resources of the national re-  
23 search institutes and national centers can  
24 best contribute to the goal of expanding

1 knowledge on human health in the United  
2 States through biomedical research.

3 “(3) CONTENTS OF PLANS.—

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

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

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

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

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



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

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

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

12           “(B) make such initial strategic plan pub-  
13           licly available on the website of the National In-  
14           stitutes of Health.

15           “(5) REVIEW; UPDATES.—

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

22           “(B) UPDATES.—Not later than the end of  
23           the 5-year period covered by the initial strategic  
24           plan under this subsection, and every 5 years  
25           thereafter, the Director of NIH, in consultation

1 with the directors of the national research insti-  
2 tutes and national centers, stakeholders in the  
3 scientific field, advocates, and the public at  
4 large, shall—

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

8 “(ii) update such plan in accordance  
9 with this section.”.

10 **SEC. 1022. INCREASING ACCOUNTABILITY AT THE NA-**  
11 **TIONAL INSTITUTES OF HEALTH.**

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

16 “(a) APPOINTMENT; TERMS.—

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

25 “(2) TERMS.—

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

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

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

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

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

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

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

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

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

20 “(B) shall take into consideration—

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

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

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

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

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

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

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

1 (1) The Scientific Management Review Board.

2 (2) The National Academy of Sciences.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 “(C) OTHER TRANSACTIONS AUTHORITY.—

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 **SEC. 1042. REPORT.**

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

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

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

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

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

#### 10 **“SEC. 490. CAPSTONE AWARD.**

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

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

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

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

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

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

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

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

9 (1) in paragraph (1)—

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

20 (B) by striking subparagraph (B);

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

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

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

7 **SEC. 1082. GLOBAL PEDIATRIC CLINICAL STUDY NETWORK**

8 **SENSE OF CONGRESS.**

9 It is the sense of Congress that—

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 “(A) privacy and confidentiality;

22 “(B) proprietary interests;

23 “(C) business confidential information;

24 “(D) intellectual property rights; and

25 “(E) other relevant rights.”.

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

4 (a) STANDARDIZATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

18          (d) STUDY AND REPORT.—

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

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

3           (A) review the effectiveness of the pilot  
4 program established under subsection (a); and

5           (B) be designed to formulate recommenda-  
6 tions on improvements to the program.

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

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

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

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

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

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

1 (e) DEFINITIONS.—In this section:

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

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

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

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

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

25 (A) that was—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6           “(C) diagnosis and progression markers;

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

10           “(A) the epidemiology of the diseases;

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

12           “(C) the prevention of the diseases;

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

3 “(2) to State and local agencies.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12       **“SEC. 13441. REFERENCES.**

13       “*In this part:*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

3           “(2) either—

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

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

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

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

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

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

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

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

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

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

10 **“SEC. 281. ESTABLISHMENT.**

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

20 **“SEC. 281A. PURPOSE.**

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

1 **“SEC. 281B. DUTIES.**

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

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

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

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

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

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

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

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

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

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

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

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

11           “(a) BOARD OF DIRECTORS.—

12           “(1) ESTABLISHMENT.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18                  “(2) TERMS AND VACANCIES.—

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

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

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

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

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

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

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

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

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

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

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

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

8                   “(4) MEETINGS.—

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22   **“SEC. 281F. FUNDING.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 benefit assessment framework under subsection  
2 (x).

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

13 (b) GUIDANCE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 (3) WORKSHOPS.—

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

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

12 (i) patients;

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9           “(b) EFFECT OF QUALIFICATION.—

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

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

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

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

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

3           “(3) RESCISSION OR MODIFICATION.—

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

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

22          “(c) TRANSPARENCY.—

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

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

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

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

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

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

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

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

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



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

5           “(E) A comprehensive list of—

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

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

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

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

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

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

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

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

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

19      “(f) DEFINITIONS.—In this section:

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

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

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

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

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

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

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

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

3           “(A) a biomarker;

4           “(B) a clinical outcome assessment; and

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

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

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

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

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

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

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

13          (d) GUIDANCE.—

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

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

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

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

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

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

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

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

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

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

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

14 (3) TAXONOMY.—

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

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

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

5           (e) MEETING AND REPORT.—

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 **“Subchapter J—Precision Medicine**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

1 (D) recommended analysis methodologies.

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

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

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

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

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

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

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

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

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

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

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

17 “(c) PROGRAM FRAMEWORK.—

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

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

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

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

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

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

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

12 “(3) CONSULTATION.—

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

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

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

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

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

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

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

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

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

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

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

8           “(f) RULE OF CONSTRUCTION.—

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

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

16                 “(A) the standards of evidence under—

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

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

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

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

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

11 “(b) PILOT DEMONSTRATIONS.—

12 “(1) IN GENERAL.—The Secretary—

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

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

22 “(ii) protecting the public health; or

23 “(iii) advancing patient-centered care;

24 and

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 “(5) the full data sets used to develop the quali-  
4 fied data summaries are submitted, unless the Sec-  
5 retary determines that the full data sets are not re-  
6 quired.

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

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

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

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

20 “(d) DEFINITIONS.—In this section:

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

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

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

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

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

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

18                 (1) shall—

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

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

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

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

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

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

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

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

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

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

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

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

22 “(2) procedures for making such requests;

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18           “(2) FORMAL MEETINGS.—

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

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

6 “(i) An early consultation meeting.

7 “(ii) An assessment meeting.

8 “(iii) A postapproval meeting.

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

24           “(A) EARLY CONSULTATION MEETING.—

25           The term ‘early consultation meeting’ means a

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

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

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

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

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

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

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

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

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

25 (d) CONFORMING AMENDMENTS.—

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

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

6                   (B) by inserting “505(z),” after “505(p),”;  
7           and

8                   (C) by adding at the end the following new  
9           paragraph:

10          “(2) In applying section 505(z) of the Federal Food,  
11          Drug, and Cosmetic Act to the licensure of biological prod-  
12          ucts under this section—

13                   “(A) references to an antibacterial or antifungal  
14                   drug that is intended to treat a serious or life-  
15                   threatening infection shall be construed to refer to  
16                   a biological product intended to treat a serious or  
17                   life-threatening bacterial or fungal infection; and

18                   “(B) references to approval of a drug under  
19                   section 505(c) of such Act shall be construed to  
20                   refer to a licensure of a biological product under  
21                   subsection (a) of this section.”.

22           (2) MISBRANDING.—Section 502 of the Federal  
23           Food, Drug, and Cosmetic Act (21 U.S.C. 352) is  
24           amended by adding at the end the following new  
25           subsection:

1 “(dd) If it is a drug approved in accordance with sec-  
2 tion 505(z) and its labeling does not meet the require-  
3 ments under paragraph (3) of such subsection, subject to  
4 paragraph (5) of such subsection.”.

5 (e) EVALUATION.—

6 (1) ASSESSMENT.—Not later than 48 months  
7 after the date of enactment of this Act, the Sec-  
8 retary of Health and Human Services shall publish  
9 for public comment an assessment of the program  
10 established under section 505(z) of the Federal  
11 Food, Drug, and Cosmetic Act, as added by sub-  
12 section (b). Such assessment shall determine if the  
13 limited-use pathway established under such section  
14 505(z) has improved or is likely to improve patient  
15 access to novel antibacterial or antifungal treat-  
16 ments and assess how the pathway could be ex-  
17 panded to cover products for serious or life-threat-  
18 ening diseases or conditions beyond bacterial and  
19 fungal infections.

20 (2) MEETING.—Not later than 90 days after  
21 the date of the publication of such assessment, the  
22 Secretary, acting through the Commissioner of Food  
23 and Drugs shall hold a public meeting to discuss the  
24 findings of the assessment, during which public  
25 stakeholders may present their views on the success

1 of the program established under section 505(z) of  
2 the Federal Food, Drug, and Cosmetic Act, as  
3 added by subsection (b), and the appropriateness of  
4 expanding such program.

5 (f) EXPANSION OF PROGRAM.—If the Secretary of  
6 Health and Human Services determines, based on the as-  
7 sessment under subsection (e)(1), evaluation of the assess-  
8 ment, and any other relevant information, that the public  
9 health would benefit from expansion of the limited-use  
10 pathway established under section 505(z) of the Federal  
11 Food, Drug, and Cosmetic Act (as added by subsection  
12 (b)) beyond the drugs approved in accordance with such  
13 section, the Secretary may expand such limited-use path-  
14 way in accordance with such a determination. The ap-  
15 proval of any drugs under any such expansion shall be  
16 subject to the considerations and requirements described  
17 in such section 505(z) for purposes of expansion to other  
18 serious or life-threatening diseases or conditions.

19 (g) MONITORING.—The Public Health Service Act is  
20 amended by inserting after section 317T (42 U.S.C.  
21 247b–22) the following:

22 **“SEC. 317U. MONITORING ANTIBACTERIAL AND**  
23 **ANTIFUNGAL DRUG USE AND RESISTANCE.**

24 “(a) MONITORING.—The Secretary shall use an ap-  
25 propriate monitoring system to monitor—

1           “(1) the use of antibacterial and antifungal  
2 drugs, including those receiving approval or licensure  
3 for a limited population pursuant to section 505(z)  
4 of the Federal Food, Drug, and Cosmetic Act; and

5           “(2) changes in bacterial and fungal resistance  
6 to drugs.

7           “(b) PUBLIC AVAILABILITY OF DATA.—The Sec-  
8 retary shall make summaries of the data derived from  
9 monitoring under this section publicly available for the  
10 purposes of—

11           “(1) improving the monitoring of important  
12 trends in antibacterial and antifungal resistance;  
13 and

14           “(2) ensuring appropriate stewardship of anti-  
15 bacterial and antifungal drugs, including those re-  
16 ceiving approval or licensure for a limited population  
17 pursuant to section 505(z) of the Federal Food,  
18 Drug, and Cosmetic Act.”.

19 **SEC. 2122. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA**  
20 **FOR MICROORGANISMS.**

21           (a) IN GENERAL.—Section 511 of the Federal Food,  
22 Drug, and Cosmetic Act (21 U.S.C. 360a) is amended to  
23 read as follows:



1 **“SEC. 511. IDENTIFYING AND UPDATING SUSCEPTIBILITY**  
2 **TEST INTERPRETIVE CRITERIA FOR MICRO-**  
3 **ORGANISMS.**

4 “(a) PURPOSE; IDENTIFICATION OF CRITERIA.—

5 “(1) PURPOSE.—The purpose of this section is  
6 to provide the Secretary with an expedited, flexible  
7 method for—

8 “(A) clearance or premarket approval of  
9 antimicrobial susceptibility testing devices uti-  
10 lizing updated, recognized susceptibility test in-  
11 terpretive criteria to characterize the in vitro  
12 susceptibility of particular bacteria, fungi, or  
13 other microorganisms to antimicrobial drugs;  
14 and

15 “(B) providing public notice of the avail-  
16 ability of recognized interpretive criteria to  
17 meet premarket submission requirements or  
18 other requirements under this Act for anti-  
19 microbial susceptibility testing devices.

20 “(2) IN GENERAL.—The Secretary shall iden-  
21 tify appropriate susceptibility test interpretive cri-  
22 teria with respect to antimicrobial drugs—

23 “(A) if such criteria are available on the  
24 date of approval of the drug under section 505  
25 of this Act or licensure of the drug under sec-

1           tion 351 of the Public Health Service Act (as  
2           applicable), upon such approval or licensure; or

3           “(B) if such criteria are unavailable on  
4           such date, on the date on which such criteria  
5           are available for such drug.

6           “(3) BASES FOR INITIAL IDENTIFICATION.—  
7           The Secretary shall identify appropriate suscepti-  
8           bility test interpretive criteria under paragraph (2),  
9           based on the Secretary’s review of, to the extent  
10          available and relevant—

11                  “(A) preclinical and clinical data, including  
12                  pharmacokinetic, pharmacodynamic, and epide-  
13                  miological data;

14                  “(B) Bayesian and pharmacometric statis-  
15                  tical methodologies; and

16                  “(C) such other evidence and information  
17                  as the Secretary considers appropriate.

18          “(b) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA  
19          WEBSITE.—

20                  “(1) IN GENERAL.—Not later than 1 year after  
21                  the date of the enactment of the 21st Century Cures  
22                  Act, the Secretary shall establish, and maintain  
23                  thereafter, on the website of the Food and Drug Ad-  
24                  ministration, a dedicated website that contains a list  
25                  of any appropriate new or updated susceptibility test

1 interpretive criteria standards in accordance with  
2 paragraph (2) (referred to in this section as the ‘In-  
3 terpretive Criteria Website’).

4 “(2) LISTING OF SUSCEPTIBILITY TEST INTER-  
5 PRETIVE CRITERIA STANDARDS.—

6 “(A) IN GENERAL.—The list described in  
7 paragraph (1) shall consist of any new or up-  
8 dated susceptibility test interpretive criteria  
9 standards that are—

10 “(i) established by a nationally or  
11 internationally recognized standard devel-  
12 opment organization that—

13 “(I) establishes and maintains  
14 procedures to address potential con-  
15 flicts of interest and ensure trans-  
16 parent decisionmaking;

17 “(II) holds open meetings to en-  
18 sure that there is an opportunity for  
19 public input by interested parties, and  
20 establishes and maintains processes to  
21 ensure that such input is considered  
22 in decisionmaking; and

23 “(III) permits its standards to be  
24 made publicly available, through the  
25 National Library of Medicine or an-

1                   other similar source acceptable to the  
2                   Secretary; and

3                   “(ii) recognized in whole, or in part,  
4                   by the Secretary under subsection (c).

5                   “(B) OTHER LIST.—The Interpretive Cri-  
6                   teria Website shall, in addition to the list de-  
7                   scribed in subparagraph (A), include a list of  
8                   interpretive criteria, if any, that the Secretary  
9                   has determined to be appropriate with respect  
10                  to legally marketed antimicrobial drugs,  
11                  where—

12                  “(i) the Secretary does not recognize,  
13                  in whole or in part, an interpretive criteria  
14                  standard described under subparagraph  
15                  (A) otherwise applicable to such a drug;

16                  “(ii) the Secretary withdraws under  
17                  subsection (c)(1)(B) recognition of a  
18                  standard, in whole or in part, otherwise  
19                  applicable to such a drug;

20                  “(iii) the Secretary approves an appli-  
21                  cation under section 505 of this Act or sec-  
22                  tion 351 of the Public Health Service Act,  
23                  as applicable, with respect to marketing of  
24                  such a drug for which there are no rel-  
25                  evant interpretive criteria included in a

1 standard recognized by the Secretary  
2 under subsection (c); or

3 “(iv) because the characteristics of  
4 such a drug differ from other drugs with  
5 the same active ingredient, the interpretive  
6 criteria with respect to such drug—

7 “(I) differ from otherwise appli-  
8 cable interpretive criteria included in  
9 a standard listed under subparagraph  
10 (A) or interpretive criteria otherwise  
11 listed under this subparagraph; and

12 “(II) are determined by the Sec-  
13 retary to be appropriate for the drug.

14 “(C) REQUIRED STATEMENTS OF LIMITA-  
15 TIONS OF INFORMATION.—The Interpretive Cri-  
16 teria Website shall include the following:

17 “(i) A statement that—

18 “(I) the website provides infor-  
19 mation about the susceptibility of bac-  
20 teria, fungi, or other microorganisms  
21 to a certain drug (or drugs); and

22 “(II) the safety and efficacy of  
23 the drug in treating clinical infections  
24 due to such bacteria, fungi, or other  
25 microorganisms may not have been es-

1                    established in adequate and well-con-  
2                    trolled clinical trials and the clinical  
3                    significance of such susceptibility in-  
4                    formation in such trials is unknown.

5                    “(ii) A statement that directs health  
6                    care practitioners to consult the approved  
7                    product labeling for specific drugs to deter-  
8                    mine the uses for which the Food and  
9                    Drug Administration has approved the  
10                    product.

11                    “(iii) Any other statement that the  
12                    Secretary determines appropriate to ade-  
13                    quately convey the limitations of the data  
14                    supporting susceptibility test interpretive  
15                    criteria standard listed on the website.

16                    “(3) NOTICE.—Not later than the date on  
17                    which the Interpretive Criteria Website is estab-  
18                    lished, the Secretary shall publish a notice of that  
19                    establishment in the Federal Register.

20                    “(4) INAPPLICABILITY OF MISBRANDING PROVI-  
21                    SION.—The inclusion in the approved labeling of an  
22                    antimicrobial drug of a reference or hyperlink to the  
23                    Interpretive Criteria Website, in and of itself, shall  
24                    not cause the drug to be misbranded in violation of

1 section 502, or the regulations promulgated there-  
2 under.

3 “(5) TRADE SECRETS AND CONFIDENTIAL IN-  
4 FORMATION.—Nothing in this section shall be con-  
5 strued as authorizing the Secretary to disclose any  
6 information that is a trade secret or confidential in-  
7 formation subject to section 552(b)(4) of title 5,  
8 United States Code.

9 “(c) RECOGNITION OF SUSCEPTIBILITY TEST INTER-  
10 PRETIVE CRITERIA FROM STANDARD DEVELOPMENT OR-  
11 GANIZATIONS.—

12 “(1) IN GENERAL.—Beginning on the date of  
13 the establishment of the Interpretive Criteria  
14 Website, and at least every 6 months thereafter, the  
15 Secretary shall—

16 “(A) evaluate any appropriate new or up-  
17 dated susceptibility test interpretive criteria  
18 standards established by a nationally or inter-  
19 nationally recognized standard development or-  
20 ganization described in subsection (b)(2)(A)(i);  
21 and

22 “(B) publish on the public website of the  
23 Food and Drug Administration a notice—

1           “(i) withdrawing recognition of any  
2           different susceptibility test interpretive cri-  
3           teria standard, in whole or in part;

4           “(ii) recognizing the new or updated  
5           standards;

6           “(iii) recognizing one or more parts of  
7           the new or updated interpretive criteria  
8           specified in such a standard and declining  
9           to recognize the remainder of such stand-  
10          ard; and

11          “(iv) making any necessary updates to  
12          the lists under subsection (b)(2).

13           “(2) BASES FOR UPDATING INTERPRETIVE CRI-  
14          TERIA STANDARDS.—In evaluating new or updated  
15          susceptibility test interpretive criteria standards  
16          under paragraph (1)(A), the Secretary may con-  
17          sider—

18           “(A) the Secretary’s determination that  
19           such a standard is not applicable to a particular  
20           drug because the characteristics of the drug dif-  
21           fer from other drugs with the same active in-  
22           gredient;

23           “(B) information provided by interested  
24           third parties, including public comment on the



1 annual compilation of notices published under  
2 paragraph (3);

3 “(C) any bases used to identify suscepti-  
4 bility test interpretive criteria under subsection  
5 (a)(2); and

6 “(D) such other information or factors as  
7 the Secretary determines appropriate.

8 “(3) ANNUAL COMPILATION OF NOTICES.—  
9 Each year, the Secretary shall compile the notices  
10 published under paragraph (1)(B) and publish such  
11 compilation in the Federal Register and provide for  
12 public comment. If the Secretary receives comments,  
13 the Secretary will review such comments and, if the  
14 Secretary determines appropriate, update pursuant  
15 to this subsection susceptibility test interpretive cri-  
16 teria standards—

17 “(A) recognized by the Secretary under  
18 this subsection; or

19 “(B) otherwise listed on the Interpretive  
20 Criteria Website under subsection (b)(2).

21 “(4) RELATION TO SECTION 514(e).—Any sus-  
22 ceptibility test interpretive standard recognized  
23 under this subsection or any criteria otherwise listed  
24 under subsection (b)(2)(B) shall be deemed to be

1 recognized as a standard by the Secretary under sec-  
2 tion 514(c)(1).

3 “(5) VOLUNTARY USE OF INTERPRETIVE CRI-  
4 TERIA.—Nothing in this section prohibits a person  
5 from seeking approval or clearance of a drug or de-  
6 vice, or changes to the drug or the device, on the  
7 basis of susceptibility test interpretive criteria stand-  
8 ards which differ from those recognized pursuant to  
9 paragraph (1).

10 “(d) ANTIMICROBIAL DRUG LABELING.—

11 “(1) DRUGS MARKETED PRIOR TO ESTABLISH-  
12 MENT OF INTERPRETIVE CRITERIA WEBSITE.—With  
13 respect to an antimicrobial drug lawfully introduced  
14 or delivered for introduction into interstate com-  
15 merce for commercial distribution before the estab-  
16 lishment of the Interpretive Criteria Website, a hold-  
17 er of an approved application under section 505 or  
18 section 351 of the Public Health Service Act, as ap-  
19 plicable, for each such drug—

20 “(A) not later than 1 year after establish-  
21 ment of the Interpretive Criteria Website, shall  
22 submit to the Secretary a supplemental applica-  
23 tion for purposes of changing the drug’s label-  
24 ing to substitute a reference or hyperlink to

1           such Website for any susceptibility test inter-  
2           pretive criteria and related information; and

3                   “(B) may begin distribution of the drug in-  
4           volved upon receipt by the Secretary of the sup-  
5           plemental application for such change.

6           “(2) DRUGS MARKETED SUBSEQUENT TO ES-  
7           TABLISHMENT OF INTERPRETIVE CRITERIA  
8           WEBSITE.—With respect to antimicrobial drugs law-  
9           fully introduced or delivered for introduction into  
10          interstate commerce for commercial distribution on  
11          or after the date of the establishment of the Inter-  
12          pretive Criteria Website, the labeling for such a drug  
13          shall include, in lieu of susceptibility test interpretive  
14          criteria and related information, a reference to such  
15          Website.

16          “(e) SPECIAL CONDITION FOR MARKETING OF ANTI-  
17          MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

18                   “(1) IN GENERAL.—Notwithstanding sections  
19          501, 502, 510, 513, and 515, if the conditions speci-  
20          fied in paragraph (2) are met (in addition to other  
21          applicable provisions under this chapter) with re-  
22          spect to an antimicrobial susceptibility testing device  
23          described in subsection (f)(1), the Secretary may au-  
24          thorize the marketing of such device for a use de-  
25          scribed in such subsection.

1           “(2) CONDITIONS APPLICABLE TO ANTI-  
2           MICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

3           The conditions specified in this paragraph are the  
4           following:

5                   “(A) The device is used to make a deter-  
6                   mination of susceptibility using susceptibility  
7                   test interpretive criteria that are—

8                           “(i) included in a standard recognized  
9                           by the Secretary under subsection (c); or

10                           “(ii) otherwise listed on the Interpre-  
11                           tive Criteria Website under subsection  
12                           (b)(2).

13                   “(B) The labeling of such device promi-  
14                   nently and conspicuously—

15                           “(i) includes a statement that—

16                                   “(I) the device provides informa-  
17                                   tion about the susceptibility of bac-  
18                                   teria and fungi to certain drugs; and

19                                   “(II) the safety and efficacy of  
20                                   such drugs in treating clinical infec-  
21                                   tions due to such bacteria or fungi  
22                                   may not have been established in ade-  
23                                   quate and well-controlled clinical trials  
24                                   and the clinical significance of such

1                   susceptibility information in those in-  
2                   stances is unknown;

3                   “(ii) includes a statement directing  
4                   health care practitioners to consult the ap-  
5                   proved labeling for drugs tested using such  
6                   a device, to determine the uses for which  
7                   the Food and Drug Administration has ap-  
8                   proved such drugs; and

9                   “(iii) includes any other statement the  
10                  Secretary determines appropriate to ade-  
11                  quately convey the limitations of the data  
12                  supporting the interpretive criteria de-  
13                  scribed in subparagraph (A).

14               “(f) DEFINITIONS.—In this section:

15               “(1) The term ‘antimicrobial susceptibility test-  
16               ing device’ means a device that utilizes susceptibility  
17               test interpretive criteria to determine and report the  
18               in vitro susceptibility of certain microorganisms to a  
19               drug (or drugs).

20               “(2) The term ‘qualified infectious disease  
21               product’ means a qualified infectious disease product  
22               designated under section 505E(d).

23               “(3) The term ‘susceptibility test interpretive  
24               criteria’ means—

1           “(A) one or more specific numerical values  
2           which characterize the susceptibility of bacteria  
3           or other microorganisms to the drug tested; and

4           “(B) related categorizations of such sus-  
5           ceptibility, including categorization of the drug  
6           as susceptible, intermediate, resistant, or such  
7           other term as the Secretary determines appro-  
8           priate.

9           “(4)(A) The term ‘antimicrobial drug’ means,  
10          subject to subparagraph (B), a systemic anti-  
11          bacterial or antifungal drug that—

12           “(i) is intended for human use in the treat-  
13           ment of a disease or condition caused by a bac-  
14           terium or fungus;

15           “(ii) may include a qualified infectious dis-  
16           ease product designated under section 505E(d);  
17           and

18           “(iii) is subject to section 503(b)(1).

19          “(B) If provided by the Secretary through regu-  
20          lations, such term may include—

21           “(i) drugs other than systemic anti-  
22           bacterial and antifungal drugs; and

23           “(ii) biological products (as such term is  
24           defined in section 351 of the Public Health

1 Service Act) to the extent such products exhibit  
2 antimicrobial activity.

3 “(g) RULE OF CONSTRUCTION.—Nothing in this sec-  
4 tion shall be construed—

5 “(1) to alter the standards of evidence—

6 “(A) under subsection (c) or (d) of section  
7 505, including the substantial evidence stand-  
8 ard in section 505(d), or under section 351 of  
9 the Public Health Service Act (as applicable);  
10 or

11 “(B) with respect to marketing authoriza-  
12 tion for devices, under section 510, 513, or 515;

13 “(2) to apply with respect to any drug, device,  
14 or biological product, in any context other than—

15 “(A) an antimicrobial drug; or

16 “(B) an antimicrobial susceptibility testing  
17 device that uses susceptibility test interpretive  
18 criteria to characterize and report the in vitro  
19 susceptibility of certain bacteria, fungi, or other  
20 microorganisms to antimicrobial drugs in ac-  
21 cordance with this section; or

22 “(3) unless specifically stated, to have any ef-  
23 fect on authorities provided under other sections of  
24 this Act, including any regulations issued under such  
25 sections.”.

