

**AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO H.R. 6  
OFFERED BY MR. UPTON OF MICHIGAN**

Strike all after the enacting clause and insert the following:

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

2 (a) **SHORT TITLE.**—This Act may be cited as the  
3 “21st Century Cures Act”.

4 (b) **TABLE OF CONTENTS.**—The table of contents for  
5 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—DISCOVERY

Subtitle A—National Institutes of Health Funding

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

Subtitle B—National Institutes of Health Planning and Administration

Sec. 1021. NIH research strategic plan.  
Sec. 1022. Increasing accountability at the National Institutes of Health.  
Sec. 1023. Reducing administrative burdens of researchers.  
Sec. 1024. Exemption for the National Institutes of Health from the Paper-  
work Reduction Act requirements.  
Sec. 1025. NIH travel.  
Sec. 1026. Other transactions authority.  
Sec. 1027. NCATS phase IIB restriction.  
Sec. 1028. High-risk, high-reward research.  
Sec. 1029. Sense of Congress on increased inclusion of underrepresented com-  
munities in clinical trials.

Subtitle C—Supporting Young Emerging Scientists

Sec. 1041. Improvement of loan repayment programs of the 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 the 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.
- Sec. 2285. Hiring authority for scientific, technical, and professional personnel.

Subtitle Q—Exempting From Sequestration Certain User Fees

- Sec. 2301. Exempting from sequestration certain user fees of Food and Drug Administration.

TITLE III—DELIVERY

Subtitle A—Interoperability

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

Subtitle B—Telehealth

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

Subtitle C—Encouraging Continuing Medical Education for Physicians

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

Subtitle D—Disposable Medical Technologies

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

Subtitle E—Local Coverage Decision Reforms

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

Subtitle F—Medicare Pharmaceutical and Technology Ombudsman

- Sec. 3101. Medicare pharmaceutical and technology ombudsman.

Subtitle G—Medicare Site-of-Service Price Transparency

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

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

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

TITLE IV—MEDICAID, MEDICARE, AND OTHER REFORMS

Subtitle A—Medicaid and Medicare Reforms

- Sec. 4001. Limiting Federal Medicaid reimbursement to States for durable medical equipment (DME) to Medicare payment rates.
- Sec. 4002. Medicare payment incentive for the transition from traditional x-ray imaging to digital radiography and other Medicare imaging payment provision.
- Sec. 4003. Implementation of Office of Inspector General recommendation to delay certain Medicare prescription drug plan prepayments.

Subtitle B—Cures Innovation Fund

- Sec. 4041. Cures Innovation Fund.

Subtitle C—Other Reforms

- Sec. 4061. SPR drawdown.

Subtitle D—Miscellaneous

- Sec. 4081. Lyme disease and other tick-borne diseases.

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

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

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

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

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

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

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

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

17                               and

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

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

4           (a) USE OF INNOVATION FUND.—Section 402(b) of  
5 the Public Health Service Act (42 U.S.C. 282(b)) is  
6 amended—

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

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

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

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

19           (b) ESTABLISHMENT OF INNOVATION FUND.—Sec-  
20           tion 402A of the Public Health Service Act (42 U.S.C.  
21           282a)is amended—

22           (1) by redesignating subsection (e) as sub-  
23           section (f); and

24           (2) by inserting after subsection (d) the fol-  
25           lowing new subsection:

1 “(e) NIH INNOVATION FUND.—

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

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

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

21 “(B) AVAILABILITY SUBJECT TO APPRO-  
22 PRIATIONS.—Amounts in the Fund shall not be  
23 available except to the extent and in such  
24 amounts as are provided in advance in appro-  
25 priation Acts.

1           “(C) ALLOCATION OF AMOUNTS.—Of the  
2 amounts made available from the NIH Innova-  
3 tion Fund for allocations under section  
4 402(b)(25) for a fiscal year—

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

8           “(ii) not less than 35 percent of such  
9 amounts remaining after subtracting the  
10 allocation for the Accelerating Advance-  
11 ment Program shall be for early stage in-  
12 vestigators (as defined in paragraph (7));

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

18           “(iv) not more than 10 percent of  
19 such amounts (without subtracting the al-  
20 location for the Accelerating Advancement  
21 Program) shall be for intramural research.

22           “(D) INAPPLICABILITY OF CERTAIN PROVI-  
23 SIONS.—Amounts in the NIH Innovation Fund  
24 shall not be subject to—



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

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

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

14           “(A) Research in which—

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

17           “(ii) funding is tied to pursuit of such  
18           project or objectives.

19           “(B) Research in which—

20           “(i) a principal investigator has shown  
21           promise in biomedical research; and

22           “(ii) funding is not tied to a specific  
23           project or specific objectives.

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

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

7           “(E) The Accelerating Advancement Pro-  
8           gram under paragraph (5).

9           “(F) Development and implementation of  
10          the strategic plan under paragraph (6).

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

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

19                 “(B) minimize unnecessary duplication.

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

24                 “(A) the Director of NIH partners with  
25                 national research institutes and national centers

1 to accomplish important biomedical research ob-  
2 jectives; and

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

9 “(6) STRATEGIC PLAN.—

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

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

21 “(ii) identifies areas, to be known as  
22 strategic focus areas, in which the re-  
23 sources of the NIH Innovation Fund can  
24 contribute to the goals of expanding knowl-  
25 edge to address, and find more effective

1 treatments for, unmet medical needs in the  
2 United States, including the areas of—

3 “(I) biomarkers;

4 “(II) precision medicine;

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

12 “(IV) antibiotics;

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

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

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

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

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

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

5           “(C) is within 10 years of having com-  
6           pleted—

7                   “(i) the investigator’s terminal degree;

8                   or

9                   “(ii) a medical residency (or the  
10                  equivalent).”.

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

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

18                  (2) notwithstanding any transfer authority in  
19                  any appropriation Act, shall not be used for any  
20                  purpose other than allocating funds for conducting  
21                  and supporting innovation fund initiatives as de-  
22                  scribed in section 402(b)(25) of the Public Health  
23                  Service Act, as added by subsection (a).

1 **Subtitle B—National Institutes of**  
2 **Health Planning and Adminis-**  
3 **tration**

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

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

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

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

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

16 “(m) RESEARCH STRATEGIC PLAN.—

17 “(1) FIVE-YEAR PLANS FOR BIOMEDICAL RE-  
18 SEARCH STRATEGY.—

19 “(A) IN GENERAL.—For each successive  
20 five-year period beginning with the period of fis-  
21 cal years 2016 through 2020, the Director of  
22 NIH, in consultation with the entities described  
23 in subparagraph (B), shall develop and main-  
24 tain a biomedical research strategic plan that—

1           “(i) is designed to increase the effi-  
2           cient and effective focus of biomedical re-  
3           search in a manner that leverages the best  
4           scientific opportunities through a delibera-  
5           tive planning process;

6           “(ii) identifies areas, to be known as  
7           strategic focus areas, in which the re-  
8           sources of the National Institutes of  
9           Health can best contribute to the goal of  
10          expanding knowledge on human health in  
11          the United States through biomedical re-  
12          search; and

13          “(iii) includes objectives for each such  
14          strategic focus area.

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

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

23                 “(A) to identify research opportunities;  
24                 and

1           “(B) to develop individual strategic plans  
2           for the research activities of each of the na-  
3           tional research institutes and national centers  
4           that—

5                   “(i) have a common template; and

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

12           “(3) CONTENTS OF PLANS.—

13                   “(A) STRATEGIC FOCUS AREAS.—The stra-  
14                   tegic focus areas identified pursuant to para-  
15                   graph (1)(A)(ii) shall—

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

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

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



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

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

14                  “(C) WORKFORCE.—In developing and  
15                  maintaining a strategic plan under this sub-  
16                  section, the Director of NIH shall ensure that  
17                  maintaining the biomedical workforce of the fu-  
18                  ture, including the participation by scientists  
19                  from groups traditionally underrepresented in  
20                  the scientific workforce, remains a priority.

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

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

3           “(B) make such initial strategic plan pub-  
4           licly available on the website of the National In-  
5           stitutes of Health.

6           “(5) REVIEW; UPDATES.—

7           “(A) PROGRESS REVIEWS.—Not less than  
8           annually, the Director of NIH, in consultation  
9           with the directors of the national research insti-  
10          tutes and national centers, shall conduct  
11          progress reviews for each strategic focus area  
12          identified under paragraph (1)(A)(ii).

13          “(B) UPDATES.—Not later than the end of  
14          the 5-year period covered by the initial strategic  
15          plan under this subsection, and every 5 years  
16          thereafter, the Director of NIH, in consultation  
17          with the directors of the national research insti-  
18          tutes and national centers, stakeholders in the  
19          scientific field, advocates, and the public at  
20          large, shall—

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

24                 “(ii) update such plan in accordance  
25                 with this section.”.

1 **SEC. 1022. INCREASING ACCOUNTABILITY AT THE NA-**  
2 **TIONAL INSTITUTES OF HEALTH.**

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

7 “(a) APPOINTMENT; TERMS.—

8 “(1) APPOINTMENT.—The Director of the Na-  
9 tional Cancer Institute shall be appointed by the  
10 President and the directors of the other national re-  
11 search institutes, as well as the directors of the na-  
12 tional centers, shall be appointed by the Director of  
13 NIH. The directors of the national research insti-  
14 tutes, as well as national centers, shall report di-  
15 rectly to the Director of NIH.

16 “(2) TERMS.—

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

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

25 “(C) REAPPOINTMENT.—At the end of the  
26 term of a director of a national research insti-

1           tute or national center, the director may be re-  
2           appointed. There is no limit on the number of  
3           terms a director may serve.

4           “(D) VACANCIES.—If the office of a direc-  
5           tor of a national research institute or national  
6           center becomes vacant before the end of such  
7           director’s term, the director appointed to fill the  
8           vacancy shall be appointed for a 5-year term  
9           starting on the date of such appointment.

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

16           (b) COMPENSATION TO CONSULTANTS OR INDI-  
17           VIDUAL SCIENTISTS.—Section 202 of the Departments of  
18           Labor, Health and Human Services, and Education, and  
19           Related Agencies Appropriations Act, 1993 (Public Law  
20           102–394; 42 U.S.C. 238f note) is amended by striking  
21           “portable structures;” and all that follows and inserting  
22           “portable structures.”.

23           (c) REVIEW OF CERTAIN AWARDS BY DIRECTORS.—  
24           Section 405(b) of the Public Health Service Act (42

1 U.S.C. 284(b)) is amended by adding at the end the fol-  
2 lowing:

3 “(3) Before an award is made by a national research  
4 institute or by a national center for a grant for a research  
5 program or project (commonly referred to as an ‘R-series  
6 grant’), other than an award constituting a noncompeting  
7 renewal of such grant, or a noncompeting administrative  
8 supplement to such grant, the director of such national  
9 research institute or national center—

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

11 “(B) shall take into consideration—

12 “(i) the mission of the national research  
13 institute or national center and the scientific  
14 priorities identified in the strategic plan under  
15 section 402(m); and

16 “(ii) whether other agencies are funding  
17 programs or projects to accomplish the same  
18 goal.”.

19 (d) IOM STUDY ON DUPLICATION IN FEDERAL BIO-  
20 MEDICAL RESEARCH.—The Secretary of Health and  
21 Human Services shall enter into an arrangement with the  
22 Institute of Medicine of the National Academies (or, if the  
23 Institute declines, another appropriate entity) under which  
24 the Institute (or other appropriate entity) not later than  
25 2 years after the date of enactment of this Act will—

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

4           (2) submit a report to the Congress on the re-  
5           sults of such study, including recommendations on  
6           how to prevent such duplication.

7   **SEC. 1023. REDUCING ADMINISTRATIVE BURDENS OF RE-**  
8                                   **SEARCHERS.**

9           (a) PLAN PREPARATION AND IMPLEMENTATION OF  
10          MEASURES TO REDUCE ADMINISTRATIVE BURDENS.—

11         The Director of the National Institutes of Health shall  
12         prepare a plan, including time frames, and implement  
13         measures to reduce the administrative burdens of re-  
14         searchers funded by the National Institutes of Health,  
15         taking into account the recommendations, evaluations,  
16         and plans researched by the following entities:

17                 (1) The Scientific Management Review Board.

18                 (2) The National Academy of Sciences.

19                 (3) The 2007 and 2012 Faculty Burden Survey  
20         conducted by The Federal Demonstration Partner-  
21         ship.

22                 (4) Relevant recommendations from the Re-  
23         search Business Models Working Group.

24         (b) REPORT.—Not later than two years after the date  
25         of enactment of this Act, the Director of the National In-

1 stitutes of Health shall submit to Congress a report on  
2 the extent to which the Director has implemented meas-  
3 ures pursuant to subsection (a).

4 **SEC. 1024. EXEMPTION FOR THE NATIONAL INSTITUTES OF**  
5 **HEALTH FROM THE PAPERWORK REDUCTION**  
6 **ACT REQUIREMENTS.**

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

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

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

13 (3) by inserting at the end the following new  
14 subparagraph:

15 “(E) during the conduct of research by the  
16 National Institutes of Health.”.

17 **SEC. 1025. NIH TRAVEL.**

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

21 **SEC. 1026. OTHER TRANSACTIONS AUTHORITY.**

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

24 (1) in subsection (b), by striking “the appro-  
25 priation of funds as described in subsection (g)” and

1 inserting “the availability of funds as described in  
2 subsection (f)”;

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

5 “(C) OTHER TRANSACTIONS AUTHORITY.—

6 The Director of the Center shall have other  
7 transactions authority in entering into trans-  
8 actions to fund projects in accordance with the  
9 terms and conditions of this section.”;

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

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

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

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

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

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

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

22 Part B of title IV of the Public Health Service Act  
23 (42 U.S.C. 284 et seq.) is amended by adding at the end  
24 the following:



1 **“SEC. 409K. HIGH-RISK, HIGH-REWARD RESEARCH PRO-**  
2 **GRAM.**

3 “The director of each national research institute  
4 shall, as appropriate—

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

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

13 **SEC. 1029. SENSE OF CONGRESS ON INCREASED INCLUSION**  
14 **OF UNDERREPRESENTED COMMUNITIES IN**  
15 **CLINICAL TRIALS.**

16 It is the sense of Congress that the National Institute  
17 on Minority Health and Health Disparities (NIMHD)  
18 should include within its strategic plan ways to increase  
19 representation of underrepresented communities in clinical  
20 trials.

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

3   **SEC. 1041. IMPROVEMENT OF LOAN REPAYMENT PRO-**  
4                           **GRAMS OF THE 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 conclusions 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 the**  
2 **National 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 includes at least—

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

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

4                   “(iii) exclusion criteria such as spe-  
5                   cific diagnosis or diagnoses, laboratory val-  
6                   ues, or 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 under this sec-  
6 tion with an eligible entity unless such entity submits an  
7 application including 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 under  
10 subsection (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 Comptroller General of  
20 the United States shall conduct a study and issue a  
21 report to the Congress and the Secretary with re-  
22 spect to the pilot program established under sub-  
23 section (a), not later than 6 years after the date on  
24 which the pilot program is established under sub-  
25 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 to 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 analysis of privacy and data integ-  
25 rity 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 section 201(g) of the Federal Food,  
16 Drug, and Cosmetic Act (21 U.S.C. 331(g))), a de-  
17 vice (as defined in section 201(h) of such Act (21  
18 U.S.C. 331(h)), a biological product (as defined in  
19 section 351 of the Public Health Service Act (42  
20 U.S.C. 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—

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

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

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

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

21 (ii) the sponsor of the original inves-  
22 tigational development program has pro-  
23 vided its consent to the Secretary for inclu-  
24 sion of data regarding such product in the  
25 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 to 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 that spon-  
14                 sor or maintain disease registries, including disease  
15                 registries 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 to facili-  
18 tate 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 ered entity for research purposes, including studies whose  
2 purpose is to obtain generalizable knowledge, to be treated  
3 as the use and disclosure of such information for health  
4 care operations described in subparagraph (1) of the defi-  
5 nition of health care operations in section 164.501 of part  
6 164.

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

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

14 “(A) another covered entity for health care  
15 operations (as defined in section 164.501 of  
16 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 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 appointed by the  
13                   Comptroller General of the United States  
14                   from a list of nominations submitted by  
15                   leading trade associations—

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                   resentatives 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 the Federal Food, Drug, and Cos-  
16 metic Act, as added by subsection (c)) can play a  
17 valuable role in helping to develop and qualify drug  
18 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, the Secretary shall  
21              conduct such review in accordance with this sec-  
22              tion.

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

1           “(A) IN GENERAL.—The succeeding provi-  
2           sions of this paragraph shall apply with respect  
3           to the treatment of a letter of intent, a quali-  
4           fication plan, or a full qualification package  
5           submitted under paragraph (1) (referred to in  
6           this paragraph as ‘qualification submissions’).

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

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

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

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

11          “(D) ENGAGEMENT OF EXTERNAL EX-  
12          PERTS.—The Secretary may, for purposes of  
13          the review of qualification submissions, through  
14          the use of cooperative agreements, grants, or  
15          other appropriate mechanisms, consult with bio-  
16          medical research consortia and may consider  
17          the recommendations of such consortia with re-  
18          spect to the review of any qualification plan  
19          submitted under paragraph (1) or the review of  
20          any full qualification package under paragraph  
21          (3).

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

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

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

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

12          “(b) EFFECT OF QUALIFICATION.—

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

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

21           “(A) supporting or obtaining approval or  
22           licensure (as applicable) of a drug or biological  
23           product (including in accordance with section  
24           506(c)) under section 505 of this Act or section  
25           351 of the Public Health Service Act; or

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

5           “(3) RESCISSION OR MODIFICATION.—

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

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

24           “(c) TRANSPARENCY.—



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

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

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

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

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

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

22                   “(B) The Secretary’s formal written deter-  
23                   minations in response to such qualification sub-  
24                   missions.

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

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

8           “(E) A comprehensive list of—

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

11                   “(ii) all surrogate endpoints which  
12                  were the basis of approval or licensure (as  
13                  applicable) of a drug or biological product  
14                  (including in accordance with section  
15                  506(e)) under section 505 of this Act or  
16                  section 351 of the Public Health Service  
17                  Act.

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

23           “(3) APPLICABILITY.—Nothing in this section  
24           shall be construed as authorizing the Secretary to  
25           disclose any information contained in an application

1 submitted under section 505 of this Act or section  
2 351 of the Public Health Service Act that is con-  
3 fidential commercial or trade secret information sub-  
4 ject to section 552(b)(4) of title 5, United States  
5 Code, or section 1905 of title 18, United States  
6 Code.

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

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

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

19 “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
20 are authorized to be appropriated to carry out this section,  
21 \$10,000,000 for each of fiscal years 2016 through 2020.

22 “(f) DEFINITIONS.—In this section:

23 “(1) BIOMARKER.—(A) The term ‘biomarker’  
24 means a characteristic (such as a physiologic,  
25 pathologic, or anatomic characteristic or measure-

1       ment) that is objectively measured and evaluated as  
2       an indicator of normal biologic processes, pathologic  
3       processes, or biological responses to a therapeutic  
4       intervention; and

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

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

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

20          “(B) such term includes a patient-reported out-  
21      come.

22          “(4) CONTEXT OF USE.—The term ‘context of  
23      use’ means, with respect to a drug development tool,  
24      a statement that describes the circumstances under

1       which the drug development tool is to be used in  
2       drug development and regulatory review.

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

5           “(A) a biomarker;

6           “(B) a clinical outcome assessment; and

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

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

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

23          “(8) REQUESTOR.—The term ‘requestor’ means  
24      an entity or entities, including a drug sponsor or a  
25      biomedical research consortia, seeking to qualify a

1 drug development tool for a proposed context of use  
2 under this section.

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

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

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

15 (d) GUIDANCE.—

16 (1) IN GENERAL.—The Secretary of Health and  
17 Human Services shall, in consultation with bio-  
18 medical research consortia (as defined in subsection  
19 (f) of section 507 the Federal Food, Drug, and Cos-  
20 metic Act (as added by subsection (c))) and other  
21 interested parties through a collaborative public  
22 process, issue guidance to implement such section  
23 507 that—

24 (A) provides a conceptual framework de-  
25 scribing appropriate standards and scientific

1 approaches to support the development of bio-  
2 markers delineated under the taxonomy estab-  
3 lished under paragraph (3);

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

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

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

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

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

1 Secretary in the review of qualification  
2 plans and full qualification submissions  
3 under such section; and

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

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

16 (3) TAXONOMY.—

17 (A) IN GENERAL.—For purposes of in-  
18 forming guidance under this subsection, the  
19 Secretary of Health and Human Services shall,  
20 in consultation with biomedical research con-  
21 sortia and other interested parties through a  
22 collaborative public process, establish a tax-  
23 onomy for the classification of biomarkers (and  
24 related scientific concepts) for use in drug de-  
25 velopment.



1 (B) PUBLIC AVAILABILITY.—Not later  
2 than 12 months after the date of the enactment  
3 of this Act, the Secretary of Health and Human  
4 Services shall make such taxonomy publicly  
5 available in draft form for public comment. The  
6 Secretary shall finalize the taxonomy not later  
7 than 12 months after the close of the public  
8 comment period.

