COMMITTEE PRINT

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

114TH CONGRESS
1ST SESSION

H. R. _____

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

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''21st Century Cures Act''.

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

TITLE I—DISCOVERY

Subtitle A—National Institutes of Health Funding

SEC. 1001. NATIONAL INSTITUTES OF HEALTH REAUTHORIZATION.

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

(1) in subparagraph (B), by striking at the end ''and'';

(2) in subparagraph (C), by striking at the end the period and inserting ''; and''; and

(3) by adding at the end the following new subparagraphs:

''(D) $31,811,000,000 for fiscal year 2016;

''(E) $33,331,000,000 for fiscal year 2017; and

"(F) $34,851,000,000 for fiscal year 2018.".

SEC. 1002. NIH INNOVATION FUND.

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

(1) in paragraph (23), by striking at the end "and";

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

(3) by inserting after paragraph (24), the following new paragraph:

"(25) shall, with respect to funds appropriated under section 402A(e) to the NIH Innovation Fund, allocate such funds to the national research institutes and national centers for conducting and supporting innovation fund initiatives identified under paragraph (3) of such section.".

(b) ESTABLISHMENT OF INNOVATION FUND.—Section 402A of the Public Health Service Act is amended—

(1) by redesignating subsection (e) as subsection (f); and

(2) by inserting after subsection (d) the following new subsection:

"(e) NIH INNOVATION FUND.—

''(1) ESTABLISHMENT.—For the purpose of allocations under section 402(b)(25), there is established a fund to be known as the NIH Innovation Fund. The Director of NIH shall, with respect to funds appropriated to the NIH Innovation Fund, allocate such funds to support biomedical research through the funding of basic, translational, and clinical research.

''(2) AMOUNTS MADE AVAILABLE TO FUND.—

''(A) IN GENERAL.—Subject to subparagraph (B), there is authorized to be appropriated, and appropriated, to the NIH Innovation Fund out of any funds in the Treasury not otherwise appropriated, $2,000,000,000 for each of fiscal years 2016 through 2020. The amounts appropriated to the Fund by the preceding sentence shall be in addition to any amounts otherwise made available to the National Institutes of Health.

''(B) MAINTAINING BASE APPROPRIATIONS LEVEL.—The amounts appropriated by subparagraph (A) for a fiscal year shall not be available for obligation or expenditure unless and until the total amount of funds made available to the National Institutes of Health for

such fiscal year, without regard to this subsection, are not less than the total amount of funds made available to the National Institutes of Health for fiscal year 2016.

''(C) ALLOCATION OF AMOUNTS.—Of the amounts made available from the NIH Innovation Fund for allocations under section 402(b)(25) for a fiscal year—

''(i) not less than $500,000,000 shall be for the Accelerating Advancement Program under paragraph (5);

''(ii) not less than 35 percent of such amounts remaining after subtracting the allocation for the Accelerating Advancement Program shall be for research under paragraph (3)(B);

''(iii) not less than 20 percent of such amounts remaining after subtracting the allocation for the Accelerating Advancement Program shall be for high-risk, high-reward research under section 409K; and

''(iv) not more than 10 percent of such amounts (without subtracting the allocation for the Accelerating Advancement Program) shall be for intramural research.

''(D) INAPPLICABILITY OF CERTAIN PROVISIONS.—Amounts in the NIH Innovation Fund shall not be subject to—

''(i) any transfer authority of the Secretary or the Director of NIH under section 241, subsection (c), subsection (d), or any other provision of law (other than section 402(b)(25) and this subsection); or

''(ii) the Nonrecurring expenses fund under section 223 of division G of the Consolidated Appropriations Act, 2008 (42 U.S.C. 3514a).

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

''(A) Research in which—

''(i) a principal investigator has a specific project or specific objectives; and

''(ii) funding is tied to pursuit of such project or objectives.

''(B) Research in which—

''(i) a principal investigator has shown promise in biomedical research; and

"(ii) funding is not tied to a specific project or specific objectives.

"(C) Research to be carried out by an early stage investigator (as defined in paragraph (7)).

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

"(E) The Accelerating Advancement Program under paragraph (5).

"(F) Development and implementation of the strategic plan under paragraph (6).

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

"(A) ensure coordination among the national research institutes, the national centers, and other departments, agencies, and offices of the Federal Government; and

"(B) minimize unnecessary duplication.

"(5) ACCELERATING ADVANCEMENT PROGRAM.—The Director of NIH shall establish a program, to be known as the Accelerating Advancement Program, under which—

''(A) the Director of NIH partners with national research institutes and national centers to accomplish important biomedical research objectives; and

''(B) for every $1 made available by the Director of NIH to a national research institute or national center for a research project, the institute or center makes $1 available for such project from funds that are not derived from the NIH Innovation Fund.

''(6) STRATEGIC PLAN.—

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

''(i) is designed to increase the efficient and effective focus of biomedical research in a manner that leverages the best scientific opportunities through a deliberative planning process;

''(ii) identifies areas, to be known as strategic focus areas, in which the resources of the NIH Innovation Fund can

contribute to the goals of expanding knowledge to address, and find more effective treatments for, unmet medical needs in the United States, including the areas of—

''(I) biomarkers;

''(II) precision medicine;

''(III) infectious diseases, including pathogens listed as a qualifying pathogen under section 505E(f) of the Federal Food, Drug, and Cosmetic Act or listed or designated as a tropical disease under section 524 of such Act; and

''(IV) antibiotics;

''(iii) includes objectives for each such strategic focus area; and

''(iv) ensures that basic research remains a priority.

''(B) UPDATES AND REVIEWS.—The Director shall review and, as appropriate, update the research strategic plan under subparagraph (A) not less than every 18 months.

''(7) DEFINITION.—In this subsection, the term 'early stage investigator' means an investigator who—

''(A) will be the principal investigator or the program director of the proposed research;

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

''(C) is within 10 years of having completed—

''(i) the investigator's terminal degree; or

''(ii) a medical residency (or the equivalent).''.

Subtitle B—National Institutes of Health Planning and Administration

SEC. 1021. NIH RESEARCH STRATEGIC PLAN.

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

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

''(5) shall ensure that scientifically based strategic planning is implemented in support of research priorities as determined by the agencies of the National Institutes of Health, including through devel-

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

(2) by adding at the end the following:

''(m) RESEARCH STRATEGIC PLAN.—

''(1) FIVE-YEAR PLANS FOR BIOMEDICAL RESEARCH STRATEGY.—

''(A) IN GENERAL.—For each successive five-year period beginning with the period of fiscal years 2016 through 2020, the Director of NIH, in consultation with the entities described in subparagraph (B), shall develop and maintain a biomedical research strategic plan.