1 (b) CONFORMING AMENDMENTS.—

2 (1) REPEAL OF RELATED AUTHORITY.—Section  
3 1111 of the Food and Drug Administration Amend-  
4 ments Act of 2007 (42 U.S.C. 247d–5a; relating to  
5 identification of clinically susceptible concentrations  
6 of antimicrobials) is repealed.

7 (2) MISBRANDING.—Section 502 of the Federal  
8 Food, Drug, and Cosmetic Act (21 U.S.C. 352), as  
9 amended by section 2121, is further amended by  
10 adding at the end the following:

11 “(ee) If it is an antimicrobial drug and its labeling  
12 fails to conform with the requirements under section  
13 511(d).”.

14 (3) RECOGNITION OF INTERPRETIVE CRITERIA  
15 AS DEVICE STANDARD.—Section 514(e)(1)(A) of the  
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
17 360d(e)(1)(A)) is amended by inserting after “the  
18 Secretary shall, by publication in the Federal Reg-  
19 ister” the following: “(or, with respect to suscepti-  
20 bility test interpretive criteria or standards recog-  
21 nized or otherwise listed under section 511, by post-  
22 ing on the Interpretive Criteria Website in accord-  
23 ance with such section)”.

24 (c) REPORT TO CONGRESS.—Not later than two  
25 years after the date of enactment of this Act, the Sec-



1   retary of Health and Human Services shall submit to the  
2   Committee on Energy and Commerce of the House of  
3   Representatives and the Committee on Health, Education,  
4   Labor and Pensions of the Senate a report on the progress  
5   made in implementing section 511 of the Federal Food,  
6   Drug, and Cosmetic Act (21 U.S.C. 360a), as amended  
7   by this section.

8           (d) REQUESTS FOR UPDATES TO INTERPRETIVE CRI-  
9   TERIA WEBSITE.—Chapter 35 of title 44, United States  
10   Code, shall not apply to the collection of information from  
11   interested parties regarding the updating of lists under  
12   paragraph (2) of subsection (b) section 511 of the Federal  
13   Food, Drug, and Cosmetic Act (as amended by subsection  
14   (a)) and posted on the Interpretive Criteria Website estab-  
15   lished under paragraph (1) of such subsection (b).

16           (e) NO EFFECT ON HEALTH CARE PRACTICE.—  
17   Nothing in this subtitle (including the amendments made  
18   by this subtitle) shall be construed to restrict, in any man-  
19   ner, the prescribing or administering of antibiotics or  
20   other products by health care practitioners, or to limit the  
21   practice of health care.

22   **SEC. 2123. ENCOURAGING THE DEVELOPMENT AND USE OF**  
23                           **NEW ANTIMICROBIAL DRUGS.**

24           (a) ADDITIONAL PAYMENT FOR NEW ANTI-  
25   MICROBIAL DRUGS UNDER MEDICARE.—

1           (1) IN GENERAL.—Section 1886(d)(5) of the  
2           Social Security Act (42 U.S.C. 1395ww(d)(5)) is  
3           amended by adding at the end the following new  
4           subparagraph:

5           “(M)(i)(I) Effective for discharges beginning on or  
6           after October 1, 2017, the Secretary shall, after notice and  
7           opportunity for public comment (in the publications re-  
8           quired by subsection (e)(5) for a fiscal year or otherwise),  
9           provide for additional payment to be made under this sub-  
10          section in accordance with the provisions of this subpara-  
11          graph with respect to discharges by eligible hospitals that  
12          involve new antimicrobial drugs in the amount, subject to  
13          clause (vi), provided for under section 1847A.

14          “(II) Additional payments to be made under this sub-  
15          section shall be with respect to discharges involving a new  
16          antimicrobial drug that occur during the four-fiscal-year  
17          period beginning on which an inpatient hospital code is  
18          issued with respect to the drug.

19          “(ii) For purposes of this subparagraph, the term  
20          ‘new antimicrobial drug’ means a product that is approved  
21          for use, or a product for which an indication is first ap-  
22          proved for use, by the Food and Drug Administration on  
23          or after December 1, 2014, and that the Food and Drug  
24          Administration determines—

25                 “(I) either—

1           “(aa) is intended to treat an infection  
2           caused by, or likely to be caused by, a quali-  
3           fying pathogen (as defined under section  
4           505E(f) of the Federal Food, Drug, and Cos-  
5           metic Act); or

6           “(bb) meets the definition of a qualified in-  
7           fectious disease product under section 505E(g)  
8           of the Federal Food, Drug, and Cosmetic Act;

9           “(II) is intended to treat an infection for which  
10          there is an ‘unmet medical need’; and

11          “(III) is intended to treat an infection associ-  
12          ated with high rates of mortality or significant pa-  
13          tient morbidity, as determined in consultation with  
14          the infectious disease professional community.

15          “(iii) For purposes of this subparagraph, the term  
16          ‘eligible hospital’ means a hospital that participates in the  
17          National Healthcare Safety Network of the Centers for  
18          Disease Control and Prevention (or, to the extent a similar  
19          surveillance system reporting program that includes re-  
20          porting about antimicrobial drugs is determined by the  
21          Secretary to be available to such hospitals, such similar  
22          surveillance system as the Secretary may specify).

23          “(iv) The Secretary may only revoke a determination  
24          of a product under this subparagraph as a new anti-  
25          microbial drug if the Secretary finds that the request for

1 such determination contained an untrue statement of ma-  
2 terial fact.

3 “(v) Not later than October 1, 2017, the Secretary  
4 shall first publish in the Federal Register a list of the new  
5 antimicrobial drugs. Each fiscal year thereafter, the Sec-  
6 retary shall publish a list of the new antimicrobial drugs  
7 for such fiscal year as part of the annual rulemaking  
8 under this subsection.

9 “(vi)(I) The total of the additional payments made  
10 under this subsection pursuant to this subparagraph for  
11 discharges in a fiscal year (as estimated by the Secretary  
12 as part of the rulemaking under this subsection for the  
13 fiscal year) may not exceed the applicable percentage  
14 (specified in subclause (II)) of the total program payments  
15 estimated to be made under this subsection for all dis-  
16 charges in such fiscal year (as calculated by the Secretary  
17 as part of the rulemaking under this subsection for the  
18 fiscal year). For purposes of the preceding sentence, in  
19 the case that, with respect to a fiscal year, such additional  
20 payments are made only with respect to discharges during  
21 a portion of such fiscal year, the reference to ‘all dis-  
22 charges in such fiscal year’ shall be considered a reference  
23 to all discharges during such portion of such fiscal year.

1       “(II) For purposes of subclause (I), the term ‘appli-  
2 cable percentage’ means, for fiscal year 2018 and each fis-  
3 cal year thereafter, 0.06807 percent.

4       “(III) If the Secretary estimates before the beginning  
5 of a fiscal year that the amount of the additional payments  
6 under this subsection pursuant to this subparagraph for  
7 the fiscal year (or portion thereof) as determined under  
8 subclause (I) will exceed the limit established under such  
9 subclause, the Secretary shall reduce pro rata the amount  
10 of each of the additional payments under this subsection  
11 pursuant to this subparagraph for such fiscal year (or por-  
12 tion thereof) in order to ensure that the aggregate addi-  
13 tional payments under this subsection pursuant to this  
14 paragraph (as so estimated) do not exceed such limit.”.

15           (2) CONFORMING AMENDMENTS.—

16           (A) NO DUPLICATIVE NTAP PAYMENTS.—

17           Section 1886(d)(5)(K)(i) of the Social Security  
18 Act (42 U.S.C. 1395ww(d)(5)(K)(i)) is amend-  
19 ed by inserting “and with respect to which an  
20 additional payment is not made pursuant to  
21 subparagraph (M),” after “2001,”.

22           (B) ACCESS TO PRICE INFORMATION.—

23           Section 1927(b)(3)(A)(iii) of the Social Security  
24 Act (42 U.S.C. 1396r-8(b)(3)(A)(iii)) is  
25 amended—

1 (i) in subclause (II), by inserting “, or  
2 under section 1886(d) pursuant to para-  
3 graph (5)(M) of such section,” after  
4 “1847A,”; and

5 (ii) in the matter following subclause  
6 (III), by inserting “or section  
7 1886(d)(5)(M)” after  
8 “1881(b)(13)(A)(ii)”.

9 (b) STUDY AND REPORT ON REMOVING BARRIERS TO  
10 DEVELOPMENT OF NEW ANTIMICROBIAL DRUGS.—

11 (1) STUDY.—The Comptroller General of the  
12 United States shall conduct a study to—

13 (A) identify and examine the barriers that  
14 prevent the development of new antimicrobial  
15 drugs, as defined in section 1886(d)(5)(M)(iii)  
16 of the Social Security Act (42 U.S.C.  
17 1395ww(d)(5)(M)(iii)); and

18 (B) develop recommendations for actions  
19 to be taken in order to overcome any barriers  
20 identified under subparagraph (A).

21 (2) CONSIDERATION.—In conducting such  
22 study, the Comptroller General shall take into ac-  
23 count the perspectives of the Director of the Na-  
24 tional Institutes of Health, the Commissioner of the

1 Food and Drugs, and the Director of the Centers for  
2 Disease Control and Prevention.

3 (3) REPORT.—Not later than 1 year after the  
4 date of the enactment of this Act, the Comptroller  
5 General shall submit to Congress a report on the  
6 study conducted under paragraph (1).

7 **Subtitle H—Vaccine Access,**  
8 **Certainty, and Innovation**

9 **SEC. 2141. TIMELY REVIEW OF VACCINES BY THE ADVISORY**  
10 **COMMITTEE ON IMMUNIZATION PRACTICES.**

11 Section 2102(a) of the Public Health Service Act (42  
12 U.S.C. 300aa–2(a)) is amended by adding at the end the  
13 following:

14 “(10) ADVISORY COMMITTEE ON IMMUNIZATION  
15 PRACTICES.—

16 “(A) STANDARD PERIODS OF TIME FOR  
17 MAKING RECOMMENDATIONS.—Upon the licen-  
18 sure of any vaccine or any new indication for a  
19 vaccine, the Director of the Program shall di-  
20 rect the Advisory Committee on Immunization  
21 Practices, at its next regularly scheduled meet-  
22 ing, to consider the use of the vaccine.

23 “(B) EXPEDITED REVIEW PURSUANT TO  
24 REQUEST BY SPONSOR OR MANUFACTURER.—If  
25 the Advisory Committee does not make rec-

1           ommendations with respect to the use of a vac-  
2           cine at the Advisory Committee’s first regularly  
3           scheduled meeting after the licensure of the  
4           vaccine or any new indication for the vaccine,  
5           the Advisory Committee, at the request of the  
6           sponsor of the vaccine, shall make such rec-  
7           ommendations on an expedited basis.

8           “(C) EXPEDITED REVIEW FOR BREAK-  
9           THROUGH THERAPIES AND FOR USE DURING  
10          PUBLIC HEALTH EMERGENCIES.—If a vaccine  
11          is designated as a breakthrough therapy under  
12          section 506 of the Federal Food, Drug, and  
13          Cosmetic Act and is licensed under section 351  
14          of this Act, the Advisory Committee shall make  
15          recommendations with respect to the use of the  
16          vaccine on an expedited basis.

17          “(D) DEFINITION.—In this paragraph, the  
18          terms ‘Advisory Committee on Immunization  
19          Practices’ and ‘Advisory Committee’ mean the  
20          advisory committee on immunization practices  
21          established by the Secretary pursuant to section  
22          222, acting through the Director of the Centers  
23          for Disease Control and Prevention.”.



1 **SEC. 2142. REVIEW OF PROCESSES AND CONSISTENCY OF**  
2 **ACIP RECOMMENDATIONS.**

3 (a) REVIEW.—The Director of the Centers for Dis-  
4 ease Control and Prevention shall conduct a review of the  
5 process used by the Advisory Committee on Immunization  
6 Practices to evaluate consistency in formulating and  
7 issuing recommendations pertaining to vaccines.

8 (b) CONSIDERATIONS.—The review under subsection  
9 (a) shall include assessment of—

10 (1) the criteria used to evaluate new and exist-  
11 ing vaccines;

12 (2) the Grading of Recommendations, Assess-  
13 ment, Development, and Evaluation (GRADE) ap-  
14 proach to the review and analysis of scientific and  
15 economic data, including the scientific basis for such  
16 approach; and

17 (3) the extent to which the processes used by  
18 the working groups of the Advisory Committee on  
19 Immunization Practices are consistent among  
20 groups.

21 (c) STAKEHOLDERS.—In carrying out the review  
22 under subsection (a), the Director of the Centers for Dis-  
23 ease Control and Prevention shall solicit input from vac-  
24 cine stakeholders.

25 (d) REPORT.—Not later than 18 months after the  
26 date of enactment of this Act, the Director of the Centers

1 for Disease Control and Prevention shall submit to the  
2 appropriate committees of the Congress and make publicly  
3 available a report on the results of the review under sub-  
4 section (a), including recommendations on improving the  
5 consistency of the process described in such subsection.

6 (e) DEFINITION.—In this section, the term “Advisory  
7 Committee on Immunization Practices” means the advi-  
8 sory committee on immunization practices established by  
9 the Secretary of Health and Human Services pursuant to  
10 section 222 of the Public Health Service Act (42 U.S.C.  
11 217a), acting through the Director of the Centers for Dis-  
12 ease Control and Prevention.

13 **SEC. 2143. MEETINGS BETWEEN CDC AND VACCINE DEVEL-**  
14 **OPERS.**

15 Section 310 of the Public Health Service Act (42  
16 U.S.C. 242o) is amended by adding at the end the fol-  
17 lowing:

18 “(c)(1) In this subsection, the term ‘vaccine devel-  
19 oper’ means a nongovernmental entity engaged in—

20 “(A)(i) the development of a vaccine with the  
21 intent to pursue licensing of the vaccine by the Food  
22 and Drug Administration; or

23 “(ii) the production of a vaccine licensed by the  
24 Food and Drug Administration; and

25 “(B) vaccine research.

1           “(2)(A) Upon the submission of a written request for  
2 a meeting by a vaccine developer, that includes a justifica-  
3 tion for the meeting, the Secretary, acting through the Di-  
4 rector of the Centers for Disease Control and Prevention,  
5 shall convene a meeting of representatives of the vaccine  
6 developer and experts from the Centers for Disease Con-  
7 trol and Prevention in immunization programs, epidemi-  
8 ology, and other relevant areas at which the Director (or  
9 the Director’s designee), for the purpose of informing the  
10 vaccine developer’s understanding of public health needs  
11 and priorities, shall provide the perspectives of the Centers  
12 for Disease Control and Prevention and other relevant  
13 Federal agencies regarding—

14           “(i) public health needs, epidemiology, and im-  
15 plementation considerations with regard to a vaccine  
16 developer’s potential vaccine profile; and

17           “(ii) potential implications of such perspectives  
18 for the vaccine developer’s vaccine research and de-  
19 velopment planning.

20           “(B) In addition to the representatives specified in  
21 subparagraph (A), the Secretary may, with the agreement  
22 of the vaccine developer requesting a meeting under such  
23 subparagraph, include in such meeting representatives  
24 of—

25           “(i) the Food and Drug Administration; and

1           “(ii) the National Vaccine Program.

2           “(C) The Secretary shall convene a meeting re-  
3 requested under subparagraph (A) not later than 120 days  
4 after receipt of the request for the meeting.

5           “(3)(A) Upon the submission of a written request by  
6 a vaccine developer, the Secretary, acting through the Di-  
7 rector of the Centers for Disease Control and Prevention,  
8 shall provide to the vaccine developer any age-based or  
9 other demographically assessed disease epidemiological  
10 analyses or data that—

11           “(i) are specified in the request;

12           “(ii) have been published;

13           “(iii) have been performed by or are in the pos-  
14 session of the Centers;

15           “(iv) are not a trade secret or commercial or fi-  
16 nancial information that is privileged or confidential  
17 and subject to section 552(b)(4) of title 5, United  
18 States Code, or section 1905 of title 18, United  
19 States Code; and

20           “(v) do not contain individually identifiable in-  
21 formation.

22           “(B) The Secretary shall provide analyses requested  
23 by a vaccine manufacturer under subparagraph (A) not  
24 later than 120calendar days after receipt of the request  
25 for the analyses.

1 “(4) The Secretary shall promptly notify a vaccine  
2 developer if—

3 “(A) the Secretary becomes aware of any  
4 change to information that was—

5 “(i) shared by the Secretary with the vac-  
6 cine developer during a meeting under para-  
7 graph (2); or

8 “(ii) provided by the Secretary to the vac-  
9 cine developer in one or more analyses under  
10 paragraph (3); and

11 “(B) the change may have implications for the  
12 vaccine developer’s vaccine research and develop-  
13 ment.”.

14 **Subtitle I—Orphan Product Exten-**  
15 **sions Now; Incentives for Cer-**  
16 **tain Products for Limited Popu-**  
17 **lations**

18 **SEC. 2151. EXTENSION OF EXCLUSIVITY PERIODS FOR A**  
19 **DRUG APPROVED FOR A NEW INDICATION**  
20 **FOR A RARE DISEASE OR CONDITION.**

21 (a) IN GENERAL.—Chapter V of the Federal Food,  
22 Drug, and Cosmetic Act, as amended by section 2063, is  
23 further amended by inserting after section 505F of such  
24 Act the following:

1 **“SEC. 505G. EXTENSION OF EXCLUSIVITY PERIODS FOR A**  
2 **DRUG APPROVED FOR A NEW INDICATION**  
3 **FOR A RARE DISEASE OR CONDITION.**

4 “(a) DESIGNATION.—

5 “(1) IN GENERAL.—The Secretary shall des-  
6 ignate a drug as a drug approved for a new indica-  
7 tion to prevent, diagnose, or treat a rare disease or  
8 condition for purposes of granting the extensions  
9 under subsection (b) if—

10 “(A) prior to approval of an application or  
11 supplemental application for the new indication,  
12 the drug was approved or licensed for mar-  
13 keting under section 505(c) of this Act or sec-  
14 tion 351(a) of the Public Health Service Act,  
15 but was not so approved or licensed for the new  
16 indication;

17 “(B)(i) the sponsor of the approved or li-  
18 censed drug files an application or a supple-  
19 mental application for approval of the new indi-  
20 cation for use of the drug to prevent, diagnose,  
21 or treat the rare disease or condition; and

22 “(ii) the Secretary approves the application  
23 or supplemental application; and

24 “(C) the application or supplemental appli-  
25 cation for the new indication contains the con-  
26 sent of the applicant to notice being given by

1 the Secretary under paragraph (4) respecting  
2 the designation of the drug.

3 “(2) REVOCATION OF DESIGNATION.—

4 “(A) IN GENERAL.—Except as provided in  
5 subparagraph (B), a designation under this  
6 subsection shall not be revoked for any reason.

7 “(B) EXCEPTION.—The Secretary may re-  
8 voke a designation of a drug under paragraph  
9 (1) if the Secretary finds that the application or  
10 supplemental application resulting in such des-  
11 ignation contained an untrue statement of ma-  
12 terial fact.

13 “(3) NOTIFICATION PRIOR TO DISCONTINUANCE  
14 OF PRODUCTION FOR SOLELY COMMERCIAL REA-  
15 SONS.—A designation of a drug under paragraph (1)  
16 shall be subject to the condition that the sponsor of  
17 the drug will notify the Secretary of any discontinu-  
18 ance of the production of the drug for solely com-  
19 mercial reasons at least one year before such dis-  
20 continuance.

21 “(4) NOTICE TO PUBLIC.—Notice respecting  
22 the designation of a drug under paragraph (1) shall  
23 be made available to the public.

1       “(b) EXTENSION.—If the Secretary designates a  
2 drug as a drug approved for a new indication for a rare  
3 disease or condition, as described in subsection (a)(1)—

4               “(1)(A) the 4-, 5-, and 7 ½-year periods de-  
5 scribed in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii)  
6 of section 505, the 3-year periods described in  
7 clauses (iii) and (iv) of subsection (c)(3)(E) and  
8 clauses (iii) and (iv) of subsection (j)(5)(F) of sec-  
9 tion 505, and the 7-year period described in section  
10 527, as applicable, shall be extended by 6 months;  
11 or

12               “(B) the 4- and 12-year periods described in  
13 subparagraphs (A) and (B) of section 351(k)(7) of  
14 the Public Health Service Act and the 7-year period  
15 described in section 527, as applicable, shall be ex-  
16 tended by 6 months; and

17               “(2)(A) if the drug is the subject of a listed  
18 patent for which a certification has been submitted  
19 under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of  
20 section 505 or a listed patent for which a certifi-  
21 cation has been submitted under subsections  
22 (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,  
23 the period during which an application may not be  
24 approved under section 505(c)(3) or section  
25 505(j)(5)(B) shall be extended by a period of 6



1 months after the date the patent expires (including  
2 any patent extensions); or

3 “(B) if the drug is the subject of a listed patent  
4 for which a certification has been submitted under  
5 subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of sec-  
6 tion 505, and in the patent infringement litigation  
7 resulting from the certification the court determines  
8 that the patent is valid and would be infringed, the  
9 period during which an application may not be ap-  
10 proved under section 505(c)(3) or section  
11 505(j)(5)(B) shall be extended by a period of 6  
12 months after the date the patent expires (including  
13 any patent extensions).

14 “(c) RELATION TO PEDIATRIC AND QUALIFIED IN-  
15 FECTIOUS DISEASE PRODUCT EXCLUSIVITY.—Any exten-  
16 sion under subsection (b) of a period shall be in addition  
17 to any extension of the periods under sections 505A and  
18 505E of this Act and section 351(m) of the Public Health  
19 Service Act, as applicable, with respect to the drug.

20 “(d) LIMITATIONS.—The extension described in sub-  
21 section (b) shall not apply if the drug designated under  
22 subsection (a)(1) has previously received an extension by  
23 operation of subsection (b).

1       “(e) DEFINITION.—In this section, the term ‘rare  
2 disease or condition’ has the meaning given to such term  
3 in section 526(a)(2).”.

4       (b) APPLICATION.—Section 505G of the Federal  
5 Food, Drug, and Cosmetic Act, as added by subsection  
6 (a), applies only with respect to a drug for which an appli-  
7 cation or supplemental application described in subsection  
8 (a)(1)(B)(i) of such section 505G is first approved under  
9 section 505(c) of such Act (21 U.S.C. 355(c)) or section  
10 351(a) of the Public Health Service Act (42 U.S.C.  
11 262(a)) on or after the date of the enactment of this Act.

12       (c) CONFORMING AMENDMENTS.—

13               (1) RELATION TO PEDIATRIC EXCLUSIVITY FOR  
14 DRUGS.—Section 505A of the Federal Food, Drug,  
15 and Cosmetic Act (21 U.S.C. 355a) is amended—

16                       (A) in subsection (b), by adding at the end  
17                       the following:

18               “(3) RELATION TO EXCLUSIVITY FOR A DRUG  
19 APPROVED FOR A NEW INDICATION FOR A RARE DIS-  
20 EASE OR CONDITION.—Notwithstanding the ref-  
21 erences in subsection (b)(1) to the lengths of the ex-  
22 clusivity periods after application of pediatric exclu-  
23 sivity, the 6-month extensions described in sub-  
24 section (b)(1) shall be in addition to any extensions  
25 under section 505G.”; and

1 (B) in subsection (c), by adding at the end  
2 the following:

3 “(3) RELATION TO EXCLUSIVITY FOR A DRUG  
4 APPROVED FOR A NEW INDICATION FOR A RARE DIS-  
5 EASE OR CONDITION.—Notwithstanding the ref-  
6 erences in subsection (c)(1) to the lengths of the ex-  
7 clusivity periods after application of pediatric exclu-  
8 sivity, the 6-month extensions described in sub-  
9 section (c)(1) shall be in addition to any extensions  
10 under section 505G.”.

11 (2) RELATION TO EXCLUSIVITY FOR NEW  
12 QUALIFIED INFECTIOUS DISEASE PRODUCTS THAT  
13 ARE DRUGS.—Subsection (b) of section 505E of the  
14 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
15 355f) is amended—

16 (A) by amending the subsection heading to  
17 read as follows: “RELATION TO PEDIATRIC EX-  
18 CLUSIVITY AND EXCLUSIVITY FOR A DRUG AP-  
19 PROVED FOR A NEW INDICATION FOR A RARE  
20 DISEASE OR CONDITION”; and

21 (B) by striking “any extension of the pe-  
22 riod under section 505A” and inserting “any  
23 extension of the periods under sections 505A  
24 and 505G, as applicable,”.

1           (3) RELATION TO PEDIATRIC EXCLUSIVITY FOR  
2 BIOLOGICAL PRODUCTS.—Section 351(m) of the  
3 Public Health Service Act (42 U.S.C. 262(m)) is  
4 amended by adding at the end the following:

5           “(5) RELATION TO EXCLUSIVITY FOR A BIO-  
6 LOGICAL PRODUCT APPROVED FOR A NEW INDICA-  
7 TION FOR A RARE DISEASE OR CONDITION.—Not-  
8 withstanding the references in paragraphs (2)(A),  
9 (2)(B), (3)(A), and (3)(B) to the lengths of the ex-  
10 clusivity periods after application of pediatric exclu-  
11 sivity, the 6-month extensions described in such  
12 paragraphs shall be in addition to any extensions  
13 under section 505G.”.