9 (e) MEETING AND REPORT.—

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

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

1 (A) the number of requests submitted, as  
2 a letter of intent, for qualification of a drug de-  
3 velopment tool (as defined in subsection (f) of  
4 such section);

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

10 (C) the number of such requests for which  
11 external scientific experts were utilized in the  
12 development of a qualification plan or review of  
13 a full qualification package; and

14 (D) the number of qualification plans and  
15 full qualification packages, respectively, sub-  
16 mitted to the Secretary; and

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

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

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

1       “(g) ACCELERATED APPROVAL DEVELOPMENT  
2 PLAN.—

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

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

16           “(A) the surrogate endpoint to be assessed  
17 under such plan;

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

20           “(C) the magnitude of the effect of the  
21 drug on the surrogate endpoint that is the sub-  
22 ject of the agreement that would be sufficient  
23 to form the primary basis of a claim that the  
24 drug is effective.

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

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

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

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

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

24                   “(A) is reasonably likely to predict clinical  
25                  benefit; and

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

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

7 (1) by striking “(f) AWARENESS EFFORTS” and  
8 inserting “(e) AWARENESS EFFORTS”; and

9 (2) by striking “(e) CONSTRUCTION” and in-  
10 sserting “(f) CONSTRUCTION”.

## 11 **Subtitle C—FDA Advancement of** 12 **Precision Medicine**

### 13 **SEC. 2041. PRECISION MEDICINE GUIDANCE AND OTHER** 14 **PROGRAMS OF FOOD AND DRUG ADMINIS-** 15 **TRATION.**

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

#### 19 **“Subchapter J—Precision Medicine**

#### 20 **“SEC. 591. GENERAL AGENCY GUIDANCE ON PRECISION** 21 **MEDICINE.**

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

1           “(1) define the term ‘precision drug or biological  
2           cal product’; and

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

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

7           “(1) the evidence needed to support the use of  
8           biomarkers (as defined in section 507(e)) that identify  
9           subsets of patients as likely responders to therapies  
10          in order to streamline the conduct of clinical  
11          trials;

12          “(2) recommendations for the design of studies  
13          to demonstrate the validity of a biomarker as a predictor  
14          of drug or biological product response;

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

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

21          “(5) considerations for developing biomarkers  
22          that inform prescribing decisions for a drug or biological  
23          product, and when information regarding a  
24          biomarker may be included in the approved prescrip-

1           tion labeling for a precision drug or biological prod-  
2           uct.

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

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

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

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

1 under section 351(a) of the Public Health Service  
2 Act, as applicable—

3 “(A) for a different drug or biological  
4 product; or

5 “(B) for a different indication for such  
6 precision drug or biological product,

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

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

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

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

24 “(2) confer any new rights, beyond those au-  
25 thorized under this Act prior to enactment of this



1 section, with respect to a sponsor’s ability to ref-  
2 erence information contained in another application  
3 submitted under section 505(b)(1) of this Act or sec-  
4 tion 351(a) of the Public Health Service Act.”.

5 **Subtitle D—Modern Trial Design**  
6 **and Evidence Development**

7 **SEC. 2061. BROADER APPLICATION OF BAYESIAN STATIS-**  
8 **TICS AND ADAPTIVE TRIAL DESIGNS.**

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

20 (b) GUIDANCE ADDRESSING USE OF ADAPTIVE  
21 TRIAL DESIGNS AND BAYESIAN METHODS.—

22 (1) IN GENERAL.—The Secretary of Health and  
23 Human Services, acting through the Commissioner  
24 of Food and Drugs (in this subsection referred to as  
25 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 to  
13 satisfy 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 to support the approval of a new  
7 indication for a drug approved under section 505(b);  
8 and

9 “(2) to help to 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 under sub-  
14                   section (a), 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 nonspecified use.

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

16                 “(A) the standards of evidence under—

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

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

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

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

4 “(a) IN GENERAL.—The Secretary shall, in parallel  
5 to implementing the program established under section  
6 505F and in order to build capacity for utilizing the evi-  
7 dence from clinical experience described in that section,  
8 identify and execute pilot demonstrations to extend exist-  
9 ing use of the Sentinel System surveillance infrastructure  
10 authorized 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 analysis 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 nonmis-  
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 to expedite the development and availability of treatments  
9 for serious or life-threatening bacterial or fungal infections  
10 in patients with unmet needs, while maintaining safety  
11 and effectiveness standards for such treatments, taking  
12 into account the severity of the infection and the avail-  
13 ability 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 in accordance with this  
7 subsection only if a written agreement is  
8 reached under subparagraph (A);

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

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

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

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

19           “(iii) only if the standards for ap-  
20 proval under subsections (c) and (d) of this  
21 section or licensure under section 351 of  
22 the Public Health Service Act, as applica-  
23 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 to expedite  
20 and facilitate the development and review of a  
21 drug for which a sponsor intends to request ap-  
22 proval in accordance with this subsection, the  
23 Secretary may, at the request of the sponsor,  
24 conduct meetings that provide early consulta-  
25 tion, timely advice, and sufficient opportunities

1 to 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  
24 the findings of the assessment, during which public  
25 stakeholders may present their views on the success

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

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

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

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

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



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

5           “(2) changes in bacterial and fungal resistance  
6           to drugs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20           “(1) IN GENERAL.—Not later than 1 year after  
21           the date of the enactment of the 21st Century Cures  
22           Act, the Secretary shall establish, and maintain  
23           thereafter, on the website of the Food and Drug Ad-  
24           ministration, a dedicated website that contains a list  
25           of any appropriate new or updated susceptibility test

1 interpretive criteria standards in accordance with  
2 paragraph (2) (referred to in this section as the ‘In-  
3 terpretive Criteria Website’).

4 “(2) LISTING OF SUSCEPTIBILITY TEST INTER-  
5 PRETIVE CRITERIA STANDARDS.—

6 “(A) IN GENERAL.—The list described in  
7 paragraph (1) shall consist of any new or up-  
8 dated susceptibility test interpretive criteria  
9 standards that are—

10 “(i) established by a nationally or  
11 internationally recognized standard devel-  
12 opment organization that—

13 “(I) establishes and maintains  
14 procedures to address potential con-  
15 flicts of interest and ensure trans-  
16 parent decisionmaking;

17 “(II) holds open meetings to en-  
18 sure that there is an opportunity for  
19 public input by interested parties, and  
20 establishes and maintains processes to  
21 ensure that such input is considered  
22 in decisionmaking; and

23 “(III) permits its standards to be  
24 made publicly available, through the  
25 National Library of Medicine or an-

1 other similar source acceptable to the  
2 Secretary; and

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

5 “(B) OTHER LIST.—The Interpretive Cri-  
6 teria Website shall, in addition to the list de-  
7 scribed in subparagraph (A), include a list of  
8 interpretive criteria, if any, that the Secretary  
9 has determined to be appropriate with respect  
10 to legally marketed antimicrobial drugs,  
11 where—

12 “(i) the Secretary does not recognize,  
13 in whole or in part, an interpretive criteria  
14 standard described under subparagraph  
15 (A) otherwise applicable to such a drug;

16 “(ii) the Secretary withdraws under  
17 subsection (c)(1)(B) recognition of a  
18 standard, in whole or in part, otherwise  
19 applicable to such a drug;

20 “(iii) the Secretary approves an appli-  
21 cation under section 505 of this Act or sec-  
22 tion 351 of the Public Health Service Act,  
23 as applicable, with respect to marketing of  
24 such a drug for which there are no rel-  
25 evant interpretive criteria included in a

1 standard recognized by the Secretary  
2 under subsection (c); or

3 “(iv) because the characteristics of  
4 such a drug differ from other drugs with  
5 the same active ingredient, the interpretive  
6 criteria with respect to such drug—

7 “(I) differ from otherwise appli-  
8 cable interpretive criteria included in  
9 a standard listed under subparagraph  
10 (A) or interpretive criteria otherwise  
11 listed under this subparagraph; and

12 “(II) are determined by the Sec-  
13 retary to be appropriate for the drug.

14 “(C) REQUIRED STATEMENTS OF LIMITA-  
15 TIONS OF INFORMATION.—The Interpretive Cri-  
16 teria Website shall include the following:

17 “(i) A statement that—

18 “(I) the website provides infor-  
19 mation about the susceptibility of bac-  
20 teria, fungi, or other microorganisms  
21 to a certain drug (or drugs); and

22 “(II) the safety and efficacy of  
23 the drug in treating clinical infections  
24 due to such bacteria, fungi, or other  
25 microorganisms may not have been es-

1                   tablished in adequate and well-con-  
2                   trolled clinical trials and the clinical  
3                   significance of such susceptibility in-  
4                   formation in such trials is unknown.

5                   “(ii) A statement that directs health  
6                   care practitioners to consult the approved  
7                   product labeling for specific drugs to deter-  
8                   mine the uses for which the Food and  
9                   Drug Administration has approved the  
10                  product.

11                  “(iii) Any other statement that the  
12                  Secretary determines appropriate to ade-  
13                  quately convey the limitations of the data  
14                  supporting susceptibility test interpretive  
15                  criteria standard listed on the website.

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

20                  “(4) INAPPLICABILITY OF MISBRANDING PROVI-  
21                  SION.—The inclusion in the approved labeling of an  
22                  antimicrobial drug of a reference or hyperlink to the  
23                  Interpretive Criteria Website, in and of itself, shall  
24                  not cause the drug to be misbranded in violation of

1 section 502, or the regulations promulgated there-  
2 under.

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

9 “(c) RECOGNITION OF SUSCEPTIBILITY TEST INTER-  
10 PRETIVE CRITERIA FROM STANDARD DEVELOPMENT OR-  
11 GANIZATIONS.—

12 “(1) IN GENERAL.—Beginning on the date of  
13 the establishment of the Interpretive Criteria  
14 Website, and at least every 6 months thereafter, the  
15 Secretary shall—

16 “(A) evaluate any appropriate new or up-  
17 dated susceptibility test interpretive criteria  
18 standards established by a nationally or inter-  
19 nationally recognized standard development or-  
20 ganization described in subsection (b)(2)(A)(i);  
21 and

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



1 “(i) withdrawing recognition of any  
2 different susceptibility test interpretive cri-  
3 teria standard, in whole or in part;

4 “(ii) recognizing the new or updated  
5 standards;

6 “(iii) recognizing one or more parts of  
7 the new or updated interpretive criteria  
8 specified in such a standard and declining  
9 to recognize the remainder of such stand-  
10 ard; and

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

13 “(2) BASES FOR UPDATING INTERPRETIVE CRI-  
14 TERIA STANDARDS.—In evaluating new or updated  
15 susceptibility test interpretive criteria standards  
16 under paragraph (1)(A), the Secretary may con-  
17 sider—

18 “(A) the Secretary’s determination that  
19 such a standard is not applicable to a particular  
20 drug because the characteristics of the drug dif-  
21 fer from other drugs with the same active in-  
22 gredient;

23 “(B) information provided by interested  
24 third parties, including public comment on the

1 annual compilation of notices published under  
2 paragraph (3);

3 “(C) any bases used to identify suscepti-  
4 bility test interpretive criteria under subsection  
5 (a)(2); and

6 “(D) such other information or factors as  
7 the Secretary determines appropriate.

8 “(3) ANNUAL COMPILATION OF NOTICES.—  
9 Each year, the Secretary shall compile the notices  
10 published under paragraph (1)(B) and publish such  
11 compilation in the Federal Register and provide for  
12 public comment. If the Secretary receives comments,  
13 the Secretary will review such comments and, if the  
14 Secretary determines appropriate, update pursuant  
15 to this subsection susceptibility test interpretive cri-  
16 teria standards—

17 “(A) recognized by the Secretary under  
18 this subsection; or

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

21 “(4) RELATION TO SECTION 514(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 of  
18 this Act or section 351 of the Public Health Service  
19 Act, as applicable, 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) As part of the annual rulemaking under this  
6           subsection for payment for subsection (d) hospitals for  
7           each fiscal year beginning with fiscal year 2018, the Sec-  
8           retary shall—

9           “(I) include publication of a list of the new  
10          antimicrobial drugs for such fiscal year; and

11          “(II) with respect to discharges by eligible hos-  
12          pitals that involve a drug so published, provide for  
13          an additional payment to be made under this sub-  
14          section in accordance with the provisions of this sub-  
15          paragraph.

16          “(ii) Additional payments may not be made for a  
17          drug under this subparagraph—

18                 “(I) other than during the 5-fiscal-year period  
19                 beginning with the fiscal year for which the drug is  
20                 first included in the publication described in clause  
21                 (i)(I); and

22                 “(II) with respect to which payment has ever  
23                 been made pursuant to subparagraph (K).

24          “(iii) For purposes of this subparagraph, the term  
25          ‘new antimicrobial drug’ means a product that is approved

1 for use, or a product for which an indication is first ap-  
2 proved for use, by the Food and Drug Administration on  
3 or after December 1, 2014, and that the Food and Drug  
4 Administration determines—

5 “(I) either—

6 “(aa) is intended to treat an infection  
7 caused by, or likely to be caused by, a quali-  
8 fying pathogen (as defined under section  
9 505E(f) of the Federal Food, Drug, and Cos-  
10 metic Act); or

11 “(bb) meets the definition of a qualified in-  
12 fectious disease product under section 505E(g)  
13 of the Federal Food, Drug, and Cosmetic Act;  
14 and

15 “(II) is intended to treat an infection—

16 “(aa) for which there is an unmet medical  
17 need; and

18 “(bb) which is associated with high rates  
19 of mortality or significant patient morbidity, as  
20 determined in consultation with the Director of  
21 the Centers for Disease Control and Prevention  
22 and the infectious disease professional commu-  
23 nity.

1 Such determination may be revoked only upon a finding  
2 that the request for such determination contained an un-  
3 true statement of material fact.

4 “(iv) For purposes of this subparagraph, the term ‘el-  
5 igible hospital’ means a subsection (d) hospital that par-  
6 ticipates in the National Healthcare Safety Network of the  
7 Centers for Disease Control and Prevention (or, to the ex-  
8 tent a similar surveillance system reporting program that  
9 includes reporting about antimicrobial drugs is determined  
10 by the Secretary to be available to such hospitals, such  
11 similar surveillance system as the Secretary may specify).

12 “(v)(I) Subject to the succeeding provisions of this  
13 clause, the additional payment under this subparagraph,  
14 with respect to a drug, shall be in the amount provided  
15 for such drug under section 1847A.

16 “(II) The Secretary shall, as part of the rulemaking  
17 referred to in clause (i) for each fiscal year, estimate—

18 “(aa) the total amount of the additional pay-  
19 ments that will be made under this subsection pur-  
20 suant to this subparagraph for discharges in such  
21 fiscal year without regard to the application of sub-  
22 clause (III); and

23 “(bb) the total program payments to be made  
24 under this subsection for all discharges in such fiscal  
25 year.

1           “(III) If the estimated total amount described in sub-  
2 clause (II)(aa) for a fiscal year exceeds the applicable per-  
3 centage of the estimated total program payments de-  
4 scribed in subclause (II)(bb) for such fiscal year, the Sec-  
5 retary shall reduce in a pro rata manner the amount of  
6 each additional payment under this subsection pursuant  
7 to this subparagraph for such fiscal year in order to en-  
8 sure that the total amount of the additional payments  
9 under this subsection pursuant to this subparagraph for  
10 such fiscal year do not exceed the applicable percentage  
11 of the estimated total program payments described in sub-  
12 clause (II)(bb) for such fiscal year.

13           “(IV) For purposes of subclause (III), the term ‘ap-  
14 plicable percentage’ means 0.03 percent.”.

15           (2) CONFORMING AMENDMENTS.—

16           (A) NO DUPLICATIVE NTAP PAYMENTS.—  
17           Section 1886(d)(5)(K)(vi) of the Social Security  
18           Act (42 U.S.C. 1395ww(d)(5)(K)(vi)) is amend-  
19           ed by inserting “if additional payment has  
20           never been made under this subsection pursu-  
21           ant to subparagraph (M) with respect to the  
22           service or technology” after “if the service or  
23           technology”.

24           (B) ACCESS TO PRICE INFORMATION.—  
25           Section 1927(b)(3)(A)(iii) of the Social Security

1 Act (42 U.S.C. 1396r-8(b)(3)(A)(iii)) is  
2 amended—

3 (i) in subclause (II), by inserting “, or  
4 under section 1886(d) pursuant to para-  
5 graph (5)(M) of such section,” after  
6 “1847A,”; and

7 (ii) in the matter following subclause  
8 (III), by inserting “or section  
9 1886(d)(5)(M)” after  
10 “1881(b)(13)(A)(ii)”.

11 (b) STUDY AND REPORT ON REMOVING BARRIERS TO  
12 DEVELOPMENT OF NEW ANTIMICROBIAL DRUGS.—

13 (1) STUDY.—The Comptroller General of the  
14 United States shall, in consultation with the Direc-  
15 tor of the National Institutes of Health, the Com-  
16 missioner of Food and Drugs, and the Director of  
17 the Centers for Disease Control and Prevention, con-  
18 duct a study to—

19 (A) identify and examine the barriers that  
20 prevent the development of new antimicrobial  
21 drugs, as defined in section 1886(d)(5)(M)(iii)  
22 of the Social Security Act (42 U.S.C.  
23 1395ww(d)(5)(M)(iii)), as added by subsection  
24 (a)(1); and

1 (B) develop recommendations for actions  
2 to be taken in order to overcome any barriers  
3 identified under subparagraph (A).

4 (2) REPORT.—Not later than 1 year after the  
5 date of the enactment of this Act, the Comptroller  
6 General shall submit to Congress a report on the  
7 study conducted under paragraph (1).

8 **Subtitle H—Vaccine Access,**  
9 **Certainty, and Innovation**

10 **SEC. 2141. TIMELY REVIEW OF VACCINES BY THE ADVISORY**  
11 **COMMITTEE ON IMMUNIZATION PRACTICES.**

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

15 “(10) ADVISORY COMMITTEE ON IMMUNIZATION  
16 PRACTICES.—

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

24 “(B) EXPEDITED REVIEW PURSUANT TO  
25 REQUEST BY SPONSOR OR MANUFACTURER.—If



1 the Advisory Committee does not make rec-  
2 ommendations with respect to the use of a vac-  
3 cine at the Advisory Committee’s first regularly  
4 scheduled meeting after the licensure of the  
5 vaccine or any new indication for the vaccine,  
6 the Advisory Committee, at the request of the  
7 sponsor of the vaccine, shall make such rec-  
8 ommendations on an expedited basis.

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

18 “(D) DEFINITION.—In this paragraph, the  
19 terms ‘Advisory Committee on Immunization  
20 Practices’ and ‘Advisory Committee’ mean the  
21 advisory committee on immunization practices  
22 established by the Secretary pursuant to section  
23 222, acting through the Director of the Centers  
24 for Disease Control and Prevention.”.

1 **SEC. 2142. REVIEW OF PROCESSES AND CONSISTENCY OF**  
2 **ACIP RECOMMENDATIONS.**

3 (a) REVIEW.—The Director of the Centers for Dis-  
4 ease Control and Prevention shall conduct a review of the  
5 process used by the Advisory Committee on Immunization  
6 Practices to evaluate 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 120 calendar 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 to such information may have  
12 implications for the vaccine developer’s vaccine re-  
13 search and development.”.

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 para-  
6 graph (1) 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 7½-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 paragraph (1) to the lengths of the exclu-  
22 sivity periods after application of pediatric exclu-  
23 sivity, the 6-month extensions described in para-  
24 graph (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 paragraph (1) to the lengths of the exclu-  
7 sivity periods after application of pediatric exclu-  
8 sivity, the 6-month extensions described in para-  
9 graph (1) shall be in addition to any extensions  
10 under section 505G.”.

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” at the end;

6 (ii) in subparagraph (F), by striking  
7 the period at the end and inserting “;  
8 and”; and

9 (iii) by adding at the end the fol-  
10 lowing:

11 “(G) is for a drug or biological product for  
12 which a priority review voucher has not been  
13 issued under section 524 (relating to tropical  
14 disease products).”; and

15 (2) in subsection (b), by striking paragraph (5)  
16 and inserting the following:

17 “(5) TERMINATION OF AUTHORITY.—The Sec-  
18 retary may not award any priority review vouchers  
19 under paragraph (1) after December 31, 2018.”.

20 (b) GAO STUDY AND REPORT.—

21 (1) STUDY.—The Comptroller General of the  
22 United States shall conduct a study on the effective-  
23 ness of awarding priority review vouchers under sec-  
24 tion 529 of the Federal Food, Drug, and Cosmetic  
25 Act (21 U.S.C. 360ff) in providing incentives for the

1 development of drugs that treat or prevent rare pe-  
2 diatric diseases (as defined in subsection (a)(3) of  
3 such section) that would not otherwise have been de-  
4 veloped. In conducting such study, the Comptroller  
5 General shall examine the following:

6 (A) The indications for which each drug  
7 for which a priority review voucher was award-  
8 ed under such section 529 was approved under  
9 section 505 of such Act (21 U.S.C. 355) or sec-  
10 tion 351 of the Public Health Service Act (42  
11 U.S.C. 262).

12 (B) Whether the priority review voucher  
13 impacted a sponsor's decision to invest in devel-  
14 oping a drug to treat or prevent a rare pedi-  
15 atric disease.