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

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

''(A) to identify research opportunities; and

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

tional research institutes and national centers that—

''(i) have a common template; and

''(ii) identify strategic focus areas in which the resources of the national research institutes and national centers can best contribute to the goal of expanding knowledge on human health in the United States through biomedical research.

''(3) CONTENTS OF PLANS.—

''(A) STRATEGIC FOCUS AREAS.—The strategic focus areas identified pursuant to paragraph (2)(B) shall—

''(i) be identified in a manner that—

''(I) considers the return on investment to the United States public through the investments of the National Institutes of Health in biomedical research; and

''(II) contributes to expanding knowledge to improve the United States public's health through biomedical research; and

''(ii) include overarching and trans-National Institutes of Health strategic

focus areas, to be known as Mission Priority Focus Areas, which best serve the goals of preventing or eliminating the burden of a disease or condition and scientifically merit enhanced and focused research over the next 5 years.

''(B) RARE AND PEDIATRIC DISEASES AND CONDITIONS.—In developing and maintaining a strategic plan under this subsection, the Director of NIH shall ensure that rare and pediatric diseases and conditions remain a priority.

''(4) INITIAL PLAN.—Not later than 270 days after the date of enactment of this subsection, the Director of NIH and the directors of the national research institutes and national centers shall—

''(A) complete the initial strategic plan required by paragraphs (1) and (2); and

''(B) make such initial strategic plan publicly available on the website of the National Institutes of Health.

''(5) REVIEW; UPDATES.—

''(A) PROGRESS REVIEWS.—Not less than annually, the Director of NIH, in consultation with the directors of the national research institutes and national centers, shall conduct

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

''(B) UPDATES.—Not later than the end of the 5-year period covered by the initial strategic plan under this subsection, and every 5 years thereafter, the Director of NIH, in consultation with the directors of the national research institutes and national centers, stakeholders in the scientific field, advocates, and the public at large, shall—

''(i) conduct a review of the plan, including each strategic focus area identified under paragraph (2)(B); and

''(ii) update such plan in accordance with this section.''.

SEC. 1022. INCREASING ACCOUNTABILITY AT THE NATIONAL INSTITUTES OF HEALTH.

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

''(a) APPOINTMENT; TERMS.—

''(1) APPOINTMENT.—The Director of the National Cancer Institute shall be appointed by the President and the directors of the other national re-

search institutes, as well as the directors of the national centers, shall be appointed by the Director of NIH. The directors of the national research institutes, as well as national centers, shall report directly to the Director of NIH.

''(2) TERMS.—

''(A) IN GENERAL.—The term of office of a director of a national research institute or national center shall be 5 years.

''(B) REMOVAL.—The director of a national research institute or national center may be removed from office by the Director of NIH prior to the expiration of such director's 5-year term.

''(C) REAPPOINTMENT.—At the end of the term of a director of a national research institute or national center, the director may be reappointed. There is no limit on the number of terms a director may serve.

''(D) VACANCIES.—If the office of a director of a national research institute or national center becomes vacant before the end of such director's term, the director appointed to fill the vacancy shall be appointed for a 5-year term starting on the date of such appointment.

''(E) TRANSITIONAL PROVISION.—Each director of a national research institute or national center serving on the date of enactment of the 21st Century Cures Act is deemed to be appointed for a 5-year term under this subsection starting on such date of enactment.''.

(b) COMPENSATION TO CONSULTANTS OR INDIVIDUAL SCIENTISTS.—Section 202 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1993 (Public Law 102–394; 42 U.S.C. 238f note) is amended by striking ''portable structures;'' and all that follows and inserting ''portable structures.''.

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

''(3) Before an award is made by a national research institute or by a national center for a grant for a research program or project (commonly referred to as an 'R-series grant'), other than an award constituting a noncompeting renewal of such grant, or a noncompeting administrative supplement to such grant, the director of such national research institute or national center—

''(A) shall review and approve the award; and

''(B) shall take into consideration—

''(i) the mission of the national research institute or national center and the scientific priorities identified in the strategic plan under section 402(m); and

''(ii) whether other agencies are funding programs or projects to accomplish the same goal.''.

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

(1) complete a study on the extent to which biomedical research conducted or supported by Federal agencies is duplicative; and

(2) submit a report to the Congress on the results of such study, including recommendations on how to prevent such duplication.

[SEC. 1023. BIOMEDICAL RESEARCH WORKING GROUP.

[(a) ESTABLISHMENT.—There is established a working group to be known as the ''Biomedical Research Working Group''.]

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

[(1) provide recommendations to the Director of the National Institutes of Health to reduce administrative burdens of researchers funded by the National Institutes of Health, including with respect to the extent to which (and how) grant proposals, grant review, and management should be restructured, streamlined, and simplified;]

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

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

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

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

[(2) representatives of the Office of the Director; and]

[(3) representatives of other national research institutes and national centers of the National Institutes of Health, as determined necessary.]

[(d) IMPLEMENTATION OF MEASURES TO REDUCE ADMINISTRATIVE BURDENS.—The Director of the National Institutes of Health, taking into account the recommendations, evaluations, and plan described in subsection (b), shall implement measures to reduce the administrative burdens of researchers funded by the National Institutes of Health.]

[(e) REPORTS.—]

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

[(2) REPORT BY DIRECTOR OF NIH ON IMPLEMENTATION OF MEASURES TO REDUCE ADMINISTRATIVE BURDENS.—The Director of the National Institutes of Health shall submit to Congress a report on the extent to which the Director has implemented measures pursuant to subsection (d).]

SEC. 1024. EXEMPTION FOR THE NATIONAL INSTITUTES OF HEALTH FROM THE PAPERWORK REDUCTION ACT REQUIREMENTS.

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

(1) in subparagraph (C), by striking ''; or'' and inserting a semicolon;

(2) in subparagraph (D), by striking the period at the end and inserting ''; or''; and

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

''(E) during the conduct of research by the National Institutes of Health.''.

SEC. 1025. NIH TRAVEL.

It is the sense of Congress that participation in or sponsorship of scientific conferences and meetings is essential to the mission of the National Institutes of Health.

SEC. 1026. OTHER TRANSACTIONS AUTHORITY.

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

(1) in subsection (b), by striking ''the appropriation of funds as described in subsection (g)'' and inserting ''the availability of funds as described in subsection (f)'';

(2) in subsection (e)(3), by amending subparagraph (C) to read as follows:

''(C) OTHER TRANSACTIONS AUTHORITY.—The Director of the Center shall have other transactions authority in entering into transactions to fund projects in accordance with the terms and conditions of this section.'';

(3) by striking subsection (f); and

(4) by redesignating subsection (g) as subsection (f).

SEC. 1027. NCATS PHASE IIB RESTRICTION.