14 **SEC. 2152. REAUTHORIZATION OF RARE PEDIATRIC DIS-**  
15 **EASE PRIORITY REVIEW VOUCHER INCEN-**  
16 **TIVE PROGRAM.**

17           (a) IN GENERAL.—Section 529 of the Federal Food,  
18 Drug, and Cosmetic Act (21 U.S.C. 360ff) is amended—

19           (1) in subsection (a)—

20           (A) in paragraph (3), by amending sub-  
21 paragraph (A) to read as follows:

22           “(A) The disease is a serious or life-threat-  
23 ening disease in which the serious or life-threat-  
24 ening manifestations primarily affect individ-  
25 uals aged from birth to 18 years, including age

1 groups often called neonates, infants, children,  
2 and adolescents.”; and

3 (B) in paragraph (4)(A)—

4 (i) in subparagraph (E), by striking  
5 “and”;

6 (ii) in subparagraph (F), by striking  
7 the period and inserting “; and”; and

8 (iii) by adding at the end the fol-  
9 lowing:

10 “(G) is for a drug or biological product for  
11 which a priority review voucher has not been  
12 issued under section 524 (relating to tropical  
13 disease products).”; and

14 (2) in subsection (b), by striking paragraph (5)  
15 and inserting the following:

16 “(5) TERMINATION OF AUTHORITY.—The Sec-  
17 retary may not award any priority review vouchers  
18 under paragraph (1) after December 31, 2018.”.

19 (b) GAO STUDY AND REPORT.—

20 (1) STUDY.—The Comptroller General of the  
21 United States shall conduct a study on the effective-  
22 ness of awarding priority review vouchers under sec-  
23 tion 529 of the Federal Food, Drug, and Cosmetic  
24 Act (21 U.S.C. 360ff) in providing incentives for the  
25 development of drugs that treat or prevent rare pe-

1 diatric diseases that would not otherwise have been  
2 developed. In conducting such study, the Comp-  
3 troller General shall examine the following:

4 (A) The indications for which each drug  
5 for which a priority review voucher was award-  
6 ed under such section 529 was approved under  
7 section 505 of such Act (21 U.S.C. 355) or sec-  
8 tion 351 of the Public Health Service Act (42  
9 U.S.C. 262).

10 (B) Whether the priority review voucher  
11 impacted a sponsor's decision to invest in devel-  
12 oping a drug to treat or prevent a rare pedi-  
13 atric disease.

14 (C) An analysis of the drugs that utilized  
15 such priority review vouchers, which shall in-  
16 clude—

17 (i) the indications for which such  
18 drugs were approved under section 505 of  
19 the Federal Food, Drug, and Cosmetic Act  
20 (21 U.S.C. 355) or section 351 of the Pub-  
21 lic Health Service Act (42 U.S.C. 262);

22 (ii) whether unmet medical needs were  
23 addressed through the approval of such  
24 drugs, including, for each such drug—

1 (I) if an alternative therapy was  
2 previously available to treat the indi-  
3 cation; and

4 (II) the benefit or advantage the  
5 drug provided over another available  
6 therapy;

7 (iii) the number of patients potentially  
8 treated by such drugs;

9 (iv) the value of the priority review  
10 voucher if transferred; and

11 (v) the length of time between the  
12 date on which a priority review voucher  
13 was awarded and the date on which it was  
14 used.

15 (D) With respect to the priority review  
16 voucher program under section 529 of the Fed-  
17 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
18 360ff)—

19 (i) the resources used by, and burden  
20 placed on, the Food and Drug Administra-  
21 tion in implementing such program, includ-  
22 ing the effect of such program on the Food  
23 and Drug Administration's review of drugs  
24 for which a priority review voucher was not  
25 awarded or used;

1           (ii) the impact of the priority review  
2           voucher program on the public health as a  
3           result of the expedited review of applica-  
4           tions for drugs that treat or prevent non-  
5           serious indications that are generally used  
6           by the broader public; and

7           (iii) alternative approaches to improv-  
8           ing such program so that the program is  
9           appropriately targeted towards providing  
10          incentives for the development of clinically  
11          important drugs that—

12                   (I) prevent or treat rare pediatric  
13                   diseases; and

14                   (II) would likely not otherwise  
15                   have been developed to prevent or  
16                   treat such diseases.

17           (2) REPORT.—Not later than December 31,  
18           2017, the Comptroller General of the United States  
19           shall submit to the Committee on Energy and Com-  
20           merce of the House of Representatives and the Com-  
21           mittee on Health, Education, Labor and Pensions of  
22           the Senate a report containing the results of the  
23           study of conducted under paragraph (1).



1 **Subtitle J—Domestic Manufac-**  
2 **turing and Export Efficiencies**

3 **SEC. 2161. GRANTS FOR STUDYING THE PROCESS OF CON-**  
4 **TINUOUS DRUG MANUFACTURING.**

5 (a) IN GENERAL.—The Commissioner of Food and  
6 Drugs may award grants to institutions of higher edu-  
7 cation and nonprofit organizations for the purpose of  
8 studying and recommending improvements to the process  
9 of continuous manufacturing of drugs and biological prod-  
10 ucts and similar innovative monitoring and control tech-  
11 niques.

12 (b) DEFINITIONS.—In this section:

13 (1) The term “drug” has the meaning given to  
14 such term in section 201 of the Federal Food, Drug,  
15 and Cosmetic Act (21 U.S.C. 321).

16 (2) The term “biological product” has the  
17 meaning given to such term in section 351(i) of the  
18 Public Health Service Act (42 U.S.C. 262(i)).

19 (3) The term “institution of higher education”  
20 has the meaning given to such term in section 101  
21 of the Higher Education Act of 1965 (20 U.S.C.  
22 1001).

23 (c) AUTHORIZATION OF APPROPRIATIONS.—There is  
24 authorized to be appropriated \$5,000,000 for each of fis-  
25 cal years 2016 through 2020 to carry out this section.

1 **SEC. 2162. RE-EXPORTATION AMONG MEMBERS OF THE EU-**  
2 **ROPEAN ECONOMIC AREA.**

3 Section 1003 of the Controlled Substances Import  
4 and Export Act (21 U.S.C. 953) is amended—

5 (1) in subsection (f)—

6 (A) in paragraph (5)—

7 (i) by striking “(5)” and inserting  
8 “(5)(A)”;

9 (ii) by inserting “, except that the  
10 controlled substance may be exported from  
11 the second country to another country that  
12 is a member of the European Economic  
13 Area” before the period at the end; and

14 (iii) by adding at the end the fol-  
15 lowing:

16 “(B) Subsequent to any re-exportation de-  
17 scribed in subparagraph (A), a controlled substance  
18 may continue to be exported from any country that  
19 is a member of the European Economic Area to any  
20 other such country, provided that—

21 “(i) the conditions applicable with respect  
22 to the first country under paragraphs (1), (2),  
23 (3), (4), (6), and (7) are met by each subse-  
24 quent country from which the controlled sub-  
25 stance is exported pursuant to this paragraph;  
26 and

1           “(ii) the conditions applicable with respect  
2           to the second country under such paragraphs  
3           are met by each subsequent country to which  
4           the controlled substance is exported pursuant to  
5           this paragraph.”; and

6           (B) in paragraph (6)—

7                 (i) by striking “(6)” and inserting  
8                 “(6)(A)”; and

9                 (ii) by adding at the end the fol-  
10                lowing:

11           “(B) In the case of re-exportation among mem-  
12           bers of the European Economic Area, within 30  
13           days after each re-exportation, the person who ex-  
14           ported the controlled substance from the United  
15           States delivers to the Attorney General—

16                 “(i) documentation certifying that such re-  
17                 exportation has occurred; and

18                 “(ii) information concerning the consignee,  
19                 country, and product.”; and

20           (2) by adding at the end the following:

21           “(g) LIMITATION.—The Attorney General shall not  
22           promulgate nor enforce any regulation, subregulatory  
23           guidance, or enforcement policy which impedes re-expor-  
24           tation among European Economic Area countries (as pro-

1 vided in subsection (f)(5)), including by promulgating or  
2 enforcing any requirement that—

3 “(1) re-exportation from the first country to the  
4 second country or re-exportation from the second  
5 country to another country (as such terms are used  
6 in subsection (f)) occur within a specified period of  
7 time; or

8 “(2) information concerning the consignee,  
9 country, and product be provided prior to expor-  
10 tation of the controlled substance from the United  
11 States or prior to each re-exportation among mem-  
12 bers of the European Economic Area.”.

## 13 **Subtitle K—Enhancing** 14 **Combination Products Review**

### 15 **SEC. 2181. ENHANCING COMBINATION PRODUCTS REVIEW.**

16 Section 503(g)(4)(C) of the Federal Food, Drug, and  
17 Cosmetic Act (21 U.S.C. 353(g)(4)(C)) is amended by  
18 adding at the end the following new clause:

19 “(iii) Not later than 18 months after the date  
20 of the enactment of the 21st Century Cures Act, the  
21 Secretary shall issue final guidance that describes  
22 the responsibilities of each agency center regarding  
23 its review of combination products. The Secretary  
24 shall, after soliciting public comment, review and up-  
25 date the guidance periodically.”.

1       **Subtitle L—Priority Review for**  
2                   **Breakthrough Devices**

3       **SEC. 2201. PRIORITY REVIEW FOR BREAKTHROUGH DE-**  
4                   **VICES.**

5           (a) IN GENERAL.—Chapter V of the Federal Food,  
6 Drug, and Cosmetic Act is amended—

7               (1) in section 515(d)—

8                   (A) by striking paragraph (5); and

9                   (B) by redesignating paragraph (6) as  
10 paragraph (5); and

11               (2) by inserting after section 515A (21 U.S.C.  
12 360e–1) the following:

13       **“SEC. 515B. PRIORITY REVIEW FOR BREAKTHROUGH DE-**  
14                   **VICES.**

15           “(a) IN GENERAL.—In order to provide for more ef-  
16 fective treatment or diagnosis of life-threatening or irre-  
17 versibly debilitating human diseases or conditions, the  
18 Secretary shall establish a program to provide priority re-  
19 view for devices—

20               “(1) representing breakthrough technologies;

21               “(2) for which no approved alternatives exist;

22               “(3) offering significant advantages over exist-  
23 ing approved or cleared alternatives, including the  
24 potential to, compared to existing approved or  
25 cleared alternatives, reduce or eliminate the need for

1 hospitalization, improve patient quality of life, facili-  
2 tate patients' ability to manage their own care (such  
3 as through self-directed personal assistance), or es-  
4 tablish long-term clinical efficiencies; or

5 “(4) the availability of which is in the best in-  
6 terest of patients.

7 “(b) REQUEST FOR DESIGNATION.—A sponsor of a  
8 device may request that the Secretary designate the device  
9 for priority review under this section. Any such request  
10 for designation may be made at any time prior to the sub-  
11 mission of an application under section 515(c), a petition  
12 for classification under section 513(f)(2), or a notification  
13 under section 510(k).

14 “(c) DESIGNATION PROCESS.—

15 “(1) IN GENERAL.—Not later than 60 calendar  
16 days after the receipt of a request under subsection  
17 (b), the Secretary shall determine whether the device  
18 that is the subject of the request meets the criteria  
19 described in subsection (a). If the Secretary deter-  
20 mines that the device meets the criteria, the Sec-  
21 retary shall designate the device for priority review.

22 “(2) REVIEW.—Review of a request under sub-  
23 section (b) shall be undertaken by a team that is  
24 composed of experienced staff and managers of the

1 Food and Drug Administration and is chaired by a  
2 senior manager.

3 “(3) DESIGNATION DETERMINATION.—A deter-  
4 mination approving or denying a request under sub-  
5 section (b) shall be considered a significant decision  
6 under section 517A and the Secretary shall provide  
7 a written, substantive summary of the basis for the  
8 determination in accordance with section 517A(a).

9 “(4) RECONSIDERATION.—

10 “(A) REQUEST FOR RECONSIDERATION.—  
11 Any person whose request under subsection (b)  
12 is denied may, within 30 days of the denial, re-  
13 quest reconsideration of the denial in accord-  
14 ance with section 517A(b)—

15 “(i) based upon the submission of  
16 documents by such person; or

17 “(ii) based upon such documents and  
18 a meeting or teleconference.

19 “(B) RESPONSE.—Reconsideration of a  
20 designation determination under this paragraph  
21 shall be conducted in accordance with section  
22 517A(b).

23 “(5) WITHDRAWAL.—If the Secretary approves  
24 a priority review designation for a device under this  
25 section, the Secretary may not withdraw the des-

1       ignation based on the fact that the criteria specified  
2       in subsection (a) are no longer met because of the  
3       subsequent clearance or approval of another device  
4       that was designated under—

5               “(A) this section; or

6               “(B) section 515(d)(5) (as in effect imme-  
7               diately prior to the enactment of the 21st Cen-  
8               tury Cures Act).

9       “(d) PRIORITY REVIEW.—

10           “(1) ACTIONS.—For purposes of expediting the  
11           development and review of devices designated under  
12           subsection (c), the Secretary shall—

13               “(A) assign a team of staff, including a  
14               team leader with appropriate subject matter ex-  
15               pertise and experience, for each device for  
16               which a request is submitted under subsection  
17               (b);

18               “(B) provide for oversight of the team by  
19               senior agency personnel to facilitate the effi-  
20               cient development of the device and the efficient  
21               review of any submission described in sub-  
22               section (b) for the device;

23               “(C) adopt an efficient process for timely  
24               dispute resolution;



1           “(D) provide for interactive communication  
2 with the sponsor of the device during the review  
3 process;

4           “(E) expedite the Secretary’s review of  
5 manufacturing and quality systems compliance,  
6 as applicable;

7           “(F) disclose to the sponsor in advance the  
8 topics of any consultation concerning the spon-  
9 sor’s device that the Secretary intends to under-  
10 take with external experts or an advisory com-  
11 mittee and provide the sponsor an opportunity  
12 to recommend such external experts;

13           “(G) for applications submitted under sec-  
14 tion 515(c), provide for advisory committee  
15 input, as the Secretary determines appropriate  
16 (including in response to the request of the  
17 sponsor); and

18           “(H) assign staff to be available within a  
19 reasonable time to address questions by institu-  
20 tional review committees concerning the condi-  
21 tions and clinical testing requirements applica-  
22 ble to the investigational use of the device pur-  
23 suant to an exemption under section 520(g).

24           “(2) ADDITIONAL ACTIONS.—In addition to the  
25 actions described in paragraph (1), for purposes of

1 expediting the development and review of devices  
2 designated under subsection (c), the Secretary, in  
3 collaboration with the device sponsor, may, as appro-  
4 priate—

5 “(A) coordinate with the sponsor regarding  
6 early agreement on a data development plan;

7 “(B) take steps to ensure that the design  
8 of clinical trials is as efficient as practicable,  
9 such as through adoption of shorter or smaller  
10 clinical trials, application of surrogate  
11 endpoints, and use of adaptive trial designs and  
12 Bayesian statistics, to the extent scientifically  
13 appropriate;

14 “(C) facilitate, to the extent scientifically  
15 appropriate, expedited and efficient develop-  
16 ment and review of the device through utiliza-  
17 tion of timely postmarket data collection, with  
18 regard to applications for approval under sec-  
19 tion 515(c); and

20 “(D) agree to clinical protocols that the  
21 Secretary will consider binding on the Secretary  
22 and the sponsor, subject to—

23 “(i) changes agreed to by the sponsor  
24 and the Secretary;

1           “(ii) changes that the Secretary deter-  
2           mines are required to prevent an unreason-  
3           able risk to the public health; or

4           “(iii) the identification of a substan-  
5           tial scientific issue determined by the Sec-  
6           retary to be essential to the safety or effec-  
7           tiveness of the device involved.

8           “(e) PRIORITY REVIEW GUIDANCE.—

9           “(1) CONTENT.—The Secretary shall issue  
10          guidance on the implementation of this section. Such  
11          guidance shall include the following:

12           “(A) The process for a person to seek a  
13          priority review designation.

14           “(B) A template for requests under sub-  
15          section (b).

16           “(C) The criteria the Secretary will use in  
17          evaluating a request for priority review.

18           “(D) The standards the Secretary will use  
19          in assigning a team of staff, including team  
20          leaders, to review devices designated for priority  
21          review, including any training required for such  
22          personnel on effective and efficient review.

23           “(2) PROCESS.—Prior to finalizing the guid-  
24          ance under paragraph (1), the Secretary shall pro-  
25          pose such guidance for public comment.

1 “(f) CONSTRUCTION.—

2 “(1) PURPOSE.—This section is intended to en-  
3 courage the Secretary and provide the Secretary suf-  
4 ficient authorities to apply efficient and flexible ap-  
5 proaches to expedite the development of, and  
6 prioritize the agency’s review of, devices that rep-  
7 resent breakthrough technologies.

8 “(2) CONSTRUCTION.—Nothing in this section  
9 shall be construed to alter the criteria and standards  
10 for evaluating an application pursuant to section  
11 515(c), a report and request for classification under  
12 section 513(f)(2), or a report under section 510(k),  
13 including the recognition of valid scientific evidence  
14 as described in section 513(a)(3)(B), and consider-  
15 ation of the least burdensome means of evaluating  
16 device effectiveness or demonstrating substantial  
17 equivalence between devices with differing techno-  
18 logical characteristics, as applicable. Nothing in this  
19 section alters the authority of the Secretary to act  
20 on an application pursuant to section 515(d) before  
21 completion of an establishment inspection, as the  
22 Secretary deems appropriate.”.

23 (b) CONFORMING AMENDMENT RELATED TO DES-  
24 IGNATION DETERMINATIONS.—Section 517A(a)(1) of the  
25 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–

1 1(a)(1)) is amended by inserting “a request for designa-  
2 tion under section 515B,” after “an application under sec-  
3 tion 515,”.

4 **Subtitle M—Medical Device**  
5 **Regulatory Process Improvements**

6 **SEC. 2221. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

7 (a) ESTABLISHMENT OF THIRD-PARTY QUALITY  
8 SYSTEM ASSESSMENT PROGRAM.—Chapter V of the Fed-  
9 eral Food, Drug, and Cosmetic Act is amended by insert-  
10 ing after section 524A (21 U.S.C. 360n–1) the following  
11 new section:

12 **“SEC. 524B. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

13 **“(a) ACCREDITATION AND ASSESSMENT.—**

14 **“(1) IN GENERAL; CERTIFICATION OF DEVICE**  
15 **QUALITY SYSTEM.—**The Secretary shall, in accord-  
16 **ance with this section, establish a third-party quality**  
17 **system assessment program—**

18 **“(A) to accredit persons to assess whether**  
19 **a requestor’s quality system, including its de-**  
20 **sign controls, can reasonably assure the safety**  
21 **and effectiveness of in-scope devices subject to**  
22 **device-related changes (as defined in paragraph**  
23 **(2));**

24 **“(B) under which accredited persons shall,**  
25 **as applicable, certify that a requestor’s quality**

1 system meets the criteria issued under para-  
2 graph (5) with respect to the in-scope devices at  
3 issue; and

4 “(C) under which the Secretary shall rely  
5 on such certifications for purposes of deter-  
6 mining the safety and effectiveness of in-scope  
7 devices subject to the device-related changes in-  
8 volved, in lieu of compliance with the following  
9 submission requirements:

10 “(i) A thirty-day notice (as defined in  
11 paragraph (2)).

12 “(ii) A Special PMA supplement (as  
13 defined in paragraph (2)).

14 “(2) DEFINITIONS.—For purposes of this sec-  
15 tion—

16 “(A) the term ‘device-related changes’  
17 means changes made by a requestor with re-  
18 spect to in-scope devices, which are—

19 “(i) manufacturing changes subject to  
20 a 30-day notice;

21 “(ii) changes that qualify for a Spe-  
22 cial PMA supplement; and

23 “(iii) such other changes relating to  
24 the devices or the device manufacturing

1 process as the Secretary determines appro-  
2 priate;

3 “(B) the term ‘in-scope device’ means a  
4 device within the scope of devices agreed to by  
5 the requestor and the accredited person for pur-  
6 poses of a request for certification under this  
7 section;

8 “(C) the term ‘quality system’ means a  
9 quality system described in section 520(f);

10 “(D) the term ‘requestor’ means a device  
11 manufacturer that is seeking certification under  
12 this section of a quality system used by such  
13 manufacturer;

14 “(E) the term ‘Special PMA’ means a Spe-  
15 cial PMA supplement under section 814.39(d)  
16 of title 21, Code of Federal Regulations (or any  
17 successor regulations); and

18 “(F) the term ‘thirty-day notice’ means a  
19 notice described in section 515(d)(6).

20 “(3) ACCREDITATION PROCESS; ACCREDITATION  
21 RENEWAL.—Except as inconsistent with this section,  
22 the process and qualifications for accreditation of  
23 persons and renewal of such accreditation under sec-  
24 tion 704(g) shall apply with respect to accreditation

1 of persons and renewal of such accreditation under  
2 this section.

3 “(4) USE OF ACCREDITED PARTIES TO CON-  
4 DUCT ASSESSMENTS.—

5 “(A) INITIATION OF ASSESSMENT SERV-  
6 ICES.—

7 “(i) DATE ASSESSMENTS AUTHOR-  
8 IZED.—Beginning after issuance of the  
9 final guidance under paragraph (5), an ac-  
10 credited person may conduct an assess-  
11 ment under this section.

12 “(ii) INITIATION OF ASSESSMENTS.—  
13 Use of one or more accredited persons to  
14 assess a requestor’s quality system under  
15 this section with respect to in-scope devices  
16 shall be at the initiation of the person who  
17 registers and lists the devices at issue  
18 under section 510.

19 “(B) COMPENSATION.—Compensation for  
20 such accredited persons shall—

21 “(i) be determined by agreement be-  
22 tween the accredited person and the person  
23 who engages the services of the accredited  
24 person; and



1                   “(ii) be paid by the person who en-  
2                   gages such services.

3                   “(C) ACCREDITED PERSON SELECTION.—

4                   Each person who chooses to use an accredited  
5                   person to assess a requestor’s quality system,  
6                   as described in this section, shall select the ac-  
7                   credited person from a list of such persons pub-  
8                   lished by the Secretary in accordance with sec-  
9                   tion 704(g)(4).

10                  “(5) GUIDANCE; CRITERIA FOR CERTIFI-  
11                  CATION.—

12                   “(A) IN GENERAL.—The criteria for cer-  
13                   tification of a quality system under this section  
14                   shall be as specified by the Secretary in guid-  
15                   ance issued under this paragraph.

16                   “(B) CONTENTS; CERTIFICATION CRI-  
17                   TERIA.—The guidance under this paragraph  
18                   shall include specification of—

19                   “(i) evaluative criteria to be used by  
20                   an accredited person to assess and as ap-  
21                   plicable certify a requestor’s quality system  
22                   under this section with respect to in-scope  
23                   devices ; and

1           “(ii) criteria for accredited persons to  
2           apply a waiver of and exemptions from the  
3           certification criteria under clause (i).

4           “(C) TIMEFRAME FOR ISSUING GUID-  
5           ANCE.—The Secretary shall issue under this  
6           paragraph—

7                   “(i) draft guidance not later than 12  
8                   months after the enactment of the 21st  
9                   Century Cures Act; and

10                   “(ii) final guidance not later than 12  
11                   months after issuance of the draft guid-  
12                   ance under clause (i).

13           “(b) USE OF THIRD-PARTY ASSESSMENT.—

14                   “(1) ASSESSMENT SUMMARY; CERTIFI-  
15                   CATION.—

16                   “(A) SUBMISSION OF ASSESSMENT TO SEC-  
17                   RETARY.—An accredited person who assesses a  
18                   requestor’s quality system under subsection (a)  
19                   shall submit to the Secretary a summary of the  
20                   assessment—

21                           “(i) within 30 days of the assessment;  
22                           and

23                           “(ii) which as applicable shall in-  
24                           clude—

1           “(I) the accredited person’s cer-  
2           tification that the requestor has satis-  
3           fied the criteria issued under sub-  
4           section (a)(5) for quality system cer-  
5           tification with respect to the in-scope  
6           devices at issue; and

7           “(II) any waivers or exemptions  
8           from such criteria applied by the ac-  
9           credited person.

10           “(B) TREATMENT OF ASSESSMENTS.—

11           Subject to action by the Secretary under sub-  
12           paragraph (C), with respect to assessments  
13           which include a certification under this sec-  
14           tion—

15           “(i) the Secretary’s review of the as-  
16           sessment summary shall be deemed com-  
17           plete on the day that is 30 days after the  
18           date on which the Secretary receives the  
19           summary under subparagraph (A); and

20           “(ii) the assessment summary and  
21           certification of the requestor shall be  
22           deemed accepted by the Secretary on such  
23           30th day.

24           “(C) ACTIONS BY SECRETARY.—

1           “(i) IN GENERAL.—Within 30 days of  
2 receiving an assessment summary and cer-  
3 tification under subparagraph (A), the Sec-  
4 retary may, by written notice to the ac-  
5 credited person submitting such assess-  
6 ment certification, deem any such certifi-  
7 cation to be provisional beyond such 30-  
8 day period, suspended pending further re-  
9 view by the Secretary, or otherwise quali-  
10 fied or cancelled, based on the Secretary’s  
11 determination that (as applicable)—

12                   “(I) additional information is  
13 needed to support such certification;

14                   “(II) such assessment or certifi-  
15 cation is unwarranted; or

16                   “(III) such action with regard to  
17 the certification is otherwise justified  
18 according to such factors and criteria  
19 as the Secretary finds appropriate.

20           “(ii) ACCEPTANCE OF CERTIFI-  
21 CATION.—If following action by the Sec-  
22 retary under clause (i) with respect to a  
23 certification, the Secretary determines that  
24 such certification is acceptable, the Sec-  
25 retary shall issue written notice to the ap-

1           plicable accredited person indicating such  
2           acceptance.

3           “(2) NOTIFICATIONS TO SECRETARY BY CER-  
4           TIFIED MANUFACTURERS FOR PROGRAM EVALUA-  
5           TION PURPOSES.—

6           “(A) PERIODIC NOTIFICATION FOR MANU-  
7           FACTURING CHANGES OTHERWISE SUBJECT TO  
8           THIRTY-DAY NOTICE.—A requestor certified  
9           under this section that effectuates device-re-  
10          lated changes with respect to in-scope devices,  
11          without prior submission of a thirty-day notice,  
12          shall provide notification to the Secretary of  
13          such changes in the requestor’s next periodic  
14          report under section 814.84(b) of title 21, Code  
15          of Federal Regulations (or any successor regu-  
16          lation). Such notification shall—

17                   “(i) describe the changes made; and

18                   “(ii) indicate the effective dates of  
19                   such changes.