16 (C) An analysis of the drugs that utilized  
17 such priority review vouchers, which shall in-  
18 clude—

19 (i) the indications for which such  
20 drugs were approved under section 505 of  
21 the Federal Food, Drug, and Cosmetic Act  
22 (21 U.S.C. 355) or section 351 of the Pub-  
23 lic Health Service Act (42 U.S.C. 262);

1 (ii) whether unmet medical needs were  
2 addressed through the approval of such  
3 drugs, including, for each such drug—

4 (I) if an alternative therapy was  
5 previously available to treat the indi-  
6 cation; and

7 (II) the benefit or advantage the  
8 drug provided over another available  
9 therapy;

10 (iii) the number of patients potentially  
11 treated by such drugs;

12 (iv) the value of the priority review  
13 voucher if transferred; and

14 (v) the length of time between the  
15 date on which a priority review voucher  
16 was awarded and the date on which it was  
17 used.

18 (D) With respect to the priority review  
19 voucher program under section 529 of the Fed-  
20 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
21 360ff)—

22 (i) the resources used by, and burden  
23 placed on, the Food and Drug Administra-  
24 tion in implementing such program, includ-  
25 ing the effect of such program on the Food



1 and Drug Administration's review of drugs  
2 for which a priority review voucher was not  
3 awarded or used;

4 (ii) the impact of the program on the  
5 public health as a result of the expedited  
6 review of applications for drugs that treat  
7 or prevent non-serious indications that are  
8 generally used by the broader public; and

9 (iii) alternative approaches to improv-  
10 ing such program so that the program is  
11 appropriately targeted toward providing in-  
12 centives for the development of clinically  
13 important drugs that—

14 (I) prevent or treat rare pediatric  
15 diseases; and

16 (II) would likely not otherwise  
17 have been developed to prevent or  
18 treat such diseases.

19 (2) REPORT.—Not later than December 31,  
20 2017, the Comptroller General of the United States  
21 shall submit to the Committee on Energy and Com-  
22 merce of the House of Representatives and the Com-  
23 mittee on Health, Education, Labor and Pensions of  
24 the Senate a report containing the results of the  
25 study of conducted under paragraph (1).

1 **Subtitle J—Domestic Manufac-**  
2 **turing and Export Efficiencies**

3 **SEC. 2161. GRANTS FOR STUDYING THE PROCESS OF CON-**  
4 **TINUOUS DRUG MANUFACTURING.**

5 (a) IN GENERAL.—The Commissioner of Food and  
6 Drugs may award grants to institutions of higher edu-  
7 cation and nonprofit organizations for the purpose of  
8 studying and recommending improvements to the process  
9 of continuous manufacturing of drugs and biological prod-  
10 ucts and similar innovative monitoring and control tech-  
11 niques.

12 (b) DEFINITIONS.—In this section:

13 (1) The term “drug” has the meaning given to  
14 such term in section 201 of the Federal Food, Drug,  
15 and Cosmetic Act (21 U.S.C. 321).

16 (2) The term “biological product” has the  
17 meaning given to such term in section 351(i) of the  
18 Public Health Service Act (42 U.S.C. 262(i)).

19 (3) The term “institution of higher education”  
20 has the meaning given to such term in section 101  
21 of the Higher Education Act of 1965 (20 U.S.C.  
22 1001).

23 (c) AUTHORIZATION OF APPROPRIATIONS.—There is  
24 authorized to be appropriated to carry out this section  
25 \$5,000,000 for each of fiscal years 2016 through 2020.

1 **SEC. 2162. RE-EXPORTATION AMONG MEMBERS OF THE EU-**  
2 **ROPEAN ECONOMIC AREA.**

3 Section 1003 of the Controlled Substances Import  
4 and Export Act (21 U.S.C. 953) is amended—

5 (1) in subsection (f)—

6 (A) in paragraph (5)—

7 (i) by striking “(5)” and inserting  
8 “(5)(A)”;

9 (ii) by inserting “, except that the  
10 controlled substance may be exported from  
11 the second country to another country that  
12 is a member of the European Economic  
13 Area” before the period at the end; and

14 (iii) by adding at the end the fol-  
15 lowing:

16 “(B) Subsequent to any re-exportation de-  
17 scribed in subparagraph (A), a controlled substance  
18 may continue to be exported from any country that  
19 is a member of the European Economic Area to any  
20 other such country, provided that—

21 “(i) the conditions applicable with respect  
22 to the first country under paragraphs (1), (2),  
23 (3), (4), (6), and (7) are met by each subse-  
24 quent country from which the controlled sub-  
25 stance is exported pursuant to this paragraph;  
26 and

1           “(ii) the conditions applicable with respect  
2           to the second country under such paragraphs  
3           are met by each subsequent country to which  
4           the controlled substance is exported pursuant to  
5           this paragraph.”; and

6           (B) in paragraph (6)—

7           (i) by striking “(6)” and inserting  
8           “(6)(A)”; and

9           (ii) by adding at the end the fol-  
10          lowing:

11          “(B) In the case of re-exportation among mem-  
12          bers of the European Economic Area, within 30  
13          days after each re-exportation, the person who ex-  
14          ported the controlled substance from the United  
15          States delivers to the Attorney General—

16                 “(i) documentation certifying that such re-  
17                 exportation has occurred; and

18                 “(ii) information concerning the consignee,  
19                 country, and product.”; and

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

21          “(g) LIMITATION.—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 posed by  
20 institutional review committees concerning the  
21 conditions and clinical testing requirements ap-  
22 plicable to the investigational use of the device  
23 pursuant to an exemption under section 520(g).

24           “(2) ADDITIONAL ACTIONS.—In addition to the  
25 actions described in paragraph (1), for purposes of

1       expediting the development and review of devices  
2       designated under subsection (c), the Secretary, in  
3       collaboration with the device sponsor, may, as appro-  
4       priate—

5               “(A) coordinate with the sponsor regarding  
6       early agreement on a data development plan;

7               “(B) take steps to ensure that the design  
8       of clinical trials is as efficient as practicable,  
9       such as through adoption of shorter or smaller  
10      clinical trials, application of surrogate  
11      endpoints, and use of adaptive trial designs and  
12      Bayesian statistics, to the extent scientifically  
13      appropriate;

14              “(C) facilitate, to the extent scientifically  
15      appropriate, expedited and efficient develop-  
16      ment and review of the device through utiliza-  
17      tion of timely postmarket data collection, with  
18      regard to applications for approval under sec-  
19      tion 515(c); and

20              “(D) agree to clinical protocols that the  
21      Secretary will consider binding on the Secretary  
22      and the sponsor, subject to—

23                      “(i) changes agreed to by the sponsor  
24                      and the Secretary;

1 “(ii) changes that the Secretary deter-  
2 mines are required to prevent an unreason-  
3 able risk to the public health; or

4 “(iii) the identification of a substan-  
5 tial scientific issue determined by the Sec-  
6 retary to be essential to the safety or effec-  
7 tiveness of the device involved.

8 “(e) PRIORITY REVIEW GUIDANCE.—

9 “(1) CONTENT.—The Secretary shall issue  
10 guidance on the implementation of this section. Such  
11 guidance shall include the following:

12 “(A) The process for a person to seek a  
13 priority review designation.

14 “(B) A template for requests under sub-  
15 section (b).

16 “(C) The criteria the Secretary will use in  
17 evaluating a request for priority review.

18 “(D) The standards the Secretary will use  
19 in assigning a team of staff, including team  
20 leaders, to review devices designated for priority  
21 review, including any training required for such  
22 personnel on effective and efficient review.

23 “(2) PROCESS.—Prior to finalizing the guid-  
24 ance under paragraph (1), the Secretary shall pro-  
25 pose such guidance for public comment.

1 “(f) CONSTRUCTION.—

2 “(1) PURPOSE.—This section is intended to en-  
3 courage the Secretary and provide the Secretary suf-  
4 ficient authorities to apply efficient and flexible ap-  
5 proaches to expedite the development of, and  
6 prioritize the agency’s review of, devices that rep-  
7 resent breakthrough technologies.

8 “(2) CONSTRUCTION.—Nothing in this section  
9 shall be construed to alter the criteria and standards  
10 for evaluating an application pursuant to section  
11 515(c), a report and request for classification under  
12 section 513(f)(2), or a report under section 510(k),  
13 including the recognition of valid scientific evidence  
14 as described in section 513(a)(3)(B), and consider-  
15 ation of the least burdensome means of evaluating  
16 device effectiveness or demonstrating substantial  
17 equivalence between devices with differing techno-  
18 logical characteristics, as applicable. Nothing in this  
19 section alters the authority of the Secretary to act  
20 on an application pursuant to section 515(d) before  
21 completion of an establishment inspection, as the  
22 Secretary deems appropriate.”.

23 (b) CONFORMING AMENDMENT RELATED TO DES-  
24 IGNATION DETERMINATIONS.—Section 517A(a)(1) of the  
25 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–

1 1(a)(1)) is amended by inserting “a request for designa-  
2 tion under section 515B,” after “an application under sec-  
3 tion 515,”.

4 **Subtitle M—Medical Device**  
5 **Regulatory Process Improvements**

6 **SEC. 2221. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

7 (a) ESTABLISHMENT OF THIRD-PARTY QUALITY  
8 SYSTEM ASSESSMENT PROGRAM.—Chapter V of the Fed-  
9 eral Food, Drug, and Cosmetic Act is amended by insert-  
10 ing after section 524A (21 U.S.C. 360n–1) the following  
11 new section:

12 **“SEC. 524B. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

13 **“(a) ACCREDITATION AND ASSESSMENT.—**

14 **“(1) IN GENERAL; CERTIFICATION OF DEVICE**  
15 **QUALITY SYSTEM.—**The Secretary shall, in accord-  
16 ance with this section, establish a third-party quality  
17 system assessment program—

18 **“(A) to accredit persons to assess whether**  
19 **a requestor’s quality system, including its de-**  
20 **sign controls, can reasonably assure the safety**  
21 **and effectiveness of in-scope devices subject to**  
22 **device-related changes;**

23 **“(B) under which accredited persons shall**  
24 **(as applicable) certify that a requestor’s quality**  
25 **system meets the criteria included in the guid-**

1           ance issued under paragraph (5) with respect to  
2           the in-scope devices at issue; and

3                   “(C) under which the Secretary shall rely  
4           on such certifications for purposes of deter-  
5           mining the safety and effectiveness (or as appli-  
6           cable, substantial equivalence) of in-scope de-  
7           vices subject to the device-related changes in-  
8           volved, in lieu of compliance with the following  
9           submission requirements:

10                           “(i) A premarket notification.

11                           “(ii) A thirty-day notice.

12                           “(iii) A Special PMA supplement.

13                   “(2) DEFINITIONS.—For purposes of this sec-  
14           tion—

15                           “(A) the term ‘device-related changes’  
16           means changes made by a requestor with re-  
17           spect to in-scope devices, which are—

18                                   “(i) changes to a device found to be  
19                                   substantially equivalent under sections  
20                                   513(i) and 510(k) to a predicate device,  
21                                   that—

22   “(I) would otherwise be subject  
23   to a premarket notification; and

24   “(II) do not alter—

1                   “(aa) the intended use of  
2                   the changed device; or

3                   “(bb) the fundamental sci-  
4                   entific technology of such device;

5                   “(ii) manufacturing changes subject  
6                   to a 30-day notice;

7                   “(iii) changes that qualify for a Spe-  
8                   cial PMA Supplement; and

9                   “(iv) such other changes relating to  
10                  the devices or the device manufacturing  
11                  process as the Secretary determines appro-  
12                  priate;

13                  “(B) the term ‘in-scope device’ means a  
14                  device within the scope of devices agreed to by  
15                  the requestor and the accredited person for pur-  
16                  poses of a request for certification under this  
17                  section;

18                  “(C) the term ‘premarket notification’  
19                  means a premarket notification under section  
20                  510(k);

21                  “(D) the term ‘quality system’ means the  
22                  methods used in, and the facilities and controls  
23                  used for, the design, manufacture, packaging,  
24                  labeling, storage, installation, and servicing of  
25                  devices, as described in section 520(f);



1           “(E) the term ‘requestor’ means a device  
2 manufacturer that is seeking certification under  
3 this section of a quality system used by such  
4 manufacturer;

5           “(F) the term ‘Special PMA’ means a Spe-  
6 cial PMA supplement under section 814.39(d)  
7 of title 21, Code of Federal Regulations (or any  
8 successor regulations); and

9           “(G) the term ‘thirty-day notice’ means a  
10 notice described in section 515(d)(6).

11           “(3) ACCREDITATION PROCESS; ACCREDITATION  
12 RENEWAL.—Except as inconsistent with this section,  
13 the process and qualifications for accreditation of  
14 persons and renewal of such accreditation under sec-  
15 tion 704(g) shall apply with respect to accreditation  
16 of persons and renewal of such accreditation under  
17 this section.

18           “(4) USE OF ACCREDITED PARTIES TO CON-  
19 DUCT ASSESSMENTS.—

20           “(A) INITIATION OF ASSESSMENT SERV-  
21 ICES.—

22           “(i) DATE ASSESSMENTS AUTHOR-  
23 IZED.—Beginning after the date on which  
24 the final guidance is issued under para-

1 graph (5), an accredited person may con-  
2 duct an assessment under this section.

3 “(ii) INITIATION OF ASSESSMENTS.—  
4 Use of one or more accredited persons to  
5 assess a requestor’s quality system under  
6 this section with respect to in-scope devices  
7 shall be at the initiation of the person who  
8 registers and lists the devices at issue  
9 under section 510.

10 “(B) COMPENSATION.—Compensation for  
11 such accredited persons shall—

12 “(i) be determined by agreement be-  
13 tween the accredited person and the person  
14 who engages the services of the accredited  
15 person; and

16 “(ii) be paid by the person who en-  
17 gages such services.

18 “(C) ACCREDITED PERSON SELECTION.—  
19 Each person who chooses to use an accredited  
20 person to assess a requestor’s quality system,  
21 as described in this section, shall select the ac-  
22 credited person from a list of such persons pub-  
23 lished by the Secretary in accordance with sec-  
24 tion 704(g)(4).

1           “(5) GUIDANCE; CRITERIA FOR CERTIFI-  
2           CATION.—

3           “(A) IN GENERAL.—The criteria for cer-  
4           tification of a quality system under this section  
5           shall be as specified by the Secretary in guid-  
6           ance issued under this paragraph.

7           “(B) CONTENTS; CERTIFICATION CRI-  
8           TERIA.—The guidance under this paragraph  
9           shall include specification of—

10           “(i) evaluative criteria to be used by  
11           an accredited person to assess and, as ap-  
12           plicable, certify a requestor’s quality sys-  
13           tem under this section with respect to in-  
14           scope devices; and

15           “(ii) criteria for accredited persons to  
16           apply for a waiver of, and exemptions  
17           from, the certification criteria under clause  
18           (i).

19           “(C) TIMEFRAME FOR ISSUING GUID-  
20           ANCE.—The Secretary shall issue under this  
21           paragraph—

22           “(i) draft guidance not later than 12  
23           months after the enactment of the 21st  
24           Century Cures Act; and

1                   “(ii) final guidance not later than 12  
2                   months after issuance of the draft guid-  
3                   ance under clause (i).

4                   “(b) USE OF THIRD-PARTY ASSESSMENT.—

5                   “(1) ASSESSMENT SUMMARY; CERTIFI-  
6                   CATION.—

7                   “(A) SUBMISSION OF ASSESSMENT TO SEC-  
8                   RETARY.—An accredited person who assesses a  
9                   requestor’s quality system under subsection (a)  
10                  shall submit to the Secretary a summary of the  
11                  assessment—

12                  “(i) within 30 days of the assessment;  
13                  and

14                  “(ii) which shall include (as applica-  
15                  ble)—

16                  “(I) the accredited person’s cer-  
17                  tification that the requestor has satis-  
18                  fied the criteria specified in the guid-  
19                  ance issued under subsection (a)(5)  
20                  for quality system certification with  
21                  respect to the in-scope devices at  
22                  issue; and

23                  “(II) any waivers or exemptions  
24                  from such criteria applied by the ac-  
25                  credited person.

1           “(B) TREATMENT OF ASSESSMENTS.—  
2           Subject to action by the Secretary under sub-  
3           paragraph (C), with respect to assessments  
4           which include a certification under this sec-  
5           tion—

6                   “(i) the Secretary’s review of the as-  
7                   sessment summary shall be deemed com-  
8                   plete on the day that is 30 days after the  
9                   date on which the Secretary receives the  
10                  summary under subparagraph (A); and

11                  “(ii) the assessment summary and  
12                  certification of the quality system of a re-  
13                  questor shall be deemed accepted by the  
14                  Secretary on such 30th day.

15           “(C) ACTIONS BY SECRETARY.—

16                   “(i) IN GENERAL.—Within 30 days of  
17                   receiving an assessment summary and cer-  
18                   tification under subparagraph (A), the Sec-  
19                   retary may, by written notice to the ac-  
20                   credited person submitting such assess-  
21                   ment certification, deem any such certifi-  
22                   cation to be provisional beyond such 30-  
23                   day period, suspended pending further re-  
24                   view by the Secretary, or otherwise quali-

1                   fied or cancelled, based on the Secretary’s  
2                   determination that (as applicable)—

3                   “(I) additional information is  
4                   needed to support such certification;

5                   “(II) such assessment or certifi-  
6                   cation is unwarranted; or

7                   “(III) such action with regard to  
8                   the certification is otherwise justified  
9                   according to such factors and criteria  
10                  as the Secretary finds appropriate.

11                  “(ii) ACCEPTANCE OF CERTIFI-  
12                  CATION.—If following action by the Sec-  
13                  retary under clause (i) with respect to a  
14                  certification, the Secretary determines that  
15                  such certification is acceptable, the Sec-  
16                  retary shall issue written notice to the ap-  
17                  plicable accredited person indicating such  
18                  acceptance.

19                  “(2) NOTIFICATIONS TO SECRETARY BY CER-  
20                  TIFIED REQUESTORS OR ACCREDITED PERSONS FOR  
21                  PROGRAM EVALUATION PURPOSES.—

22                  “(A) ANNUAL SUMMARY REPORT FOR DE-  
23                  VICE-RELATED CHANGES OTHERWISE SUBJECT  
24                  TO PREMARKET NOTIFICATION.—A requestor  
25                  whose quality system is certified under this sec-

1           tion that effectuates device-related changes with  
2           respect to in-scope devices, without prior sub-  
3           mission of a premarket notification, shall en-  
4           sure that an annual summary report is sub-  
5           mitted to the Secretary by the accredited per-  
6           son which—

7                   “(i) describes the changes made to the  
8                   in-scope device; and

9                   “(ii) indicates the effective dates of  
10                  such changes.

11                  “(B) PERIODIC NOTIFICATION FOR MANU-  
12                  FACTURING CHANGES OTHERWISE SUBJECT TO  
13                  THIRTY-DAY NOTICE.—A requestor whose qual-  
14                  ity system is certified under this section that ef-  
15                  fectuates device-related changes with respect to  
16                  in-scope devices, without prior submission of a  
17                  thirty-day notice, shall provide notification to  
18                  the Secretary of such changes in the requestor’s  
19                  next periodic report under section 814.84(b) of  
20                  title 21, Code of Federal Regulations (or any  
21                  successor regulation). Such notification shall—

22                   “(i) describe the changes made; and

23                   “(ii) indicate the effective dates of  
24                  such changes.

1           “(C) PERIODIC NOTIFICATION FOR DE-  
2           VICE-RELATED CHANGES OTHERWISE SUBJECT  
3           TO SPECIAL PMA SUPPLEMENT.—A requestor  
4           whose quality system is certified under this sec-  
5           tion that effectuates device-related changes with  
6           respect to in-scope devices, without prior sub-  
7           mission of a Special PMA Supplement, shall  
8           provide notification to the Secretary of such  
9           changes in the requestor’s next periodic report  
10          under section 814.84(b) of title 21, Code of  
11          Federal Regulations (or any successor regula-  
12          tion). Such notification shall—

13                   “(i) describe the changes made, in-  
14                   cluding a full explanation of the basis for  
15                   the changes; and

16                   “(ii) indicate the effective dates of  
17                   such changes.

18          “(D) USE OF NOTIFICATIONS FOR PRO-  
19          GRAM EVALUATION PURPOSES.—Information  
20          submitted to the Secretary under subpara-  
21          graphs (A) through (C) shall be used by the  
22          Secretary for purposes of the program evalua-  
23          tion under subsection (d).

24          “(e) DURATION AND EFFECT OF CERTIFICATION.—  
25          A certification under this section—



1           “(1) shall remain in effect for a period of 2  
2           years from the date such certification is accepted by  
3           the Secretary, subject to paragraph (6);

4           “(2) may be renewed through the process de-  
5           scribed in subsection (a)(3);

6           “(3) shall continue to apply with respect to de-  
7           vice-related changes made during such 2-year period,  
8           provided the certification remains in effect, irrespec-  
9           tive of whether such certification is renewed after  
10          such 2-year period;

11          “(4) shall have no effect on the need to comply  
12          with applicable submission requirements specified in  
13          subsection (a)(1)(C) with respect to any change per-  
14          taining to in-scope devices which is not a device-re-  
15          lated change under subsection (a)(2);

16          “(5) shall have no effect on the authority of the  
17          Secretary to conduct an inspection or otherwise de-  
18          termine whether the requestor has complied with the  
19          applicable requirements of this Act; and

20          “(6) may be revoked by the Secretary upon a  
21          determination that the requestor’s quality system no  
22          longer meets the certification criteria specified in the  
23          guidance issued under subsection (a)(5) with respect  
24          to the in-scope devices at issue.