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

(1) prior to making the amendments under paragraph (2), by striking ''IIB'' each place it appears and inserting ''III''; and

(2) by striking ''IIA'' each place it appears and inserting ''IIB''.

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

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

''SEC. 409K. HIGH-RISK, HIGH-REWARD RESEARCH PROGRAM.

''The director of each national research institute shall, as appropriate—

''(1) establish programs to conduct or support research projects that pursue innovative approaches to major contemporary challenges in biomedical research that involve inherent high risk, but have the potential to lead to breakthroughs; and

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

Subtitle C—Supporting Young Emerging Scientists

SEC. 1041. IMPROVEMENT OF LOAN REPAYMENT PROGRAMS OF NATIONAL INSTITUTES OF HEALTH.

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

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

(2) by inserting after section 487G, as so redesignated, the following:

''SEC. 487H. LOAN REPAYMENT PROGRAM.

''(a) IN GENERAL.—The Secretary shall establish a program, based on workforce and scientific needs, of entering into contracts with qualified health professionals under which such health professionals agree to engage in

research in consideration of the Federal Government agreeing to pay, for each year of engaging in such research, not more than $50,000 of the principal and interest of the educational loans of such health professionals.

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

''(c) LIMITATION.—The Secretary may not enter into a contract with a health professional pursuant to subsection (a) unless such professional has a substantial amount of educational loans relative to income.

''(d) APPLICABILITY OF CERTAIN PROVISIONS REGARDING OBLIGATED SERVICE.—Except to the extent inconsistent with this section, the provisions of sections 338B, 338C, and 338E shall apply to the program established under this section to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established under section 338B.

''(e) AVAILABILITY OF APPROPRIATIONS.—Amounts appropriated for a fiscal year for contracts under subsection (a) are authorized to remain available until the ex-

piration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.''.

(b) UPDATE OF OTHER LOAN REPAYMENT PROGRAMS.—

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

(A) in subsection (a), by striking ''$35,000'' and inserting ''$50,000''; and

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

(2) LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME.—Section 487A(a) of such Act (42 U.S.C. 288–1(a)) is amended—

(A) by striking ''$35,000'' and inserting ''$50,000''; and

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

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

(3) LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO CONTRACEPTION AND INFERTILITY.—Section 487B(a) of such Act (42 U.S.C. 288–2(a)) is amended—

(A) by striking ''$35,000'' and inserting ''$50,000''; and

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

(4) LOAN REPAYMENT PROGRAM FOR RESEARCH GENERALLY.—Section 487C(a)(1) of such Act (42 U.S.C. 288–3(a)(1)) is amended—

(A) by striking ''$35,000'' and inserting ''$50,000''; and

(B) by adding at the end the following new sentence: ''Subsection (b) of section 487H shall apply with respect to the maximum amount specified in this paragraph in the same manner

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

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

(A) by striking ''$35,000'' and inserting ''$50,000''; and

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

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

(A) by striking ''$35,000'' and inserting ''$50,000''; and

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

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

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

(A) in subsection (a)(1), by striking ''$35,000'' and inserting ''$50,000'';

(B) in subsection (b), by adding at the end the following new sentence: ''Subsection (b) of section 487H shall apply with respect to the maximum amount specified in subsection (a)(1) in the same manner as it applies to the maximum amount specified in such subsection (a) of such section.''; and

(C) by redesignating such section as section 487G.

SEC. 1042. REPORT.

Not later than 18 months after the date of the enactment of this Act, the Director of the National Institutes of Health shall submit to Congress a report on efforts of the National Institutes of Health to attract, retain, and develop emerging scientists.

Subtitle D—Capstone Grant Program

SEC. 1061. CAPSTONE AWARD.

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

"SEC. 490. CAPSTONE AWARD.

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

''(b) PURPOSE.—Capstone Awards shall be made to facilitate the successful transition or conclusion of research programs, or for other purposes, as determined by the Director of NIH, in consultation with the directors of the national research institutes and national centers.

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

''(d) LIMITATION.—Individuals who have received a Capstone Award shall not be eligible to have principle investigator status on subsequent awards from the National Institutes of Health.''.

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

SEC. 1081. NATIONAL PEDIATRIC RESEARCH NETWORK.

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

(1) in paragraph (1)—

(A) by striking ''in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and in collaboration with other appropriate national research institutes and national centers that carry out activities involving pediatric research'' and inserting ''in collaboration with the national research institutes and national centers that carry out activities involving pediatric research'';

(B) by striking subparagraph (B);

(C) by striking ''may be comprised of, as appropriate'' and all that follows through ''the pediatric research consortia'' and inserting ''may be comprised of, as appropriate, the pediatric research consortia''; and

(D) by striking ''; or'' at the end and inserting a period; and

(2) in paragraph (1), paragraph (2)(A), the first sentence of paragraph (2)(E), and paragraph (4), by striking ''may'' each place it appears and inserting ''shall''.

SEC. 1082. GLOBAL PEDIATRIC CLINICAL TRIAL NETWORK SENSE OF CONGRESS.

It is the sense of Congress that—

(1) the National Institutes of Health should encourage a global pediatric clinical trial network through the allocation of grants, contracts, or cooperative agreements to supplement the salaries of new and early investigators who participate in the global pediatric clinical trial network;

(2) National Institutes of Health grants, contracts, or cooperative agreements should be awarded, solely for the purpose of supplementing the salaries of new and early investigators, to entities that participate in the global pediatric clinical trial network;

(3) the Food and Drug Administration should engage the European Medicines Agency and other foreign regulatory entities during the formation of the global pediatric clinical trials network to encourage their participation; and

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

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

SEC. 1083. APPROPRIATE AGE GROUPINGS IN CLINICAL RESEARCH.

(a) INPUT FROM EXPERTS.—Not later than 180 days after the date of enactment of this Act, the Director of the National Institutes of Health shall convene a workshop of experts on pediatrics and experts on geriatrics to provide input on—

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

(2) acceptable scientific justifications for excluding participants from a range of age groups from human subjects research studies.

(b) GUIDELINES.—Not later than 180 days after the conclusion of the workshop under subsection (a), the Director of the National Institutes of Health shall publish guidelines—

(1) addressing the consideration of age as an inclusion variable in research involving human subjects; and

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

(c) PUBLIC AVAILABILITY OF FINDINGS AND CONCLUSIONS.—The Director of the National Institutes of Health shall—

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

(2) not less than biennially, disclose to the public on such website the number of children included in research that is conducted or supported by the National Institutes of Health, disaggregated by developmentally appropriate age group, race, and gender.

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

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

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

"SEC. 498E. SHARING OF DATA GENERATED THROUGH NIH-FUNDED RESEARCH.