20          “(B) PERIODIC NOTIFICATION FOR DE-  
21          VICE-RELATED CHANGES OTHERWISE SUBJECT  
22          TO SPECIAL PMA SUPPLEMENT.—A requestor  
23          certified under this section that effectuates de-  
24          vice-related changes with respect to in-scope de-  
25          vices, without prior submission of a Special

1 PMA Supplement, shall provide notification to  
2 the Secretary of such changes in the requestor's  
3 next periodic report under section 814.84(b) of  
4 title 21, Code of Federal Regulations (or any  
5 successor regulation). Such notification shall—

6 “(i) describe the changes made, in-  
7 cluding a full explanation of the basis for  
8 the changes; and

9 “(ii) indicate the effective dates of  
10 such changes.

11 “(C) USE OF NOTIFICATIONS FOR PRO-  
12 GRAM EVALUATION PURPOSES.—Information  
13 submitted to the Secretary under subpara-  
14 graphs (A) and (B) shall be used by the Sec-  
15 retary for purposes of the program evaluation  
16 under subsection (d).

17 “(c) DURATION AND EFFECT OF CERTIFICATION.—

18 A certification under this section—

19 “(1) shall remain in effect for a period of two  
20 years from the date such certification is accepted by  
21 the Secretary, subject to paragraph (6);

22 “(2) may be renewed through the process de-  
23 scribed in subsection (a)(3);

24 “(3) shall continue to apply with respect to de-  
25 vice-related changes made during such 2-year period,

1 provided the certification remains in effect, irrespec-  
2 tive of whether such certification is renewed after  
3 such 2-year period;

4 “(4) shall have no effect on the need to comply  
5 with applicable submission requirements specified in  
6 subsection (a)(1)(C) with respect to any change per-  
7 taining to in-scope devices which is not a device-re-  
8 lated change under subsection (a)(2);

9 “(5) shall have no effect on the authority of the  
10 Secretary to conduct an inspection or otherwise de-  
11 termine the requestor’s conformance with the appli-  
12 cable requirements of this Act; and

13 “(6) shall be considered to be revoked if the  
14 Secretary provides written notification to the cer-  
15 tified requestor that its quality system does not sat-  
16 isfy the certification criteria issued under subsection  
17 (a)(5) with respect to the in-scope devices at issue,  
18 such that the applicable submission requirements  
19 specified in subsection (a)(1)(C) must be met for  
20 changes made after receipt of such written notifica-  
21 tion, with respect to such devices.

22 “(d) PROGRAM EVALUATION; SUNSET.—

23 “(1) PROGRAM EVALUATION AND REPORT.—

24 “(A) EVALUATION.—The Secretary shall  
25 complete an evaluation of the third-party qual-

1           ity system assessment program under this sec-  
2           tion no later than January 31, 2021, based  
3           on—

4                   “(i) analysis of information from a  
5                   representative group of device manufactur-  
6                   ers obtained from notifications provided by  
7                   certified requestors under subsection  
8                   (b)(2); and

9                   “(ii) such other available information  
10                  and data as the Secretary determines ap-  
11                  propriate.

12               “(B) REPORT.—No later than 1 year after  
13               completing the evaluation under subparagraph  
14               (A), the Secretary shall issue a report of the  
15               evaluation’s findings on the website of the Food  
16               and Drug Administration, which shall include  
17               the Secretary’s recommendations with respect  
18               to continuation and as applicable expansion of  
19               the program under this section to include addi-  
20               tional types of submissions and additional types  
21               of changes beyond those identified in subsection  
22               (a)(1)(C), including changes to devices cleared  
23               under section 510(k). At the discretion of the  
24               Secretary, the program may be expanded prior  
25               to January 31, 2021.



1           “(2) SUNSET.—This section shall cease to be  
2           effective October 1, 2022.

3           “(e) RULE OF CONSTRUCTION.—Nothing in this sec-  
4           tion shall be construed to limit the authority of the Sec-  
5           retary to request and review the complete assessment of  
6           a certified requestor under this section on a for-cause  
7           basis.”.

8           (b) CONFORMING AMENDMENTS.—

9           (1) REQUIREMENTS FOR PREMARKET AP-  
10          PROVAL SUPPLEMENTS.—Section 515(d)(6)(A)(i) of  
11          the Federal Food, Drug, and Cosmetic Act (21  
12          U.S.C. 360e(d)(6)(A)(i)) is amended by inserting “,  
13          subject to section 524B,” after “that affects safety  
14          or effectiveness”.

15          (2) REQUIREMENTS FOR THIRTY-DAY NO-  
16          TICE.—Section 515(d)(6)(A)(ii) of the Federal  
17          Food, Drug, and Cosmetic Act (21 U.S.C.  
18          360e(d)(6)(A)(ii)) is amended by inserting “, subject  
19          to section 524B,” after “the date on which the Sec-  
20          retary receives the notice”.

21       **SEC. 2222. VALID SCIENTIFIC EVIDENCE.**

22          Section 513(a)(3)(B) of the Federal Food, Drug, and  
23          Cosmetic Act (21 U.S.C. 360c(a)(3)(B)) is amended—

24               (1) by redesignating clauses (i) and (ii) as sub-  
25               clauses (I) and (II), respectively;

1           (2) by striking “(B) If the Secretary” and in-  
2           serting “(B)(i) If the Secretary”; and

3           (3) by adding at the end the following:

4                   “(ii) Valid scientific evidence for purposes  
5           of clause (i) may include:

6                           “(I) evidence described in well-docu-  
7                           mented case histories, including registry  
8                           data, that are collected and monitored  
9                           under an acceptable protocol;

10                           “(II) studies published in peer-re-  
11                           viewed journals; and

12                           “(III) data collected in countries other  
13                           than the United States so long as such  
14                           data otherwise meets the criteria specified  
15                           in this subparagraph.

16                   “(iii) In the case of a study published in  
17           a peer-reviewed journal that is offered as valid  
18           scientific evidence for purposes of clause (i), the  
19           Secretary may request data underlying the  
20           study if—

21                           “(I) the Secretary, in making such re-  
22                           quest, complies with the requirement of  
23                           subparagraph (D)(ii) to consider the least  
24                           burdensome appropriate means of evalu-  
25                           ating device effectiveness or subsection

1 (i)(1)(D) to consider the least burdensome  
2 means of determining substantial equiva-  
3 lence, as applicable;

4 “(II) the Secretary furnishes a written  
5 rationale for so requesting the underlying  
6 data together with such request; and

7 “(III) if the requested underlying data  
8 for such a study are unavailable, the Sec-  
9 retary shall consider such study to be part  
10 of the totality of the evidence with respect  
11 to the device, as the Secretary determines  
12 appropriate.”.

13 **SEC. 2223. TRAINING AND OVERSIGHT IN LEAST BURDEN-**  
14 **SOME APPROPRIATE MEANS CONCEPT.**

15 (a) IN GENERAL.—Section 513 of the Federal Food,  
16 Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by  
17 inserting after subsection (i) the following:

18 “(j) TRAINING AND OVERSIGHT IN LEAST BURDEN-  
19 SOME APPROPRIATE MEANS CONCEPT.—

20 “(1) TRAINING.—Each employee of the Food  
21 and Drug Administration who is involved in the re-  
22 view of premarket submissions under section 515 or  
23 section 510(k), including supervisors, shall receive  
24 training regarding the meaning and implementation  
25 of the least burdensome appropriate means concept

1 in the context of the use of that term in subsections  
2 (a)(3)(D) and (i)(1)(D) of this section and in section  
3 515(c)(5).

4 “(2) GUIDANCE DOCUMENTS.—

5 “(A) DRAFT UPDATED GUIDANCE.—Not  
6 later than 12 months after the date of enact-  
7 ment of the 21st Century Cures Act, the Sec-  
8 retary shall issue a draft guidance document  
9 updating the October 4, 2002, guidance docu-  
10 ment entitled ‘The Least Burdensome Provision  
11 of the FDA Modernization Act of 1997: Con-  
12 cept and Principles; Final Guidance for FDA  
13 and Industry’.

14 “(B) MEETING OF STAKEHOLDERS.—In  
15 developing such draft guidance document, the  
16 Secretary shall convene a meeting of stake-  
17 holders to ensure a full record to support the  
18 publication of such document.

19 “(3) OMBUDSMAN AUDIT.—Not later than 18  
20 months after the date of issuance of final version of  
21 the draft guidance under paragraph (2), the om-  
22 budsman for the organizational unit of the Food and  
23 Drug Administration responsible for the premarket  
24 review of devices shall—

1           “(A) conduct, or have conducted, an audit  
2           of the training described in paragraph (1); and

3           “(B) include in such audit interviews with  
4           a representative sample of persons from indus-  
5           try regarding their experience in the device pre-  
6           market review process.”.

7           (b) **ADDITIONAL INFORMATION REGARDING PRE-**  
8 **MARKET APPLICATIONS.**—Subsection (c) of section 515 of  
9 the Federal Food, Drug, and Cosmetic Act (21 U.S. C.  
10 29 360e) is amended by adding at the end the follows:

11           “(5)(A) Whenever the Secretary requests additional  
12 information from an applicant regarding an application  
13 under paragraph (1), the Secretary shall consider the least  
14 burdensome appropriate means necessary to demonstrate  
15 device safety and effectiveness, and request information  
16 accordingly.

17           “(B) For purposes of subparagraph (A), the term  
18 ‘necessary’ means the minimum required information that  
19 would support a determination by the Secretary that an  
20 application provides a reasonable assurance of the safety  
21 and effectiveness of the device.

22           “(C) Nothing in this paragraph alters the standards  
23 for premarket approval of a device.”.

1 **SEC. 2224. RECOGNITION OF STANDARDS.**

2 Section 514(c) of the Federal Food, Drug, and Cos-  
3 metic Act (21 U.S.C. 360d(c)) is amended—

4 (1) in paragraph (1), by inserting after sub-  
5 paragraph (B) the following new subparagraphs:

6 “(C)(i) Any person may submit a request  
7 for recognition under subparagraph (A) of all  
8 or part of an appropriate standard established  
9 by a nationally or internationally recognized  
10 standard organization.

11 “(ii) Not later than 60 days after the Sec-  
12 retary receives such a request, the Secretary  
13 shall—

14 “(I) make a determination to recog-  
15 nize all, part, or none of the standard that  
16 is the subject of the request; and

17 “(II) issue to the person who sub-  
18 mitted such request a response in writing  
19 that states the Secretary’s rationale for  
20 that determination, including the scientific,  
21 technical, regulatory, or other basis for  
22 such determination;

23 “(iii) The Secretary shall make a response  
24 issued under clause (ii)(II) publicly available, in  
25 such manner as the Secretary determines ap-  
26 propriate.

1           “(iv) The Secretary shall take such actions  
2           as may be necessary to implement all or part of  
3           a standard recognized under subclause (I), in  
4           accordance with subparagraph (A).

5           “(D) The Secretary shall make publicly  
6           available, in such manner as the Secretary de-  
7           termines appropriate, the rationale for recogni-  
8           tion under subparagraph (A) of part of a stand-  
9           ard, including the scientific, technical, regu-  
10          latory, or other basis for such recognition.”;  
11          and

12          (2) by adding at the end the following new  
13          paragraphs:

14           “(4) TRAINING ON USE OF STANDARDS.—The  
15          Secretary shall provide to all employees of the Food  
16          and Drug Administration who review premarket sub-  
17          missions for devices periodic training on the concept  
18          and use of recognized standards for purposes of  
19          meeting a premarket submission requirement or  
20          other applicable requirement under this Act, includ-  
21          ing standards relevant to an employee’s area of de-  
22          vice review.

23           “(5) GUIDANCE.—

24           “(A) DRAFT GUIDANCE.—The Secretary  
25          shall publish guidance identifying the principles

1 for recognizing standards under this section. In  
2 publishing such guidance, the Secretary shall  
3 consider the experience with, and reliance on, a  
4 standard by other Federal regulatory authori-  
5 ties and the device industry, and whether rec-  
6 ognition of a standard will promote harmoni-  
7 zation among regulatory authorities in the regu-  
8 lation of devices.

9 “(B) TIMING.—The Secretary shall pub-  
10 lish—

11 “(i) draft guidance under subpara-  
12 graph (A) not later than 12 months after  
13 the date of the enactment of the 21st Cen-  
14 tury Cures Act; and

15 “(ii) final guidance not later than 12  
16 months of the close of the public comment  
17 period for the draft guidance under clause  
18 (i).”.

19 **SEC. 2225. EASING REGULATORY BURDEN WITH RESPECT**  
20 **TO CERTAIN CLASS I AND CLASS II DEVICES.**

21 (a) CLASS I DEVICES.—Section 510(l) of the Federal  
22 Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is  
23 amended—



1           (1) by striking “A report under subsection (k)”  
2           and inserting “(1) A report under subsection (k)”;  
3           and

4           (2) by adding at the end the following new  
5           paragraph:

6           “(2) Not later than 120 days after the date of the  
7           enactment of the 21st Century Cures Act, the Secretary  
8           shall identify, through publication in the Federal Register,  
9           any type of class I device that the Secretary determines  
10          no longer requires a report under subsection (k) to provide  
11          reasonable assurance of safety and effectiveness. Upon  
12          such publication—

13                 “(A) each type of class I device so identified  
14                 shall be exempt from the requirement for a report  
15                 under subsection (k); and

16                 “(B) the classification regulation applicable to  
17                 each such type of device shall be deemed amended  
18                 to incorporate such exemption.”.

19          (b) CLASS II DEVICES.—Section 510(m) of the Fed-  
20          eral Food, Drug, and Cosmetic Act (21 U.S.C. 360(m))  
21          is amended—

22                 (1) by striking paragraph (1) and inserting the  
23                 following new paragraph:

24                 “(1) The Secretary shall—

1           “(A) not later than 60 days after the date of  
2           the enactment of the 21st Century Cures Act—

3                   “(i) publish in the Federal Register a no-  
4                   tice that contains a list of each type of class II  
5                   device that the Secretary determines no longer  
6                   requires a report under subsection (k) to pro-  
7                   vide reasonable assurance of safety and effec-  
8                   tiveness; and

9                   “(ii) provide for a period of not less than  
10                  60 days for public comment beginning on the  
11                  date of the publication of such notice; and

12           “(B) not later than 180 days after the date of  
13           the enactment of 21st Century Cures Act, publish in  
14           the Federal Register a list representing the Sec-  
15           retary’s final determination with respect to the de-  
16           vices contained in the list published under subpara-  
17           graph (A).”;

18           (2) in paragraph (2)—

19                   (A) by striking “1 day after the date of  
20                   publication of a list under this subsection,” and  
21                   inserting “1 day after the date of publication of  
22                   the final list under paragraph (1)(B),”; and

23                   (B) by striking “30-day period” and in-  
24                   serting “60-day period”; and

1           (3) by adding at the end the following new  
2 paragraph:

3           “(3) Upon the publication of the final list under para-  
4 graph (1)(B)—

5           “(A) each type of class II device so listed shall  
6 be exempt from the requirement for a report under  
7 subsection (k); and

8           “(B) the classification regulation applicable to  
9 each such type of device shall be deemed amended  
10 to incorporate such exemption.”.

11 **SEC. 2226. ADVISORY COMMITTEE PROCESS.**

12           (a) CLASSIFICATION PANELS.—Paragraph (5) of sec-  
13 tion 513(b) of the Federal Food, Drug, and Cosmetic Act  
14 (21 U.S.C. 360c(b)) is amended—

15           (1) by striking “(5)” and inserting “(5)(A)”;  
16 and

17           (2) by adding at the end the following:

18           “(B) When a device is specifically the sub-  
19 ject of review by a classification panel, the Sec-  
20 retary shall—

21           “(i) ensure that adequate expertise is  
22 represented on the classification panel to  
23 assess—

24           “(I) the disease or condition  
25 which the device is intended to cure,

1 treat, mitigate, prevent, or diagnose;

2 and

3 “(II) the technology of the de-  
4 vice; and

5 “(ii) as part of the process to ensure  
6 adequate expertise under clause (i), give  
7 due consideration to the recommendations  
8 of the person whose premarket submission  
9 is subject to panel review on the expertise  
10 needed among the voting members of the  
11 panel.

12 “(C) For review by a classification panel of  
13 a premarket submission for a device, the Sec-  
14 retary shall—

15 “(i) provide an opportunity for the  
16 person whose premarket submission is sub-  
17 ject to panel review to provide rec-  
18 ommendations on the expertise needed  
19 among the voting members of the panel;  
20 and

21 “(ii) give due consideration to such  
22 recommendations and ensure that adequate  
23 expertise is represented on advisory panels  
24 to assess—

1                   “(I) the disease or condition for  
2                   which the device is intended to cure,  
3                   treat, mitigate, prevent, or diagnose;  
4                   and

5                   “(II) the technology of the de-  
6                   vice.

7                   “(D) For purposes of subparagraph  
8                   (B)(ii), the term ‘adequate expertise’ means  
9                   that the membership of the classification panel  
10                  reviewing a premarket submission includes—

11                  “(i) two or more voting members, with  
12                  a specialty or other expertise clinically rel-  
13                  evant to the device under review; and

14                  “(ii) at least one voting member who  
15                  is knowledgeable about the technology of  
16                  the device.”.

17                  (b) PANEL REVIEW PROCESS.—Section 513(b)(6) of  
18                  the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
19                  360c(b)(6)) is amended—

20                  (1) in subparagraph (A)(iii), by inserting before  
21                  the period at the end “, including by designating a  
22                  representative who will be provided a time during  
23                  the panel meeting to address the panel individually  
24                  (or accompanied by experts selected by such rep-  
25                  resentative) for the purpose of correcting

1 misstatements of fact or providing clarifying infor-  
2 mation, subject to the discretion of panel chair-  
3 person.”.

4 (2) by striking subparagraph (B) and inserting  
5 the following new subparagraph:

6 “(B)(i) Any meeting of a classification  
7 panel for a device that is specifically the subject  
8 of review shall—

9 “(I) provide adequate time for initial  
10 presentations by the person whose device is  
11 specifically the subject of a classification  
12 panel review and by the Secretary; and

13 “(II) encourage free and open partici-  
14 pation by all interested persons.

15 “(ii) Following the initial presentations de-  
16 scribed in clause (i), the panel may—

17 “(I) pose questions to a designated  
18 representative described in subparagraph  
19 (A)(iii); and

20 “(II) consider the responses to such  
21 questions in the panel’s review of the de-  
22 vice that is specifically the subject of re-  
23 view by the classification panel.”.

1 **SEC. 2227. HUMANITARIAN DEVICE EXEMPTION APPLICA-**  
2 **TION.**

3 (a) IN GENERAL.—Section 520(m) of the Federal  
4 Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amend-  
5 ed—

6 (1) in paragraph (1) by striking “fewer than  
7 4,000” and inserting “not more than 8,000”;

8 (2) in paragraph (2)(A) by striking “fewer than  
9 4,000” and inserting “not more than 8,000”; and

10 (3) in paragraph (6)(A)(ii), by striking “4,000”  
11 and inserting “8,000”

12 (b) GUIDANCE DOCUMENT ON PROBABLE BEN-  
13 EFIT.—Not later than 18 months after the date of enact-  
14 ment of this Act, the Secretary of Health and Human  
15 Services, acting through the Commissioner of Food and  
16 Drugs, shall publish a draft guidance document that de-  
17 fines the criteria for establishing “probable benefit” as  
18 that term is used in section 520(m)(2)(C) of the Federal  
19 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)(C)).

20 **SEC. 2228. CLIA WAIVER STUDY DESIGN GUIDANCE FOR IN**  
21 **VITRO DIAGNOSTICS.**

22 (a) DRAFT REVISED GUIDANCE.—Not later than 12  
23 months after the date of the enactment of this Act, the  
24 Secretary of Health and Human Services shall publish a  
25 draft guidance that—

1 (1) revises section V “Demonstrating Insignifi-  
2 cant Risk of an Erroneous Result—‘Accuracy’” of  
3 the guidance entitled “Recommendations for Clinical  
4 Laboratory Improvement Amendments of 1988  
5 (CLIA) Waiver Applications for Manufacturers of In  
6 Vitro Diagnostic Devices” and dated January 30,  
7 2008; and

8 (2) includes guidance on the appropriate use of  
9 comparable performance between a waived user and  
10 a moderately complex laboratory user to dem-  
11 onstrate accuracy.

12 (b) FINAL REVISED GUIDANCE.—The Secretary of  
13 Health and Human Services shall finalize the draft guid-  
14 ance published under subsection (a) not later than 12  
15 months after the comment period for such draft guidance  
16 closes.

17 **Subtitle N—Sensible Oversight for**  
18 **Technology Which Advances**  
19 **Regulatory Efficiency**

20 **SEC. 2241. HEALTH SOFTWARE.**

21 Section 201 of the Federal Food, Drug, and Cosmetic  
22 Act (21 U.S.C. 321) is amended by adding at the end the  
23 following:

24 “(ss)(1) The term ‘health software’ means software  
25 that does not, through use of an in vitro diagnostic device



1 or signal acquisition system, acquire, process, or analyze  
2 an image or physiological signal, is not an accessory, is  
3 not an integral part of a device necessary to support the  
4 use of the device, is not used in the manufacture and  
5 transfusion of blood and blood components to assist in the  
6 prevention of disease in humans, and—

7           “(A) is intended for use for administrative  
8           or operational support or the processing and  
9           maintenance of financial records;

10           “(B) is intended for use in clinical, labora-  
11           tory, or administrative workflow and related  
12           recordkeeping;

13           “(C)(i) is intended for use solely in the  
14           transfer, aggregation, conversion (in accordance  
15           with a present specification), storage, manage-  
16           ment, retrieval, or transmission of data or in-  
17           formation;

18           “(ii) utilizes a connectivity software plat-  
19           form, electronic or electrical hardware, or a  
20           physical communications infrastructure; and

21           “(iii) is not intended for use—

22                   “(I) in active patient monitoring; or

23                   “(II) in controlling or altering the  
24           functions or parameters of a device that is  
25           connected to such software;

1           “(D) is intended for use to organize and  
2           present information for health or wellness edu-  
3           cation or for use in maintaining a healthy life-  
4           style, including medication adherence and  
5           health management tools;

6           “(E) is intended for use to analyze infor-  
7           mation to provide general health information  
8           that does not include patient-specific rec-  
9           ommended options to consider in the preven-  
10          tion, diagnosis, treatment, cure, or mitigation of  
11          a particular disease or condition; or

12          “(F) is intended for use to analyze infor-  
13          mation to provide patient-specific recommended  
14          options to consider in the prevention, diagnosis,  
15          treatment, cure, or mitigation of a particular  
16          disease or condition.

17          “(2) The term ‘accessory’ means a product that—

18                 “(A) is intended for use with one or more par-  
19                 ent devices;

20                 “(B) is intended to support, supplement, or  
21                 augment the performance of one or more parent de-  
22                 vices; and

23                 “(C) shall be classified by the Secretary—

24                         “(i) according to its intended use; and

1                   “(ii) independently of any classification of  
2                   any parent device with which it is used.”.

3 **SEC. 2242. APPLICABILITY AND INAPPLICABILITY OF REGU-**  
4 **LATION.**

5           Subchapter A of chapter V of the Federal Food,  
6 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-  
7 ed by adding at the end the following:

8 **“SEC. 524B. HEALTH SOFTWARE.**

9           “(a) INAPPLICABILITY OF REGULATION TO HEALTH  
10 SOFTWARE.—Except as provided in subsection (b), health  
11 software shall not be subject to regulation under this Act.

12           “(b) EXCEPTION.—

13                   “(1) IN GENERAL.—Subsection (a) shall not  
14 apply with respect to a software product—

15                           “(A) of a type described in subparagraph  
16 (F) of section 201(ss)(1); and

17                           “(B) that the Secretary determines poses a  
18 significant risk to patient safety.

19                   “(2) CONSIDERATIONS.—In making a deter-  
20 mination under subparagraph (B) of paragraph (1)  
21 with respect to a product to which such paragraph  
22 applies, the Secretary shall consider the following:

23                           “(A) The likelihood and severity of patient  
24 harm if the product were to not perform as in-  
25 tended.

1           “(B) The extent to which the product is  
2           intended to support the clinical judgment of a  
3           medical professional.

4           “(C) Whether there is a reasonable oppor-  
5           tunity for a medical professional to review the  
6           basis of the information or treatment rec-  
7           ommendation provided by the product.

8           “(D) The intended user and user environ-  
9           ment, such as whether a medical professional  
10          will use a software product of a type described  
11          in subparagraph (F) of section 201(ss)(1).

12          “(c) DELEGATION.—The Secretary shall delegate pri-  
13          mary jurisdiction for regulating a software product deter-  
14          mined under subsection (b) to be subject to regulation  
15          under this Act to the center at the Food and Drug Admin-  
16          istration charged with regulating devices.

17          “(d) REGULATION OF SOFTWARE.—

18                 “(1) IN GENERAL.—The Secretary shall review  
19                 existing regulations and guidance regarding the reg-  
20                 ulation of software under this Act. The Secretary  
21                 may implement a new framework for the regulation  
22                 of software and shall, as appropriate, modify such  
23                 regulations and guidance or issue new regulations or  
24                 guidance.

1           “(2) ISSUANCE BY ORDER.—Notwithstanding  
2           subchapter II of chapter 5 of title 5, United States  
3           Code, the Secretary may modify or issue regulations  
4           for the regulation of software under this Act by ad-  
5           ministrative order published in the Federal Register  
6           following the publication of a proposed order.

7           “(3) AREAS UNDER REVIEW.—The review of ex-  
8           isting regulations and guidance under paragraph (1)  
9           may include review of the following areas:

10                   “(A) Classification of software.

11                   “(B) Standards for development of soft-  
12           ware.

13                   “(C) Standards for validation and  
14           verification of software.

15                   “(D) Review of software.

16                   “(E) Modifications to software.

17                   “(F) Manufacturing of software.

18                   “(G) Quality systems for software.