1       “(d) NOTICE OF REVOCATION.—The Secretary shall  
2 provide written notification to the requestor of a revoca-  
3 tion pursuant to subsection (c)(6) not later than 10 busi-  
4 ness days after the determination described in such sub-  
5 section. Upon receipt of the written notification, the re-  
6 questor shall satisfy the applicable submission require-  
7 ments specified in subsection (a)(1)(C) for any device-re-  
8 lated changes effectuated after the date of such deter-  
9 mination. After such revocation, such requestor is eligible  
10 to seek re-certification under this section of its quality sys-  
11 tem.

12       “(e) PROGRAM EVALUATION; SUNSET.—

13               “(1) PROGRAM EVALUATION AND REPORT.—

14                       “(A) EVALUATION.—The Secretary shall  
15 complete an evaluation of the third-party qual-  
16 ity system assessment program under this sec-  
17 tion no later than January 31, 2021, based  
18 on—

19                               “(i) analysis of information from a  
20 representative group of device manufactur-  
21 ers obtained from notifications provided by  
22 certified requestors or accredited persons  
23 under subsection (b)(2); and

1                   “(ii) such other available information  
2                   and data as the Secretary determines ap-  
3                   propriate.

4                   “(B) REPORT.—No later than 1 year after  
5                   completing the evaluation under subparagraph  
6                   (A), the Secretary shall issue a report of the  
7                   evaluation’s findings on the website of the Food  
8                   and Drug Administration, which shall include  
9                   the Secretary’s recommendations with respect  
10                  to continuation and as applicable expansion of  
11                  the program under this section to encompass—

12                   “(i) device submissions beyond those  
13                   identified in subsection (a)(1)(C); and

14                   “(ii) device changes beyond those de-  
15                   scribed in subsection (a)(2)(A).

16                  “(2) SUNSET.—This section shall cease to be  
17                  effective October 1, 2022.

18                  “(f) RULE OF CONSTRUCTION.—Nothing in this sec-  
19                  tion shall be construed to limit the authority of the Sec-  
20                  retary to request and review the complete assessment of  
21                  a certified requestor under this section on a for-cause  
22                  basis.”.

23                  (b) CONFORMING AMENDMENTS.—

24                   (1) REQUIREMENTS FOR PREMARKET AP-  
25                   PROVAL SUPPLEMENTS.—Section 515(d)(6)(A)(i) of

1 the Federal Food, Drug, and Cosmetic Act (21  
2 U.S.C. 360e(d)(6)(A)(i)) is amended by inserting “,  
3 subject to section 524B,” after “that affects safety  
4 or effectiveness”.

5 (2) REQUIREMENTS FOR THIRTY-DAY NO-  
6 TICE.—Section 515(d)(6)(A)(ii) of the Federal  
7 Food, Drug, and Cosmetic Act (21 U.S.C.  
8 360e(d)(6)(A)(ii)) is amended by inserting “, subject  
9 to section 524B,” after “the date on which the Sec-  
10 retary receives the notice”.

11 (3) REQUIREMENTS FOR PREMARKET NOTIFI-  
12 CATION; TECHNICAL CORRECTION TO REFERENCE  
13 TO SECTION 510(K).—Section 510(l) of the Federal  
14 Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is  
15 amended by striking “of this subsection under sub-  
16 section (m)” and inserting “of subsection (k) under  
17 subsection (m) or section 524B”.

18 (4) MISBRANDED DEVICES.—Section 502(t) of  
19 the Federal Food, Drug, and Cosmetic Act (21  
20 U.S.C. 352(t)) is amended by inserting “or 524B”  
21 after “section 519”.

22 **SEC. 2222. VALID SCIENTIFIC EVIDENCE.**

23 Section 513(a)(3)(B) of the Federal Food, Drug, and  
24 Cosmetic Act (21 U.S.C. 360c(a)(3)(B)) is amended—

1           (1) by redesignating clauses (i) and (ii) as sub-  
2 clauses (I) and (II), respectively;

3           (2) by striking “(B) If the Secretary” and in-  
4 sserting “(B)(i) If the Secretary”; and

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

6                   “(ii) For purposes of clause (i), valid sci-  
7 entific evidence may include—

8                           “(I) evidence described in well-docu-  
9 mented case histories, including registry  
10 data, that are collected and monitored  
11 under an acceptable protocol;

12                           “(II) studies published in peer-re-  
13 viewed journals; and

14                           “(III) data collected in countries other  
15 than the United States so long as such  
16 data otherwise meet the criteria specified  
17 in this subparagraph.

18                   “(iii) In the case of a study published in  
19 a peer-reviewed journal that is offered as valid  
20 scientific evidence for purposes of clause (i), the  
21 Secretary may request data underlying the  
22 study if—

23                           “(I) the Secretary, in making such re-  
24 quest, complies with the requirement of  
25 subparagraph (D)(ii) to consider the least

1           burdensome appropriate means of evalu-  
2           ating device effectiveness or subsection  
3           (i)(1)(D) to consider the least burdensome  
4           means of determining substantial equiva-  
5           lence, as applicable;

6                   “(II) the Secretary furnishes a written  
7           rationale for so requesting the underlying  
8           data together with such request; and

9                   “(III) if the requested underlying data  
10          for such a study are unavailable, the Sec-  
11          retary shall consider such study to be part  
12          of the totality of the evidence with respect  
13          to the device, as the Secretary determines  
14          appropriate.”.

15 **SEC. 2223. TRAINING AND OVERSIGHT IN LEAST BURDEN-**  
16 **SOME APPROPRIATE MEANS CONCEPT.**

17          (a) IN GENERAL.—Section 513 of the Federal Food,  
18          Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by  
19          adding at the end the following:

20                   “(j) TRAINING AND OVERSIGHT IN LEAST BURDEN-  
21          SOME APPROPRIATE MEANS CONCEPT.—

22                   “(1) TRAINING.—Each employee of the Food  
23          and Drug Administration who is involved in the re-  
24          view of premarket submissions under section 515 or  
25          section 510(k), including supervisors, shall receive

1 training regarding the meaning and implementation  
2 of the least burdensome appropriate means concept  
3 in the context of the use of that term in subsections  
4 (a)(3)(D) and (i)(1)(D) of this section and in section  
5 515(c)(5).

6 “(2) GUIDANCE DOCUMENTS.—

7 “(A) DRAFT UPDATED GUIDANCE.—Not  
8 later than 12 months after the date of enact-  
9 ment of the 21st Century Cures Act, the Sec-  
10 retary shall issue a draft guidance document  
11 updating the October 4, 2002, guidance docu-  
12 ment entitled ‘The Least Burdensome Provision  
13 of the FDA Modernization Act of 1997: Con-  
14 cept and Principles; Final Guidance for FDA  
15 and Industry’.

16 “(B) MEETING OF STAKEHOLDERS.—In  
17 developing such draft guidance document, the  
18 Secretary shall convene a meeting of stake-  
19 holders to ensure a full record to support the  
20 publication of such document.

21 “(3) OMBUDSMAN AUDIT.—Not later than 18  
22 months after the date of issuance of final version of  
23 the draft guidance under paragraph (2), the om-  
24 budsman for the organizational unit of the Food and

1 Drug Administration responsible for the premarket  
2 review of devices shall—

3 “(A) conduct, or have conducted, an audit  
4 of the training described in paragraph (1); and

5 “(B) include in such audit interviews with  
6 a representative sample of persons from indus-  
7 try regarding their experience in the device pre-  
8 market review process.”.

9 (b) ADDITIONAL INFORMATION REGARDING PRE-  
10 MARKET APPLICATIONS.—Subsection (c) of section 515 of  
11 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
12 360e) is amended by adding at the end the following:

13 “(5)(A) Whenever the Secretary requests additional  
14 information from an applicant regarding an application  
15 under paragraph (1), the Secretary shall consider the least  
16 burdensome appropriate means necessary to demonstrate  
17 device safety and effectiveness, and request information  
18 accordingly.

19 “(B) For purposes of subparagraph (A), the term  
20 ‘necessary’ means the minimum required information that  
21 would support a determination by the Secretary that an  
22 application provides a reasonable assurance of the safety  
23 and effectiveness of the device.

24 “(C) Nothing in this paragraph alters the standards  
25 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 clause (i)(I), in ac-  
4           cordance 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—

4 “(i) the experience with, and reliance  
5 on, a standard by other Federal regulatory  
6 authorities and the device industry; and

7 “(ii) whether recognition of a stand-  
8 ard will promote harmonization among reg-  
9 ulatory authorities in the regulation of de-  
10 vices.

11 “(B) TIMING.—The Secretary shall pub-  
12 lish—

13 “(i) draft guidance under subpara-  
14 graph (A) not later than 12 months after  
15 the date of the enactment of the 21st Cen-  
16 tury Cures Act; and

17 “(ii) final guidance not later than 12  
18 months after the close of the public com-  
19 ment period for the draft guidance under  
20 clause (i).”

21 **SEC. 2225. EASING REGULATORY BURDEN WITH RESPECT**  
22 **TO CERTAIN CLASS I AND CLASS II DEVICES.**

23 (a) CLASS I DEVICES.—Section 510(l) of the Federal  
24 Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is  
25 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 included 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 with respect to the membership of the classi-  
10 fication panel reviewing a premarket submis-  
11 sion, that such membership includes—

12 “(i) two or more voting members, with  
13 a specialty or other expertise clinically rel-  
14 evant to the device under review; and

15 “(ii) at least one voting member who  
16 is knowledgeable about the technology of  
17 the device.”.

18 (b) PANEL REVIEW PROCESS.—Section 513(b)(6) of  
19 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
20 360c(b)(6)) is amended—

21 (1) in subparagraph (A)(iii), by inserting before  
22 the period at the end “, including by designating a  
23 representative who will be provided a time during  
24 the panel meeting to address the panel individually  
25 (or accompanied by experts selected by such rep-



1       representative) for the purpose of correcting  
2       misstatements of fact or providing clarifying infor-  
3       mation, subject to the discretion of the panel chair-  
4       person”); and

5               (2) by striking subparagraph (B) and inserting  
6       the following new subparagraph:

7               “(B)(i) Any meeting of a classification  
8       panel for a device that is specifically the subject  
9       of review shall—

10              “(I) provide adequate time for initial  
11       presentations by the person whose device is  
12       specifically the subject of a classification  
13       panel review and by the Secretary; and

14              “(II) encourage free and open partici-  
15       pation by all interested persons.

16              “(ii) Following the initial presentations de-  
17       scribed in clause (i), the panel may—

18              “(I) pose questions to a designated  
19       representative described in subparagraph  
20       (A)(iii); and

21              “(II) consider the responses to such  
22       questions in the panel’s review of the de-  
23       vice that is specifically the subject of re-  
24       view by the 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 the protection of human subjects in research, the Sec-  
8 retary of Health and Human Services shall, to the extent  
9 possible and consistent with other statutory provisions,  
10 harmonize differences between the HHS Human Subject  
11 Regulations and the FDA Human Subject Regulations in  
12 accordance 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 the FDA Human Subject Regulations, and the  
19 vulnerable-populations rules as may be nec-  
20 essary—

21                                 (i) to reduce regulatory duplication  
22 and unnecessary delays;

23                                 (ii) to modernize such provisions in  
24 the context of multisite and cooperative re-  
25 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 36 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 to facilitate the broader use of sin-  
2 gle, central, or lead institutional review boards. Such  
3 regulations and guidance shall clarify the require-  
4 ments and policies relating to the following:

5 (A) Arrangements to avoid duplication de-  
6 scribed in paragraph (1)(A)(i), including—

7 (i) delineating the roles of institu-  
8 tional review boards in multisite or cooper-  
9 ative, multisite studies where one or more  
10 local institutional review boards are relied  
11 upon, or similar arrangements are used;

12 (ii) the risks and benefits to human  
13 subjects;

14 (iii) standardizing the informed con-  
15 sent and other processes and legal docu-  
16 ments; and

17 (iv) incorporating community values  
18 through the use of local institutional re-  
19 view boards while continuing to use central  
20 or lead institutional review boards.

21 (B) Concerns about regulatory and legal li-  
22 ability contributing to decisions by the sponsors  
23 of research to rely on local institutional review  
24 boards for multisite research.

1           (3) CONSULTATION.—In issuing regulations or  
2           guidance under paragraph (2), the Secretary shall  
3           consult with stakeholders (including researchers,  
4           academic organizations, hospitals, institutional re-  
5           search 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 toward  
14          completing such harmonization.

15          (e) DRAFT NIH POLICY.—Not later than 12 months  
16          after the date of enactment of this Act, the Secretary, act-  
17          ing through the Director of the National Institutes of  
18          Health, shall finalize the draft policy entitled “Draft NIH  
19          Policy on Use of a Single Institutional Review Board for  
20          Multi-Site Research”.

21          (f) DEFINITIONS.—

22                  (1) HUMAN SUBJECT REGULATIONS.—In this  
23          section:

24                          (A) FDA HUMAN SUBJECT REGULA-  
25                  TIONS.—The term “FDA Human Subject Reg-

1           ulations” means the provisions of parts 50, 56,  
2           312, and 812 of title 21, Code of Federal Regu-  
3           lations (or any successor regulations).

4           (B) HHS HUMAN SUBJECT REGULA-  
5           TIONS.—The term “HHS Human Subject Reg-  
6           ulations” means the provisions of subpart A of  
7           part 46 of title 45, Code of Federal Regulations  
8           (or any successor regulations).

9           (C) VULNERABLE-POPULATIONS RULES.—  
10          The term “vulnerable-populations rules”—

11           (i) subject to clause (ii), means the  
12           provisions of subparts B through D of  
13           such part 46 (or any successor regula-  
14           tions); or

15           (ii) as applicable to research that is  
16           subject to the FDA Human Subject Regu-  
17           lations, means the provisions applicable to  
18           vulnerable populations under part 56 of  
19           such title 21 (or any successor regulations)  
20           and subpart D of part 50 of such title 21  
21           (or any successor regulations).

22          (2) OTHER DEFINITIONS.—In this section:

23           (A) INSTITUTIONAL REVIEW BOARD.—The  
24           term “institutional review board” has the mean-  
25           ing that applies to the term “institutional re-

1 view board” under the HHS Human Subject  
2 Regulations.

3 (B) LEAD INSTITUTIONAL REVIEW  
4 BOARD.—The term “lead institutional review  
5 board” means an institutional review board that  
6 otherwise meets the requirements of the HHS  
7 Human Subject Regulations and enters into a  
8 written agreement with an institution, another  
9 institutional review board, a sponsor, or a prin-  
10 cipal investigator to approve and oversee human  
11 subject research that is conducted at multiple  
12 locations. References to an institutional review  
13 board include an institutional review board that  
14 serves a single institution as well as a lead in-  
15 stitutional review board.

16 **SEC. 2262. USE OF NON-LOCAL INSTITUTIONAL REVIEW**  
17 **BOARDS FOR REVIEW OF INVESTIGATIONAL**  
18 **DEVICE EXEMPTIONS AND HUMAN DEVICE**  
19 **EXEMPTIONS.**

20 (a) IN GENERAL.—Section 520 of the Federal Food,  
21 Drug, and Cosmetic Act (21 U.S.C. 360(j)) is amended—

22 (1) in subsection (g)(3)—

23 (A) by striking “local” each place it ap-  
24 pears; and

1 (B) in subparagraph (A)(i), by striking  
2 “which has been”; and

3 (2) in subsection (m)(4)—

4 (A) by striking “local” each place it ap-  
5 pears; and

6 (B) by striking subparagraph (A) and in-  
7 serting the following new subparagraph:

8 “(A) in facilities in which clinical testing of de-  
9 vices is supervised by an institutional review com-  
10 mittee established in accordance with the regulations  
11 of the Secretary, and”.

12 (b) REGULATIONS.—Not later than 12 months after  
13 the date of the enactment of this Act, the Secretary of  
14 Health and Human Services shall revise or issue such reg-  
15 ulations or guidance as may be necessary to carry out the  
16 amendments made by subsection (a).

17 **SEC. 2263. ALTERATION OR WAIVER OF INFORMED CON-**  
18 **SENT FOR CLINICAL INVESTIGATIONS.**

19 (a) DEVICES.—Section 520(g)(3) of the Federal  
20 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(3)) is  
21 amended—

22 (1) in subparagraph (D), by striking “except  
23 where subject to such conditions as the Secretary  
24 may prescribe, the investigator” and inserting the



1 following: “except where, subject to such conditions  
2 as the Secretary may prescribe—

3 “(i) the proposed clinical testing poses  
4 no more than minimal risk to the human  
5 subject and includes appropriate safe-  
6 guards to protect the rights, safety, and  
7 welfare of the human subject; or

8 “(ii) the investigator”; and

9 (2) in the matter following subparagraph (D),  
10 by striking “subparagraph (D)” and inserting “sub-  
11 paragraph (D)(ii)”.

12 (b) DRUGS.—Section 505(i)(4) of the Federal Food,  
13 Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) is amended  
14 by striking “except where it is not feasible or it is contrary  
15 to the best interests of such human beings” and inserting  
16 “except where it is not feasible, it is contrary to the best  
17 interests of such human beings, or the proposed clinical  
18 testing poses no more than minimal risk to such human  
19 beings and includes appropriate safeguards as prescribed  
20 to protect the rights, safety, and welfare of such human  
21 beings”.

1     **Subtitle P—Improving Scientific**  
2     **Expertise and Outreach at FDA**

3     **SEC. 2281. SILVIO O. CONTE SENIOR BIOMEDICAL RE-**  
4             **SEARCH SERVICE.**

5             (a) HIRING AND RETENTION AUTHORITY.—Section  
6     228 of the Public Health Service Act (42 U.S.C. 237) is  
7     amended—

8             (1) in the section heading, by inserting “AND  
9     BIOMEDICAL PRODUCT ASSESSMENT” after “RE-  
10    SEARCH”;

11            (2) in subsection (a)(1), by striking “Silvio O.  
12    Conte Senior Biomedical Research Service, not to  
13    exceed 500 members” and inserting “Silvio O. Conte  
14    Senior Biomedical Research and Biomedical Product  
15    Assessment Service (in this section referred to as the  
16    ‘Service’), the purpose of which is to recruit and re-  
17    tain competitive and qualified scientific and tech-  
18    nical experts outstanding in the field of biomedical  
19    research, clinical research evaluation, and biomedical  
20    product assessment”;

21            (3) by amending subsection (a)(2) to read as  
22    follows:

23            “(2) The authority established in paragraph (1) may  
24    not be construed to require the Secretary to reduce the  
25    number of employees serving under any other employment

1 system in order to offset the number of members serving  
2 in the Service.”;

3 (4) in subsection (b)—

4 (A) in the matter preceding paragraph (1),  
5 by striking “or clinical research evaluation” and  
6 inserting “, clinical research evaluation or bio-  
7 medical product assessment”; and

8 (B) in paragraph (1), by inserting “or a  
9 master’s level degree in engineering,  
10 bioinformatics, or a related or emerging field,”  
11 after the comma;

12 (5) in subsection (d)(2), by striking “and shall  
13 not exceed the rate payable for level I of the Execu-  
14 tive Schedule unless approved by the President  
15 under section 5377(d)(2) of title 5, United States  
16 Code” and inserting “and shall not exceed the rate  
17 payable for the President”;

18 (6) by striking subsection (e); and

19 (7) by redesignating subsections (f) and (g) as  
20 subsections (e) and (f), respectively.

21 (b) REPORT.—Not later than 3 years after the date  
22 of the enactment of this Act, the Secretary of Health and  
23 Human Services shall submit, and publish on the website  
24 of the Department of Health and Human Services a report  
25 on the implementation of the amendments made by sub-

1 section (a), including whether the amendments have im-  
2 proved the ability of the Food and Drug Administration  
3 to hire and retain qualified experts to fulfill obligations  
4 specified under user fee agreements.

5 **SEC. 2282. ENABLING FDA SCIENTIFIC ENGAGEMENT.**

6 It is the sense of Congress that the participation in,  
7 or sponsorship of, scientific conferences and meetings is  
8 essential to the mission of the Food and Drug Administra-  
9 tion.

10 **SEC. 2283. REAGAN-UDALL FOUNDATION FOR THE FOOD**  
11 **AND DRUG ADMINISTRATION.**

12 (a) BOARD OF DIRECTORS.—

13 (1) COMPOSITION AND SIZE.—Section  
14 770(d)(1)(C) of the Federal Food, Drug, and Cos-  
15 metic Act (21 U.S.C. 379dd(d)(1)(C)) is amended—

16 (A) by redesignating clause (ii) as clause  
17 (iii);

18 (B) by inserting after clause (i) the fol-  
19 lowing:

20 “(ii) ADDITIONAL MEMBERS.—The  
21 Board, through amendments to the bylaws  
22 of the Foundation, may provide that the  
23 number of voting members of the Board  
24 shall be a number (to be specified in such  
25 amendment) greater than 14. Any Board

1 positions that are established by any such  
2 amendment shall be appointed (by majority  
3 vote) by the individuals who, as of the date  
4 of such amendment, are voting members of  
5 the Board and persons so appointed may  
6 represent any of the categories specified in  
7 subclauses (I) through (V) of clause (i), so  
8 long as no more than 30 percent of the  
9 total voting members of the Board (includ-  
10 ing members whose positions are estab-  
11 lished by such amendment) are representa-  
12 tives of the general pharmaceutical, device,  
13 food, cosmetic, and biotechnology indus-  
14 tries.”; and

15 (C) in clause (iii)(I), as redesignated by  
16 subparagraph (A), by striking “The ex officio  
17 members shall ensure” and inserting “The ex  
18 officio members, acting pursuant to clause (i),  
19 and the Board, acting pursuant to clause (ii),  
20 shall ensure”.