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

"(b) LIMITATION.—The Director of NIH shall not require as a condition on the award of a grant or the provision of other financial support for research under subsection (a) the sharing of—

"(1) any individually identifiable information with respect to a human subject participating in the research; or

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

SEC. 1102. STANDARDIZATION OF DATA IN CLINICAL TRIAL REGISTRY DATA BANK ON ELIGIBILITY FOR CLINICAL TRIALS.

(a) STANDARDIZATION.—

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

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

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

''(7) STANDARDIZATION.—The Director of NIH shall—

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

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

''(C) ensure that information required to be submitted to the registry and results data bank, including recruitment information under paragraph (2)(A)(ii)(II), is submitted by persons and posted by the Director of NIH in a standardized format and shall include at least—

''(i) the disease or indication being studied;

''(ii) inclusion criteria such as age, gender, diagnosis or diagnoses, lab values, or imaging results; and

''(iii) exclusion criteria such as specific diagnosis or diagnoses, lab values, or prohibited medications; and

''(D) to the extent possible, in carrying out this paragraph, make use of standard health care terminologies, such as the International Classification of Diseases or the Current Procedural Terminology, that facilitate electronic matching to data in electronic health records or other relevant health information technologies.''.

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

(b) CONSULTATION.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall consult with stakeholders (including patients, researchers, physicians, industry representatives, health information technology providers, the Food and Drug Administration, and standard setting organizations such as CDISC that have experience working with Federal agencies to standardize health data submissions) to receive advice on enhancements to the clinical trial registry data bank under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)) (including enhance-

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

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

Subtitle G—Facilitating Collaborative Research

SEC. 1121. CLINICAL TRIAL DATA SYSTEM.

(a) ESTABLISHMENT.—The Secretary, acting through the Commissioner of Food and Drugs and the Director of the National Institutes of Health, shall enter into a collaborative agreement for a period of 7 years, to be known as the Clinical Trial Data System Agreement, with one or more eligible entities to implement a pilot program with respect to all clinical trial data obtained from qualified clinical trials for purposes of conducting further research on such data.

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

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

(1) A certification that each applicant is not currently and does not plan to be involved in sponsoring, operating, or participating in a clinical trial nor collaborating with another entity for the purposes of sponsoring, operating, or participating in a clinical trial.

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

(3) Documentation establishing that each applicant has a plan in place to allow registered users to access and use de-identified clinical trial data, gathered from qualified clinical trials, available under carefully controlled contractual terms as defined by the Secretary.

(4) Evidence demonstrating the ability to ensure dissemination of the results of the research to

interested parties to serve as a guide to future medical product development or scientific research.

(5) The plan of each applicant for securing funding for the partnership described in paragraph (2) from governmental sources and private foundations, entities, and individuals.

(6) Evidence demonstrating a proven track record of—

(A) being a neutral third party in working with medical product manufacturers, academic institutions, and the Food and Drug Administration; and

(B) having the ability to protect confidential data.

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

(d) REPORTS.—

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

the eligible entities entering into a cooperative agreement with the Secretary under such section shall submit to Congress a report that—

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

(B) makes recommendations to the Secretary and the Congress on improvements to the program.

(2) GAO INTERIM AND FINAL REPORT.—

(A) IN GENERAL.—The Comptroller General of the United States shall submit to Congress two reports, with respect to the pilot program established under subsection (a), that contains the following information:

(i) The new discoveries, research inquiries, or clinical trials that have resulted from accessing clinical trial data under the program.

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

(iii) An analysis of whether the program has helped reduce adverse events in clinical trials.

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

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

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

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

(B) makes recommendations to the Secretary and the Congress on improvements to the program;

(e) DEFINITIONS.—In this section:

(1) The term ''eligible entity'' means an entity that has experienced personnel with clinical and other technical expertise in the biomedical sciences and biomedical ethics and that is—

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

(B) an organization described in section 501(c)(3) of title 26 of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such title.

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

(3) The term ''qualified clinical trial'' means a clinical trial sponsored solely by an agency of the Department of Health and Human Services with respect to a medical product—

(A) that was—

(i) approved or cleared under section 505, 510(k), or 515, or has an exemption for investigational use in effect under section 505 or 520(m), of the Federal Food,

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

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

(B) that is an investigational product for which the original development was discontinued and with respect to which—

(i) no additional work to support approval, licensure, or clearance of such medical product is being or is planned to be undertaken by the sponsor of the original development program, its successors, assigns, or collaborators; and

(ii) the sponsor of the original investigational development program has provided its consent to the Secretary for inclusion of data regarding such product in the system established under this section.

SEC. 1122. NATIONAL NEUROLOGICAL DISEASES SURVEILLANCE SYSTEM.

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

"SEC. 399V–6 SURVEILLANCE OF NEUROLOGICAL DISEASES.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other agencies as determined appropriate by the Secretary, shall—

''(1) enhance and expand infrastructure and activities to track the epidemiology of neurological diseases, including multiple sclerosis and Parkinson's disease; and

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

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

''(c) CONTENT.—In carrying out subsection (a), the Secretary—

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

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

tion on neurological diseases, such as information concerning—

''(A) demographics and other information associated or possibly associated with neurological diseases, such as age, race, ethnicity, sex, geographic location, and family history;

''(B) risk factors associated or possibly associated with neurological diseases, including genetic and environmental risk factors; and

''(C) diagnosis and progression markers;

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

''(A) the epidemiology of the diseases;

''(B) the natural history of the diseases;

''(C) the prevention of the diseases;

''(D) the detection, management, and treatment approaches for the diseases; and

''(E) the development of outcomes measures; and

''(4) may address issues identified during the consultation process under subsection (d).

''(d) CONSULTATION.—In carrying out this section, the Secretary shall consult with individuals with appropriate expertise, including—

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

''(2) representatives of national voluntary health associations that—

''(A) focus on neurological diseases, including multiple sclerosis and Parkinson's disease; and

''(B) have demonstrated experience in research, care, or patient services;

''(3) health information technology experts or other information management specialists;

''(4) clinicians with expertise in neurological diseases; and

''(5) research scientists with experience conducting translational research or utilizing surveillance systems for scientific research purposes.

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

''(f) COORDINATION WITH OTHER FEDERAL, STATE, AND LOCAL AGENCIES.—Subject to subsection (h), the Secretary shall make information and analysis in the National Neurological Diseases Surveillance System available, as appropriate—

''(1) to Federal departments and agencies, such as the National Institutes of Health, the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Agency for Healthcare Research and Quality, the Department of Veterans Affairs, and the Department of Defense; and

''(2) to State and local agencies.

''(g) PUBLIC ACCESS.—Subject to subsection (h), the Secretary shall make information and analysis in the National Neurological Diseases Surveillance System available, as appropriate, to the public, including researchers.