19                   “(H) Labeling requirements for software.

20                   “(I) Postmarketing requirements for re-  
21           porting of adverse events.

22           “(4) PROCESS FOR ISSUING PROPOSED REGU-  
23           LATIONS, ADMINISTRATIVE ORDER, AND GUID-  
24           ANCE.—Not later than 18 months after the date of  
25           enactment of this section, the Secretary shall consult

1 with external stakeholders (including patients, indus-  
2 try, health care providers, academia, and govern-  
3 ment) to gather input before issuing regulations, an  
4 administrative order, and guidance under this sub-  
5 section.

6 “(e) **RULE OF CONSTRUCTION.**—Nothing in this sec-  
7 tion shall be construed as providing the Secretary with the  
8 authority to regulate under this Act any health software  
9 product of the type described in subparagraph (F) of sec-  
10 tion 201(ss)(1) unless and until the Secretary has made  
11 a determination described in subsection (b)(1)(B) with re-  
12 spect to such product.”.

13 **SEC. 2243. EXCLUSION FROM DEFINITION OF DEVICE.**

14 Section 201(h) of the Federal Food, Drug, and Cos-  
15 metic Act (21 U.S.C. 321) is amended—

16 (1) in subparagraph (2), by striking “or” after  
17 “or other animals,”;

18 (2) in subparagraph (3), by striking “and” and  
19 inserting “or”; and

20 (3) by inserting after subparagraph (3) the fol-  
21 lowing:

22 “(4) is not health software (other than software  
23 determined to be a risk to patient safety under sec-  
24 tion 524B(b)), and”.

1     **Subtitle O—Streamlining Clinical**  
2                     **Trials**

3     **SEC. 2261. PROTECTION OF HUMAN SUBJECTS IN RE-**  
4                     **SEARCH; APPLICABILITY OF RULES.**

5             (a) IN GENERAL.—In order to simplify and facilitate  
6 compliance by researchers with applicable regulations for  
7 protection of human subjects in research, the Secretary  
8 of Health and Human Services shall, to the extent possible  
9 and consistent with other statutory provisions, harmonize  
10 differences between the HHS Human Subject Regulations  
11 and the FDA Human Subject Regulations in accordance  
12 with subsection (b).

13             (b) AVOIDING REGULATORY DUPLICATION AND UN-  
14 NECESSARY DELAYS.—

15                 (1) IN GENERAL.—The Secretary shall—

16                     (A) make such modifications to the provi-  
17 sions of the HHS Human Subject Regulations  
18 and the vulnerable-populations rules as may be  
19 necessary—

20                         (i) to reduce regulatory duplication  
21 and unnecessary delays;

22                         (ii) to modernize such provisions in  
23 the context of multisite and cooperative re-  
24 search projects; and

1 (iii) to incorporate local consider-  
2 ations, community values, and mechanisms  
3 to protect vulnerable populations; and

4 (B) ensure that human subject research  
5 that is subject to the HHS Human Subject  
6 Regulations or to the FDA Human Subject  
7 Regulations may—

8 (i) use joint or shared review;

9 (ii) rely upon the review of—

10 (I) an independent institutional  
11 review board; or

12 (II) an institutional review board  
13 of an entity other than the sponsor of  
14 the research; or

15 (iii) use similar arrangements to avoid  
16 duplication of effort.

17 (2) REGULATIONS AND GUIDANCE.—Not later  
18 than 12 months after the date of enactment of this  
19 Act, the Secretary, acting through the relevant agen-  
20 cies and offices of the Department of Health and  
21 Human Services, including the Office for Human  
22 Research Protections and relevant agencies and of-  
23 fices of the Food and Drug Administration, shall  
24 issue such regulations and guidance and take such  
25 other actions as may be necessary to implement this



1 section and help facilitate the broader use of single,  
2 central, or lead institutional review boards. Such  
3 regulations and guidance shall include clarification  
4 of requirements and policies relating to the fol-  
5 lowing:

6 (A) Arrangements to avoid duplication de-  
7 scribed in paragraph (1)(A)(i), including—

8 (i) delineating the roles of institu-  
9 tional review boards in multisite or cooper-  
10 ative, multisite studies where one or more  
11 local institutional review boards are relied  
12 upon, or similar arrangements are used;

13 (ii) the risks and benefits to human  
14 subjects;

15 (iii) standardization of informed con-  
16 sent and other processes and legal docu-  
17 ments; and

18 (iv) incorporating community values  
19 through the use of local institutional re-  
20 view boards while continuing to use central  
21 or lead institutional review boards.

22 (B) Concerns about regulatory and legal li-  
23 ability contributing to decisions by the sponsors  
24 of research to rely on local institutional review  
25 boards for multisite research.

1           (3) CONSULTATION.—In issuing regulations or  
2           guidance pursuant to paragraph (2), the Secretary  
3           shall consult with stakeholders (including research-  
4           ers, academic organizations, hospitals, institutional  
5           research boards, pharmaceutical, biotechnology and  
6           medical device developers, clinical research organiza-  
7           tions, patient groups, and others).

8           (c) TIMING.—The Secretary shall complete the har-  
9           monization described in subsection (a) not later than 36  
10          months after the date of enactment of this Act.

11          (d) PROGRESS REPORT.—Not later than 24 months  
12          after the date of enactment of this Act, the Secretary shall  
13          submit to Congress a report on the progress made towards  
14          completing such harmonization.

15          (d) DEFINITIONS.—

16                (1) HUMAN SUBJECT REGULATIONS.—In this  
17                section:

18                    (A) FDA HUMAN SUBJECT REGULA-  
19                    TIONS.—The term “FDA Human Subject Reg-  
20                    ulations” means the provisions of parts 50, 56,  
21                    312, and 812 of title 21, Code of Federal Regu-  
22                    lations (or any successor regulations).

23                    (B) HHS HUMAN SUBJECT REGULA-  
24                    TIONS.—The term “HHS Human Subject Reg-  
25                    ulations” subject to clause (ii), means the provi-

1 sions of subpart A of part 46 of title 45, Code  
2 of Federal Regulations (or any successor regu-  
3 lations).

4 (C) VULNERABLE-POPULATIONS RULES.—

5 The term “vulnerable-populations rules”—

6 (i) subject to clause (ii), means the  
7 provisions of subparts B through D of  
8 such part 46 (or any successor regula-  
9 tions); or

10 (ii) as applicable to the human sub-  
11 jects involved in research described in sub-  
12 paragraph (B), means the provisions appli-  
13 cable to vulnerable populations under part  
14 56 of such title 21 (or any successor regu-  
15 lations) and subpart D of part 50 of such  
16 title 21 (or any successor regulations).

17 (2) HUMAN SUBJECT RESEARCH.—

18 (A) Except as provided in subparagraph  
19 (B), the term “human subject research” means  
20 research, as defined in subpart A of part 46 of  
21 title 45, Code of Federal Regulations (or any  
22 successor regulations), that involves a human  
23 subject, as defined in such subpart A (or any  
24 successor regulations); and

1           (B) In the case of an investigation that is  
2 subject to the provisions of part 50 of title 21,  
3 Code of Federal Regulations (or any successor  
4 regulations), the term “human subject” has the  
5 meaning given such term in such part 50, and  
6 the term “human subject research” means a  
7 clinical investigation as defined in such part 50.

8 (3) OTHER DEFINITIONS.—In this section:

9           (A) INSTITUTIONAL REVIEW BOARD.—The  
10 term “institutional review board” has the mean-  
11 ing that applies to the term “institutional re-  
12 view board” under the HHS Human Subject  
13 Regulations.

14           (B) LEAD INSTITUTIONAL REVIEW  
15 BOARD.—The term “lead institutional review  
16 board” means an institutional review board that  
17 otherwise meets the requirements of the HHS  
18 Human Subject Regulations and enters into a  
19 written agreement with an institution, another  
20 institutional review board, a sponsor, or a prin-  
21 cipal investigator to approve and oversee human  
22 subject research that is conducted at multiple  
23 locations. References to an institutional review  
24 board include an institutional review board that

1 serves a single institution as well as a lead in-  
2 stitutional review board.

3 **SEC. 2262. USE OF NON-LOCAL INSTITUTIONAL REVIEW**  
4 **BOARDS FOR REVIEW OF INVESTIGATIONAL**  
5 **DEVICE EXEMPTIONS AND HUMAN DEVICE**  
6 **EXEMPTIONS.**

7 (a) IN GENERAL.—Section 520 of the Federal Food,  
8 Drug, and Cosmetic Act (21 U.S.C. 360(j)) is amended—

9 (1) in subsection (g)(3)—

10 (A) by striking “local” each place it ap-  
11 pears; and

12 (B) in subparagraph (A)(i), by striking  
13 “which has been”; and

14 (2) in subsection (m)(4)—

15 (A) by striking “local” each place it ap-  
16 pears; and

17 (B) by striking subparagraph (A) and in-  
18 serting the following new subparagraph:

19 “(A) in facilities in which clinical testing of de-  
20 vices is supervised by an institutional review com-  
21 mittee established in accordance with the regulations  
22 of the Secretary, and”.

23 (b) REGULATIONS.—Not later than 12 months after  
24 the date of the enactment of this Act, the Secretary of  
25 Health and Human Services shall revise or issue such reg-

1 ulations or guidance as may be necessary to carry out the  
2 amendments made by subsection (a).

3 **SEC. 2263. ALTERATION OR WAIVER OF INFORMED CON-**  
4 **SENT FOR CLINICAL INVESTIGATIONS.**

5 (a) DEVICES.—Section 520(g)(3) of the Federal  
6 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(3)) is  
7 amended—

8 (1) in subparagraph (D), by striking “except  
9 where subject to such conditions as the Secretary  
10 may prescribe, the investigator” and inserting the  
11 following: “except where, subject to such conditions  
12 as the Secretary may prescribe—

13 “(i) the proposed clinical testing poses  
14 no more than minimal risk to the human  
15 subject and includes appropriate safe-  
16 guards to protect the rights, safety, and  
17 welfare of the human subject; or

18 “(ii) the investigator”; and

19 (2) in the matter following subparagraph (D),  
20 by striking “subparagraph (D)” and inserting “sub-  
21 paragraph (D)(ii)”.

22 (b) DRUGS.—Section 505(i)(4) of the Federal Food,  
23 Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) is amended  
24 by striking “except where it is not feasible or it is contrary  
25 to the best interests of such human beings” and inserting

1 “except where it is not feasible, it is contrary to the best  
2 interests of such human beings, or the proposed clinical  
3 testing poses no more than minimal risk to such human  
4 beings and includes appropriate safeguards as prescribed  
5 to protect the rights, safety, and welfare of such human  
6 beings”.

7 **Subtitle P—Improving Scientific**  
8 **Expertise and Outreach at FDA**

9 **SEC. 2281. SILVIO O. CONTE SENIOR BIOMEDICAL RE-**  
10 **SEARCH SERVICE.**

11 (a) **HIRING AND RETENTION AUTHORITY.**—Section  
12 228 of the Public Health Service Act (42 U.S.C. 237) is  
13 amended—

14 (1) in the section heading, by inserting “AND  
15 BIOMEDICAL PRODUCT ASSESSMENT” after “RE-  
16 SEARCH”;

17 (2) in subsection (a)(1), by striking “Silvio O.  
18 Conte Senior Biomedical Research Service, not to  
19 exceed 500 members” and inserting “Silvio O. Conte  
20 Senior Biomedical Research and Biomedical Product  
21 Assessment Service (in this section referred to as the  
22 ‘Service’), the purpose of which is to recruit and re-  
23 tain competitive and qualified scientific and tech-  
24 nical experts outstanding in the field of biomedical

1 research, clinical research evaluation, and biomedical  
2 product assessment”;

3 (3) by amending subsection (a)(2) to read as  
4 follows:

5 “(2) The authority established in paragraph (1) may  
6 not be construed to require the Secretary to reduce the  
7 number of employees serving under any other employment  
8 system in order to offset the number of members serving  
9 in the Service.”;

10 (4) in subsection (b)—

11 (A) in the matter preceding paragraph (1),  
12 by striking “or clinical research evaluation” and  
13 inserting “, clinical research evaluation or bio-  
14 medical product assessment” after “evalua-  
15 tion”; and

16 (B) in paragraph (1), by inserting “or a  
17 master’s level degree in engineering,  
18 bioinformatics, or a related or emerging field,”  
19 after the comma;

20 (5) in subsection (d), by striking “and shall not  
21 exceed the rate payable for level I of the Executive  
22 Schedule unless approved by the President under  
23 section 5377(d)(2) of title 5, United States Code”  
24 and inserting “and shall not exceed the rate payable  
25 for the President”;



1 (6) by striking subsection (e); and

2 (7) by redesignating subsections (f) and (g) as  
3 subsections (e) and (f), respectively.

4 (b) REPORT.—Not later than 3 years after the date  
5 of the enactment of this Act, the Secretary of Health and  
6 Human Services shall submit, and publish on the website  
7 of the Department of Health and Human Services a report  
8 on the implementation of the amendments made by sub-  
9 section (a), including whether the amendments have im-  
10 proved the ability of the Food and Drug Administration  
11 to hire and retain qualified experts to fulfill obligations  
12 specified under user fee agreements.

13 **SEC. 2282. ENABLING FDA SCIENTIFIC ENGAGEMENT.**

14 It is the sense of Congress that participation in or  
15 sponsorship of scientific conferences and meetings is es-  
16 sential to the mission of the Food and Drug Administra-  
17 tion.

18 **SEC. 2283. REAGAN-UDALL FOUNDATION FOR THE FOOD**  
19 **AND DRUG ADMINISTRATION.**

20 (a) BOARD OF DIRECTORS.—

21 (1) COMPOSITION AND SIZE.—Section  
22 770(d)(1)(C) of the Federal Food, Drug, and Cos-  
23 metic Act (21 U.S.C. 379dd(d)(1)(C)) is amended—

24 (A) by redesignating clause (ii) as clause  
25 (iii);

1 (B) by inserting after clause (i) the fol-  
2 lowing:

3 “(ii) ADDITIONAL MEMBERS.—The  
4 Board, through amendments to the bylaws  
5 of the Foundation, may provide that the  
6 number of voting members of the Board  
7 shall be a number (to be specified in such  
8 amendment) greater than 14. Any Board  
9 positions that are established by any such  
10 amendment shall be appointed (by majority  
11 vote) by the individuals who, as of the date  
12 of such amendment, are voting members of  
13 the Board and persons so appointed may  
14 represent any of the categories specified in  
15 subclauses (I) through (V) of clause (i), so  
16 long as no more than 30 percent of the  
17 total voting members of the Board (includ-  
18 ing members whose positions are estab-  
19 lished by such amendment) are representa-  
20 tives of the general pharmaceutical, device,  
21 food, cosmetic, and biotechnology indus-  
22 tries.”; and

23 (C) in clause (iii)(I), as redesignated by  
24 subparagraph (A), by striking “The ex officio  
25 members shall ensure” and inserting “The ex

1 officio members, acting pursuant to clause (i),  
2 and the Board, acting pursuant to clause (ii),  
3 shall ensure”.

4 (2) FEDERAL EMPLOYEES ALLOWED TO SERVE  
5 ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C)  
6 of the Federal Food, Drug, and Cosmetic Act (21  
7 U.S.C. 379dd(d)(1)(C)), as redesignated by para-  
8 graph (1)(A), is amended by adding at the end the  
9 following: “For purposes of this section, the term  
10 ‘employee of the Federal Government’ does not in-  
11 clude a ‘special Government employee’, as that term  
12 is defined in section 202(a) of title 18, United  
13 States Code.”.

14 (3) STAGGERED TERMS.—Subparagraph (A) of  
15 section 770(d)(3) of the Federal Food, Drug, and  
16 Cosmetic Act (21 U.S.C. 379dd(d)(3)) is amended  
17 to read as follows:

18 “(A) TERM.—The term of office of each  
19 member of the Board appointed under para-  
20 graph (1)(C)(i), and the term of office of any  
21 member of the Board whose position is estab-  
22 lished pursuant to paragraph (1)(C)(ii), shall be  
23 4 years, except that—

24 “(i) the terms of offices for the mem-  
25 bers of the Board initially appointed under

1 paragraph (1)(C)(i) shall expire on a stag-  
2 gered basis as determined by the ex officio  
3 members; and

4 “(ii) the terms of office for the per-  
5 sons initially appointed to positions estab-  
6 lished pursuant to paragraph (1)(C)(ii)  
7 may be made to expire on a staggered  
8 basis, as determined by the individuals  
9 who, as of the date of the amendment es-  
10 tablishing such positions, are members of  
11 the Board.”.

12 (b) EXECUTIVE DIRECTOR COMPENSATION.—Section  
13 770(g)(2) of the Federal Food, Drug, and Cosmetic Act  
14 (21 U.S.C. 379dd(g)(2)) is amended by striking “but shall  
15 not be greater than the compensation of the Commis-  
16 sioner”.

17 (c) SEPARATION OF FUNDS.—Section 770(m) of the  
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
19 379dd(m)) is amended by striking “are held in separate  
20 accounts from funds received from entities under sub-  
21 section (i)” and inserting “are managed as individual pro-  
22 grammatic funds under subsection (i), according to best  
23 accounting practices”.

1 **SEC. 2284. COLLECTION OF CERTAIN VOLUNTARY INFOR-**  
 2 **MATION EXEMPTED FROM PAPERWORK RE-**  
 3 **DUCTION ACT.**

4 Chapter VII of the Federal Food, Drug, and Cos-  
 5 metic Act is amended by inserting after section 708 of  
 6 such Act (21 U.S.C. 379) the following:

7 **“SEC. 708A. COLLECTION OF CERTAIN VOLUNTARY INFOR-**  
 8 **MATION EXEMPTED FROM PAPERWORK RE-**  
 9 **DUCTION ACT.**

10 “Chapter 35 of title 44, United States Code, shall  
 11 not apply to the collection from patients, industry, aca-  
 12 demia, and other stakeholders, of voluntary information  
 13 such as through voluntary surveys or questionnaires, initi-  
 14 ated by the Secretary.”.

15 **TITLE III—DELIVERY**

16 **Subtitle A—Interoperability**

17 **SEC. 3001. ENSURING INTEROPERABILITY OF HEALTH IN-**  
 18 **FORMATION TECHNOLOGY.**

19 (a) INTEROPERABILITY STANDARDS.—

20 (1) IN GENERAL.—Subtitle A of title XXX of  
 21 the Public Health Service Act (42 U.S.C. 300jj–11  
 22 et seq.) is amended by adding at the end the fol-  
 23 lowing new section:

1 **“SEC. 3010. ENSURING INTEROPERABILITY OF HEALTH IN-**  
2 **FORMATION TECHNOLOGY.**

3 “(a) INTEROPERABILITY.—In order for health infor-  
4 mation technology to be considered interoperable, such  
5 technology must satisfy the following criteria:

6 “(1) SECURE TRANSFER.—The technology al-  
7 lows the secure transfer of the entirety of a patient’s  
8 data from any and all health information technology  
9 for authorized use under applicable law.

10 “(2) COMPLETE ACCESS TO HEALTH DATA.—  
11 The technology allows access to the entirety of a pa-  
12 tient’s available data for authorized use under appli-  
13 cable law without special effort, as defined by rec-  
14 ommendations adopted in accordance with this sec-  
15 tion, by the requestor of such data unless such data  
16 is not disclosable under applicable law.

17 “(3) NO INFORMATION BLOCKING.—The tech-  
18 nology is not configured, set up, or implemented to  
19 engage in information blocking, as defined in section  
20 3010A(f).

21 “(b) CATEGORIES FOR INTEROPERABILITY STAND-  
22 ARDS.—The categories described in this subsection, with  
23 respect to standards for determining if health information  
24 technology is interoperable, consistent with the criteria de-  
25 scribed in subsection (a), include the following categories  
26 of standards:

1           “(1) Standards with respect to vocabulary and  
2           terminology.

3           “(2) Standards with respect to content and  
4           structure.

5           “(3) Standards with respect to transport of in-  
6           formation.

7           “(4) Security standards.

8           “(5) Service standards.”.

9           (2) GUIDANCE.—Not later than January 1,  
10          2017, the Secretary of Health and Human Services,  
11          through the National Coordinator of the Office of  
12          the National Coordinator for Health Information  
13          Technology, shall issue guidance with respect to the  
14          implementation of section 3010 of the Public Health  
15          Service Act, as added by paragraph (1), including  
16          with respect to defining and providing examples of  
17          authorized use of health information technology, as  
18          described in such section.

19          (b) IMPROVEMENTS TO RECOMMENDATION PROC-  
20          ESS.—

21                 (1) HIT POLICY COMMITTEE TO INCORPORATE  
22                 POLICIES FOR UPDATES TO INTEROPERABILITY  
23                 STANDARDS.—Section 3002 of the Public Health  
24                 Service Act (42 U.S.C. 300jj–12) is amended—

25                         (A) in subsection (a)—

1 (i) by striking “National Coordinator”  
2 and inserting “Secretary, in consultation  
3 with the National Coordinator,”; and

4 (ii) by adding at the end the following  
5 new sentence: “The HIT Policy Committee  
6 is authorized only to provide policy and  
7 priority recommendations to the Secretary  
8 and not authorized to otherwise affect the  
9 development or modification of any stand-  
10 ard, implementation specification, or cer-  
11 tification criterion under this title.”; and

12 (B) in subsection (b)(2)—

13 (i) in subparagraph (A), in the first  
14 sentence—

15 (I) by striking “The HIT Policy  
16 Committee” and inserting “Subject to  
17 subparagraph (D), the HIT Policy  
18 Committee”; and

19 (II) by inserting “(including the  
20 areas in which modifications and addi-  
21 tions to interoperability standards  
22 under section 3010 are needed for the  
23 electronic exchange and use of health  
24 information for purposes of adoption  
25 of such modifications and additions



1 under section 3004)” after “section  
2 3004”.

3 (ii) by adding at the end the following  
4 new subparagraph:

5 “(D) SPECIAL RULE RELATED TO INTER-  
6 OPERABILITY.—Any recommendation made by  
7 the HIT Policy Committee on or after the date  
8 of the enactment of this subparagraph with re-  
9 spect to interoperability of health information  
10 technology shall be consistent with the criteria  
11 described in subsection (a) of section 3010.”.

12 (2) SUNSET OF HIT STANDARDS COMMITTEE.—  
13 Section 3003 of the Public Health Service Act (42  
14 U.S.C. 300jj–13) is amended by adding at the end  
15 the following new subsection:

16 “(f) TERMINATION.—The HIT Standards Committee  
17 shall terminate on the date that is 90 days after the date  
18 of the enactment of this subsection.”.

19 (3) STANDARDS DEVELOPMENT ORGANIZA-  
20 TIONS.—Title XXX of the Public Health Service Act  
21 is amended by inserting after section 3003 the fol-  
22 lowing new section:

1 **“SEC. 3003A. RECOMMENDATIONS FOR STANDARDS**  
2 **THROUGH CONTRACT WITH STANDARDS DE-**  
3 **VELOPMENT ORGANIZATIONS.**

4 “(a) CONTRACT.—

5 “(1) IN GENERAL.—For purposes of activities  
6 conducted under this title, the Secretary shall enter  
7 into contracts with health care standards develop-  
8 ment organizations accredited by the American Na-  
9 tional Standards Institute to carry out the duties de-  
10 scribed in subsection (b), as applicable.

11 “(2) TIMING FOR FIRST CONTRACT.—As soon  
12 as practicable after the date of the enactment of this  
13 section, the Secretary shall enter into the first con-  
14 tract under paragraph (1).

15 “(3) PERIOD OF CONTRACT.—Each contract  
16 under paragraph (1) shall be for a period deter-  
17 mined necessary by the Secretary, in consultation  
18 with the National Coordinator, to carry out the ap-  
19 plicable duties described in subsection (b).

20 “(4) APPROPRIATE ORGANIZATIONS.—The Sec-  
21 retary shall ensure the most appropriate organiza-  
22 tions described in paragraph (1) are selected for  
23 each contract under paragraph (1).

24 “(b) DUTIES.—

1           “(1) INITIAL CONTRACT.—Under the initial  
2 contract under subsection (a)(1), the standards de-  
3 velopment organizations—

4           “(A) shall provide to the Secretary, in con-  
5 sultation with the National Coordinator, for  
6 adoption under section 3004, recommendations,  
7 in accordance with section 3010, for interoper-  
8 ability standards consistent with the criteria de-  
9 scribed in subsection (a) of such section and  
10 with respect to the categories described in sub-  
11 section (b)(1) of such section; and

12           “(B) may provide to the Secretary, in con-  
13 sultation with the National Coordinator, rec-  
14 ommendations described in paragraph (2).

15           “(2) SUBSEQUENT CONTRACTS.—Under each  
16 subsequent contract, the organizations shall provide  
17 to the Secretary, in consultation with the National  
18 Coordinator, for adoption under section 3004 rec-  
19 ommendations for any standards (including inter-  
20 operability criteria), implementation specifications,  
21 and certification criteria (and modifications, includ-  
22 ing additions to such standards, specifications, and  
23 criteria), which are in accordance with the policies  
24 and priorities developed by the Secretary, in con-  
25 sultation with the National Coordinator.

1       “(c) MODIFICATIONS AND SUBSEQUENT CON-  
2 TRACTS.—

3               “(1) IN GENERAL.—The Secretary, in consulta-  
4 tion with the National Coordinator, shall periodically  
5 conduct hearings to evaluate and review the stand-  
6 ards, implementation specification, and certification  
7 criteria adopted under section 3004 for purposes of  
8 determining if modifications, including any addi-  
9 tions, are needed with respect to such standards,  
10 specifications, and criteria.

11              “(2) CONTRACT TRIGGER.—Based on the needs  
12 for standards, implementation specifications, and  
13 certification criteria (and modifications, including  
14 additions to such standards, specifications, and cri-  
15 teria) under this title, as determined by the Sec-  
16 retary, in consultation with the National Coordi-  
17 nator, the Secretary shall, as needed, enter into con-  
18 tracts under subsection (a) in addition to the initial  
19 contract.