21 (2) FEDERAL EMPLOYEES ALLOWED TO SERVE  
22 ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C)  
23 of the Federal Food, Drug, and Cosmetic Act (21  
24 U.S.C. 379dd(d)(1)(C)), as redesignated by para-  
25 graph (1)(A), is amended by adding at the end the

1 following: “For purposes of this section, the term  
2 ‘employee of the Federal Government’ does not in-  
3 clude a ‘special Government employee’, as that term  
4 is defined in section 202(a) of title 18, United  
5 States Code.”.

6 (3) STAGGERED TERMS.—Subparagraph (A) of  
7 section 770(d)(3) of the Federal Food, Drug, and  
8 Cosmetic Act (21 U.S.C. 379dd(d)(3)) is amended  
9 to read as follows:

10 “(A) TERM.—The term of office of each  
11 member of the Board appointed under para-  
12 graph (1)(C)(i), and the term of office of any  
13 member of the Board whose position is estab-  
14 lished pursuant to paragraph (1)(C)(ii), shall be  
15 4 years, except that—

16 “(i) the terms of offices for the mem-  
17 bers of the Board initially appointed under  
18 paragraph (1)(C)(i) shall expire on a stag-  
19 gered basis as determined by the ex officio  
20 members; and

21 “(ii) the terms of office for the per-  
22 sons initially appointed to positions estab-  
23 lished pursuant to paragraph (1)(C)(ii)  
24 may be made to expire on a staggered  
25 basis, as determined by the individuals

1                   who, as of the date of the amendment es-  
2                   tablishing such positions, are members of  
3                   the Board.”.

4           (b) EXECUTIVE DIRECTOR COMPENSATION.—Section  
5 770(g)(2) of the Federal Food, Drug, and Cosmetic Act  
6 (21 U.S.C. 379dd(g)(2)) is amended by striking “but shall  
7 not be greater than the compensation of the Commis-  
8 sioner”.

9           (c) SEPARATION OF FUNDS.—Section 770(m) of the  
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
11 379dd(m)) is amended by striking “are held in separate  
12 accounts from funds received from entities under sub-  
13 section (i)” and inserting “are managed as individual pro-  
14 grammatic funds under subsection (i), according to best  
15 accounting practices”.

16 **SEC. 2284. COLLECTION OF CERTAIN VOLUNTARY INFOR-**  
17 **MATION EXEMPTED FROM PAPERWORK RE-**  
18 **DUCTION ACT.**

19           Chapter VII of the Federal Food, Drug, and Cos-  
20 metic Act is amended by inserting after section 708 of  
21 such Act (21 U.S.C. 379) the following:

1 **“SEC. 708A. COLLECTION OF CERTAIN VOLUNTARY INFOR-**  
2 **MATION EXEMPTED FROM PAPERWORK RE-**  
3 **DUCTION ACT.**

4 “Chapter 35 of title 44, United States Code, shall  
5 not apply to the collection from patients, industry, aca-  
6 demia, and other stakeholders, of voluntary information  
7 such as through voluntary surveys or questionnaires, initi-  
8 ated by the Secretary.”.

9 **SEC. 2285. HIRING AUTHORITY FOR SCIENTIFIC, TECH-**  
10 **NICAL, AND PROFESSIONAL PERSONNEL.**

11 (a) IN GENERAL.—The Federal Food, Drug, and  
12 Cosmetic Act is amended by inserting after section 714  
13 (21 U.S.C. 379d–3) the following:

14 **“SEC. 714A. ADDITIONAL HIRING AUTHORITY.**

15 “(a) IN GENERAL.—The Secretary may, without re-  
16 gard to the provisions of title 5, United States Code, gov-  
17 erning appointments in the competitive service, appoint  
18 qualified candidates to scientific, technical, or professional  
19 positions within the following centers of the Food and  
20 Drug Administration:

21 “(1) The Center for Drug Evaluation and Re-  
22 search.

23 “(2) The Center for Biologics Evaluation and  
24 Research.

25 “(3) The Center for Devices and Radiological  
26 Health.



1 Such positions shall be within the competitive service.

2 “(b) COMPENSATION.—

3 “(1) IN GENERAL.—Notwithstanding any other  
4 provision of law, including any requirement with re-  
5 spect to General Schedule pay rates under sub-  
6 chapter III of chapter 53 of title 5, United States  
7 Code, and consistent with the requirements of para-  
8 graph (2), the Secretary may determine and fix—

9 “(A) the annual rate of pay of any indi-  
10 vidual appointed under subsection (a); and

11 “(B) for purposes of retaining qualified  
12 employees, the annual rate of pay for any high-  
13 ly qualified scientific, technical, or professional  
14 personnel appointed to a position at any of the  
15 centers listed under subsection (a) before the  
16 date of enactment of this section.

17 “(2) LIMITATION.—The annual rate of pay es-  
18 tablished pursuant to paragraph (1) may not exceed  
19 the annual rate of pay of the President.

20 “(c) SUNSET.—The authority to appoint employees  
21 under this section shall terminate on September 30, 2022.

22 “(d) REPORT.—

23 “(1) IN GENERAL.—Not later than September  
24 30, 2021, the Secretary shall submit a report to  
25 Congress that examines the extent to which the au-

1       thority to appoint and retain personnel under this  
2       section enhanced the Food and Drug Administra-  
3       tion’s ability to meet the agency’s critical need for  
4       highly qualified individuals for scientific, technical,  
5       or professional positions.

6               “(2) RECOMMENDATIONS.—The report under  
7       paragraph (1) shall include the recommendations of  
8       the Secretary on—

9               “(A) whether the authority to appoint per-  
10       sonnel under this section should be reauthor-  
11       ized; and

12               “(B) other personnel authorities that  
13       would help the Food and Drug Administration  
14       to better recruit and retain highly qualified in-  
15       dividuals for scientific, technical, or professional  
16       positions in the agency’s medical product cen-  
17       ters.”.

18       (b) RULE OF CONSTRUCTION.—The authority pro-  
19       vided by section 714A of the Federal Food, Drug, and  
20       Cosmetic Act (as added by subsection (a)) shall not be  
21       construed to affect the authority provided under section  
22       714 of such Act.

1           **Subtitle Q—Exempting From**  
2           **Sequestration Certain User Fees**

3           **SEC. 2301. EXEMPTING FROM SEQUESTRATION CERTAIN**  
4                           **USER FEES OF FOOD AND DRUG ADMINIS-**  
5                           **TRATION.**

6           The Balanced Budget and Emergency Deficit Control  
7 Act of 1985 is amended—

8                   (1) in section 255(g)(1)(A) (2 U.S.C.  
9                   905(g)(1)(A)), by inserting after “Financial Agent  
10                   Services” the following new item:

11                           “Food and Drug Administration, Salaries  
12                           and Expenses, but only the portion of appro-  
13                           priations under such account corresponding to  
14                           fees collected under sections 736, 738, 740,  
15                           741, 744B, and 744H of the Federal Food,  
16                           Drug, and Cosmetic Act (75–9911–0–1–554)”;  
17                           and

18                   (2) in section 256(h) (2 U.S.C. 906(h)), by  
19                   adding at the end the following new paragraph:

20                           “(5) Notwithstanding any other provision of the  
21                           law, this subsection shall not apply with respect to  
22                           the portion of administrative expenses incurred by  
23                           the Food and Drug Administration that are funded  
24                           through fees collected under sections 736, 738, 740,

1 741, 744B, and 744H of the Federal Food, Drug,  
2 and Cosmetic Act.”.

### 3 **TITLE III—DELIVERY**

#### 4 **Subtitle A—Interoperability**

5 **SEC. 3001. ENSURING INTEROPERABILITY OF HEALTH IN-**  
6 **FORMATION TECHNOLOGY.**

7 (a) INTEROPERABILITY STANDARDS.—

8 (1) IN GENERAL.—Subtitle A of title XXX of  
9 the Public Health Service Act (42 U.S.C. 300jj–11  
10 et seq.) is amended by adding at the end the fol-  
11 lowing new section:

12 **“SEC. 3010. ENSURING INTEROPERABILITY OF HEALTH IN-**  
13 **FORMATION TECHNOLOGY.**

14 “(a) INTEROPERABILITY.—In order for health infor-  
15 mation technology to be considered interoperable, such  
16 technology must satisfy the following criteria:

17 “(1) SECURE TRANSFER.—The technology al-  
18 lows the secure transfer of the entirety of a patient’s  
19 data from any and all health information technology  
20 for authorized use under applicable law.

21 “(2) COMPLETE ACCESS TO HEALTH DATA.—  
22 The technology allows access to the entirety of a pa-  
23 tient’s available data for authorized use under appli-  
24 cable law without special effort, as defined by rec-  
25 ommendations for interoperability standards adopted

1 under section 3004, by the requestor of such data  
2 unless such data is not disclosable under applicable  
3 law.

4 “(3) NO INFORMATION BLOCKING.—The tech-  
5 nology is not configured, set up, or implemented to  
6 engage in information blocking, as defined in section  
7 3010A(f).

8 “(b) CATEGORIES FOR INTEROPERABILITY STAND-  
9 ARDS.—The categories described in this subsection, with  
10 respect to standards for determining if health information  
11 technology is interoperable, consistent with the criteria de-  
12 scribed in subsection (a), include the following categories  
13 of standards:

14 “(1) Standards with respect to vocabulary and  
15 terminology.

16 “(2) Standards with respect to content and  
17 structure.

18 “(3) Standards with respect to transport of in-  
19 formation.

20 “(4) Security standards.

21 “(5) Service standards.”.

22 (2) GUIDANCE.—Not later than January 1,  
23 2017, the Secretary of Health and Human Services,  
24 through the National Coordinator of the Office of  
25 the National Coordinator for Health Information

1 Technology, shall issue guidance with respect to the  
2 implementation of section 3010 of the Public Health  
3 Service Act, as added by paragraph (1), including  
4 with respect to defining and providing examples of  
5 authorized use of health information technology, as  
6 described in such section.

7 (b) IMPROVEMENTS TO RECOMMENDATION PROC-  
8 ESS.—

9 (1) HIT POLICY COMMITTEE TO INCORPORATE  
10 POLICIES FOR UPDATES TO INTEROPERABILITY  
11 STANDARDS.—Section 3002 of the Public Health  
12 Service Act (42 U.S.C. 300jj–12) is amended—

13 (A) in subsection (a)—

14 (i) by striking “National Coordinator”  
15 and inserting “Secretary, in consultation  
16 with the National Coordinator,”; and

17 (ii) by adding at the end the following  
18 new sentence: “The HIT Policy Committee  
19 is authorized only to provide policy and  
20 priority recommendations to the Secretary  
21 and not authorized to otherwise affect the  
22 development or modification of any stand-  
23 ard, implementation specification, or cer-  
24 tification criterion under this title.”; and

25 (B) in subsection (b)(2)—

1 (i) in subparagraph (A), in the first  
2 sentence—

3 (I) by striking “The HIT Policy  
4 Committee” and inserting “Subject to  
5 subparagraph (D), the HIT Policy  
6 Committee”; and

7 (II) by inserting “(including the  
8 areas in which modifications and addi-  
9 tions to interoperability standards  
10 under section 3010 are needed for the  
11 electronic exchange and use of health  
12 information for purposes of adoption  
13 of such modifications and additions  
14 under section 3004)” after “section  
15 3004”.

16 (ii) by adding at the end the following  
17 new subparagraph:

18 “(D) SPECIAL RULE RELATED TO INTER-  
19 OPERABILITY.—Any recommendation made by  
20 the HIT Policy Committee on or after the date  
21 of the enactment of this subparagraph with re-  
22 spect to interoperability of health information  
23 technology shall be consistent with the criteria  
24 described in subsection (a) of section 3010.”.

1           (2) SUNSET OF HIT STANDARDS COMMITTEE.—  
2           Section 3003 of the Public Health Service Act (42  
3           U.S.C. 300jj–13) is amended by adding at the end  
4           the following new subsection:

5           “(f) TERMINATION.—The HIT Standards Committee  
6           shall terminate on the date that is 90 days after the date  
7           of the enactment of this subsection.”.

8           (3) STANDARDS DEVELOPMENT ORGANIZA-  
9           TIONS.—Title XXX of the Public Health Service Act  
10          is amended by inserting after section 3003 the fol-  
11          lowing new section:

12       **“SEC. 3003A. RECOMMENDATIONS FOR STANDARDS**  
13                       **THROUGH CONTRACTS WITH STANDARDS DE-**  
14                       **VELOPMENT ORGANIZATIONS.**

15       “(a) CONTRACTS.—

16           “(1) IN GENERAL.—For purposes of activities  
17           conducted under this title, the Secretary shall enter  
18           into contracts with health care standards develop-  
19           ment organizations accredited by the American Na-  
20           tional Standards Institute to carry out the duties de-  
21           scribed in subsection (b), as applicable.

22           “(2) TIMING FOR FIRST CONTRACT.—As soon  
23           as practicable after the date of the enactment of this  
24           section, the Secretary shall enter into the first con-  
25           tract under paragraph (1).



1           “(3) PERIOD OF CONTRACT.—Each contract  
2 under paragraph (1) shall be for a period deter-  
3 mined necessary by the Secretary, in consultation  
4 with the National Coordinator, to carry out the ap-  
5 plicable duties described in subsection (b).

6           “(4) APPROPRIATE ORGANIZATIONS.—The Sec-  
7 retary shall ensure the most appropriate organiza-  
8 tions described in paragraph (1) are selected for  
9 each contract under such paragraph.

10           “(5) ALLOWANCE FOR VARIATIONS.—Standards  
11 developed pursuant to a contract under this sub-  
12 section, and the methods to test such standards,  
13 shall allow for variations on such standards as long  
14 as such variations are consistent with the standards  
15 so developed under this section.

16           “(b) DUTIES.—

17           “(1) INITIAL CONTRACT.—Under the initial  
18 contract under subsection (a)(1), the standards de-  
19 velopment organizations—

20           “(A) shall provide to the Secretary, in con-  
21 sultation with the National Coordinator, for  
22 adoption under section 3004, recommendations,  
23 in accordance with section 3010, for interoper-  
24 ability standards, and methods to test such  
25 standards, consistent with the criteria described

1 in subsection (a) of such section and with re-  
2 spect to the categories described in subsection  
3 (b)(1) of such section; and

4 “(B) may provide to the Secretary rec-  
5 ommendations described in paragraph (2).

6 “(2) SUBSEQUENT CONTRACTS.—Under each  
7 subsequent contract, the organizations shall provide  
8 to the Secretary, in consultation with the National  
9 Coordinator, for adoption under section 3004 rec-  
10 ommendations for any standards (including inter-  
11 operability standards and methods to test such  
12 standards), implementation specifications, and cer-  
13 tification criteria (and modifications, including addi-  
14 tions, to such standards, specifications, and criteria),  
15 which are in accordance with the policies and prior-  
16 ities developed by the Secretary, in consultation with  
17 the National Coordinator.

18 “(3) MULTIPLE METHODS TO TEST INTEROPER-  
19 ABILITY STANDARDS.—For the purposes of devel-  
20 oping methods to test interoperability standards for  
21 adoption under section 3004, the Secretary shall en-  
22 sure that contracts under this section allow for mul-  
23 tiple methods to test such standards to account for  
24 variations in the adoption of such standards that do  
25 not conflict with section 3010(a).

1       “(c) MODIFICATIONS AND SUBSEQUENT CON-  
2 TRACTS.—

3               “(1) IN GENERAL.—The Secretary, in consulta-  
4 tion with the National Coordinator, shall periodically  
5 conduct hearings to evaluate and review the stand-  
6 ards, implementation specifications, and certification  
7 criteria adopted under section 3004 for purposes of  
8 determining if modifications, including any addi-  
9 tions, are needed with respect to such standards,  
10 specifications, and criteria.

11              “(2) CONTRACT TRIGGER.—Based on the needs  
12 for standards, implementation specifications, and  
13 certification criteria (and modifications, including  
14 additions, to such standards, specifications, and cri-  
15 teria) under this title, as determined by the Sec-  
16 retary, 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 subsections (c) and (d).

25       In the case of a standard, specification, or criterion

1 that has been adopted under this section and is in-  
2 consistent or duplicative of such an interoperability  
3 standard that is subsequently adopted under this  
4 section, such interoperability standard shall  
5 supercede such other standard, specification, or cri-  
6 terion and such other standard, specification, or cri-  
7 terion shall no longer be considered adopted under  
8 this section beginning on the date that such inter-  
9 operability standard becomes 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 appli-  
10                  cable standards development organizations with  
11                  a contract under section 3003A in writing of  
12                  such determination and the reasons for not pro-  
13                  posing the adoption of the recommendation for  
14                  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               “(d) 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 criterion 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 criterion.

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) FOLLOWUP 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 are 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 records.

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 Federal Trade Commis-  
22 sion for purposes of such investigations.

23 “(2) PROTECTION FROM DISCLOSURE OF IN-  
24 FORMATION.—Any information shared by the Na-  
25 tional Coordinator under paragraph (1) shall not be

1 subject to the provisions of section 552 of title 5,  
2 United States Code (commonly referred to as the  
3 Freedom of Information Act). Any information ac-  
4 quired pursuant to paragraph (1) shall be held in  
5 confidence and shall not be disclosed to any person  
6 except as may be necessary to carry out the pur-  
7 poses of subsection (a).

8 “(3) NON-APPLICATION OF PAPERWORK REDUC-  
9 TION ACT.—Chapter 35 of title 44, United States  
10 Code (commonly referred to as the Paperwork Re-  
11 duction Act of 1995) shall not apply to the National  
12 Coordinator or to the Office of the National Coordi-  
13 nator for Health Information Technology with re-  
14 spect to the collection of complaints relating to  
15 claims described in subsection (a).

16 “(d) PENALTY.—Any person or entity determined to  
17 have committed an act described in paragraph (1), (2),  
18 or (3) of subsection (a), in connection with a specified  
19 meaningful use incentive program, shall be subject to a  
20 civil monetary penalty of not more than \$10,000 for each  
21 such act. The provisions of section 1128A (other than sub-  
22 sections (a) and (b)) shall apply to a civil money penalty  
23 applied under this subsection in the same manner as they  
24 apply to a civil money penalty or proceeding under section  
25 1128A(a).

1           “(e) SPECIFIED MEANINGFUL USE INCENTIVE PRO-  
2 GRAM.—For purposes of this section, the term ‘specified  
3 meaningful use incentive program’ includes the following:

4           “(1) The incentive payments under subsection  
5 (o) of section 1848 of the Social Security Act (42  
6 U.S.C. 1395w–4) and adjustments under subsection  
7 (a)(7) of such section.

8           “(2) The incentive payments under subsection  
9 (n) of section 1848 of such Act (42 U.S.C. 1395ww)  
10 and adjustments under subsection (b)(3)(B) of such  
11 section.

12           “(3) The incentive payments and adjustments  
13 made under subsections (l) and (m) of section 1853  
14 of such Act (42 U.S.C. 1395w–23).

15           “(4) The incentive payment under paragraph  
16 (3) of section 1814(l) of such Act (42 U.S.C.  
17 1395f(1)) and adjustment under paragraph (4) of  
18 such section.

19           “(5) The shared savings program under section  
20 1899 of such Act (42 U.S.C. 1395jjj).

21           “(6) The payments to Medicaid providers de-  
22 scribed in section 1903(t) of such Act (42 U.S.C.  
23 1396b(t)).

24           “(f) INFORMATION BLOCKING.—



1           “(1) IN GENERAL.—For purposes of this sec-  
2           tion and section 3010, the term ‘information block-  
3           ing’ means, with respect to the use of qualified elec-  
4           tronic health records or other health information  
5           technology under a specified meaningful use incen-  
6           tive program, business, technical, and organizational  
7           practices, including practices described in paragraph  
8           (2), that—

9                   “(A) prevent or materially discourage the  
10                  exchange of electronic health information;

11                   “(B) the actor knows or should know (as  
12                  defined in section 1128A(i)(7) of the Social Se-  
13                  curity Act) are likely to interfere with the ex-  
14                  change or use of electronic health information;  
15                  and

16                   “(C) do not serve to protect patient safety,  
17                  maintain the privacy and security of individ-  
18                  uals’ health information or promote competition  
19                  and consumer welfare.

20           “(2) PRACTICES DESCRIBED.—For purposes of  
21           paragraph (1), the practices described in this para-  
22           graph are the following:

23                   “(A) Contract terms, policies, or other  
24                  business or organizational practices that restrict  
25                  individuals’ access to their electronic health in-

1           formation or restrict the exchange or use of  
2           that information for treatment and other per-  
3           mitted purposes.

4           “(B) Charging prices or fees (such as for  
5           data exchange, portability, and interfaces) that  
6           make exchanging and using electronic health in-  
7           formation cost prohibitive.

8           “(C) Developing or implementing health  
9           information technology in nonstandard ways  
10          that are likely to substantially increase the  
11          costs, complexity, or burden of sharing elec-  
12          tronic health information, especially in cases in  
13          which relevant interoperability standards or  
14          methods to measure interoperability have been  
15          adopted by the Secretary.

16          “(D) Developing or implementing health  
17          information technology in ways that are likely  
18          to lock in users or electronic health information,  
19          such as not allowing for the full export of data;  
20          lead to fraud, waste, or abuse; or impede inno-  
21          vations and advancements in health information  
22          exchange and health information technology-en-  
23          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 of the Of-  
10 fice of the National Coordinator of Health In-  
11 formation Technology shall, through rule-  
12 making, implement the provisions of this sec-  
13 tion, and amendments made by this section, re-  
14 lating to information blocking.