''(h) PRIVACY.—The Secretary shall ensure that privacy and security protections applicable to the National Neurological Diseases Surveillance System are at least as stringent as the privacy and security protections under HIPAA privacy and security law (as defined in section 3009(a)(2)).

''(i) REPORT.—Not later than 4 years after the date of the enactment of this section, the Secretary shall submit a report to the Congress concerning the implementation of this section. Such report shall include information on—

''(1) the development and maintenance of the National Neurological Diseases Surveillance System;

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

''(3) the use and availability of such information, including guidelines for such use; and

''(4) the use and coordination of databases that collect or maintain information on neurological diseases.

''(j) DEFINITION.—In this section, the term 'national voluntary health association' means a national nonprofit organization with chapters, other affiliated organizations, or networks in States throughout the United States.

''(k) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $5,000,000 for each of fiscal years 2016 through 2020.''.

SEC. 1123. DATA ON NATURAL HISTORY OF DISEASES.

(a) SENSE OF CONGRESS.—It is the sense of the Congress that studies on the natural history of diseases can help facilitate and expedite the development of medical products for such diseases.

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

"SEC. 229A. DATA ON NATURAL HISTORY OF DISEASES.

''(a) IN GENERAL.—The Secretary may, for the purposes described in subsection (b)—

''(1) participate in public-private partnerships engaged in one or more activities specified in subsection (c); and

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

''(b) PURPOSES DESCRIBED.—The purposes described in this subsection are to establish or facilitate the collection, maintenance, analysis, and interpretation of data regarding the natural history of diseases, with a particular focus on rare diseases.

''(c) ACTIVITIES OF PUBLIC-PRIVATE PARTNERSHIPS.—The activities of public-private partnerships in which the Secretary may participate for purposes of this section include—

''(1) cooperating with other entities to sponsor or maintain disease registries, including disease registries and disease registry platforms for rare diseases;

''(2) developing or enhancing a secure information technology system that—

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

''(B) is easily modified as knowledge is gained during such studies; and

''(C) is capable of handling increasing amounts of data as more studies are carried out; and

''(3) providing advice to clinical researchers, patient advocacy groups, and other entities with respect to—

''(A) the design and conduct of disease studies;

''(B) the modification of any such ongoing studies; and

''(C) addressing associated patient privacy issues.

''(d) AVAILABILITY OF DATA ON NATURAL HISTORY OF DISEASES.—Data relating to the natural history of diseases obtained, aggregated, or otherwise maintained by a public-private partnership in which the Secretary participates under subsection (a) shall be made available, consistent with otherwise applicable Federal and State privacy laws, to the public (including patient advocacy groups, researchers, and drug developers) to help facilitate and expedite medical product development programs.

''(e) CONFIDENTIALITY.—Notwithstanding subsection (d), nothing in this section authorizes the disclo-

sure of any information that is a trade secret or commercial or financial information that is privileged or confidential and subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

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

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

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

"PART 4—ACCESSING, SHARING, AND USING HEALTH DATA FOR RESEARCH PURPOSES

"SEC. 13441. REFERENCES.

''In this part:

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

''(b) PART 164.—References to a specified section of 'part 164', refer to such specified section of part 164 of title 45, Code of Federal Regulations (or any successor section).

"SEC. 13442. DEFINING HEALTH DATA RESEARCH AS PART OF HEALTH CARE OPERATIONS.

''(a) IN GENERAL.—Subject to subsection (b), the Secretary shall revise or clarify the rule to allow the use and disclosure of protected health information by a covered entity for research purposes, including studies whose purpose is to obtain generalizable knowledge, to be treated as the use and disclosure of such information for health care operations described in subparagraph (1) of the definition of health care operations in section 164.501 of part 164.

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

''(1) the Secretary shall revise or clarify the Rule so that the disclosure may be made by the covered entity to only—

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

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

''(C) a business associate that has entered into a contract under section 164.504(e) of part 164 for the purpose of data aggregation (as defined in such section 164.501 of part 164); and

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

''(c) RULE OF CONSTRUCTION.—This section shall not be construed as prohibiting or restricting a use or disclosure of protected health information for research purposes that is otherwise permitted under part 164.

''SEC. 13443. TREATING DISCLOSURES OF PROTECTED HEALTH INFORMATION FOR RESEARCH SIMILARLY TO DISCLOSURES OF SUCH INFORMATION FOR PUBLIC HEALTH PURPOSES.

''(a) REMUNERATION.—The Secretary shall revise or clarify the Rule so that disclosures of protected health information for research purposes are not subject to the limitation on remuneration described in section 164.502(a)(5)(ii)(B)(2)(ii) of part 164.

''(b) PERMITTED USES AND DISCLOSURES.—The Secretary shall revise or clarify the Rule so that research activities, including comparative research activities, related to the quality, safety, or effectiveness of a product

or activity that is regulated by the Food and Drug Administration are included as public health activities for purposes of which a covered entity may disclose protected health information to a person described in section 164.512(b)(1)(iii) of part 164.

"SEC. 13444. PERMITTING REMOTE ACCESS TO PROTECTED HEALTH INFORMATION BY RESEARCHERS.

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

''(1) appropriate security and privacy safeguards are maintained by the covered entity and the researcher; and

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

"SEC. 13445. ALLOWING ONE-TIME AUTHORIZATION OF USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES.

''(a) IN GENERAL.—The Secretary shall revise or clarify the Rule to specify that an authorization for the use or disclosure of protected health information, with respect to an individual, for future research purposes shall

be deemed to contain a sufficient description of the purpose of the use or disclosure if the authorization—

''(1) sufficiently describes the purposes such that it would be reasonable for the individual to expect that the protected health information could be used or disclosed for such future research;

''(2) either—

''(A) states that the authorization will expire on a particular date or on the occurrence of a particular event; or

''(B) states that the authorization will remain valid unless and until it is revoked by the individual; and

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

''(b) REVOCATION OF AUTHORIZATION.—The Secretary shall revise or clarify the Rule to specify that, if an individual revokes an authorization for future research purposes such as is described by subsection (a), the covered entity may not make any further uses or disclosures based on that authorization, except, as provided in paragraph (b)(5) of section 164.508 of part 164, to the extent that the covered entity has taken action in reliance on the authorization.''.

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

Subtitle H—Council for 21st Century Cures

SEC. 1141. COUNCIL FOR 21ST CENTURY CURES.

Title II of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by adding at the end the following:

"PART E—COUNCIL FOR 21ST CENTURY CURES

"SEC. 281. ESTABLISHMENT.

''A nonprofit corporation to be known as the Council for 21st Century Cures (referred to in this part as the 'Council') shall be established in accordance with this section. The Council shall be a public-private partnership headed by an Executive Director (referred to in this part as the 'Executive Director'), appointed by the members of the Board of Directors. The Council shall not be an agency or instrumentality of the United States Government.