20              “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
21 is authorized to be appropriated \$10,000,000 for contracts  
22 under subsection (a), to remain available until expended.”.

23              (4) MODIFICATIONS TO ROLE OF ONCHIT.—  
24 Section 3001(c)(1)(A) of the Public Health Service  
25 Act (42 U.S.C. 300jj–11(c)(1)(A)) is amended by in-

1       serting “for recommendations made before the date  
2       of the enactment of the 21st Century Cures Act,”  
3       before “review and determine”.

4       (c) ADOPTION.—Section 3004 of the Public Health  
5       Service Act (42 U.S.C. 300jj–14) is amended—

6             (1) in subsection (a)—

7                     (A) in paragraph (1), by inserting after  
8                     “section 3001(c)” the following: “(or, subject to  
9                     subsection (c), in the case of a standard, speci-  
10                    fication, or criterion recommended on or after  
11                    the date of the enactment of the 21st Century  
12                    Cures Act, after the date of submission of the  
13                    recommendation to the Secretary under section  
14                    3003A)”; and

15                    (B) in paragraph (2), by striking “and the  
16                    HIT Standards Committee”;

17             (2) in subsection (b), by adding at the end the  
18       following new paragraph:

19                     “(4) LIMITATION.—The Secretary may not  
20                     adopt any standards, implementation specifications,  
21                     or certification criteria under this subsection or sub-  
22                     section (a) that are inconsistent with or duplicative  
23                     of an interoperability standard adopted under this  
24                     section, in accordance with section 3010. In the case  
25                     of a standard, specification, or criterion that has

1       been adopted under this section and is inconsistent  
2       or duplicative of such an interoperability standard  
3       that is subsequently adopted under this section, such  
4       interoperability standard shall supercede such other  
5       standard, specification, or criterion and such other  
6       standard, specification, or criterion shall no longer  
7       be considered adopted under this section beginning  
8       on the date that such interoperability standard be-  
9       comes effective.”; and

10               (3) by adding at the end the following new sub-  
11       sections:

12       “(c) ADOPTION OF INITIAL INTEROPERABILITY  
13 STANDARDS.—Notwithstanding the previous subsections  
14 of this section, the following shall apply in the case of the  
15 initial set of interoperability standards recommended  
16 under section 3003A:

17               “(1) REVIEW OF STANDARDS.—Not later than  
18       90 days after the date of receipt of recommendations  
19       for such interoperability standards, the Secretary, in  
20       consultation with the National Coordinator and rep-  
21       resentatives of other relevant Federal agencies, shall  
22       jointly review such standards and shall determine  
23       whether or not to propose adoption of such stand-  
24       ards.

1           “(2) DETERMINATION TO ADOPT.—If the Sec-  
2           retary determines—

3                   “(A) to propose adoption of such stand-  
4                   ards, the Secretary shall, by regulation under  
5                   section 553 of title 5, United States Code, de-  
6                   termine whether or not to adopt such stand-  
7                   ards; or

8                   “(B) not to propose adoption of such  
9                   standards, the Secretary shall notify the Na-  
10                  tional Coordinator and the standards develop-  
11                  ment organizations under section 3003A in  
12                  writing of such determination and the reasons  
13                  for not proposing the adoption of the rec-  
14                  ommendation for such standards.

15               “(3) PUBLICATION.—The Secretary shall pro-  
16               vide for publication in the Federal Register of all de-  
17               terminations made by the Secretary under para-  
18               graph (1).

19               “(4) APPLICATION.—Any standard adopted  
20               under this subsection shall be effective 12 months  
21               after the date of publication of the determination to  
22               adopt such standard.

23               “(c) RULES FOR ADOPTION.—In the case of a stand-  
24               ard (including interoperability standard), implementation  
25               specification, or certification criteria adopted under this

1 section on or after the date of the enactment of the 21st  
2 Century Cures Act, the following shall apply:

3 “(1) IN GENERAL.—Except as provided in para-  
4 graph (2), any such standard (including interoper-  
5 ability standard), implementation specification, or  
6 certification criteria shall be a standard, specifica-  
7 tion, or criterion that has been recommended by the  
8 standards development organizations with which the  
9 Secretary has entered into a contract under section  
10 3003A.

11 “(2) SPECIAL RULE IF NO STANDARD, SPECI-  
12 FICATION, OR CRITERION RECOMMENDED.—If no  
13 standard is recommended under paragraph (1)—

14 “(A) in the case of interoperability stand-  
15 ards, relating to a category described in section  
16 3010(b)—

17 “(i) paragraph (1) shall not apply;

18 and

19 “(ii) paragraph (4) shall apply; or

20 “(B) in the case of any other standard, im-  
21 plementation specification, or certification cri-  
22 teria, relating to a policy or priority to carry  
23 out this title, as determined by the Secretary,  
24 in consultation with the National Coordinator—



1 “(i) paragraph (1) shall not apply;

2 and

3 “(ii) paragraph (4) shall apply.

4 “(3) EFFECTIVE DATE.—Any standard, imple-  
5 mentation specification, or certification criterion  
6 adopted under this section shall be effective 12  
7 months after the date of publication of the final rule  
8 to adopt such standard, implementation specifica-  
9 tion, or certification criteria.

10 “(4) ASSISTANCE TO THE SECRETARY.—In  
11 complying with the requirements of this subsection,  
12 the Secretary shall rely on the recommendations of  
13 the National Committee on Vital and Health Statis-  
14 tics established under section 306(k), and shall con-  
15 sult with appropriate Federal and State agencies  
16 and private organizations. The Secretary shall pub-  
17 lish in the Federal Register any recommendation of  
18 the National Committee on Vital and Health Statis-  
19 tics regarding the adoption of a standard implemen-  
20 tation specification, or certification criterion under  
21 this section. Any standard, implementation specifica-  
22 tion, or certification criterion adopted pursuant to  
23 this paragraph shall be promulgated in accordance  
24 with the rulemaking procedures of subchapter III of  
25 chapter 5 of title 5, United States Code.”.

1 (d) REPORTS AND NOTIFICATIONS.—Section 3010 of  
2 the Public Health Service Act, as added by subsection (a),  
3 is amended by adding at the end the following new sub-  
4 section:

5 “(c) DISSEMINATION OF INFORMATION.—

6 “(1) INITIAL SUMMARY REPORT.—Not later  
7 than July 1, 2017, the Secretary, after consultation  
8 with relevant stakeholders, shall submit to Congress  
9 and provide for publication in the Federal Register  
10 and the posting on the Internet website of the Office  
11 of the National Coordinator for Health Information  
12 Technology of a report on the following:

13 “(A) The initial set of interoperability  
14 standards adopted under section 3004(c).

15 “(B) The strategies for achieving wide-  
16 spread interoperability.

17 “(C) An overview of the extent to which  
18 electronic health records and health information  
19 technology offered as of such date satisfy such  
20 initial set.

21 “(D) Any barriers that are preventing  
22 widespread interoperability.

23 “(E) The plan and milestones, including  
24 specific steps, to achieve widespread interoper-  
25 ability.

1           “(2) FOLLOW-UP DETERMINATION AND REPORT  
2           ON WIDESPREAD INTEROPERABILITY.—Not later  
3           than December 31, 2019, the Secretary shall provide  
4           for publication in the Federal Register and the post-  
5           ing on the Internet website of the Office of the Na-  
6           tional Coordinator for Health Information Tech-  
7           nology of the following:

8                   “(A) A determination by the Secretary  
9                   whether the goal of widespread interoperability  
10                  has been achieved.

11                  “(B) A list identifying the vendors of, or  
12                  other entities offering, qualified electronic  
13                  health records, which categorizes such entities,  
14                  with respect to such records, as in compliance  
15                  or not in compliance with the certification cri-  
16                  teria described in section 3001(c)(5)(B)(ii) and  
17                  with the requirements under clause (i) of sec-  
18                  tion 3001(c)(5)(C) (including with the terms of  
19                  the attestation and other requirements under  
20                  such clause).

21                  “(C) Actions that may be taken by entities  
22                  identified under subparagraph (B) as not being  
23                  in compliance with such criteria and require-  
24                  ments in order for such entities to become in  
25                  compliance with such criteria and requirements.

1           “(D) Penalties described in section  
2           3010A(d) to which entities, with respect to such  
3           qualified electronic health records, beginning  
4           January 1, 2019, are subject if such technology  
5           and entities are not in compliance with the cer-  
6           tification criteria described in section  
7           3001(c)(5)(B)(ii) and with the requirements  
8           under clause (i) of section 3001(c)(5)(C), re-  
9           spectively.

10           “(3) ONGOING PUBLICATION OF RECOMMENDA-  
11           TIONS.—The Secretary shall provide for publication  
12           in the Federal Register and the posting on the  
13           Internet website of the Office of the National Coor-  
14           dinator for Health Information Technology of all  
15           recommendations made under this section.”.

16           (e) CERTIFICATION AND OTHER ENFORCEMENT  
17           PROVISIONS.—

18           (1) CERTIFICATION OF QUALIFIED ELECTRONIC  
19           HEALTH RECORDS.—

20           (A) IN GENERAL.—Section 3007(b) of the  
21           Public Health Service Act (42 U.S.C. 300jj–  
22           17(b)) is amended by striking “under section  
23           3001(c)(3) to be in compliance with” and all  
24           that follows through the period at the end and  
25           inserting “under section 3001(c)(3)—

1           “(1) for certifications made before January 1,  
2           2018, to be in compliance with applicable standards  
3           adopted under subsections (a) and (b) of section  
4           3004; and

5           “(2) for certifications made on or after January  
6           1, 2018, to be in compliance with applicable stand-  
7           ards adopted under subsections (a) and (b) of sec-  
8           tion 3004 and to be interoperable in accordance with  
9           section 3010, including by being in compliance with  
10          interoperability standards adopted under section  
11          3004.”.

12                       (B) REQUIREMENTS OF SECRETARY.—Sec-  
13                       tion 3001(c)(5) of the Public Health Service  
14                       Act (42 U.S.C. 300jj–11(c)(5)) is amended—

15                       (i) by amending subparagraph (B) of  
16                       such section to read as follows:

17                       “(B) CERTIFICATION CRITERIA DE-  
18                       SCRIBED.—In this title, the term ‘certification  
19                       criteria’ means, with respect to qualified elec-  
20                       tronic health records—

21                       “(i) for certifications made before  
22                       January 1, 2018, criteria to establish that  
23                       the records meet standards and implemen-  
24                       tation specifications adopted under sub-

1 sections (a) and (b) of section 3004 for  
2 qualified electronic health records; and

3 “(ii) for certifications made on or  
4 after January 1, 2018, criteria described  
5 in clause (i) and criteria to establish that  
6 the records are interoperable, in accord-  
7 ance with section 3010, including by being  
8 in compliance with interoperability stand-  
9 ards adopted under section 3004.”; and

10 (ii) by adding at the end the following  
11 new subparagraph:

12 “(C) ENFORCEMENT;

13 DECERTIFICATIONS.—

14 “(i) REQUIREMENTS.—Under any  
15 program kept or recognized under subpara-  
16 graph (A), the Secretary shall ensure that  
17 any vendor of or other entity offering  
18 qualified electronic health records seeking  
19 a certification of such records under such  
20 program on or after January 1, 2018,  
21 shall, as a condition of certification (and  
22 maintenance of certification) of such a  
23 record under such program—

24 “(I) provide to the Secretary an  
25 attestation—

1           “(aa) that the entity, unless  
2           for a legitimate purpose specified  
3           by the Secretary, has not taken  
4           any action, including through any  
5           financial, administrative, or tech-  
6           nological barrier, which the entity  
7           knows or should know (as defined  
8           in section 1128A(i)(7) of the So-  
9           cial Security Act), is to limit or  
10          restrict the exchange of informa-  
11          tion or to prevent or  
12          disincentivize widespread inter-  
13          operability between any providers  
14          using such records or other  
15          health information technology in  
16          connection with such record;

17          “(bb) on the pricing infor-  
18          mation described in clause (v) for  
19          purposes of the portal created  
20          under paragraph (9), that such  
21          information will be available on a  
22          public Web site of such entity  
23          and in marketing materials, com-  
24          munications statements, and  
25          other assertions of such entity re-

1           lated to such record, and that the  
2           entity will voluntarily provide  
3           such information to customers  
4           prior to providing any qualified  
5           electronic health records or re-  
6           lated product or service (includ-  
7           ing subsequent updates, add-ons,  
8           or additional products or services  
9           to be provided during the course  
10          of an on-going contract), prospec-  
11          tive customers (such as persons  
12          who request or receive a  
13          quotation, estimate, or other  
14          similar marketing or promotional  
15          material), and other persons who  
16          request such information;

17                 “(cc) that the software with  
18                 respect to such records have pub-  
19                 lished application programming  
20                 interfaces for medical records  
21                 data, search and indexing, se-  
22                 mantic harmonization and vocab-  
23                 ulary translation, and user inter-  
24                 face applications;



1           “(dd) that the entity has  
2 successfully tested the use of the  
3 record in the type of setting in  
4 which it would be marketed;

5           “(ee) the entity has in place  
6 implementation guidelines for  
7 such record that support inter-  
8 operability, consistent with sec-  
9 tion 3010; and

10           “(ff) that the entity has in  
11 place data sharing programs or  
12 capabilities based on common  
13 data elements through applica-  
14 tion programming interfaces  
15 without the requirement for ven-  
16 dor-specific interfaces;

17           “(II) publish application pro-  
18 gramming interfaces and associated  
19 documentation, with respect to such  
20 records, for medical records data,  
21 search and indexing, semantic harmo-  
22 nization and vocabulary translation,  
23 and user interface applications; and

24           “(III) demonstrate to the satis-  
25 faction of the Secretary that data

1 from such records is able to be ex-  
2 changed through the use of applica-  
3 tion programming interfaces and used  
4 in a manner that allows for exchange  
5 and everyday use, as authorized under  
6 applicable law, of such record.

7 “(ii) DECERTIFICATION.—Under any  
8 program kept or recognized under subpara-  
9 graph (A), the Secretary shall ensure that  
10 beginning January 1, 2019, any qualified  
11 electronic health records that do not sat-  
12 isfy the certification criteria described in  
13 section 3001(c)(5)(B)(ii) or with respect to  
14 which the vendor or other entity described  
15 in clause (i) does not satisfy the require-  
16 ments under such clause (or is determined  
17 to be in violation of the terms of the attes-  
18 tation or other requirements under such  
19 clause) shall no longer be considered as  
20 certified under such program.

21 “(iii) ANNUAL PUBLICATION.—For  
22 2019 and each subsequent year, the Sec-  
23 retary shall post on the public Internet  
24 website of the Department of Health and  
25 Human Services a list of any vendors of or

1 other entities offering qualified electronic  
2 health records with respect to which cer-  
3 tification has been withdrawn under clause  
4 (ii) during such year.

5 “(iv) PERIODIC REVIEW.—The Sec-  
6 retary shall periodically review and confirm  
7 that vendors of and other entities offering  
8 qualified electronic health records have  
9 publicly published application program-  
10 ming interfaces and associated documenta-  
11 tion as required by clause (i)(II) for pur-  
12 poses of certification and maintaining cer-  
13 tification under any program kept or rec-  
14 ognized under subparagraph (A).

15 “(v) PRICING INFORMATION.—For  
16 purposes of clause (i)(I)(bb), the pricing  
17 information described in this clause, with  
18 respect to a vendor of or other entity offer-  
19 ing a qualified electronic health record, is  
20 the following:

21 “(I) Additional types of costs or  
22 fees (whether fixed, recurring, trans-  
23 action based, or otherwise) imposed by  
24 the entity (or any third-party from  
25 whom the entity purchases, licenses,

1 or obtains any technology, products,  
2 or services in connection with the  
3 qualified electronic health record) to  
4 purchase, license, implement, main-  
5 tain, upgrade, use, or otherwise enable  
6 and support the use of capabilities to  
7 which such record is to be certified  
8 under this section; or in connection  
9 with any data generated in the course  
10 of using any capability to which the  
11 record is to be so certified.

12 “(II) Limitations, whether by  
13 contract or otherwise, on the use of  
14 any capability to which the record is  
15 to be certified under this section for  
16 any purpose within the scope of the  
17 record’s certification; or in connection  
18 with any data generated in the course  
19 of using any capability to which the  
20 record is to be certified under this  
21 section.

22 “(III) Limitations, including  
23 technical or practical limitations of  
24 technology or its capabilities, that  
25 could prevent or impair the successful

1 implementation, configuration,  
2 customization, maintenance, support,  
3 or use of any capabilities to which the  
4 record is to be certified under this  
5 section; or that could prevent or limit  
6 the use, exchange, or portability of  
7 any data generated in the course of  
8 using any capability to which the  
9 record is to be so certified.”.

10 (2) ADDITIONAL ENFORCEMENT PROVISIONS  
11 UNDER THE PUBLIC HEALTH SERVICE ACT.—Sub-  
12 title A of title XXX of the Public Health Service Act  
13 (42 U.S.C. 300jj–11 et seq.), as amended by sub-  
14 section (a)(1), is further amended by adding at the  
15 end the following new section:

16 **“SEC. 3010A. ENFORCEMENT MECHANISMS.**

17 “(a) INSPECTOR GENERAL AUTHORITY.—The In-  
18 spector General of the Department of Health and Human  
19 Services shall have the authority to investigate claims of—

20 “(1) vendors of, or other entities offering, quali-  
21 fied electronic health records—

22 “(A) being in violation of an attestation  
23 made under section 3001(c)(5)(C)(i)(I), with  
24 respect to the use of such records by a health

1 care provider under a specified meaningful use  
2 incentive program; and

3 “(B) having engaged in information block-  
4 ing (as defined in subsection (f)), unless for a  
5 legitimate purpose specified by the Secretary,  
6 with respect to the use of such records by a  
7 health care provider under such a program;

8 “(2) health care providers, with respect to the  
9 use of such records under a specified meaningful use  
10 incentive program, having, unless for a legitimate  
11 purpose specified by the Secretary, engaged in infor-  
12 mation blocking (as so defined);

13 “(3) health information system providers de-  
14 scribed in subsection (b) having engaged in informa-  
15 tion blocking (as so defined), unless for a legitimate  
16 purpose specified by the Secretary, with respect to  
17 the use of such records under a specified meaningful  
18 use incentive program; and

19 “(4) vendors of, or other entities offering,  
20 health information technology (other than technology  
21 described in paragraph (1)), health care providers,  
22 with respect to the use of such technology, and  
23 health information system providers, with respect to  
24 such technology, unless for a legitimate purpose

1 specified by the Secretary, having engaged in infor-  
2 mation blocking (as so defined).

3 “(b) HEALTH INFORMATION SYSTEM PROVIDERS.—

4 The Inspector General of the Department of Health and  
5 Human Services shall, in coordination with the Federal  
6 Trade Commission, ensure that health information system  
7 providers (such as operators of health information ex-  
8 changes and other systems that facilitate the exchange of  
9 information) investigate claims of information blocking,  
10 with respect to the use of such records under a specified  
11 meaningful use incentive program.

12 “(c) INFORMATION SHARING PROVISIONS.—

13 “(1) IN GENERAL.—The National Coordinator  
14 may serve as a technical consultant to the Inspector  
15 General of the Department of Health and Human  
16 Services and the Federal Trade Commission for pur-  
17 poses of carrying out this section. As such technical  
18 consultant, the National Coordinator may, notwith-  
19 standing any other provision of law, share informa-  
20 tion related to claims or investigations under sub-  
21 section (a) or (b) with the Inspector General and  
22 Federal Trade Commission for purposes of such in-  
23 vestigations.

24 “(2) PROTECTION FROM DISCLOSURE OF IN-  
25 FORMATION.—Any information shared by the Na-

1 tional Coordinator under paragraph (1) shall not be  
2 subject to the provisions of section 552 of title 5,  
3 United States Code (commonly referred to as the  
4 Freedom of Information Act). Any information ac-  
5 quired pursuant to paragraph (1) shall be held in  
6 confidence and shall not be disclosed to any person  
7 except as may be necessary to carry out the pur-  
8 poses of subsection (a).

9 “(3) NON-APPLICATION OF PAPERWORK REDUC-  
10 TION ACT.—Chapter 35 of title 44, United States  
11 Code (commonly referred to as the Paperwork Re-  
12 duction Act of 1995) shall not apply to the National  
13 Coordinator or to the Office of the National Coordi-  
14 nator for Health Information Technology with re-  
15 spect to the collection of complaints relating to  
16 claims described in subsection (a).

17 “(d) PENALTY.—Any person or entity determined to  
18 have committed an act described in paragraph (1), (2),  
19 or (3) of subsection (a), in connection with a specified  
20 meaningful use incentive program, shall be subject to a  
21 civil monetary penalty of not more than \$10,000 for each  
22 such act. The provisions of section 1128A (other than sub-  
23 sections (a) and (b)) shall apply to a civil money penalty  
24 applied under this subsection in the same manner as they



1 apply to a civil money penalty or proceeding under section  
2 1128A(a).

3 “(e) SPECIFIED MEANINGFUL USE INCENTIVE PRO-  
4 GRAM.—For purposes of this section, the term ‘specified  
5 meaningful use incentive program’ includes the following:

6 “(1) The incentive payments under subsection  
7 (o) of section 1848 of the Social Security Act (42  
8 U.S.C. 1395w-4) and adjustments under subsection  
9 (a)(7) of such section.

10 “(2) The incentive payments under subsection  
11 (n) of section 1848 of such Act (42 U.S.C. 1395ww)  
12 and adjustments under subsection (b)(3)(B) of such  
13 section.

14 “(3) The incentive payments and adjustments  
15 made under subsections (l) and (m) of section 1853  
16 of such Act (42 U.S.C. 1395w-23).

17 “(4) The incentive payment under paragraph  
18 (3) of section 1814(l) of such Act (42 U.S.C.  
19 1395f(l)) and adjustment under paragraph (4) of  
20 such section.

21 “(5) The shared savings program under section  
22 1899 of such Act (42 U.S.C. 1395jjj).

23 “(6) The payments to Medicaid providers de-  
24 scribed in section 1903(t) of such Act (42 U.S.C.  
25 1396b(t)).

1 “(f) INFORMATION BLOCKING.—

2 “(1) IN GENERAL.—For purposes of this sec-  
3 tion and section 3010, the term ‘information block-  
4 ing’ means, with respect to the use of qualified elec-  
5 tronic health records or other health information  
6 technology under a specified meaningful use incen-  
7 tive program, business, technical, and organizational  
8 practices, including practices described in paragraph  
9 (2), that—

10 “(A) prevent or materially discourage the  
11 exchange of electronic health information;

12 “(B) the actor knows or should know (as  
13 defined in section 1128A(i)(7) of the Social Se-  
14 curity Act) is likely to interfere with the ex-  
15 change or use of electronic health information;  
16 and

17 “(C) do not serve to protect patient safety,  
18 maintain the privacy and security of individ-  
19 uals’ health information or promote competition  
20 and consumer welfare.

21 “(2) PRACTICES DESCRIBED.—For purposes of  
22 paragraph (1), the practices described in this para-  
23 graph are the following:

24 “(A) Contract terms, policies, or other  
25 business or organizational practices that restrict

1 individuals' access to their electronic health in-  
2 formation or restrict the exchange or use of  
3 that information for treatment and other per-  
4 mitted purposes.

5 “(B) Charging prices or fees (such as for  
6 data exchange, portability, and interfaces) that  
7 make exchanging and using electronic health in-  
8 formation cost prohibitive.

9 “(C) Developing or implementing health  
10 information technology in non-standard ways  
11 that are likely to substantially increase the  
12 costs, complexity, or burden of sharing elec-  
13 tronic health information, especially in cases in  
14 which relevant interoperability standards or  
15 methods to measure interoperability have been  
16 adopted by the Secretary.

17 “(D) Developing or implementing health  
18 information technology in ways that are likely  
19 to lock in users or electronic health information,  
20 such as not allowing for the full export of data;  
21 lead to fraud, waste, or abuse; or impede inno-  
22 vations and advancements in health information  
23 exchange and health information technology-en-  
24 abled care delivery.

1       “(g) TREATMENT OF VENDORS WITH RESPECT TO  
2 PATIENT SAFETY ORGANIZATIONS.—In applying part C  
3 of title IX—

4           “(1) vendors shall be treated as a provider (as  
5 defined in section 921) for purposes of reporting re-  
6 quirements under such part, to the extent that such  
7 reports are related to attestation requirements under  
8 section 3001(c)(5)(C)(i)(I);

9           “(2) claims of information blocking described in  
10 subsection (a) shall be treated as a patient safety ac-  
11 tivity under such part for purposes of reporting re-  
12 quirements under such part; and

13           “(3) health care providers that are not mem-  
14 bers of patient safety organizations shall be treated  
15 in the same manner as health care providers that  
16 are such members for purposes of such reporting re-  
17 quirements with respect to claims of information  
18 blocking described in subsection (a).”.

19           (3) ONCHIT.—

20           (A) PORTAL.—Section 3001(c) of the Pub-  
21 lic Health Service Act (42 U.S.C. 300jj–11(c))  
22 is amended by adding at the end the following  
23 new paragraph:

24           “(9) PORTAL.—Not later than January 1,  
25 2019, the National Coordinator shall create a portal

1 to make the information described in paragraph  
2 (5)(C)(I)(i)(bb) available to the public in a manner  
3 that allows for comparison of price information  
4 among health information technology products and  
5 that aids in making informed decisions for pur-  
6 chasing such a product.”.

7 (B) INFORMATION BLOCKING.—Not later  
8 than 12 months after the date of the enactment  
9 of this Act, the National Coordinator shall,  
10 through rulemaking, implement the provisions  
11 of this section, and amendments made by this  
12 section, relating to information blocking.

13 (C) HIPAA.—Not later than January 1,  
14 2017, the National Coordinator shall publish  
15 guidance to clarify the relationship of the  
16 HIPAA privacy and security law, as defined in  
17 section 3009(a)(2) of the Public Health Service  
18 Act (42 U.S.C. 300jj–19(a)(2)) as such provi-  
19 sions relate to information blocking (as defined  
20 in section 3010A(f) of such Act, as added by  
21 paragraph (2), including examples of how such  
22 provisions may result in information blocking.