15 (C) HIPAA.—Not later than January 1,  
16 2017, the National Coordinator shall publish  
17 guidance to clarify the relationship of the  
18 HIPAA privacy and security law, as defined in  
19 section 3009(a)(2) of the Public Health Service  
20 Act (42 U.S.C. 300jj–19(a)(2)) as such provi-  
21 sions relate to information blocking (as defined  
22 in section 3010A(f) of such Act, as added by  
23 paragraph (2)), including examples of how such  
24 provisions may result in information blocking.

1           (4) DEMONSTRATION REQUIRED FOR MEANING-  
2           FUL EHR USE INCENTIVES UNDER MEDICARE.—

3           (A) INCENTIVES FOR PROFESSIONALS.—

4                   (i)           IN           GENERAL.—Section  
5           1848(o)(2)(C) of the Social Security Act  
6           (42 U.S.C. 1395w-4(o)(2)(C)) is amended  
7           by adding at the end the following new  
8           clause:

9                   “(iii) INTEROPERABILITY.—With re-  
10           spect to EHR reporting periods for pay-  
11           ment years beginning with 2018, the  
12           means described in clause (i) specified by  
13           the Secretary shall include a demonstra-  
14           tion, through means such as an attesta-  
15           tion, that the professional has not taken  
16           any action described in subsection (a)(2) of  
17           section 3010A of the Public Health Service  
18           Act, with respect to the use of any certified  
19           EHR technology.”.

20                   (ii)          HARDSHIP EXEMPTION IN CASE  
21           OF DECERTIFIED EHR.—Subparagraph (B)  
22           of section 1848(a)(7) of the Social Security  
23           Act (42 U.S.C. 1395w-4(a)(7)) is amend-  
24           ed to read as follows:

1                   “(B) SIGNIFICANT HARDSHIP EXCEP-  
2                   TION.—

3                   “(i) IN GENERAL.—The Secretary  
4                   may, on a case-by-case basis, exempt an el-  
5                   igible professional from the application of  
6                   the payment adjustment under subpara-  
7                   graph (A) if the Secretary determines, sub-  
8                   ject to annual renewal, that compliance  
9                   with the requirement for being a meaning-  
10                  ful EHR user would result in a significant  
11                  hardship, such as in the case of an eligible  
12                  professional who practices in a rural area  
13                  without sufficient Internet access.

14                  “(ii) DECERTIFICATION.—

15                  “(I) IN GENERAL.—The Sec-  
16                  retary may, on a case-by-case basis,  
17                  exempt an eligible professional from  
18                  the application of the payment adjust-  
19                  ment under subparagraph (A) if the  
20                  Secretary determines that such pro-  
21                  fessional was determined to not be a  
22                  meaningful EHR user because the  
23                  qualified electronic health record used  
24                  by such professional was decertified  
25                  under section 3001(c)(5)(C) of the

1 Public Health Service Act. An exemp-  
2 tion under the previous sentence may  
3 be applied to an eligible professional  
4 only, subject to subclause (II), during  
5 the first payment year with respect to  
6 the first EHR reporting period to  
7 which such decertification applies.

8 “(II) DURATION.—

9 “(aa) IN GENERAL.—In no  
10 case shall an exemption by rea-  
11 son of this clause be for a period  
12 of less than 12 months.

13 “(bb) EXTENSION.—An ex-  
14 emption under this clause may be  
15 extended for a period of an addi-  
16 tional 12 months subject to the  
17 limitation described in clause (ii).

18 “(iii) LIMITATION.—Subject to clause  
19 (ii)(II)(aa), in no case may an eligible pro-  
20 fessional be granted an exemption under  
21 this subparagraph for more than 5 years.”.

22 (B) INCENTIVES FOR HOSPITALS.—

23 (i) IN GENERAL.—Section 1886(o)(1)  
24 of the Social Security Act (42 U.S.C.  
25 1395ww(o)(1)) is amended—

1 (I) in subparagraph (A), by in-  
2 serting before the period at the end  
3 the following: “and, for performance  
4 periods for fiscal year 2018 or a sub-  
5 sequent fiscal year, that provide a  
6 demonstration described in subpara-  
7 graph (D) to the Secretary”; and

8 (II) by adding at the end the fol-  
9 lowing new subparagraph:

10 “(D) DEMONSTRATION DESCRIBED.—The  
11 demonstration described in this subparagraph is  
12 a demonstration, through means such as an at-  
13 testation, that the hospital has not taken any  
14 action described in subsection (a)(2) of section  
15 3010A of the Public Health Service Act, with  
16 respect to the use of any certified EHR tech-  
17 nology.”.

18 (ii) HARDSHIP EXEMPTION IN CASE  
19 OF DECERTIFIED EHR.—Subclause (II) of  
20 section 1886(b)(3)(B)(ix) of the Social Se-  
21 curity Act (42 U.S.C.  
22 1395ww(b)(3)(B)(ix)) is amended to read  
23 as follows:

24 “(II)(aa) The Secretary may, on  
25 a case-by-case basis, exempt a sub-



1 section (d) hospital from the applica-  
2 tion of subclause (I) with respect to a  
3 fiscal year if the Secretary deter-  
4 mines, subject to annual renewal, that  
5 requiring such hospital to be a mean-  
6 ingful EHR user during such fiscal  
7 year would result in a significant  
8 hardship, such as in the case of a hos-  
9 pital in a rural area without sufficient  
10 Internet access.

11 “(bb) The Secretary may, on a  
12 case-by-case basis, exempt a sub-  
13 section (d) hospital from the applica-  
14 tion of subclause (I) with respect to a  
15 fiscal year if the Secretary deter-  
16 mines, subject to annual renewal, that  
17 such hospital was determined to not  
18 be a meaningful EHR user because  
19 the qualified electronic health record  
20 used by such hospital was decertified  
21 under section 3001(c)(5)(C) of the  
22 Public Health Service Act. An exemp-  
23 tion under the previous sentence may  
24 be applied to a subsection (d) hospital  
25 only, subject to items (cc) and (dd),

1 during the first payment year with re-  
2 spect to the first EHR reporting pe-  
3 riod to which such decertification ap-  
4 plies.

5 “(cc) In no case shall an exemp-  
6 tion by reason of item (bb) be for a  
7 period of less than 12 months.

8 “(dd) An exemption under item  
9 (bb) may be extended for a period of  
10 an additional 12 months subject to  
11 the limitation described in item (ee).

12 “(ee) Subject to item (cc), in no  
13 case may a hospital be granted an ex-  
14 emption under this subclause for more  
15 than 5 years.”.

16 (C) DEMONSTRATION REQUIRED FOR  
17 MEANINGFUL EHR USE INCENTIVES UNDER  
18 MEDICAID.—Section 1903(t)(2) of the Social  
19 Security Act (42 U.S.C. 1396b(t)(2)) is amend-  
20 ed by adding at the end the following: “An eli-  
21 gible professional shall not qualify as a Med-  
22 icaid provider under this subsection, with re-  
23 spect to a year beginning with 2018, unless  
24 such provider demonstrates to the Secretary,  
25 through means such as an attestation, that the

1 provider has not taken any action described in  
2 subsection (a)(2) of section 3010A of the Public  
3 Health Service Act with respect to which the  
4 provider knows or should know (as defined in  
5 section 1128A(i)(7) of the Social Security Act)  
6 about, with respect to the use of any certified  
7 EHR technology.”.

8 (f) DEFINITIONS.—

9 (1) CERTIFIED EHR TECHNOLOGY.—Paragraph  
10 (1) of section 3000 of the Public Health Service Act  
11 (42 U.S.C. 300jj) is amended to read as follows:

12 “(1) CERTIFIED EHR TECHNOLOGY.—The term  
13 ‘certified EHR technology’ means a qualified elec-  
14 tronic health record that is certified pursuant to sec-  
15 tion 3001(c)(5) as meeting the certification criteria  
16 defined in subparagraph (B) of such section that are  
17 applicable to the type of record involved (as deter-  
18 mined by the Secretary, such as an ambulatory elec-  
19 tronic health record for office-based physicians or an  
20 inpatient hospital electronic health record for hos-  
21 pitals) including, beginning January 1, 2018, with  
22 respect to which the vendor or other entity offering  
23 such technology is in compliance with the require-  
24 ments under section 3001(c)(5)(C)(i).”.

1           (2) WIDESPREAD INTEROPERABILITY.—Section  
2           3000 of the Public Health Service Act (42 U.S.C.  
3           300jj) is amended by adding at the end the following  
4           new paragraph:

5           “(15) WIDESPREAD INTEROPERABILITY.—The  
6           term ‘widespread interoperability’ means that, on a  
7           nationwide basis—

8                   “(A) health information technology is  
9                   interoperable, in accordance with section 3010;  
10                  and

11                   “(B) such technology is employed by mean-  
12                   ingful EHR users under the specified meaning-  
13                   ful use incentive programs (as defined in sec-  
14                   tion 3010A(e)) and by other clinicians and  
15                   health care providers.”.

16           (g) CONFORMING AMENDMENTS.—

17           (1) VOLUNTARY USE OF STANDARDS.—Section  
18           3006 of the Public Health Service Act (42 U.S.C.  
19           300jj–16) is amended—

20                   (A) in subsection (a)(1), by inserting “, in-  
21                   cluding an interoperability standard adopted  
22                   under such section” after “section 3004”.

23                   (B) in subsection (b), by inserting “, in-  
24                   cluding the interoperability standards adopted  
25                   under such section” 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 patients, including such  
10          information contained in an electronic health record  
11          of such patients;

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 1  
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 (42 U.S.C. 1395 et seq.) and the Medicaid  
20 program under title XIX of such Act (42 U.S.C.  
21 1396 et seq.) and those with chronic conditions,  
22 whose care may be improved most in terms of qual-  
23 ity and efficiency by the expansion, in a manner that  
24 meets or exceeds the existing in-person standard of  
25 care under the Medicare program under title XVIII

1 of 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 1 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 (42 U.S.C. 1395w–21 et seq.), provide information to the  
23 committees of jurisdiction of the House of Representatives  
24 and the Senate that identifies—

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) IN GENERAL.—Section 1834 of the Social Secu-  
18 rity Act (42 U.S.C. 1395m) is amended by adding at the  
19 end the following new subsection:

20 “(r) PAYMENT FOR CERTAIN DISPOSABLE DE-  
21 VICES.—

22 “(1) IN GENERAL.—The Secretary shall make  
23 separate payment in the amount established under  
24 paragraph (3) to a home health agency for a device  
25 described in paragraph (2) when furnished to an in-

1       dividual who receives home health services for which  
2       payment is made under section 1895(b).

3           “(2) DEVICE DESCRIBED.—For purposes of  
4       paragraph (1), a device described in this paragraph  
5       is a disposable device for which, as of January 1,  
6       2015, there is—

7           “(A) a Level I Healthcare Common Proce-  
8       dure Coding System (HCPCS) code for which  
9       the description for a professional service in-  
10      cludes the furnishing of such device; and

11          “(B) a separate Level I HCPCS code for  
12      a professional service that uses durable medical  
13      equipment instead of such device.

14          “(3) PAYMENT AMOUNT.—The Secretary shall  
15      establish the separate payment amount for such a  
16      device such that such amount does not exceed the  
17      payment that would be made for the HCPCS code  
18      described in paragraph (2)(A) under section 1833(t)  
19      (relating to payment for covered OPD services).”.

20          (b) CONFORMING AMENDMENT.—Section  
21      1861(m)(5) of the Social Security Act (42 U.S.C.  
22      1395x(m)(5)) is amended by inserting “and devices de-  
23      scribed in section 1834(r)(2)” after “durable medical  
24      equipment”.

1 (c) EFFECTIVE DATE.—The amendments made by  
2 this section shall apply to devices furnished on or after  
3 January 1, 2017.

## 4 **Subtitle E—Local Coverage** 5 **Decision Reforms**

### 6 **SEC. 3081. IMPROVEMENTS IN THE MEDICARE LOCAL COV-** 7 **ERAGE DETERMINATION (LCD) PROCESS.**

8 (a) IN GENERAL.—Section 1862(l)(5) of the Social  
9 Security Act (42 U.S.C. 1395y(l)(5)) is amended by add-  
10 ing at the end the following new subparagraph:

11 “(D) LOCAL COVERAGE DETERMINA-  
12 TIONS.—The Secretary shall require each medi-  
13 care administrative contractor that develops a  
14 local coverage determination to make available  
15 on the website of such contractor and in the  
16 coverage database on the Medicare website, at  
17 least 45 days before the effective date of such  
18 determination, the following information:

19 “(i) Such determination in its en-  
20 tirety.

21 “(ii) Where and when the proposed  
22 determination was first made public.

23 “(iii) Hyperlinks to the proposed de-  
24 termination and a response to comments

1 submitted to the contractor with respect to  
2 such proposed determination.

3 “(iv) A summary of evidence that was  
4 considered by the contractor during the de-  
5 velopment of such determination and a list  
6 of the sources of such evidence.

7 “(v) An explanation of the rationale  
8 that supports such determination.”.

9 (b) **EFFECTIVE DATE.**—The amendment made by  
10 subsection (a) shall apply with respect to local coverage  
11 determinations that are proposed or revised on or after  
12 the date that is 180 days after the date of the enactment  
13 of this Act.

14 **Subtitle F—Medicare Pharma-**  
15 **ceutical and Technology Om-**  
16 **budsman**

17 **SEC. 3101. MEDICARE PHARMACEUTICAL AND TECH-**  
18 **NOLOGY OMBUDSMAN.**

19 Section 1808(c) of the Social Security Act (42 U.S.C.  
20 1395b–9(c)) is amended by adding at the end the fol-  
21 lowing new paragraph:

22 “(4) **PHARMACEUTICAL AND TECHNOLOGY OM-**  
23 **BUDSMAN.**—Not later than 12 months after the date  
24 of the enactment of this paragraph, the Secretary  
25 shall provide for a pharmaceutical and technology

1 ombudsman within the Centers for Medicare & Med-  
2 icaid Services who shall receive and respond to com-  
3 plaints, grievances, and requests that—

4 “(A) are from entities that manufacture  
5 pharmaceutical, biotechnology, medical device,  
6 or diagnostic products that are covered or for  
7 which coverage is being sought under this title;  
8 and

9 “(B) are with respect to coverage, coding,  
10 or payment under this title for such products.”.

11 **Subtitle G—Medicare Site-of-**  
12 **Service Price Transparency**

13 **SEC. 3121. MEDICARE SITE-OF-SERVICE PRICE TRANS-**  
14 **PARENCY.**

15 Section 1834 of the Social Security Act (42 U.S.C.  
16 1395m), as amended by section 3061, is further amended  
17 by adding at the end the following new subsection:

18 “(s) SITE-OF-SERVICE PRICE TRANSPARENCY.—

19 “(1) IN GENERAL.—In order to facilitate price  
20 transparency with respect to items and services for  
21 which payment may be made either to a hospital  
22 outpatient department or to an ambulatory surgery  
23 center under this title, the Secretary shall, for 2017  
24 and each year thereafter, make available to the pub-



1       lic via a searchable website, with respect to an ap-  
2       propriate number of such items and services—

3               “(A) the estimated payment amount for  
4       the item or service under the outpatient depart-  
5       ment fee schedule under subsection (t) of sec-  
6       tion 1833 and the ambulatory surgical center  
7       payment system under subsection (i) of such  
8       section; and

9               “(B) the estimated amount of beneficiary  
10      liability applicable to the item or service.

11              “(2) CALCULATION OF ESTIMATED BENE-  
12      FICIARY LIABILITY.—For purposes of paragraph  
13      (1)(B), the estimated amount of beneficiary liability,  
14      with respect to an item or service, is the amount for  
15      such item or service for which an individual who  
16      does not have coverage under a medicare supple-  
17      mental policy certified under section 1882 or any  
18      other supplemental insurance coverage is respon-  
19      sible.

20              “(3) IMPLEMENTATION.—In carrying out this  
21      subsection, the Secretary—

22              “(A) shall include in the notice described  
23      in section 1804(a) a notification of the avail-  
24      ability of the estimated amounts made available  
25      under paragraph (1); and

1           “(B) may utilize mechanisms in existence  
2           on the date of the enactment of this subsection,  
3           such as the portion of the website of the Cen-  
4           ters for Medicare & Medicaid Services on which  
5           information comparing physician performance is  
6           posted (commonly referred to as the Physician  
7           Compare website), to make available such esti-  
8           mated amounts under such paragraph.

9           “(4) FUNDING.—For purposes of implementing  
10          this subsection, the Secretary shall provide for the  
11          transfer, from the Supplemental Medical Insurance  
12          Trust Fund under section 1841 to the Centers for  
13          Medicare & Medicaid Services Program Management  
14          Account, of \$6,000,000 for fiscal year 2015, to re-  
15          main available until expended.”.

16 **Subtitle H—Medicare Part D Pa-**  
17 **tient Safety and Drug Abuse**  
18 **Prevention**

19 **SEC. 3141. PROGRAMS TO PREVENT PRESCRIPTION DRUG**  
20 **ABUSE UNDER MEDICARE PARTS C AND D.**

21          (a) DRUG MANAGEMENT PROGRAM FOR AT-RISK  
22 BENEFICIARIES.—

23           (1) IN GENERAL.—Section 1860D–4(c) of the  
24          Social Security Act (42 U.S.C. 1395w–10(c)) is  
25          amended by adding at the end the following:

1           “(5) DRUG MANAGEMENT PROGRAM FOR AT-  
2 RISK BENEFICIARIES.—

3           “(A) AUTHORITY TO ESTABLISH.—A PDP  
4 sponsor may establish a drug management pro-  
5 gram for at-risk beneficiaries under which, sub-  
6 ject to subparagraph (B), the PDP sponsor  
7 may, in the case of an at-risk beneficiary for  
8 prescription drug abuse who is an enrollee in a  
9 prescription drug plan of such PDP sponsor,  
10 limit such beneficiary’s access to coverage for  
11 frequently abused drugs under such plan to fre-  
12 quently abused drugs that are prescribed for  
13 such beneficiary by one or more prescribers se-  
14 lected under subparagraph (D), and dispensed  
15 for such beneficiary by one or more pharmacies  
16 selected under such subparagraph.

17           “(B) REQUIREMENT FOR NOTICES.—

18           “(i) IN GENERAL.—A PDP sponsor  
19 may not limit the access of an at-risk ben-  
20 efiary for prescription drug abuse to cov-  
21 erage for frequently abused drugs under a  
22 prescription drug plan until such spon-  
23 sor—

24           “(I) provides to the beneficiary  
25 an initial notice described in clause

1 (ii) and a second notice described in  
2 clause (iii); and

3 “(II) verifies with the providers  
4 of the beneficiary that the beneficiary  
5 is an at-risk beneficiary for prescrip-  
6 tion drug abuse.

7 “(ii) INITIAL NOTICE.—An initial no-  
8 tice described in this clause is a notice that  
9 provides to the beneficiary—

10 “(I) notice that the PDP sponsor  
11 has identified the beneficiary as po-  
12 tentially being an at-risk beneficiary  
13 for prescription drug abuse;

14 “(II) information describing all  
15 State and Federal public health re-  
16 sources that are designed to address  
17 prescription drug abuse to which the  
18 beneficiary has access, including men-  
19 tal health services and other coun-  
20 seling services;

21 “(III) notice of, and information  
22 about, the right of the beneficiary to  
23 appeal such identification under sub-  
24 section (h) and the option of an auto-  
25 matic escalation to external review;

1           “(IV) a request for the bene-  
2           ficiary to submit to the PDP sponsor  
3           preferences for which prescribers and  
4           pharmacies the beneficiary would pre-  
5           fer the PDP sponsor to select under  
6           subparagraph (D) in the case that the  
7           beneficiary is identified as an at-risk  
8           beneficiary for prescription drug  
9           abuse as described in clause (iii)(I);

10           “(V) an explanation of the mean-  
11           ing and consequences of the identi-  
12           fication of the beneficiary as poten-  
13           tially being an at-risk beneficiary for  
14           prescription drug abuse, including an  
15           explanation of the drug management  
16           program established by the PDP  
17           sponsor pursuant to subparagraph  
18           (A);

19           “(VI) clear instructions that ex-  
20           plain how the beneficiary can contact  
21           the PDP sponsor in order to submit  
22           to the PDP sponsor the preferences  
23           described in subclause (IV) and any  
24           other communications relating to the  
25           drug management program for at-risk

1 beneficiaries established by the PDP  
2 sponsor; and

3 “(VII) contact information for  
4 other organizations that can provide  
5 the beneficiary with assistance regard-  
6 ing such drug management program  
7 (similar to the information provided  
8 by the Secretary in other standardized  
9 notices provided to part D eligible in-  
10 dividuals enrolled in prescription drug  
11 plans under this part).