"SEC. 281A. PURPOSE.

"The purpose of the Council is to accelerate the discovery, development, and delivery in the United States of innovative cures, treatments, and preventive measures for patients.

"SEC. 281B. DUTIES.

"For the purpose described in section 281A, the Council shall—

"(1) foster collaboration and coordination among the entities that comprise the Council, including academia, government agencies, industry, health care payors and providers, patient advocates, and others engaged in the cycle of discovery, development, and delivery of life-saving and health-enhancing innovative interventions;

"(2) undertake communication and dissemination activities;

"(3) publish information on the activities funded under section 281D;

"(4) establish a strategic agenda for accelerating the discovery, development, and delivery in the United States of innovative cures, treatments, and preventive measures for patients;

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

''(6) develop and propose recommendations based on the gaps and opportunities so identified;

''(7) facilitate the interoperability of the components of the discovery, development, and delivery cycle;

''(8) propose recommendations that will facilitate precompetitive collaboration;

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

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

''SEC. 281C. ORGANIZATION; ADMINISTRATION.

''(a) BOARD OF DIRECTORS.—

''(1) ESTABLISHMENT.—

''(A) IN GENERAL.—The Council shall have a Board of Directors (in this part referred to as the 'Board of Directors'), which shall be composed of the ex officio members under subparagraph (B) and the appointed members under subparagraph (C). All members of the Board shall be voting members.

''(B) EX OFFICIO MEMBERS.—The ex officio members of the Board shall be the following individuals or their designees:

''(i) The Director of the National Institutes of Health.

''(ii) The Commissioner of Food and Drugs.

''(iii) The Administrator of the Centers for Medicare & Medicaid Services.

''(iv) The heads of five other Federal agencies deemed by the Secretary to be engaged in biomedical research and development.

''(C) APPOINTED MEMBERS.—The appointed members of the Board shall consist of 17 individuals, of whom—

''(i) 8 shall be by the Comptroller General of the United States from a list of nominations submitted by leading trade associations—

''(I) 4 of whom shall be representatives of the biopharmaceutical industry;

''(II) 2 of whom shall be representatives of the medical device industry; and

''(III) 2 of whom shall be representatives of the information and digital technology industry; and

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

''(I) 2 of whom shall be representatives of academic researchers;

''(II) 3 of whom shall be representative of patients;

''(III) 2 of whom shall be representatives of health care providers; and

''(IV) 2 of whom shall be representatives of health care plans and insurers.

''(D) CHAIR.—The Chair of the Board shall be selected by the members of the Board by majority vote from among the members of the Board.

''(2) TERMS AND VACANCIES.—

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

''(B) VACANCY.—Any vacancy in the membership of the Board—

''(i) shall not affect the power of the remaining members to execute the duties of the Board; and

''(ii) shall be filled by appointment by the appointed members described in paragraph (1)(C) by majority vote.

''(C) PARTIAL TERM.—If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed under subparagraph (B) to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

''(3) RESPONSIBILITIES.—Not later than 90 days after the date on which the Council is incorporated and its Board of Directors is fully constituted, the Board of Directors shall establish bylaws and policies for the Council that—

''(A) are published in the Federal Register and available for public comment;

''(B) establish policies for the selection and, as applicable, appointment of—

''(i) the officers, employees, agents, and contractors of the Council; and

''(ii) the members of any committees of the Council;

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

''(D) establish specific duties of the Executive Director.

''(4) MEETINGS.—

''(A) IN GENERAL.—the Board of Directors shall—

''(i) meet on a quarterly basis; and

''(ii) submit to Congress, and make publicly available, the minutes of such meetings.

''(B) AGENDA.—The Board of Directors shall, not later than 3 months after the incorporation of the Council—

''(i) issue an agenda (in this part referred to as the 'agenda') outlining how the Council will achieve the purpose described in section 281A; and

''(ii) annually thereafter, in consultation with the Executive Director, review and update such agenda.

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

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

''(2) the ex officio members of the Board of Directors under subsection (a)(1)(B) shall serve as incorporators and shall take whatever actions are necessary to incorporate the Council.

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

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

''(2) is, under subsection (a) of such section, exempt from taxation.

''(d) EXECUTIVE DIRECTOR.—The Executive Director shall—

''(1) be the chief executive officer of the Council; and

''(2) subject to the oversight of the Board of Directors, be responsible for the day-to-day management of the Council.

''SEC. 281D. OPERATIONAL ACTIVITIES AND ASSISTANCE.

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

''(b) PRIVATE SECTOR MATCHING FUNDS.—The Council may accept financial or in-kind support from participating entities or private foundations or organizations when such support is deemed appropriate.

''SEC. 281E. TERMINATION; REPORT.

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

''(b) REPORT.—Not later than one year after the date on which the Council is established and each year thereafter, the Executive Director shall submit to the appropriate congressional committees a report on the performance of the Council. In preparing such report, the Council shall consult with a nongovernmental consultant with appropriate expertise.

"SEC. 281F. FUNDING.

"For the each of fiscal years 2016 through 2023, there is authorized to be appropriated $10,000,000 to the Council for purposes of carrying out the duties of the Council under this part.".

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.

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

(1) in subsection (d), by striking "The Secretary shall implement" and all that follows through "premarket approval of a drug."; and

(2) by adding at the end the following new subsections:

"(x) STRUCTURED RISK-BENEFIT ASSESSMENT FRAMEWORK.—

"(1) IN GENERAL.—The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process—

"(A) to facilitate the balanced consideration of benefits and risks; and

"(B) to develop and implement a consistent and systematic approach to the discussion of, regulatory decisionmaking with respect to, and the communication of, the benefits and risks of new drugs.

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

"(y) DEVELOPMENT AND USE OF PATIENT EXPERIENCE DATA TO ENHANCE STRUCTURED RISK-BENEFIT ASSESSMENT FRAMEWORK.—

"(1) IN GENERAL.—Not later than two years after the date of the enactment of this subsection, the Secretary shall establish and implement processes under which—

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

"(i) initial research concepts for feedback from the Secretary; and

"(ii) with respect to patient experience data collected by the entity, draft guidance documents, completed data, and summaries and analyses of such data;

''(B) the Secretary may request such an entity to submit such documents, data, and summaries and analyses; and

''(C) patient experience data may be developed and used to enhance the structured risk-benefit assessment framework under subsection (x).

''(2) PATIENT EXPERIENCE DATA.—In this subsection, the term 'patient experience data' means data collected by patients, parents, caregivers, patient advocacy organizations, disease research foundations, medical researchers, research sponsors, or other parties determined appropriate by the Secretary that is intended to facilitate or enhance the Secretary's risk-benefit assessments, including information about the impact of a disease or a therapy on patients' lives.''.