23 (4) DEMONSTRATION REQUIRED FOR MEANING-  
24 FUL EHR USE INCENTIVES UNDER MEDICARE.—

25 (A) INCENTIVES FOR PROFESSIONALS.—

1 (i) IN GENERAL.—Section  
2 1848(o)(2)(C) of the Social Security Act  
3 (42 U.S.C. 1395w-4(o)(2)(C)) is amended  
4 by adding at the end the following new  
5 clause:

6 “(iii) INTEROPERABILITY.—With re-  
7 spect to EHR reporting periods for pay-  
8 ment years beginning with 2018, the  
9 means described in clause (i) specified by  
10 the Secretary shall include a demonstra-  
11 tion, through means such as an attesta-  
12 tion, that the professional has not taken  
13 any action described in subsection (a)(2) of  
14 section 3010A of the Public Health Service  
15 Act with respect to which the professional,  
16 with respect to the use of any certified  
17 EHR technology.”.

18 (ii) HARDSHIP EXEMPTION IN CASE  
19 OF DECERTIFIED EHR.—Subparagraph (B)  
20 of section 1848(a)(7) of the Social Security  
21 Act (42 U.S.C. 1395w-4(a)(7)(B)) is  
22 amended to read as follows:

23 “(B) SIGNIFICANT HARDSHIP EXCEP-  
24 TION.—

1           “(i) IN GENERAL.—The Secretary  
2           may, on a case-by-case basis, exempt an el-  
3           igible professional from the application of  
4           the payment adjustment under subpara-  
5           graph (A) if the Secretary determines, sub-  
6           ject to annual renewal, that compliance  
7           with the requirement for being a meaning-  
8           ful EHR user would result in a significant  
9           hardship, such as in the case of an eligible  
10          professional who practices in a rural area  
11          without sufficient Internet access.

12          “(ii) DECERTIFICATION.—

13                 “(I) IN GENERAL.—The Sec-  
14                 retary may, on a case-by-case basis,  
15                 exempt an eligible professional from  
16                 the application of the payment adjust-  
17                 ment under subparagraph (A) if the  
18                 Secretary determines that such pro-  
19                 fessional was determined to not be a  
20                 meaningful EHR user because the  
21                 qualified electronic health record used  
22                 by such professional was decertified  
23                 under section 3001(c)(5)(C) of the  
24                 Public Health Service Act. An exemp-  
25                 tion under the previous sentence may

1 be applied to an eligible professional  
2 only, subject to subclause (II), during  
3 the first payment year with respect to  
4 the first EHR reporting period to  
5 which such decertification applies.

6 “(II) DURATION.—

7 “(aa) IN GENERAL.—In no  
8 case shall an exemption by rea-  
9 son of this clause be for a period  
10 of less than 12 months.

11 “(bb) EXTENSION.—An ex-  
12 emption under this clause may be  
13 extended for a period of an addi-  
14 tional 12 months subject to the  
15 limitation described in clause (ii).

16 “(iii) LIMITATION.—Subject to clause  
17 (ii)(II)(aa), in no case may an eligible pro-  
18 fessional be granted an exemption under  
19 this subparagraph for more than 5 years.”.

20 (B) INCENTIVES FOR HOSPITALS.—

21 (i) IN GENERAL.—Section 1886(o)(1)  
22 of the Social Security Act (42 U.S.C.  
23 1395ww(o)(1)) is amended—

24 (I) in subparagraph (A), by in-  
25 serting before the period at the end



1 the following: “and, for performance  
2 periods for fiscal year 2018 or a sub-  
3 sequent fiscal year, that provide a  
4 demonstration described in subpara-  
5 graph (D) to the Secretary”; and

6 (II) by adding at the end the fol-  
7 lowing new subparagraph:

8 “(D) DEMONSTRATION DESCRIBED.—The  
9 demonstration described in this subparagraph is  
10 a demonstration, through means such as an at-  
11 testation, that the hospital has not taken any  
12 action described in subsection (a)(2) of section  
13 3010A of the Public Health Service Act with  
14 respect to which the hospital, with respect to  
15 the use of any certified EHR technology.”.

16 (ii) HARDSHIP EXEMPTION IN CASE  
17 OF DECERTIFIED EHR.—Subclause (II) of  
18 section 1886(b)(3)(B)(ix) of the Social Se-  
19 curity Act (42 U.S.C.  
20 1395ww(b)(3)(B)(ix)) is amended to read  
21 as follows:

22 “(II)(aa) The Secretary may, on  
23 a case-by-case basis, exempt a sub-  
24 section (d) hospital from the applica-  
25 tion of subclause (I) with respect to a

1 fiscal year if the Secretary deter-  
2 mines, subject to annual renewal, that  
3 requiring such hospital to be a mean-  
4 ingful EHR user during such fiscal  
5 year would result in a significant  
6 hardship, such as in the case of a hos-  
7 pital in a rural area without sufficient  
8 Internet access.

9 “(bb) The Secretary may, on a  
10 case-by-case basis, exempt a sub-  
11 section (d) hospital from the applica-  
12 tion of subclause (I) with respect to a  
13 fiscal year if the Secretary deter-  
14 mines, subject to annual renewal, that  
15 such hospital was determined to not  
16 be a meaningful EHR user because  
17 the qualified electronic health record  
18 used by such hospital was decertified  
19 under section 3001(c)(5)(C) of the  
20 Public Health Service Act. An exemp-  
21 tion under the previous sentence may  
22 be applied to a subsection (d) hospital  
23 only, subject to items (cc) and (dd),  
24 during the first payment year with re-  
25 spect to the first EHR reporting pe-

1           riod to which such decertification ap-  
2           plies.

3           “(cc) In no case shall an exemp-  
4           tion by reason of item (bb) be for a  
5           period of less than 12 months.

6           “(dd) An exemption under item  
7           (bb) may be extended for a period of  
8           an additional 12 months subject to  
9           the limitation described in item (ee).

10          “(ee) Subject to item (cc), in no  
11          case may a hospital be granted an ex-  
12          emption under this subclause for more  
13          than 5 years.”.

14                   (C) DEMONSTRATION REQUIRED FOR  
15           MEANINGFUL EHR USE INCENTIVES UNDER  
16           MEDICAID.—Section 1903(t)(2) of the Social  
17           Security Act (42 U.S.C. 1396b(t)(2)) is amend-  
18           ed by adding at the end the following: “An eli-  
19           gible professional shall not qualify as a Med-  
20           icaid provider under this subsection, with re-  
21           spect to a year beginning with 2018, unless  
22           such provider demonstrates to the Secretary,  
23           through means such as an attestation, that the  
24           provider has not taken any action described in  
25           subsection (a)(2) of section 3010A of the Public

1 Health Service Act with respect to which the  
2 provider knows or should know (as defined in  
3 section 1128A(i)(7) of the Social Security Act)  
4 about, with respect to the use of any certified  
5 EHR technology.”.

6 (f) DEFINITIONS.—

7 (1) CERTIFIED EHR TECHNOLOGY.—Paragraph  
8 (1) of section 3000 of the Public Health Service Act  
9 (42 U.S.C. 300jj) is amended to read as follows:

10 “(1) CERTIFIED EHR TECHNOLOGY.—The term  
11 ‘certified EHR technology’ means a qualified elec-  
12 tronic health record that is certified pursuant to sec-  
13 tion 3001(c)(5) as meeting the certification criteria  
14 defined in subparagraph (B) of such section that are  
15 applicable to the type of record involved (as deter-  
16 mined by the Secretary, such as an ambulatory elec-  
17 tronic health record for office-based physicians or an  
18 inpatient hospital electronic health record for hos-  
19 pitals) including, beginning January 1, 2018, with  
20 respect to which the vendor or other entity offering  
21 such technology is in compliance with the require-  
22 ments under section 3001(c)(5)(C)(i).”.

23 (2) WIDESPREAD INTEROPERABILITY.—Section  
24 3000 of the Public Health Service Act (42 U.S.C.

1 300jj) is amended by adding at the end the following  
2 new paragraph:

3 “(15) WIDESPREAD INTEROPERABILITY.—The  
4 term ‘widespread interoperability’ means that, on a  
5 nationwide basis—

6 “(A) health information technology are  
7 interoperable, in accordance with section 3010,  
8 including as measured by the methods adopted  
9 under such section; and

10 “(B) such records are employed by mean-  
11 ingful EHR users under the specified meaning-  
12 ful use incentive programs (as defined in sec-  
13 tion 3010A(e)) and other clinicians and health  
14 care providers.”.

15 (g) CONFORMING AMENDMENTS.—

16 (1) VOLUNTARY USE OF STANDARDS.—Section  
17 3006 of the Public Health Service Act (42 U.S.C.  
18 300jj–16) is amended—

19 (A) in subsection (a)(1), by inserting “in-  
20 cluding an interoperability standard adopted  
21 under section 3004” after “section 3004”.

22 (B) in subsection (b), by inserting “includ-  
23 ing the interoperability standards adopted  
24 under section 3004” after “section 3004”.

1           (2) HIPAA PRIVACY AND SECURITY LAW DEFINITION CORRECTION.—Section 3009(a)(2)(A) of the  
2           Public Health Service Act (42 U.S.C. 300jj–  
3           19(a)(2)(A)) is amended by striking “title IV” and  
4           inserting “title XIII”.

6           (3) COORDINATION OF FEDERAL ACTIVITIES.—  
7           Section 13111 of the HITECH Act is amended—

8                   (A) in subsection (a), by inserting before  
9                   the period at the end the following: “(and, be-  
10                   ginning on January 1, 2018, that are also  
11                   interoperable under section 3010 of such Act,  
12                   including by being in compliance with interoper-  
13                   ability standards adopted under section 3004 of  
14                   such Act)”; and

15                   (B) in subsection (b), by inserting “(and,  
16                   beginning on January 1, 2018, including an  
17                   interoperability standard adopted under section  
18                   3004 of such Act)” before “the President”.

19           (4) APPLICATION TO PRIVATE ENTITIES.—Sec-  
20           tion 13112 of the HITECH Act is amended by in-  
21           serting before the period at the end the following  
22           “(and, beginning on January 1, 2018, that are also  
23           interoperable under section 3010 of such Act, in-  
24           cluding by being in compliance with interoperability  
25           standards adopted under section 3004 of such Act)”.

1           (5) COORDINATION WITH RECOMMENDATIONS  
2           FOR ACHIEVING WIDESPREAD EHR INTEROPER-  
3           ABILITY.—Section 106 of the Medicare Access and  
4           CHIP Reauthorization Act of 2015 (Public Law  
5           114–10) is amended by striking subsection (b).

6           (h) PATIENT EMPOWERMENT.—It is the sense of  
7 Congress that—

8           (1) patients have the right to the entirety of the  
9           health information of such patient, including such  
10          information contained in an electronic health record  
11          of such patient;

12          (2) such right extends to both structured and  
13          unstructured data; and

14          (3) to further facilitate patient ownership over  
15          health information of such patient—

16                (A) health care providers should not have  
17                the ability to deny a patient’s request for access  
18                to the entirety of such health information of  
19                such patient; and

20                (B) health care providers do not need the  
21                consent of their patients to share personal  
22                health information of such patients with other  
23                covered entities, in compliance with the HIPAA  
24                privacy regulations promulgated pursuant to  
25                section 264(c) of the Health Insurance Port-

1 ability and Accountability Act of 1996 for the  
2 purposes of supporting patient care, except in  
3 situations where consent is specifically required  
4 under such regulations, such as in cases related  
5 to the psychiatric records of the patient.

## 6 **Subtitle B—Telehealth**

### 7 **SEC. 3021. TELEHEALTH SERVICES UNDER THE MEDICARE** 8 **PROGRAM.**

9 (a) PROVISION OF INFORMATION BY CENTERS FOR  
10 MEDICARE & MEDICAID SERVICES.—Not later than one  
11 year after the date of the enactment of this Act, the Ad-  
12 ministrator of the Centers for Medicare & Medicaid Serv-  
13 ices shall provide to the committees of jurisdiction of the  
14 House of Representatives and the Senate information on  
15 the following:

16 (1) The populations of Medicare beneficiaries,  
17 such as those who are dually eligible for the Medi-  
18 care program under title XVIII of the Social Secu-  
19 rity Act and the Medicaid program under title XIX  
20 of such Act and those with chronic conditions, whose  
21 care may be improved most in terms of quality and  
22 efficiency by the expansion, in a manner that meets  
23 or exceeds the existing in-person standard of care  
24 under the Medicare program under title XVIII of



1 such Act, of telehealth services under section  
2 1834(m)(4) of such Act (42 U.S.C. 1395m(m)(4)).

3 (2) Activities by the Center for Medicare and  
4 Medicaid Innovation which examine the use of tele-  
5 health services in models, projects, or initiatives  
6 funded through section 1115A of the Social Security  
7 Act (42 U.S.C. 1315a).

8 (3) The types of high volume procedures codes  
9 or diagnoses under such title XVIII which might be  
10 suitable to the furnishing of services via telehealth.

11 (4) Barriers that might prevent the expansion  
12 of telehealth services under section 1834(m)(4) of  
13 the Social Security Act (42 U.S.C. 1395m(m)(4))  
14 beyond such services that are in effect as of the date  
15 of the enactment of this Act.

16 (b) PROVISION OF INFORMATION BY MEDPAC.—Not  
17 later than one year after the date of the enactment of this  
18 Act, the Medicare Payment Advisory Commission estab-  
19 lished under section 1805 of the Social Security Act (42  
20 U.S.C. 1395b–6) shall, using data from the Medicare Ad-  
21 vantage program under part C of title XVIII of such Act,  
22 provide information to the committees of jurisdiction of  
23 the House of Representatives and the Senate that identi-  
24 fies—

25 (1) services—

1 (A) for which payment could not be made,  
2 as of the date of the enactment of this Act,  
3 under the fee-for-service program under parts A  
4 and B of such title by reason of any limitation  
5 imposed under section 1834(m) of such Act (42  
6 U.S.C. 1395m(m)); and

7 (B) that are services that are rec-  
8 ommended by the Commission to be included as  
9 telehealth services for which payment may be  
10 made under the fee-for-service program under  
11 parts A and B of such title; and

12 (2) barriers to furnishing telehealth services for  
13 which payment may be made under such title XVIII  
14 and solutions to address such barriers.

15 (c) SENSE OF CONGRESS.—It is the sense of Con-  
16 gress that—

17 (1) States should collaborate, through the use  
18 of State health board compacts or other mecha-  
19 nisms, to create common licensure requirements  
20 services in order to facilitate multistate practices  
21 and allow for health care providers to provide such  
22 services across State lines;

23 (2) health care providers should be appro-  
24 priately licensed in the physical location where the  
25 patient is receiving services;

1           (3) eligible originating sites should be expanded  
2 beyond those originating sites described in section  
3 1834(m)(4)(C) of the Social Security Act (42 U.S.C.  
4 1395m(m)(4)(C)); and

5           (4) any expansion of telehealth services under  
6 the Medicare program should—

7           (A) recognize that telemedicine is the deliv-  
8 ery of safe, effective, quality health care serv-  
9 ices, by a health care provider, using technology  
10 as the mode of care delivery;

11           (B) meet or exceed the conditions of cov-  
12 erage and payment with respect to the Medicare  
13 program under title XVIII unless specifically  
14 address in subsequent statute, of such Act if  
15 the service were furnished in person, including  
16 standards of care; and

17           (C) involve clinically appropriate means to  
18 furnish such services.

1 **Subtitle C—Encouraging Con-**  
2 **tinuing Medical Education for**  
3 **Physicians**

4 **SEC. 3041. EXEMPTING FROM MANUFACTURER TRANS-**  
5 **PARENCY REPORTING CERTAIN TRANSFERS**  
6 **USED FOR EDUCATIONAL PURPOSES.**

7 (a) IN GENERAL.—Section 1128G(e)(10)(B) of the  
8 Social Security Act (42 U.S.C. 1320a–7h(e)(10)(B)) is  
9 amended—

10 (1) in clause (iii), by inserting “, including  
11 peer-reviewed journals, journal reprints, journal sup-  
12 plements, medical conference reports, and medical  
13 textbooks” after “patient use”; and

14 (2) by adding at the end the following new  
15 clause:

16 “(xiii) In the case of a covered recipi-  
17 ent who is a physician, an indirect pay-  
18 ment or transfer of value to the covered re-  
19 cipient—

20 “(I) for speaking at, or preparing  
21 educational materials for, an edu-  
22 cational event for physicians or other  
23 health care professionals that does not  
24 commercially promote a covered drug,

1 device, biological, or medical supply;  
2 or

3 “(II) that serves the sole purpose  
4 of providing the covered recipient with  
5 medical education, such as by pro-  
6 viding the covered recipient with the  
7 tuition required to attend an edu-  
8 cational event or with materials pro-  
9 vided to physicians at an educational  
10 event.”.

11 (b) EFFECTIVE DATE.—The amendments made by  
12 this section shall apply with respect to transfers of value  
13 made on or after the date of the enactment of this Act.

14 **Subtitle D—Disposable Medical**  
15 **Technologies**

16 **SEC. 3061. TREATMENT OF CERTAIN ITEMS AND DEVICES.**

17 (a) PAYMENT FOR DURABLE MEDICAL ITEMS  
18 (DMI).—

19 (1) IN GENERAL.—Section 1861(s)(2) of the  
20 Social Security Act (42 U.S.C. 1395x(s)(2)) is  
21 amended—

22 (A) in subparagraph (EE), by striking  
23 “and” at the end;

24 (B) in subparagraph (FF), by inserting  
25 “and” at the end; and

1 (C) by adding at the end the following new  
2 subparagraph:

3 “(GG) a durable medical item that administers  
4 a drug described in section 1927(k)(2)(C) that  
5 would otherwise be self-administered multiple times  
6 per day and includes a disposable component and at  
7 least one component that can withstand repeated  
8 use, and supplies used in conjunction with such item  
9 (including the drug administered by such item);”.

10 (2) PAYMENT.—

11 (A) PAYMENT AMOUNT FOR DMI.—Section  
12 1834 of the Social Security Act (42 U.S.C.  
13 1395m) is amended by adding at the end the  
14 following new subsection:

15 “(r) PAYMENT METHODOLOGY FOR DURABLE MED-  
16 ICAL ITEMS (DMI).—The Secretary shall establish a pay-  
17 ment methodology for a durable medical item described  
18 in section 1861(s)(2)(GG) and supplies used in conjunc-  
19 tion with such item (other than a drug administered by  
20 such item) such that the estimated average total payment  
21 per individual for such items and supplies does not exceed  
22 the estimated average total payment per individual that  
23 would otherwise be made (taking into account the applica-  
24 tion of section 1847) for the durable medical equipment  
25 for which it is a substitute and for supplies used in con-

1 junction with such equipment (other than such a drug)  
2 as determined appropriate by the Secretary.”.

3 (B) PAYMENT FOR DRUG.—Section  
4 1842(o)(1)(D) of the Social Security Act (42  
5 U.S.C. 1395u(o)(1)(D)) is amended—

6 (i) in clause (i), by inserting “or  
7 drugs administered by a durable medical  
8 item covered under section 1861(s)(2)(GG)  
9 on or after January 1, 2017,” after “after  
10 January 1, 2004,”; and

11 (ii) in clause (ii), by striking “infu-  
12 sion”.

13 (C) COMPETITIVE ACQUISITION.—Section  
14 1847(a)(2) of the Social Security Act (42  
15 U.S.C. 1395w-3(a)(2)) is amended by adding  
16 at the end the following new subparagraph:

17 “(D) DURABLE MEDICAL ITEM.—A dura-  
18 ble medical item and supplies used in conjunc-  
19 tion with such item, described in section  
20 1861(s)(2)(GG).”.

21 (3) CONFORMING AMENDMENT.—Section  
22 1833(a)(1) of the Social Security Act (42 U.S.C.  
23 1395l(a)(1)) is amended—

24 (A) by striking “and” before “(Z)”; and

1           (B) by inserting before the semicolon at  
2           the end the following: “, and (AA) with respect  
3           to durable medical items described in section  
4           1861(s)(2)(GG), the amount paid shall be equal  
5           to 80 percent of the lesser of the actual charge  
6           or the amount determined under section  
7           1834(r)”.

8           (4) EFFECTIVE DATE.—The amendments made  
9           by this subsection shall apply to items furnished on  
10          or after January 1, 2017.

11          (b) PAYMENT FOR CERTAIN DISPOSABLE DE-  
12          VICES.—

13           (1) IN GENERAL.—Section 1834 of the Social  
14          Security Act (42 U.S.C. 1395m), as amended by  
15          subsection (a)(2), is further amended by adding at  
16          the end the following new subsection:

17          “(s) PAYMENT FOR CERTAIN DISPOSABLE DE-  
18          VICES.—

19           “(1) IN GENERAL.—The Secretary shall make  
20          separate payment in the amount established under  
21          paragraph (3) to a home health agency for a device  
22          described in paragraph (2) when furnished to an in-  
23          dividual who receives home health services for which  
24          payment is made under section 1895(b).



1           “(2) DEVICE DESCRIBED.—For purposes of  
2 paragraph (1), a device described in this paragraph  
3 is a disposable device for which, as of January 1,  
4 2015, there is—

5           “(A) a Level I Healthcare Common Proce-  
6 dure Coding System (HCPCS) code for which  
7 the description for a professional service in-  
8 cludes the furnishing of such device; and

9           “(B) a separate Level I HCPCS code for  
10 a professional service that uses durable medical  
11 equipment instead of such device.

12           “(3) PAYMENT AMOUNT.—The Secretary shall  
13 establish the separate payment amount for such a  
14 device such that such amount does not exceed the  
15 payment that would be made for the HCPCS code  
16 described in paragraph (2)(A) under section 1833(t)  
17 (relating to payment for covered OPD services).”.

18           (2) CONFORMING AMENDMENT.—Section  
19 1861(m)(5) of the Social Security Act (42 U.S.C.  
20 1395x(m)(5)) is amended by inserting “and devices  
21 described in section 1834(s)(2)” after “durable med-  
22 ical equipment”.

23           (3) EFFECTIVE DATE.—The amendments made  
24 by this subsection shall apply to devices furnished on  
25 or after January 1, 2017.

1                   **Subtitle E—Local Coverage**  
2                   **Decision Reforms**

3   **SEC. 3081. IMPROVEMENTS IN THE MEDICARE LOCAL COV-**  
4                   **ERAGE DETERMINATION (LCD) PROCESS.**

5           (a) IN GENERAL.—Section 1862(l)(5) of the Social  
6 Security Act (42 U.S.C. 1395y(l)(5)) is amended by add-  
7 ing at the end the following new subparagraph:

8                   “(D) LOCAL COVERAGE DETERMINA-  
9                   TIONS.—The Secretary shall require each medi-  
10                   care administrative contractor that develops a  
11                   local coverage determination to make available  
12                   on the website of such contractor and in the  
13                   coverage database on the Medicare website, at  
14                   least 45 days before the effective date of such  
15                   determination, the following information:

16                   “(i) Such determination in its en-  
17                   tirety.

18                   “(ii) Where and when the proposed  
19                   determination was first made public.

20                   “(iii) Links to the proposed deter-  
21                   mination and a response to comments sub-  
22                   mitted to the contractor with respect to  
23                   such proposed determination.

24                   “(iv) A summary of evidence that was  
25                   considered by the contractor during the de-

1                   velopment of such determination and a list  
2                   of the sources of such evidence.

3                   “(v) An explanation of the rationale  
4                   that supports such determination.”.

5           (b) EFFECTIVE DATE.—The amendment made by  
6 subsection (a) shall apply with respect to local coverage  
7 determinations that are proposed or revised on or after  
8 the date that is 180 days after the date of the enactment  
9 of this Act.

10 **Subtitle F—Medicare Pharma-**  
11 **ceutical and Technology Om-**  
12 **budsman**

13 **SEC. 3101. MEDICARE PHARMACEUTICAL AND TECH-**  
14 **NOLOGY OMBUDSMAN.**

15           Section 1808(c) of the Social Security Act (42 U.S.C.  
16 1395b–9(c)) is amended by adding at the end the fol-  
17 lowing new paragraph:

18                   “(4) PHARMACEUTICAL AND TECHNOLOGY OM-  
19                   BUDSMAN.—Not later than 12 months after the date  
20                   of the enactment of this paragraph, the Secretary  
21                   shall provide for a pharmaceutical and technology  
22                   ombudsman within the Centers for Medicare & Med-  
23                   icaid Services who shall receive and respond to com-  
24                   plaints, grievances, and requests that—

1           “(A) are from entities that manufacture  
2           pharmaceutical, biotechnology, medical device,  
3           or diagnostic products that are covered or for  
4           which coverage is being sought under this title;  
5           and

6           “(B) regard coverage, coding, or payment  
7           under this title for such products.”.

8           **Subtitle G—Medicare Site-of-**  
9           **Service Price Transparency**

10       **SEC. 3121. MEDICARE SITE-OF-SERVICE PRICE TRANS-**  
11       **PARENCY.**

12       Section 1834 of the Social Security Act (42 U.S.C.  
13       1395m) is amended by adding at the end the following  
14       new subsection:

15       “(r) SITE-OF-SERVICE PRICE TRANSPARENCY.—

16           “(1) IN GENERAL.—In order to facilitate price  
17           transparency with respect to items and services for  
18           which payment may be made either to a hospital  
19           outpatient department or to an ambulatory surgery  
20           center under this title, the Secretary shall, for 2017  
21           and each year thereafter, make available to the pub-  
22           lic via a searchable website, with respect to an ap-  
23           propriate number of such items and services—

24           “(A) the estimated payment amount for  
25           such items and services under the outpatient

1 department fee schedule under subsection (t) of  
2 section 1833 and the ambulatory surgical cen-  
3 ter payment system under subsection (i) of such  
4 section; and

5 “(B) the estimated amount of beneficiary  
6 liability applicable to such an item or service.