12 “(iii) SECOND NOTICE.—A second no-  
13 tice described in this clause is a notice that  
14 provides to the beneficiary notice—

15 “(I) that the PDP sponsor has  
16 identified the beneficiary as an at-risk  
17 beneficiary for prescription drug  
18 abuse;

19 “(II) that such beneficiary is  
20 subject to the requirements of the  
21 drug management program for at-risk  
22 beneficiaries established by such PDP  
23 sponsor for such plan;

24 “(III) of the prescriber (or pre-  
25 scribers) and pharmacy (or phar-

1                   macies) selected for such individual  
2                   under subparagraph (D);

3                   “(IV) of, and information about,  
4                   the beneficiary’s right to appeal such  
5                   identification under subsection (h)  
6                   and the option of an automatic esca-  
7                   lation to external review;

8                   “(V) that the beneficiary can, in  
9                   the case that the beneficiary has not  
10                  previously submitted to the PDP  
11                  sponsor preferences for which pre-  
12                  scribers and pharmacies the bene-  
13                  ficiary would prefer the PDP sponsor  
14                  select under subparagraph (D), sub-  
15                  mit such preferences to the PDP  
16                  sponsor; and

17                  “(VI) that includes clear instruc-  
18                  tions that explain how the beneficiary  
19                  can contact the PDP sponsor.

20                  “(iv) TIMING OF NOTICES.—

21                  “(I) IN GENERAL.—Subject to  
22                  subclause (II), a second notice de-  
23                  scribed in clause (iii) shall be provided  
24                  to the beneficiary on a date that is  
25                  not less than 60 days after an initial

1 notice described in clause (ii) is pro-  
2 vided to the beneficiary.

3 “(II) EXCEPTION.—In the case  
4 that the PDP sponsor, in conjunction  
5 with the Secretary, determines that  
6 concerns identified through rule-  
7 making by the Secretary regarding  
8 the health or safety of the beneficiary  
9 or regarding significant drug diversion  
10 activities require the PDP sponsor to  
11 provide a second notice described in  
12 clause (iii) to the beneficiary on a  
13 date that is earlier than the date de-  
14 scribed in subclause (I), the PDP  
15 sponsor may provide such second no-  
16 tice on such earlier date.

17 “(C) AT-RISK BENEFICIARY FOR PRE-  
18 SCRIPTION DRUG ABUSE.—

19 “(i) IN GENERAL.—For purposes of  
20 this paragraph, the term ‘at-risk bene-  
21 ficiary for prescription drug abuse’ means  
22 a part D eligible individual who is not an  
23 exempted individual described in clause (ii)  
24 and—



1                   “(I) who is identified through the  
2                   use of clinical guidelines developed by  
3                   the Secretary in consultation with  
4                   PDP sponsors and other stakeholders  
5                   described in section 3141(f)(2)(A) of  
6                   the 21st Century Cures Act; or

7                   “(II) with respect to whom the  
8                   PDP sponsor of a prescription drug  
9                   plan, upon enrolling such individual in  
10                  such plan, received notice from the  
11                  Secretary that such individual was  
12                  identified under this paragraph to be  
13                  an at-risk beneficiary for prescription  
14                  drug abuse under the prescription  
15                  drug plan in which such individual  
16                  was most recently previously enrolled  
17                  and such identification has not been  
18                  terminated under subparagraph (F).

19                  “(ii) EXEMPTED INDIVIDUAL DE-  
20                  SCRIBED.—An exempted individual de-  
21                  scribed in this clause is an individual  
22                  who—

23                         “(I) receives hospice care under  
24                         this title;

1                   “(II) is a resident of a long-term  
2                   care facility, of an intermediate care  
3                   facility for the mentally retarded, or  
4                   of another facility for which fre-  
5                   quently abused drugs are dispensed  
6                   for residents through a contract with  
7                   a single pharmacy; or

8                   “(III) the Secretary elects to  
9                   treat as an exempted individual for  
10                  purposes of clause (i).

11                  “(D) SELECTION OF PRESCRIBERS AND  
12                  PHARMACIES.—

13                  “(i) IN GENERAL.—With respect to  
14                  each at-risk beneficiary for prescription  
15                  drug abuse enrolled in a prescription drug  
16                  plan offered by such sponsor, a PDP spon-  
17                  sor shall, based on the preferences sub-  
18                  mitted to the PDP sponsor by the bene-  
19                  ficiary pursuant to clauses (ii)(IV) and  
20                  (iii)(V) of subparagraph (B), select—

21                  “(I) one or more individuals who  
22                  are authorized to prescribe frequently  
23                  abused drugs (referred to in this  
24                  paragraph as ‘prescribers’) who may

1 write prescriptions for such drugs for  
2 such beneficiary; and

3 “(II) one or more pharmacies  
4 that may dispense such drugs to such  
5 beneficiary.

6 “(ii) REASONABLE ACCESS.—In mak-  
7 ing the selections under this subpara-  
8 graph—

9 “(I) a PDP sponsor shall ensure  
10 that the beneficiary continues to have  
11 reasonable access to frequently abused  
12 drugs (as defined in subparagraph  
13 (G)), taking into account geographic  
14 location, beneficiary preference, im-  
15 pact on costsharing, and reasonable  
16 travel time; and

17 “(II) a PDP sponsor shall ensure  
18 such access (including access to pre-  
19 scribers and pharmacies with respect  
20 to frequently abused drugs) in the  
21 case of individuals with multiple resi-  
22 dences and in the case of natural dis-  
23 asters and similar emergency situa-  
24 tions.

25 “(iii) BENEFICIARY PREFERENCES.—

1                   “(I) IN GENERAL.—If an at-risk  
2                   beneficiary for prescription drug  
3                   abuse submits preferences for which  
4                   in-network prescribers and pharmacies  
5                   the beneficiary would prefer the PDP  
6                   sponsor select in response to a notice  
7                   under subparagraph (B), the PDP  
8                   sponsor shall—

9                   “(aa) review such pref-  
10                  erences;

11                  “(bb) select or change the  
12                  selection of prescribers and phar-  
13                  macies for the beneficiary based  
14                  on such preferences; and

15                  “(cc) inform the beneficiary  
16                  of such selection or change of se-  
17                  lection.

18                  “(II) EXCEPTION.—In the case  
19                  that the PDP sponsor determines that  
20                  a change to the selection of prescriber  
21                  or pharmacy under item (bb) by the  
22                  PDP sponsor is contributing or would  
23                  contribute to prescription drug abuse  
24                  or drug diversion by the beneficiary,  
25                  the PDP sponsor may change the se-

1                   lection of prescriber or pharmacy for  
2                   the beneficiary without regard to the  
3                   preferences of the beneficiary de-  
4                   scribed in subclause (I).

5                   “(iv) CONFIRMATION.—Before select-  
6                   ing a prescriber (or prescribers) or phar-  
7                   macy (or pharmacies) under this subpara-  
8                   graph, a PDP sponsor must request and  
9                   receive confirmation from such a prescriber  
10                  or pharmacy acknowledging and accepting  
11                  that the beneficiary involved is in the drug  
12                  management program for at-risk bene-  
13                  ficiaries.

14                  “(E) TERMINATIONS AND APPEALS.—The  
15                  identification of an individual as an at-risk ben-  
16                  eficiary for prescription drug abuse under this  
17                  paragraph, a coverage determination made  
18                  under a drug management program for at-risk  
19                  beneficiaries, and the selection of prescriber or  
20                  pharmacy under subparagraph (D) with respect  
21                  to such individual shall be subject to reconsider-  
22                  ation and appeal under subsection (h) and the  
23                  option of an automatic escalation to external re-  
24                  view to the extent provided by the Secretary.

25                  “(F) TERMINATION OF IDENTIFICATION.—

1                   “(i) IN GENERAL.—The Secretary  
2                   shall develop standards for the termination  
3                   of identification of an individual as an at-  
4                   risk beneficiary for prescription drug abuse  
5                   under this paragraph. Under such stand-  
6                   ards such identification shall terminate as  
7                   of the earlier of—

8                                 “(I) the date the individual dem-  
9                                 onstrates that the individual is no  
10                                longer likely, in the absence of the re-  
11                                strictions under this paragraph, to be  
12                                an at-risk beneficiary for prescription  
13                                drug abuse described in subparagraph  
14                                (C)(i); and

15                               “(II) the end of such maximum  
16                                period of identification as the Sec-  
17                                retary may specify.

18                   “(ii) RULE OF CONSTRUCTION.—  
19                   Nothing in clause (i) shall be construed as  
20                   preventing a plan from identifying an indi-  
21                   vidual as an at-risk beneficiary for pre-  
22                   scription drug abuse under subparagraph  
23                   (C)(i) after such termination on the basis  
24                   of additional information on drug use oc-

1           curing after the date of notice of such ter-  
2           mination.

3           “(G) FREQUENTLY ABUSED DRUG.—For  
4           purposes of this subsection, the term ‘frequently  
5           abused drug’ means a drug that is a controlled  
6           substance that the Secretary determines to be  
7           frequently abused or diverted.

8           “(H) DATA DISCLOSURE.—In the case of  
9           an at-risk beneficiary for prescription drug  
10          abuse whose access to coverage for frequently  
11          abused drugs under a prescription drug plan  
12          has been limited by a PDP sponsor under this  
13          paragraph, such PDP sponsor shall disclose  
14          data, including any necessary individually iden-  
15          tifiable health information, in a form and man-  
16          ner specified by the Secretary, about the deci-  
17          sion to impose such limitations and the limita-  
18          tions imposed by the sponsor under this part.

19          “(I) EDUCATION.—The Secretary shall  
20          provide education to enrollees in prescription  
21          drug plans of PDP sponsors and providers re-  
22          garding the drug management program for at-  
23          risk beneficiaries described in this paragraph,  
24          including education—

1                   “(i) provided by medicare administra-  
2                   tive contractors through the improper pay-  
3                   ment outreach and education program de-  
4                   scribed in section 1874A(h); and

5                   “(ii) through current education efforts  
6                   (such as State health insurance assistance  
7                   programs described in subsection (a)(1)(A)  
8                   of section 119 of the Medicare Improve-  
9                   ments for Patients and Providers Act of  
10                  2008 (42 U.S.C. 1395b-3 note)) and ma-  
11                  terials directed toward such enrollees.

12                  “(J)    APPLICATION    UNDER    MA-PD  
13                  PLANS.—Pursuant to section 1860D—21(c)(1),  
14                  the provisions of this paragraph apply under  
15                  part D to MA organizations offering MA-PD  
16                  plans to MA eligible individuals in the same  
17                  manner as such provisions apply under this  
18                  part to a PDP sponsor offering a prescription  
19                  drug plan to a part D eligible individual.”.

20                  (2) INFORMATION FOR CONSUMERS.—Section  
21                  1860D-4(a)(1)(B) of the Social Security Act (42  
22                  U.S.C. 1395w-104(a)(1)(B)) is amended by adding  
23                  at the end the following:



1                   “(v) The drug management program  
2                   for at-risk beneficiaries under subsection  
3                   (c)(5).”.

4           (b) UTILIZATION MANAGEMENT PROGRAMS.—Sec-  
5 tion 1860D–4(c) of the Social Security Act (42 U.S.C.  
6 1395w–104(c)), as amended by subsection (a)(1), is fur-  
7 ther amended—

8                   (1) in paragraph (1), by inserting after sub-  
9                   paragraph (D) the following new subparagraph:

10                   “(E) A utilization management tool to pre-  
11                   vent drug abuse (as described in paragraph  
12                   (6)(A)).”; and

13                   (2) by adding at the end the following new  
14                   paragraph:

15                   “(6) UTILIZATION MANAGEMENT TOOL TO PRE-  
16                   VENT DRUG ABUSE.—

17                   “(A) IN GENERAL.—A tool described in  
18                   this paragraph is any of the following:

19                   “(i) A utilization tool designed to pre-  
20                   vent the abuse of frequently abused drugs  
21                   by individuals and to prevent the diversion  
22                   of such drugs at pharmacies.

23                   “(ii) Retrospective utilization review  
24                   to identify—

1                   “(I) individuals that receive fre-  
2                   quently abused drugs at a frequency  
3                   or in amounts that are not clinically  
4                   appropriate; and

5                   “(II) providers of services or sup-  
6                   pliers that may facilitate the abuse or  
7                   diversion of frequently abused drugs  
8                   by beneficiaries.

9                   “(iii) Consultation with the contractor  
10                  described in subparagraph (B) to verify if  
11                  an individual enrolling in a prescription  
12                  drug plan offered by a PDP sponsor has  
13                  been previously identified by another PDP  
14                  sponsor as an individual described in  
15                  clause (ii)(I).

16                  “(B) REPORTING.—A PDP sponsor offer-  
17                  ing a prescription drug plan (and an MA orga-  
18                  nization offering an MA–PD plan) in a State  
19                  shall submit to the Secretary and the Medicare  
20                  drug integrity contractor with which the Sec-  
21                  retary has entered into a contract under section  
22                  1893 with respect to such State a report, on a  
23                  monthly basis, containing information on—

24                         “(i) any provider of services or sup-  
25                         plier described in subparagraph (A)(ii)(II)

1           that is identified by such plan sponsor (or  
2           organization) during the 30-day period be-  
3           fore such report is submitted; and

4                   “(ii) the name and prescription  
5           records of individuals described in para-  
6           graph (5)(C).”.

7           (c) EXPANDING ACTIVITIES OF MEDICARE DRUG IN-  
8   TEGRITY CONTRACTORS (MEDICS).—

9                   (1) IN GENERAL.—Section 1893 of the Social  
10          Security Act (42 U.S.C. 1395ddd) is amended by  
11          adding at the end the following new subsection:

12                   “(j) EXPANDING ACTIVITIES OF MEDICARE DRUG  
13   INTEGRITY CONTRACTORS (MEDICS).—

14                   “(1) ACCESS TO INFORMATION.—Under con-  
15          tracts entered into under this section with Medicare  
16          drug integrity contractors (including any successor  
17          entity to a Medicare drug integrity contractor), the  
18          Secretary shall authorize such contractors to directly  
19          accept prescription and necessary medical records  
20          from entities such as pharmacies, prescription drug  
21          plans, MA–PD plans, and physicians with respect to  
22          an individual in order for such contractors to pro-  
23          vide information relevant to the determination of  
24          whether such individual is an at-risk beneficiary for

1 prescription drug abuse, as defined in section  
2 1860D-4(c)(5)(C).

3 “(2) REQUIREMENT FOR ACKNOWLEDGMENT  
4 OF REFERRALS.—If a PDP sponsor or MA organiza-  
5 tion refers information to a contractor described in  
6 paragraph (1) in order for such contractor to assist  
7 in the determination described in such paragraph,  
8 the contractor shall—

9 “(A) acknowledge to the sponsor or organi-  
10 zation receipt of the referral; and

11 “(B) in the case that any PDP sponsor or  
12 MA organization contacts the contractor re-  
13 questing to know the determination by the con-  
14 tractor of whether or not an individual has been  
15 determined to be an individual described such  
16 paragraph, shall inform such sponsor or organi-  
17 zation of such determination on a date that is  
18 not later than 15 days after the date on which  
19 the sponsor or organization contacts the con-  
20 tractor.

21 “(3) MAKING DATA AVAILABLE TO OTHER EN-  
22 TITIES.—

23 “(A) IN GENERAL.—For purposes of car-  
24 rying out this subsection, subject to subpara-  
25 graph (B), the Secretary shall authorize MED-

1 ICs to respond to requests for information from  
2 PDP sponsors and MA organizations, State  
3 prescription drug monitoring programs, and  
4 other entities delegated by such sponsors or or-  
5 ganizations using available programs and sys-  
6 tems in the effort to prevent fraud, waste, and  
7 abuse.

8 “(B) HIPAA COMPLIANT INFORMATION  
9 ONLY.—Information may only be disclosed by a  
10 MEDIC under subparagraph (A) if the disclo-  
11 sure of such information is permitted under the  
12 Federal regulations (concerning the privacy of  
13 individually identifiable health information) pro-  
14 mulgated under section 264(c) of the Health  
15 Insurance Portability and Accountability Act of  
16 1996 (42 U.S.C. 1320d–2 note).”.

17 (2) OIG STUDY AND REPORT ON EFFECTIVE-  
18 NESS OF MEDICS.—

19 (A) STUDY.—The Inspector General of the  
20 Department of Health and Human Services  
21 shall conduct a study on the effectiveness of  
22 Medicare drug integrity contractors with which  
23 the Secretary of Health and Human Services  
24 has entered into a contract under section 1893  
25 of the Social Security Act (42 U.S.C. 1395ddd)

1 in identifying, combating, and preventing fraud  
2 under the Medicare program, including under  
3 the authority provided under section 1893(j) of  
4 the Social Security Act, added by paragraph  
5 (1).

6 (B) REPORT.—Not later than 1 year after  
7 the date of the enactment of this Act, the In-  
8 spector General shall submit to Congress a re-  
9 port on the study conducted under subpara-  
10 graph (A). Such report shall include such rec-  
11 ommendations for improvements in the effec-  
12 tiveness of such contractors as the Inspector  
13 General determines appropriate.

14 (d) TREATMENT OF CERTAIN COMPLAINTS FOR PUR-  
15 POSES OF QUALITY OR PERFORMANCE ASSESSMENT.—  
16 Section 1860D–42 of the Social Security Act (42 U.S.C.  
17 1395w–152) is amended by adding at the end the fol-  
18 lowing new subsection:

19 “(d) TREATMENT OF CERTAIN COMPLAINTS FOR  
20 PURPOSES OF QUALITY OR PERFORMANCE ASSESS-  
21 MENT.—In conducting a quality or performance assess-  
22 ment of a PDP sponsor, the Secretary shall develop or  
23 utilize existing screening methods for reviewing and con-  
24 sidering complaints that are received from enrollees in a  
25 prescription drug plan offered by such PDP sponsor and

1 that are complaints regarding the lack of access by the  
2 individual to prescription drugs due to a drug manage-  
3 ment program for at-risk beneficiaries.”.

4 (e) SENSE OF CONGRESS REGARDING USE OF TECH-  
5 NOLOGY TOOLS TO COMBAT FRAUD.—It is the sense of  
6 Congress that MA organizations and PDP sponsors  
7 should consider using e-prescribing and other health infor-  
8 mation technology tools to support combating fraud under  
9 MA–PD plans and prescription drug plans under parts C  
10 and D of the Medicare program.

11 (f) EFFECTIVE DATE.—

12 (1) IN GENERAL.—The amendments made by  
13 this section shall apply to prescription drug plans  
14 (and MA–PD plans) for plan years beginning more  
15 than 1 year after the date of the enactment of this  
16 Act.

17 (2) STAKEHOLDER MEETINGS PRIOR TO EFFEC-  
18 TIVE DATE.—

19 (A) IN GENERAL.—Not later than January  
20 1, 2016, the Secretary of Health and Human  
21 Services shall convene stakeholders, including  
22 individuals entitled to benefits under part A of  
23 title XVIII of the Social Security Act or en-  
24 rolled under part B of such title of such Act,  
25 advocacy groups representing such individuals,

1 physicians, pharmacists, and other clinicians,  
2 retail pharmacies, plan sponsors, entities dele-  
3 gated by plan sponsors, and biopharmaceutical  
4 manufacturers for input regarding the topics  
5 described in subparagraph (B).

6 (B) TOPICS DESCRIBED.—The topics de-  
7 scribed in this subparagraph are the topics of—

8 (i) the impact on cost-sharing and en-  
9 suring accessibility to prescription drugs  
10 for enrollees in prescription drug plans of  
11 PDP sponsors, and enrollees in MA–PD  
12 plans, who are at-risk beneficiaries for pre-  
13 scription drug abuse (as defined in sub-  
14 paragraph (C) of paragraph (5) of section  
15 1860D–4(c) of the Social Security Act (42  
16 U.S.C. 1395w–104(c));

17 (ii) the use of an expedited appeals  
18 process under which such an enrollee may  
19 appeal an identification of such enrollee as  
20 an at-risk beneficiary for prescription drug  
21 abuse under such paragraph (similar to the  
22 processes established under the Medicare  
23 Advantage program under part C of title  
24 XVIII of the Social Security Act that allow



1 an automatic escalation to external review  
2 of claims submitted under such part);

3 (iii) the types of enrollees that should  
4 be treated as exempted individuals, as de-  
5 scribed in subparagraph (C)(ii) of such  
6 paragraph;

7 (iv) the manner in which terms and  
8 definitions in such paragraph should be ap-  
9 plied, such as the use of clinical appro-  
10 priateness in determining whether an en-  
11 rollee is an at-risk beneficiary for prescrip-  
12 tion drug abuse as defined in subpara-  
13 graph (C) of such paragraph;

14 (v) the information to be included in  
15 the notices described in subparagraph (B)  
16 of such paragraph and the standardization  
17 of such notices; and

18 (vi) with respect to a PDP sponsor  
19 (or Medicare Advantage organization) that  
20 establishes a drug management program  
21 for at-risk beneficiaries under such para-  
22 graph, the responsibilities of such PDP  
23 sponsor (or organization) with respect to  
24 the implementation of such program.

1 (g) RULEMAKING.—The Secretary of Health and  
2 Human Services shall promulgate regulations based on the  
3 input gathered pursuant to subsection (f)(2)(A).

4 **TITLE IV—MEDICAID, MEDI-**  
5 **CARE, AND OTHER REFORMS**  
6 **Subtitle A—Medicaid and Medicare**  
7 **Reforms**

8 **SEC. 4001. LIMITING FEDERAL MEDICAID REIMBURSEMENT**  
9 **TO STATES FOR DURABLE MEDICAL EQUIP-**  
10 **MENT (DME) TO MEDICARE PAYMENT RATES.**

11 (a) MEDICAID REIMBURSEMENT.—

12 (1) IN GENERAL.—Section 1903(i) of the Social  
13 Security Act (42 U.S.C. 1396b(i)) is amended—

14 (A) in paragraph (25), by striking “or” at  
15 the end;

16 (B) in paragraph (26), by striking the pe-  
17 riod at the end and inserting “; or”; and

18 (C) by inserting after paragraph (26) the  
19 following new paragraph:

20 “(27) with respect to any amounts expended by  
21 the State on the basis of a fee schedule for items de-  
22 scribed in section 1861(n), as determined in the ag-  
23 gregate with respect to each class of such items as  
24 defined by the Secretary, in excess of the aggregate  
25 amount, if any, that would be paid for such items

1 within such class on a fee-for-service basis under the  
2 program under part B of title XVIII, including, as  
3 applicable, under a competitive acquisition program  
4 under section 1847 in an area of the State.”.