(b) GUIDANCE.—

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

(A) with respect to draft guidance documents, data, or summaries and analyses submitted to the Secretary under paragraph (1)(A) of such subsection, guidance—

(i) specifying the timelines for the review of such documents, data, or summaries and analyses by the Secretary; and

(ii) on how the Secretary will use such documents, data, or summaries and analyses to update any guidance documents published under this subsection or publish new guidance;

(B) with respect to the collection and analysis of patient experience data (as defined in paragraph (2) of such subsection (y)), guidance on—

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

(I) the experience of a patient living with a particular disease;

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

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

(IV) the effect of current therapeutic options on different aspects of the disease; and

(ii) the establishment and maintenance of registries designed to increase understanding of the natural history of a disease;

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

(D) methodologies, standards, and potential experimental designs for patient-reported outcomes.

(2) TIMING.—Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue draft guidance on the implementation of subsection (y) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as added by subsection (a). The Secretary shall issue final guidance on the implementation of such subsection not later than one

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

(3) WORKSHOPS.—

(A) IN GENERAL.—Not later than 6 months after the date of the enactment of this Act and once every 6 months during the following 12-month period, the Secretary of Health and Human Services shall convene a workshop to obtain input regarding methodologies for developing the guidance under paragraph (1), including the collection of patient experience data.

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

(i) patients;

(ii) representatives from patient advocacy organizations, biopharmaceutical companies, and disease research foundations;

(iii) representatives of the reviewing divisions of the Food and Drug Administration; and

(iv) methodological experts with significant expertise in patient experience data.

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

Subtitle B—Qualification and Use of Drug Development Tools

SEC. 2021. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.

(a) FINDINGS.—Congress finds the following:

(1) Development of new drugs has become increasingly challenging and resource intensive.

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

(3) Biomedical research consortia, consisting of public-private partnerships of government agencies, institutions of higher education, patient advocacy groups, industry representatives, clinical and scientific experts, and other relevant entities and individuals can play a valuable role in helping develop and qualify drug development tools.

(b) SENSE OF CONGRESS.—It is the sense of Congress that—

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

(A) to develop, through a transparent public process, data standards and scientific approaches to data collection accepted by the medical and clinical research community for purposes of qualifying drug development tools;

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

(C) to encourage the development of accessible databases for collecting relevant drug development tool data for such purposes; and

(2) an entity seeking to qualify a drug development tool should be encouraged, in addition to consultation with the Secretary, to consult with biomedical research consortia and other individuals and entities with expert knowledge and insights that may assist the requestor and benefit the process for such qualification.

(c) QUALIFICATION OF DRUG DEVELOPMENT TOOLS.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 506F the following new section:

"SEC. 507. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.

"(a) PROCESS FOR QUALIFICATION.—

"(1) IN GENERAL.—The Secretary shall establish a process for the qualification of drug development tools for a proposed context of use under which—

"(A)(i) a requestor initiates such process by submitting a letter of intent to the Secretary; and

"(ii) the Secretary shall accept or decline to accept such letter of intent;

"(B)(i) if the Secretary accepts the letter of intent, a requestor shall submit a qualification plan to the Secretary; and

"(ii) the Secretary shall accept or decline to accept the qualification plan; and

"(C)(i) if the Secretary accepts the qualification plan, the requestor submits to the Secretary a full qualification package;

"(ii) the Secretary shall determine whether to accept such qualification package for review; and

"(iii) if the Secretary accepts such qualification package for review, conduct such review in accordance with this section.

''(2) ACCEPTANCE AND REVIEW OF SUBMISSIONS.—With respect to a letter of intent, a qualification plan, or a full qualification package submitted under the process described in paragraph (1) (referred to in this paragraph as 'qualification submissions'), the following shall apply:

''(A) SCIENTIFIC MERIT.—The Secretary shall, consistent with available resources, determine whether to accept a qualification submission based on factors which may include the scientific merit of the submission. A determination not to accept a submission under paragraph (1) shall not be construed as a final agency determination regarding the qualification of a proposed drug development tool under paragraph (1).

''(B) PRIORITIZATION OF QUALIFICATION REVIEW.—The Secretary may prioritize the review of a full qualification package submitted under the process described in paragraph (1) with respect to a drug development tool, based on factors determined appropriate by the Secretary, including—

''(i) as applicable, the severity, rarity, or prevalence of the disease or condition

targeted by the drug development tool and the availability or lack of alternative treatments for such disease or condition; and

''(ii) the identification, by the Secretary or by biomedical research consortia and other expert stakeholders, of such a drug development tool and proposed context of use of the drug development tool as a public health priority.

''(C) ENGAGEMENT OF EXTERNAL EXPERTS.—The Secretary may, for purposes of the review of qualification submissions, through the use of cooperative agreements, grants, or other appropriate mechanisms, consult with biomedical research consortia and may consider the recommendations of such consortia with respect to the review of any qualification plan submitted under the process described in paragraph (1) or the review of any full qualification package under paragraph (2).

''(3) REVIEW OF FULL QUALIFICATION PACKAGE.—The Secretary shall—

''(A) conduct a comprehensive review of a full qualification package accepted under paragraph (1)(C); and

''(B) determine whether the drug development tool at issue is qualified for its proposed context of use.

''(4) QUALIFICATION.—The Secretary shall determine whether a drug development tool is qualified for a proposed context of use based on the scientific merit of a full qualification package reviewed under paragraph (2).

''(b) EFFECT OF QUALIFICATION.—

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

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

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

''(B) supporting the investigational use of a drug or biological product under section

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

''(3) RESCISSION OR MODIFICATION.—

''(A) IN GENERAL.—The Secretary may rescind or modify a determination under this section to qualify a drug development tool if the Secretary determines that the drug development tool is not appropriate for the proposed context of use specified by the requestor. Such a determination may be based on new information that calls into question the basis for such qualification.

''(B) MEETING FOR REVIEW.—If the Secretary rescinds or modifies a determination to qualify a drug development tool under subparagraph (A), the requestor involved shall be granted a request for a meeting with the Secretary to discuss the basis of the Secretary's decision to rescind or modify the determination before the effective date of the rescission or modification.

''(c) TRANSPARENCY.—

''(1) IN GENERAL.—Subject to paragraph (3), the Secretary shall make publicly available, and update on at least a quarterly basis, on the Internet

website of the Food and Drug Administration the following:

''(A) Information with respect to each qualification submission under the qualification process under subsection (a), including—

''(i) the stage of the review process applicable to the submission;

''(ii) the date of the most recent change in stage status; and

''(iii) whether the external scientific experts were utilized in the development of a qualification plan or the review of a full qualification package.