7 “(2) CALCULATION OF ESTIMATED BENE-  
8 FICIARY LIABILITY.—For purposes of paragraph  
9 (1)(B), the estimated amount of beneficiary liability,  
10 with respect to an item or service, is the amount for  
11 such item or service for which an individual who  
12 does not have coverage under a medicare supple-  
13 mental policy certified under section 1882 or any  
14 other supplemental insurance coverage is respon-  
15 sible.

16 “(3) IMPLEMENTATION.—In carrying out this  
17 subsection, the Secretary—

18 “(A) shall include in the notice described  
19 in section 1804(a) a notification of the avail-  
20 ability of the estimated amounts made available  
21 under paragraph (1); and

22 “(B) may utilize existing mechanisms, such  
23 as the portion of the website of the Centers for  
24 Medicare & Medicaid Services on which infor-  
25 mation comparing physician performance is

1 posted (commonly referred to as the Physician  
2 Compare website), to make available such esti-  
3 mated amounts under such paragraph.

4 “(4) FUNDING.—For purposes of implementing  
5 this subsection, the Secretary shall provide for the  
6 transfer, from the Supplemental Medical Insurance  
7 Trust Fund under section 1841 to the Centers for  
8 Medicare & Medicaid Services Program Management  
9 Account, of \$6,000,000 for fiscal year 2015, to re-  
10 main available until expended.”.

11 **Subtitle H—Medicare Part D Pa-**  
12 **tient Safety and Drug Abuse**  
13 **Prevention**

14 **SEC. 3141. PROGRAMS TO PREVENT PRESCRIPTION DRUG**  
15 **ABUSE UNDER MEDICARE PARTS C AND D.**

16 (a) DRUG MANAGEMENT PROGRAM FOR AT-RISK  
17 BENEFICIARIES.—

18 (1) IN GENERAL.—Section 1860D–4(c) of the  
19 Social Security Act (42 U.S.C. 1395w–10(c)) is  
20 amended by adding at the end the following:

21 “(5) DRUG MANAGEMENT PROGRAM FOR AT-  
22 RISK BENEFICIARIES.—

23 “(A) AUTHORITY TO ESTABLISH.—A PDP  
24 sponsor may establish a drug management pro-  
25 gram for at-risk beneficiaries under which, sub-

1           ject to subparagraph (B), the PDP sponsor  
2           may, in the case of an at-risk beneficiary for  
3           prescription drug abuse who is an enrollee in a  
4           prescription drug plan of such PDP sponsor,  
5           limit such beneficiary’s access to coverage for  
6           frequently abused drugs under such plan to fre-  
7           quently abused drugs that are prescribed for  
8           such beneficiary by one or more prescribers se-  
9           lected under subparagraph (D), and dispensed  
10          for such beneficiary by one or more pharmacies  
11          selected under such subparagraph.

12                   “(B) REQUIREMENT FOR NOTICES.—

13                           “(i) IN GENERAL.—A PDP sponsor  
14                           may not limit the access of an at-risk ben-  
15                           eficiary for prescription drug abuse to cov-  
16                           erage for frequently abused drugs under a  
17                           prescription drug plan until such spon-  
18                           sor—

19                                   “(I) provides to the beneficiary  
20                                   an initial notice described in clause  
21                                   (ii) and a second notice described in  
22                                   clause (iii); and

23                                   “(II) verifies with the providers  
24                                   of the beneficiary that the beneficiary

1 is an at-risk beneficiary for prescrip-  
2 tion drug abuse.

3 “(ii) INITIAL NOTICE.—An initial no-  
4 tice described in this clause is a notice that  
5 provides to the beneficiary—

6 “(I) notice that the PDP sponsor  
7 has identified the beneficiary as po-  
8 tentially being an at-risk beneficiary  
9 for prescription drug abuse;

10 “(II) information describing all  
11 State and Federal public health re-  
12 sources that are designed to address  
13 prescription drug abuse to which the  
14 beneficiary has access, including men-  
15 tal health services and other coun-  
16 seling services;

17 “(III) notice of, and information  
18 about, the right of the beneficiary to  
19 appeal such identification under sub-  
20 section (h) and the option of an auto-  
21 matic escalation to external review;

22 “(IV) a request for the bene-  
23 ficiary to submit to the PDP sponsor  
24 preferences for which prescribers and  
25 pharmacies the beneficiary would pre-



1           fer the PDP sponsor to select under  
2           subparagraph (D) in the case that the  
3           beneficiary is identified as an at-risk  
4           beneficiary for prescription drug  
5           abuse as described in clause (iii)(I);

6           “(V) an explanation of the mean-  
7           ing and consequences of the identi-  
8           fication of the beneficiary as poten-  
9           tially being an at-risk beneficiary for  
10          prescription drug abuse, including an  
11          explanation of the drug management  
12          program established by the PDP  
13          sponsor pursuant to subparagraph  
14          (A);

15          “(VI) clear instructions that ex-  
16          plain how the beneficiary can contact  
17          the PDP sponsor in order to submit  
18          to the PDP sponsor the preferences  
19          described in subclause (IV) and any  
20          other communications relating to the  
21          drug management program for at-risk  
22          beneficiaries established by the PDP  
23          sponsor; and

24          “(VII) contact information for  
25          other organizations that can provide

1 the beneficiary with assistance regard-  
2 ing such drug management program  
3 (similar to the information provided  
4 by the Secretary in other standardized  
5 notices provided to part D eligible in-  
6 dividuals enrolled in prescription drug  
7 plans under this part).

8 “(iii) SECOND NOTICE.—A second no-  
9 tice described in this clause is a notice that  
10 provides to the beneficiary notice—

11 “(I) that the PDP sponsor has  
12 identified the beneficiary as an at-risk  
13 beneficiary for prescription drug  
14 abuse;

15 “(II) that such beneficiary is  
16 subject to the requirements of the  
17 drug management program for at-risk  
18 beneficiaries established by such PDP  
19 sponsor for such plan;

20 “(III) of the prescriber (or pre-  
21 scribers) and pharmacy s(or phar-  
22 macies) elected for such individual  
23 under subparagraph (D);

24 “(IV) of, and information about,  
25 the beneficiary’s right to appeal such

1 identification under subsection (h)  
2 and the option of an automatic esca-  
3 lation to external review;

4 “(V) that the beneficiary can, in  
5 the case that the beneficiary has not  
6 previously submitted to the PDP  
7 sponsor preferences for which pre-  
8 scribers and pharmacies the bene-  
9 ficiary would prefer the PDP sponsor  
10 select under subparagraph (D), sub-  
11 mit such preferences to the PDP  
12 sponsor; and

13 “(VI) that includes clear instruc-  
14 tions that explain how the beneficiary  
15 can contact the PDP sponsor.

16 “(iv) TIMING OF NOTICES.—

17 “(I) IN GENERAL.—Subject to  
18 subclause (II), a second notice de-  
19 scribed in clause (iii) shall be provided  
20 to the beneficiary on a date that is  
21 not less than 60 days after an initial  
22 notice described in clause (ii) is pro-  
23 vided to the beneficiary.

24 “(II) EXCEPTION.—In the case  
25 that the PDP sponsor, in conjunction

1 with the Secretary, determines that  
2 concerns identified through rule-  
3 making by the Secretary regarding  
4 the health or safety of the beneficiary  
5 or regarding significant drug diversion  
6 activities require the PDP sponsor to  
7 provide a second notice described in  
8 clause (iii) to the beneficiary on a  
9 date that is earlier than the date de-  
10 scribed in subclause (II), the PDP  
11 sponsor may provide such second no-  
12 tice on such earlier date.

13 “(C) AT-RISK BENEFICIARY FOR PRE-  
14 SCRIPTION DRUG ABUSE.—

15 “(i) IN GENERAL.—For purposes of  
16 this paragraph, the term ‘at-risk bene-  
17 ficiary for prescription drug abuse’ means  
18 a part D eligible individual who is not an  
19 exempted individual described in clause (ii)  
20 and—

21 “(I) who is identified through the  
22 use of clinical guidelines developed by  
23 the Secretary in consultation with  
24 PDP sponsors and other stakeholders

1 described in section 3141(f)(2)(A) of  
2 the 21st Century Cures Act; or

3 “(II) with respect to whom the  
4 PDP sponsor of a prescription drug  
5 plan, upon enrolling such individual in  
6 such plan, received notice from the  
7 Secretary that such individual was  
8 identified under this paragraph to be  
9 an at-risk beneficiary for prescription  
10 drug abuse under the prescription  
11 drug plan in which such individual  
12 was most recently previously enrolled  
13 and such identification has not been  
14 terminated under subparagraph (F).

15 “(ii) EXEMPTED INDIVIDUAL DE-  
16 SCRIBED.—An exempted individual de-  
17 scribed in this clause is an individual  
18 who—

19 “(I) receives hospice care under  
20 this title;

21 “(II) is a resident of a long-term  
22 care facility, of an intermediate care  
23 facility for the mentally retarded, or  
24 of another facility for which fre-  
25 quently abused drugs are dispensed

1 for residents through a contract with  
2 a single pharmacy; or

3 “(III) the Secretary elects to  
4 treat as an exempted individual for  
5 purposes of clause (i).

6 “(D) SELECTION OF PRESCRIBERS AND  
7 PHARMACIES.—

8 “(i) IN GENERAL.—With respect to  
9 each at-risk beneficiary for prescription  
10 drug abuse enrolled in a prescription drug  
11 plan offered by such sponsor, a PDP spon-  
12 sor shall, based on the preferences sub-  
13 mitted to the PDP sponsor by the bene-  
14 ficiary pursuant to clauses (ii)(IV) and  
15 (iii)(V) of subparagraph (B), select—

16 “(I) one or more individuals who  
17 are authorized to prescribe frequently  
18 abused drugs (referred to in this  
19 paragraph as ‘prescribers’) who may  
20 write prescriptions for such drugs for  
21 such beneficiary; and

22 “(II) one or more pharmacies  
23 that may dispense such drugs to such  
24 beneficiary.

1           “(ii) REASONABLE ACCESS.—In mak-  
2           ing the selections under this subpara-  
3           graph—

4                   “(I) a PDP sponsor shall ensure  
5                   that the beneficiary continues to have  
6                   reasonable access to drugs described  
7                   in subparagraph (G), taking into ac-  
8                   count geographic location, beneficiary  
9                   preference, impact on cost-sharing,  
10                  and reasonable travel time; or

11                  “(II) a PDP sponsor shall ensure  
12                  such access to prescribers and phar-  
13                  macies in the case of individuals with  
14                  multiple residences and in the case of  
15                  natural disasters and similar emer-  
16                  gency situations.

17           “(iii) BENEFICIARY PREFERENCES.—

18                   “(I) IN GENERAL.—If an at-risk  
19                   beneficiary for prescription drug  
20                   abuse submits preferences for which  
21                   in-network prescribers and pharmacies  
22                   the beneficiary would prefer the PDP  
23                   sponsor select in response to a notice  
24                   under subparagraph (B), the PDP  
25                   sponsor shall—

1                   “(aa) review such pref-  
2                   erences;

3                   “(bb) select or change the  
4                   selection of prescribers and phar-  
5                   macies for the beneficiary based  
6                   on such preferences; and

7                   “(cc) inform the beneficiary  
8                   of such selection or change of se-  
9                   lection.

10                  “(II) EXCEPTION.—In the case  
11                  that the PDP sponsor determines that  
12                  a change to the selection of prescriber  
13                  or pharmacy under item (bb) by the  
14                  PDP sponsor is contributing or would  
15                  contribute to prescription drug abuse  
16                  or drug diversion by the beneficiary,  
17                  the PDP sponsor may change the se-  
18                  lection of prescriber or pharmacy for  
19                  the beneficiary without regard to the  
20                  preferences of the beneficiary de-  
21                  scribed in subclause (I).

22                  “(iv) CONFIRMATION.—Before select-  
23                  ing a prescriber (or prescribers) or phar-  
24                  macy (or pharmacies) under this subpara-  
25                  graph, a PDP sponsor must request and



1 receive confirmation from such a prescriber  
2 or pharmacy acknowledging and accepting  
3 that the beneficiary involved is in the drug  
4 management program for at-risk bene-  
5 ficiaries.

6 “(E) TERMINATIONS AND APPEALS.—The  
7 identification of an individual as an at-risk ben-  
8 efiary for prescription drug abuse under this  
9 paragraph, a coverage determination made  
10 under a drug management program for at-risk  
11 beneficiaries, and the selection of prescriber or  
12 pharmacy under subparagraph (D) with respect  
13 to such individual shall be subject to reconsider-  
14 ation and appeal under subsection (h) and the  
15 option of an automatic escalation to external re-  
16 view to the extent provided by the Secretary.

17 “(F) TERMINATION OF IDENTIFICATION.—

18 “(i) IN GENERAL.—The Secretary  
19 shall develop standards for the termination  
20 of identification of an individual as an at-  
21 risk beneficiary for prescription drug abuse  
22 under this paragraph. Under such stand-  
23 ards such identification shall terminate as  
24 of the earlier of—

1           “(I) the date the individual dem-  
2           onstrates that the individual is no  
3           longer likely, in the absence of the re-  
4           strictions under this paragraph, to be  
5           an at-risk beneficiary for prescription  
6           drug abuse described in subparagraph  
7           (C)(i); or

8           “(II) the end of such maximum  
9           period of identification as the Sec-  
10          retary may specify.

11          “(ii) RULE OF CONSTRUCTION.—  
12          Nothing in clause (i) shall be construed as  
13          preventing a plan from identifying an indi-  
14          vidual as an at-risk beneficiary for pre-  
15          scription drug abuse under subparagraph  
16          (C)(i) after such termination on the basis  
17          of additional information on drug use oc-  
18          curring after the date of notice of such ter-  
19          mination.

20          “(G) FREQUENTLY ABUSED DRUG.—For  
21          purposes of this subsection, the term ‘frequently  
22          abused drug’ means a drug that is a controlled  
23          substance that the Secretary determines to be  
24          frequently abused or diverted.

1           “(H) DATA DISCLOSURE.—In the case of  
2           an at-risk beneficiary for prescription drug  
3           abuse whose access to coverage for frequently  
4           abused drugs under a prescription drug plan  
5           has been limited by a PDP sponsor under this  
6           paragraph, such PDP sponsor shall disclose  
7           data, including any necessary individually iden-  
8           tifiable health information, in a form and man-  
9           ner specified by the Secretary, about the deci-  
10          sion to impose such limitations and the limita-  
11          tions imposed by the sponsor under this part.

12          “(I) EDUCATION.—The Secretary shall  
13          provide education to enrollees in prescription  
14          drug plans of PDP sponsors and providers re-  
15          garding the drug management program for at-  
16          risk beneficiaries described in this paragraph,  
17          including education—

18                 “(i) provided by medicare administra-  
19                 tive contractors through the improper pay-  
20                 ment outreach and education program de-  
21                 scribed in section 1874A(h); and

22                 “(ii) through current education efforts  
23                 (such as State health insurance assistance  
24                 programs described in subsection (a)(1)(A)  
25                 of section 119 of the Medicare Improve-

1           ments for Patients and Providers Act of  
2           2008 (42 U.S.C. 1395b–3 note)) and ma-  
3           terials directed toward such enrollees.

4           “(J) APPLICATION UNDER MA–PD  
5           PLANS.—Pursuant to section 1860D—21(c)(1),  
6           the provisions of this paragraph apply under  
7           part D to MA organizations offering MA–PD  
8           plans to MA eligible individuals in the same  
9           manner as such provisions apply under this  
10          part to a PDP sponsor offering a prescription  
11          drug plan to a part D eligible individual.”.

12          (2) INFORMATION FOR CONSUMERS.—Section  
13          1860D–4(a)(1)(B) of the Social Security Act (42  
14          U.S.C. 1395w–104(a)(1)(B)) is amended by adding  
15          at the end the following:

16                  “(v) The drug management program  
17                  for at-risk beneficiaries under subsection  
18                  (c)(5).”.

19          (b) UTILIZATION MANAGEMENT PROGRAMS.—Sec-  
20          tion 1860D–4(c) of the Social Security Act (42 U.S.C.  
21          1395w–104(c)), as amended by subsection (a)(1), is fur-  
22          ther amended—

23                  (1) in paragraph (1), by inserting after sub-  
24          paragraph (D) the following new subparagraph:

1           “(E) A utilization management tool to pre-  
2           vent drug abuse (as described in paragraph  
3           (6)(A)).”; and

4           (2) by adding at the end the following new  
5           paragraph:

6           “(6) UTILIZATION MANAGEMENT TOOL TO PRE-  
7           VENT DRUG ABUSE.—

8           “(A) IN GENERAL.—A tool described in  
9           this paragraph is any of the following:

10           “(i) A utilization tool designed to pre-  
11           vent the abuse of frequently abused drugs  
12           by individuals and to prevent the diversion  
13           of such drugs at pharmacies.

14           “(ii) Retrospective utilization review  
15           to identify—

16           “(I) individuals that receive fre-  
17           quently abused drugs at a frequency  
18           or in amounts that are not clinically  
19           appropriate; and

20           “(II) providers of services or sup-  
21           pliers that may facilitate the abuse or  
22           diversion of frequently abused drugs  
23           by beneficiaries.

24           “(iii) Consultation with the contractor  
25           described in subparagraph (B) to verify if

1 an individual enrolling in a prescription  
2 drug plan offered by a PDP sponsor has  
3 been previously identified by another PDP  
4 sponsor as an individual described in  
5 clause (ii)(I).

6 “(B) REPORTING.—A PDP sponsor offer-  
7 ing a prescription drug plan (and an MA orga-  
8 nization offering an MA–PD plan) in a State  
9 shall submit to the Secretary and the Medicare  
10 drug integrity contractor with which the Sec-  
11 retary has entered into a contract under section  
12 1893 with respect to such State a report, on a  
13 monthly basis, containing information on—

14 “(i) any provider of services or sup-  
15 plier described in subparagraph (A)(ii)(II)  
16 that is identified by such plan sponsor (or  
17 organization) during the 30-day period be-  
18 fore such report is submitted; and

19 “(ii) the name and prescription  
20 records of individuals described in para-  
21 graph (5)(C).”.

22 (c) EXPANDING ACTIVITIES OF MEDICARE DRUG IN-  
23 TEGRITY CONTRACTORS (MEDICS).—

1           (1) IN GENERAL.—Section 1893 of the Social  
2           Security Act (42 U.S.C. 1395ddd) is amended by  
3           adding at the end the following new subsection:

4           “(j) EXPANDING ACTIVITIES OF MEDICARE DRUG  
5           INTEGRITY CONTRACTORS (MEDICs).—

6           “(1) ACCESS TO INFORMATION.—Under con-  
7           tracts entered into under this section with Medicare  
8           drug integrity contractors, the Secretary shall au-  
9           thorize such contractors to directly accept prescrip-  
10          tion and necessary medical records from entities  
11          such as pharmacies, prescription drug plans, MA-  
12          PD plans, and physicians with respect to an indi-  
13          vidual in order for such contractors to provide infor-  
14          mation relevant to the determination of whether  
15          such individual is an at-risk beneficiary for prescrip-  
16          tion drug abuse, as defined in section 1860D-  
17          4(c)(5)(C).

18          “(2) REQUIREMENT FOR ACKNOWLEDGMENT  
19          OF REFERRALS.—If a PDP sponsor or MA organiza-  
20          tion refers information to a contractor described in  
21          paragraph (1) in order for such contractor to assist  
22          in the determination described in such paragraph,  
23          the contractor shall—

24                  “(A) acknowledge to the sponsor or organi-  
25                  zation receipt of the referral; and

1           “(B) in the case that any PDP sponsor or  
2 MA organization contacts the contractor re-  
3 questing to know the determination by the con-  
4 tractor of whether or not an individual has been  
5 determined to be an individual described such  
6 paragraph, shall inform such sponsor or organi-  
7 zation of such determination on a date that is  
8 not later than 15 days after the date on which  
9 the sponsor or organization contacts the con-  
10 tractor.

11           “(3) MAKING DATA AVAILABLE TO OTHER EN-  
12 TITIES.—

13           “(A) IN GENERAL.—For purposes of car-  
14 rying out this subsection, subject to subpara-  
15 graph (B), the Secretary shall authorize MED-  
16 ICs to respond to requests for information from  
17 PDP sponsors and MA organizations, State  
18 prescription drug monitoring programs, and  
19 other entities delegated by such sponsors or or-  
20 ganizations using available programs and sys-  
21 tems in the effort to prevent fraud, waste, and  
22 abuse.

23           “(B) HIPAA COMPLIANT INFORMATION  
24 ONLY.—Information may only be disclosed by a  
25 MEDIC under subparagraph (A) if the dislo-



1           sure of such information is permitted under the  
2           Federal regulations (concerning the privacy of  
3           individually identifiable health information) pro-  
4           mulgated under section 264(c) of the Health  
5           Insurance Portability and Accountability Act of  
6           1996 (42 U.S.C. 1320d–2 note).”.

7           (2) **OIG STUDY AND REPORT ON EFFECTIVE-**  
8           **NESS OF MEDICS.—**

9                   (A) **STUDY.**—The Inspector General of the  
10           Department of Health and Human Services  
11           shall conduct a study on the effectiveness of  
12           Medicare drug integrity contractors in identi-  
13           fying combating, and preventing fraud under  
14           the Medicare program, including under the au-  
15           thority provided under section 1893(j) of the  
16           Social Security Act, added by paragraph (1).

17                   (B) **REPORT.**—Not later than 1 year after  
18           the date of the enactment of this Act, the In-  
19           specter General shall submit to Congress a re-  
20           port on the study conducted under subpara-  
21           graph (A). Such report shall include such rec-  
22           ommendations for improvements in the effec-  
23           tiveness of such contractors as the Inspector  
24           General determines appropriate.

1 (d) TREATMENT OF CERTAIN COMPLAINTS FOR PUR-  
2 POSES OF QUALITY OR PERFORMANCE ASSESSMENT.—  
3 Section 1860D–42 of the Social Security Act (42 U.S.C.  
4 1395w–152) is amended by adding at the end the fol-  
5 lowing new subsection:

6 “(d) TREATMENT OF CERTAIN COMPLAINTS FOR  
7 PURPOSES OF QUALITY OR PERFORMANCE ASSESS-  
8 MENT.—In conducting a quality or performance assess-  
9 ment of a PDP sponsor, the Secretary shall develop or  
10 utilize existing screening methods for reviewing and con-  
11 sidering complaints that are received from enrollees in a  
12 prescription drug plan offered by such PDP sponsor and  
13 that are complaints regarding the lack of access by the  
14 individual to prescription drugs due to a drug manage-  
15 ment program for at-risk beneficiaries.”.

16 (e) SENSE OF CONGRESS REGARDING USE OF TECH-  
17 NOLOGY TOOLS TO COMBAT FRAUD.—It is the sense of  
18 Congress that MA organizations and PDP sponsors  
19 should consider using e-prescribing and other health infor-  
20 mation technology tools to support combating fraud under  
21 MA–PD plans and prescription drug plans under parts C  
22 and D of the Medicare program.

23 (f) EFFECTIVE DATE.—

24 (1) IN GENERAL.—The amendments made by  
25 this section shall apply to prescription drug plans

1 (and MA–PD plans) for plan years beginning more  
2 than 1 year after the date of the enactment of this  
3 Act.

4 (2) STAKEHOLDER MEETINGS PRIOR TO EFFEC-  
5 TIVE DATE.—

6 (A) IN GENERAL.—Not later than January  
7 1, 2016, the Secretary of Health and Human  
8 Services shall convene stakeholders, including  
9 individuals entitled to benefits under part A of  
10 title XVIII of the Social Security Act or en-  
11 rolled under part B of such title of such Act,  
12 advocacy groups representing such individuals,  
13 physicians, pharmacists, and other clinicians,  
14 retail pharmacies, plan sponsors, entities dele-  
15 gated by plan sponsors, and biopharmaceutical  
16 manufacturers for input regarding the topics  
17 described in subparagraph (B).

18 (B) TOPICS DESCRIBED.—The topics de-  
19 scribed in this subparagraph are the topics of—

20 (i) the impact on cost-sharing and en-  
21 suring accessibility to prescription drugs  
22 for enrollees in prescription drug plans of  
23 PDP sponsors, and enrollees in MA–PD  
24 plans, who are at-risk beneficiaries for pre-  
25 scription drug abuse (as defined in sub-

1 paragraph (C) of paragraph (5) of section  
2 1860D–4(c) of the Social Security Act (42  
3 U.S.C. 1395w–104(c));

4 (ii) the use of an expedited appeals  
5 process under which such an enrollee may  
6 appeal an identification of such enrollee as  
7 an at-risk beneficiary for prescription drug  
8 abuse under such paragraph (similar to the  
9 processes established under the Medicare  
10 Advantage program under part C of title  
11 XVIII of the Social Security Act that allow  
12 an automatic escalation to external review  
13 of claims submitted under such part);

14 (iii) the types of enrollees that should  
15 be treated as exempted individuals, as de-  
16 scribed in subparagraph (C)(ii) of such  
17 paragraph;

18 (iv) the manner in which terms and  
19 definitions in such paragraph should be ap-  
20 plied, such as the use of clinical appro-  
21 priateness in determining whether an en-  
22 rollee is an at-risk beneficiary for prescrip-  
23 tion drug abuse as defined in subpara-  
24 graph (C) of such paragraph;

1                   (v) the information to be included in  
2                   the notices described in subparagraph (B)  
3                   of such paragraph and the standardization  
4                   of such notices; and

5                   (vi) with respect to a PDP sponsor  
6                   (or Medicare Advantage organization) that  
7                   establishes a drug management program  
8                   for at-risk beneficiaries under such para-  
9                   graph, the responsibilities of such PDP  
10                  sponsor (or organization) with respect to  
11                  the implementation of such program.

12           (g) RULEMAKING.—The Secretary of Health and  
13 Human Services shall promulgate regulations based on the  
14 input gathered pursuant to subsection (f)(2)(A).

○