5 (2) EFFECTIVE DATE.—The amendments made  
6 by this subsection shall be effective with respect to  
7 payments for items furnished on or after January 1,  
8 2020.

9 (b) MEDICARE OMBUDSMAN.—Section 1808(c) of the  
10 Social Security Act (42 U.S.C. 1395b(c)), as amended by  
11 section 3101, is further amended by adding at the end  
12 the following new paragraph:

13 “(5) MONITORING DME REIMBURSEMENT  
14 UNDER MEDICAID.—The ombudsmen under each of  
15 paragraphs (1) and (4) shall evaluate the impact of  
16 the competitive acquisition program under section  
17 1847, including as applied under section  
18 1903(i)(27), on beneficiary health status and health  
19 outcomes.”.

20 **SEC. 4002. MEDICARE PAYMENT INCENTIVE FOR THE TRAN-**  
21 **SITION FROM TRADITIONAL X-RAY IMAGING**  
22 **TO DIGITAL RADIOGRAPHY AND OTHER**  
23 **MEDICARE IMAGING PAYMENT PROVISION.**

24 (a) PHYSICIAN FEE SCHEDULE.—

25 (1) PAYMENT INCENTIVE FOR TRANSITION.—

1           (A) IN GENERAL.—Section 1848(b) of the  
2           Social Security Act (42 U.S.C. 1395w-4(b)) is  
3           amended by adding at the end the following  
4           new paragraph:

5           “(9) SPECIAL RULE TO INCENTIVIZE TRANSI-  
6           TION FROM TRADITIONAL X-RAY IMAGING TO DIG-  
7           ITAL RADIOGRAPHY.—

8           “(A) LIMITATION ON PAYMENT FOR FILM  
9           X-RAY IMAGING SERVICES.—In the case of im-  
10          aging services that are X rays taken using film  
11          and that are furnished during 2017 or a subse-  
12          quent year, the payment amount for the tech-  
13          nical component (including the technical compo-  
14          nent portion of a global fee) of such services  
15          that would otherwise be determined under this  
16          section (without application of this paragraph  
17          and before application of any other adjustment  
18          under this section) for such year shall be re-  
19          duced by 20 percent.

20          “(B) PHASED-IN LIMITATION ON PAYMENT  
21          FOR COMPUTED RADIOGRAPHY IMAGING SERV-  
22          ICES.—In the case of imaging services that are  
23          X rays taken using computed radiography tech-  
24          nology—

1           “(i) in the case of such services fur-  
2           nished during 2018, 2019, 2020, 2021, or  
3           2022 the payment amount for the tech-  
4           nical component (including the technical  
5           component portion of a global fee) of such  
6           services that would otherwise be deter-  
7           mined under this section (without applica-  
8           tion of this paragraph and before applica-  
9           tion of any other adjustment under this  
10          section) for such year shall be reduced by  
11          7 percent; and

12          “(ii) in the case of such services fur-  
13          nished during 2023 or a subsequent year,  
14          the payment amount for the technical com-  
15          ponent (including the technical component  
16          portion of a global fee) of such services  
17          that would otherwise be determined under  
18          this section (without application of this  
19          paragraph and before application of any  
20          other adjustment under this section) for  
21          such year shall be reduced by 10 percent.

22          “(C) COMPUTED RADIOGRAPHY TECH-  
23          NOLOGY DEFINED.—For purposes of this para-  
24          graph, the term ‘computed radiography tech-  
25          nology’ means cassette-based imaging which

1           utilizes an imaging plate to create the image in-  
2           volved.

3           “(D) IMPLEMENTATION.—In order to im-  
4           plement this paragraph, the Secretary shall  
5           adopt appropriate mechanisms which may in-  
6           clude use of modifiers.”.

7           (B) EXEMPTION FROM BUDGET NEU-  
8           TRALITY.—Section 1848(c)(2)(B)(v) of the So-  
9           cial Security Act (42 U.S.C. 1395w-  
10          4(c)(2)(B)(v)) is amended by adding at the end  
11          the following new subclause:

12                           “(X) REDUCED EXPENDITURES  
13                           ATTRIBUTABLE TO INCENTIVES TO  
14                           TRANSITION TO DIGITAL RADIOG-  
15                           RAPHY.—Effective for fee schedules  
16                           established beginning with 2017, re-  
17                           duced expenditures attributable to  
18                           subparagraph (A) of subsection (b)(9)  
19                           and effective for fee schedules estab-  
20                           lished beginning with 2018, reduced  
21                           expenditures attributable to subpara-  
22                           graph (B) of such subsection.”.

23           (2) ELIMINATION OF APPLICATION OF MUL-  
24           TIPLE PROCEDURE PAYMENT REDUCTION.—Section  
25           1848(b)(4) of the Social Security Act (42 U.S.C.

1 1395w-4(b)(4)) is amended by adding at the end  
2 the following new subparagraph:

3 “(E) ELIMINATION OF APPLICATION OF  
4 MULTIPLE PROCEDURE PAYMENT REDUC-  
5 TION.—

6 “(i) IN GENERAL.—Not later than  
7 January 1, 2016, the Secretary shall not  
8 apply a multiple procedure payment reduc-  
9 tion policy to the professional component  
10 of imaging services furnished in any subse-  
11 quent year that is prior to a year in which  
12 the Secretary conducts and publishes, as  
13 part of the Medicare Physician Fee Sched-  
14 ule Proposed Rule for a year, the empirical  
15 analysis described in clause (ii).

16 “(ii) EMPIRICAL ANALYSIS DE-  
17 SCRIBED.—The empirical analysis de-  
18 scribed in this clause is an analysis of the  
19 Resource-Based Relative Value Scale (com-  
20 monly known as the ‘RBRVS’) Data Man-  
21 ager information that is used to determine  
22 what, if any, efficiencies exist within the  
23 professional component of imaging services  
24 when two or more studies are performed

1 on the same patient on the same day. Such  
2 empirical analysis shall include—

3 “(I) work sheets and other infor-  
4 mation detailing which physician work  
5 activities performed given the typical  
6 vignettes were assigned reduction per-  
7 centages of 0, 25, 50, 75 and 100  
8 percent;

9 “(II) a discussion of the clinical  
10 aspects that informed the assignment  
11 of the reduction percentages described  
12 in subclause (I);

13 “(III) an explanation of how the  
14 percentage reductions for pre-, intra-,  
15 and post-service work were deter-  
16 mined and calculated; and

17 “(IV) a demonstration that the  
18 Centers for Medicare & Medicaid  
19 Services has consulted with practicing  
20 radiologists to gain knowledge of how  
21 radiologists interpret studies of mul-  
22 tiple body parts on the same indi-  
23 vidual on the same day.”.

24 (b) PAYMENT INCENTIVE FOR TRANSITION UNDER  
25 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYS-



1 TEM.—Section 1833(t)(16) of the Social Security Act (42  
2 U.S.C. 1395(t)(16)) is amended by adding at the end the  
3 following new subparagraph:

4 “(F) PAYMENT INCENTIVE FOR THE TRAN-  
5 SITION FROM TRADITIONAL X-RAY IMAGING TO  
6 DIGITAL RADIOGRAPHY.—Notwithstanding the  
7 previous provisions of this subsection:

8 “(i) LIMITATION ON PAYMENT FOR  
9 FILM X-RAY IMAGING SERVICES.—In the  
10 case of imaging services that are X rays  
11 taken using film and that are furnished  
12 during 2017 or a subsequent year, the pay-  
13 ment amount for the technical component  
14 (including the technical component portion  
15 of a global fee) of such services that would  
16 otherwise be determined under this section  
17 (without application of this paragraph and  
18 before application of any other adjustment  
19 under this subsection) for such year shall  
20 be reduced by 20 percent.

21 “(ii) PHASED-IN LIMITATION ON PAY-  
22 MENT FOR COMPUTED RADIOGRAPHY IM-  
23 AGING SERVICES.—In the case of imaging  
24 services that are X rays taken using com-

1                   puted radiography technology (as defined  
2                   in section 1848(b)(9)(C))—

3                   “(I) in the case of such services  
4                   furnished during 2018, 2019, 2020,  
5                   2021, or 2022 the payment amount  
6                   for the technical component (including  
7                   the technical component portion of a  
8                   global fee) of such services that would  
9                   otherwise be determined under this  
10                  section (without application of this  
11                  paragraph and before application of  
12                  any other adjustment under this sub-  
13                  section) for such year shall be reduced  
14                  by 7 percent; and

15                  “(II) in the case of such services  
16                  furnished during 2023 or a subse-  
17                  quent year, the payment amount for  
18                  the technical component (including  
19                  the technical component portion of a  
20                  global fee) of such services that would  
21                  otherwise be determined under this  
22                  section (without application of this  
23                  paragraph and before application of  
24                  any other adjustment under this sub-

1 section) for such year shall be reduced  
2 by 10 percent.

3 “(iii) APPLICATION WITHOUT REGARD  
4 TO BUDGET NEUTRALITY.—The reductions  
5 made under this paragraph—

6 “(I) shall not be considered an  
7 adjustment under paragraph (2)(E);  
8 and

9 “(II) shall not be implemented in  
10 a budget neutral manner.”.

11 **SEC. 4003. IMPLEMENTATION OF OFFICE OF INSPECTOR**  
12 **GENERAL RECOMMENDATION TO DELAY CER-**  
13 **TAIN MEDICARE PRESCRIPTION DRUG PLAN**  
14 **PREPAYMENTS.**

15 Section 1860D–15(d) of the Social Security Act (42  
16 U.S.C. 1395w–115(d)) is amended by adding at the end  
17 the following:

18 “(5) TIMING OF PAYMENTS.—With respect to  
19 monthly reinsurance payment amounts under this  
20 section to a PDP sponsor for months in a year (be-  
21 ginning with 2020), such payment amounts for a  
22 month shall be made on the first business day occur-  
23 ring on or after the following date for that month:

24 “(A) For the month of January, January  
25 2nd.

1           “(B) For the month of February, Feb-  
2           ruary 5th.

3           “(C) For the month of March, March  
4           10th.

5           “(D) For the month of April, April 15th.

6           “(E) For the month of May, May 20th.

7           “(F) For the month of June, June 25th.

8           “(G) For the month of July and each suc-  
9           ceeding month (other than December) in a  
10          year, the first day of the next month.

11          “(H) For the month of December, Decem-  
12          ber 24th.”.

## 13   **Subtitle B—Cures Innovation Fund**

### 14   **SEC. 4041. CURES INNOVATION FUND.**

15          (a) ESTABLISHMENT.—There is hereby established in  
16          the Treasury of the United States a fund to be known  
17          as the Cures Innovation Fund (in this section referred to  
18          as the “Fund”).

19          (b) APPROPRIATIONS.—There is hereby appropriated  
20          to the Fund, out of any funds in the Treasury not other-  
21          wise appropriated, \$110,000,000 for each of fiscal years  
22          2016 through 2020.

23          (c) EXPENDITURES.—Amounts in the Fund shall be  
24          available, as provided by appropriation Acts, for making  
25          expenditures for carrying out the following:

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

4           (2) Part E of title II of the Public Health Serv-  
5 ice Act, as added by section 1141 (relating to Coun-  
6 cil for 21st Century Cures).

7           (3) Section 2001 and the amendments made by  
8 such section (relating to development and use of pa-  
9 tient experience data to enhance structured risk-ben-  
10 efit assessment framework).

11           (4) Section 2021 and the amendments made by  
12 such section (relating to qualification of drug devel-  
13 opment tools).

14           (5) Section 2062 and the amendments made by  
15 such section (relating to utilizing evidence from clin-  
16 ical experience).

17           (6) Section 2161 (relating to grants for study-  
18 ing the process of continuous drug manufacturing).

19           (d) SUPPLEMENT, NOT SUPPLANT; PROHIBITION  
20 AGAINST TRANSFER.—Funds appropriated by subsection  
21 (b)—

22           (1) shall be used to supplement, not supplant,  
23 amounts otherwise made available to the National  
24 Institutes of Health and the Food and Drug Admin-  
25 istration; and

1           (2) notwithstanding any transfer authority in  
2           any appropriation Act, shall not be used for any  
3           purpose other than the expenditures listed in sub-  
4           section (c).

## 5           **Subtitle C—Other Reforms**

### 6           **SEC. 4061. SPR DRAWDOWN.**

7           (a) DRAWDOWN AND SALE.—Notwithstanding sec-  
8           tion 161 of the Energy Policy and Conservation Act (42  
9           U.S.C. 6241), the Secretary of Energy shall draw down  
10          and sell 8,000,000 barrels of crude oil from the Strategic  
11          Petroleum Reserve during each of the fiscal years 2018  
12          through 2025, except as provided in subsection (b).  
13          Amounts received for a sale under this subsection shall  
14          be deposited in the general fund of the Treasury during  
15          the fiscal year in which the sale occurs.

16          (b) EMERGENCY PROTECTION.—The Secretary shall  
17          not draw down and sell crude oil under this section in  
18          amounts that would result in a Strategic Petroleum Re-  
19          serve that contains an inventory of petroleum products  
20          representing less than 90 days of emergency reserves,  
21          based on the average daily level of net imports of crude  
22          oil and petroleum products in the previous calendar year.

23          (c) PROCEEDS.—Proceeds from a sale under this sec-  
24          tion shall be deposited into the general fund of the Treas-  
25          ury of the United States.

1                   **Subtitle D—Miscellaneous**

2   **SEC. 4081. LYME DISEASE AND OTHER TICK-BORNE DIS-**  
3                   **EASES.**

4           (a) IN GENERAL.—Title III of the Public Health  
5 Service Act (42 U.S.C. 241 et seq.) is amended by adding  
6 at the end the following new part:

7           **“PART W—LYME DISEASE AND OTHER TICK-**  
8                   **BORNE DISEASES**

9           **“SEC. 3990O. RESEARCH.**

10           “(a) IN GENERAL.—The Secretary shall conduct or  
11 support epidemiological, basic, translational, and clinical  
12 research regarding Lyme disease and other tick-borne dis-  
13 eases.

14           “(b) BIENNIAL REPORTS.—The Secretary shall en-  
15 sure that each biennial report under section 403 includes  
16 information on actions undertaken by the National Insti-  
17 tutes of Health to carry out subsection (a) with respect  
18 to Lyme disease and other tick-borne diseases, including  
19 an assessment of the progress made in improving the out-  
20 comes of Lyme disease and such other tick-borne diseases.

21           **“SEC. 3990O–1. WORKING GROUP.**

22           “(a) ESTABLISHMENT.—The Secretary shall estab-  
23 lish a permanent working group, to be known as the Inter-  
24 agency Lyme and Tick-Borne Disease Working Group (in  
25 this section and section 3990O–2 referred to as the

1 ‘Working Group’), to review all efforts within the Depart-  
2 ment of Health and Human Services concerning Lyme dis-  
3 ease and other tick-borne diseases to ensure interagency  
4 coordination, minimize overlap, and examine research pri-  
5 orities.

6 “(b) RESPONSIBILITIES.—The Working Group  
7 shall—

8 “(1) not later than 24 months after the date of  
9 enactment of this part, and every 24 months there-  
10 after, develop or update a summary of—

11 “(A) ongoing Lyme disease and other tick-  
12 borne disease research related to causes, pre-  
13 vention, treatment, surveillance, diagnosis,  
14 diagnostics, duration of illness, intervention,  
15 and access to services and supports for individ-  
16 uals with Lyme disease or other tick-borne dis-  
17 eases;

18 “(B) advances made pursuant to such re-  
19 search;

20 “(C) the engagement of the Department of  
21 Health and Human Services with persons that  
22 participate at the public meetings required by  
23 paragraph (5); and



1           “(D) the comments received by the Work-  
2           ing Group at such public meetings and the Sec-  
3           retary’s response to such comments;

4           “(2) ensure that a broad spectrum of scientific  
5           viewpoints is represented in each such summary;

6           “(3) monitor Federal activities with respect to  
7           Lyme disease and other tick-borne diseases;

8           “(4) make recommendations to the Secretary  
9           regarding any appropriate changes to such activities;  
10          and

11          “(5) ensure public input by holding annual pub-  
12          lic meetings that address scientific advances, re-  
13          search questions, surveillance activities, and emerg-  
14          ing strains in species of pathogenic organisms.

15          “(c) MEMBERSHIP.—

16                 “(1) IN GENERAL.—The Working Group shall  
17                 be composed of a total of 14 members as follows:

18                         “(A) FEDERAL MEMBERS.—Seven Federal  
19                         members, consisting of one or more representa-  
20                         tives of each of—

21                                 “(i) the Office of the Assistant Sec-  
22                                 retary for Health;

23                                 “(ii) the Food and Drug Administra-  
24                                 tion;

1                   “(iii) the Centers for Disease Control  
2                   and Prevention;

3                   “(iv) the National Institutes of  
4                   Health; and

5                   “(v) such other agencies and offices of  
6                   the Department of Health and Human  
7                   Services as the Secretary determines ap-  
8                   propriate.

9                   “(B) NON-FEDERAL PUBLIC MEMBERS.—  
10                  Seven non-Federal public members, consisting  
11                  of representatives of the following categories:

12                   “(i) Physicians and other medical pro-  
13                   viders with experience in diagnosing and  
14                   treating Lyme disease and other tick-borne  
15                   diseases.

16                   “(ii) Scientists or researchers with ex-  
17                   pertise.

18                   “(iii) Patients and their family mem-  
19                   bers.

20                   “(iv) Nonprofit organizations that ad-  
21                   vocate for patients with respect to Lyme  
22                   disease and other tick-borne diseases.

23                   “(v) Other individuals whose expertise  
24                   is determined by the Secretary to be bene-

1                   ficial to the functioning of the Working  
2                   Group.

3                   “(2) APPOINTMENT.—The members of the  
4                   Working Group shall be appointed by the Secretary,  
5                   except that of the non-Federal public members  
6                   under paragraph (1)(B)—

7                   “(A) one shall be appointed by the Speaker  
8                   of the House of Representatives; and

9                   “(B) one shall be appointed by the major-  
10                  ity leader of the Senate.

11                  “(3) DIVERSITY OF SCIENTIFIC PERSPEC-  
12                  TIVES.—In making appointments under paragraph  
13                  (2), the Secretary, the Speaker of the House of Rep-  
14                  resentatives, and the majority leader of the Senate  
15                  shall ensure that the non-Federal public members of  
16                  the Working Group represent a diversity of scientific  
17                  perspectives.

18                  “(4) TERMS.—The non-Federal public members  
19                  of the Working Group shall each be appointed to  
20                  serve a 4-year term and may be reappointed at the  
21                  end of such term.

22                  “(d) MEETINGS.—The Working Group shall meet as  
23                  often as necessary, as determined by the Secretary, but  
24                  not less than twice each year.

1           “(e) APPLICABILITY OF FACCA.—The Working Group  
2 shall be treated as an advisory committee subject to the  
3 Federal Advisory Committee Act.

4           “(f) REPORTING.—Not later than 24 months after  
5 the date of enactment of this part, and every 24 months  
6 thereafter, the Working Group—

7                   “(1) shall submit a report on its activities, in-  
8 cluding an up-to-date summary under subsection  
9 (b)(1) and any recommendations under subsection  
10 (b)(4), to the Secretary, the Committee on Energy  
11 and Commerce of the House of Representatives, and  
12 the Committee on Health, Education, Labor and  
13 Pensions of the Senate;

14                   “(2) shall make each such report publicly avail-  
15 able on the website of the Department of Health and  
16 Human Services; and

17                   “(3) shall allow any member of the Working  
18 Group to include in any such report minority views.

19 **“SEC. 39900-2. STRATEGIC PLAN.**

20           “Not later than 3 years after the date of enactment  
21 of this section, and every 5 years thereafter, the Secretary  
22 shall submit to the Congress a strategic plan, informed  
23 by the most recent summary under section 39900-  
24 1(b)(1), for the conduct and support of Lyme disease and  
25 tick-borne disease research, including—

1           “(1) proposed budgetary requirements;

2           “(2) a plan for improving outcomes of Lyme  
3 disease and other tick-borne diseases, including  
4 progress related to chronic or persistent symptoms  
5 and chronic or persistent infection and co-infections;

6           “(3) a plan for improving diagnosis, treatment,  
7 and prevention;

8           “(4) appropriate benchmarks to measure  
9 progress on achieving the improvements described in  
10 paragraphs (2) and (3); and

11           “(5) a plan to disseminate each summary under  
12 section 39900–1(b)(1) and other relevant informa-  
13 tion developed by the Working Group to the public,  
14 including health care providers, public health depart-  
15 ments, and other relevant medical groups.”.

16       (b) NO ADDITIONAL AUTHORIZATION OF APPRO-  
17 PRIATIONS.—No additional funds are authorized to be ap-  
18 propriated for the purpose of carrying out this section and  
19 the amendment made by this section, and this section and  
20 such amendment shall be carried out using amounts other-  
21 wise available for such purpose.