''(B) The Secretary's formal written determinations in response to such qualification submissions.

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

''(D) Summary reviews that document conclusions and recommendations for determinations to qualify drug development tools under subsection (a).

''(E) A comprehensive list of all drug development tools qualified under subsection (c) or used in the labeling of drugs.

''(2) RELATION TO TRADE SECRETS ACT.—Information made publicly available by the Secretary under paragraph (1) shall be considered a disclosure authorized by law for purposes of section 1905 of title 18, United States Code.

''(3) APPLICABILITY.—Paragraph (1) shall not apply with respect to information contained in an application submitted under section 505 of this Act or section 351 of the Public Health Service Act, irrespective of whether such information is used to develop the guidance to carry out this section. Nothing in this section shall be construed as authorizing the Secretary to disclose any information contained in such an application that is confidential commercial or trade secret information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

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

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

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

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

''(f) DEFINITIONS.—In this section:

''(1) BIOMARKER.—(A) The term 'biomarker' means a characteristic (such as a physiologic, pathologic, or anatomic characteristic or measurement) that is objectively measured and evaluated as an indicator of normal biologic processes, pathologic processes, or biological responses to a therapeutic intervention.

''(B) Such term includes a surrogate endpoint.

''(2) BIOMEDICAL RESEARCH CONSORTIA.—The term 'biomedical research consortia' means public-private partnerships of government agencies, institutions of higher education (as defined in section 101(a) of the Higher Education Act of 1965 (20

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

''(3) CLINICAL OUTCOME ASSESSMENT.—(A) The term 'clinical outcome assessment' means a measurement of a patient's symptoms, overall mental state, or the effects of a disease or condition on how the patient functions.

''(B) Such term includes a patient-reported outcome.

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

''(5) DRUG DEVELOPMENT TOOL.—The term 'drug development tool' includes—

''(A) a biomarker;

''(B) a clinical outcome assessment; and

''(C) any other method, material, or measure that the Secretary determines aids drug development and regulatory review for purposes of this section.

''(6) PATIENT-REPORTED OUTCOME.—The term 'patient-reported outcome' means a measurement

based on a report from a patient regarding the status of the patient's health condition without amendment or interpretation of the patient's report by a clinician or any other person.

''(7) QUALIFICATION.—The terms 'qualification' and 'qualified' mean a determination by the Secretary that a drug development tool and its proposed context of use can be relied upon to have a specific interpretation and application in drug development and regulatory review under this Act.

''(8) REQUESTOR.—The term 'requestor' means an entity or entities, including a drug sponsor or a biomedical research consortia, seeking to qualify a drug development tool for a proposed context of use under this section.

''(9) SURROGATE ENDPOINT.—The term 'surrogate endpoint' means a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that—

''(A) is known to predict clinical benefit and could be used to support traditional approval of a drug or biological product; or

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

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

(d) GUIDANCE.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall, in consultation with biomedical research consortia (as defined in subsection (e) of section 507 the Federal Food, Drug, and Cosmetic Act (as added by subsection (c))) and other interested parties through a collaborative public process, issue guidance to implement such section 507 that—

(A) provides a conceptual framework describing appropriate standards and scientific approaches to support the development of biomarkers delineated under the taxonomy established under paragraph (3);

(B) makes recommendations for demonstrating that a surrogate endpoint is reasonably likely to predict clinical benefit for the purpose of supporting the accelerated approval of a drug under section 506(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c));

(C) with respect to the qualification process under such section 507—

(i) specifies the requirements that entities seeking to qualify a drug development tool under such section shall observe when engaging in such process;

(ii) specifies reasonable timeframes for the Secretary's review of letters, qualification plans, or full qualification packages submitted under such process; and

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

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

(2) TIMING.—Not later than 24 months after the date of the enactment of this Act, the Secretary shall issue draft guidance on the implementation of section 507 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (c)). The Secretary shall issue final guidance on the implementation of such section not later than 6 months after

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

(3) TAXONOMY.—

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

(B) PUBLIC AVAILABILITY.—Not later than 12 months after the date of the enactment of this Act, the Secretary shall make such taxonomy publicly available in draft form for public comment. The Secretary shall finalize the taxonomy not later than 12 months after the close of the public comment period.

(e) MEETING AND REPORT.—

(1) MEETING.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall convene a public meeting to describe and solicit public input regarding the qualification process under section 507

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

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

(A) the number of requests submitted, as a letter of intent, for qualification of a drug development tool (as defined in subsection (e) of such section);

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

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

(D) the number of qualification plans and full qualification packages, respectively, submitted to the Secretary; and

(3) the drug development tools qualified through the process, specified by type of tool, such as a biomarker or clinical outcome assessment (as such terms are defined in subsection (e) of such section 507).

SEC. 2022. ACCELERATED APPROVAL DEVELOPMENT PLAN.

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

''(g) ACCELERATED APPROVAL DEVELOPMENT PLAN.—

''(1) IN GENERAL.—In the case of a drug determined to be eligible for accelerated approval under subsection (c), at any time after the submission of an application for the investigation of the drug under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act, the sponsor of such drug may voluntarily request agreement by the Secretary to an accelerated approval development plan with respect to a surrogate endpoint to be used to study the drug.

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

''(A) the surrogate endpoint to be assessed under the plan;

''(B) the design of the study that will utilize the surrogate endpoint; and

''(C) the magnitude of the effect of the drug on the surrogate endpoint that is the subject of the agreement that would be sufficient to form the primary basis of a claim that the drug is effective.

''(3) MODIFICATION; TERMINATION.—The Secretary may require the sponsor of a drug that is the subject of an accelerated approval development plan to modify or terminate the plan if additional data or information indicates that—

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

''(B) the drug is no longer eligible for accelerated approval under subsection (c).

''(4) SPONSOR CONSULTATION.—If the Secretary requires the modification or termination of an accelerated approval development plan under paragraph (3), the sponsor shall be granted a request for

a meeting to discuss the basis of the Secretary's decision before the effective date of the modification or termination.

''(5) DEFINITION.—In this section, the term 'accelerated approval development plan' means a development plan agreed upon by the Secretary and the sponsor submitting the plan that contains study parameters for the use of a surrogate endpoint that—

''(A) is reasonably likely to predict clinical benefit; and

''(B) is intended to be the basis of the accelerated approval of a drug under subsection (c).''.

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

(1) by striking ''(f) AWARENESS EFFORTS'' and inserting ''(e) AWARENESS EFFORTS''; and

(2) by striking ''(e) CONSTRUCTION'' and inserting ''(f) CONSTRUCTION''.

Subtitle C—FDA Advancement of Precision Medicine

SEC. 2041. PRECISION MEDICINE GUIDANCE AND OTHER PROGRAMS OF FOOD AND DRUG ADMINISTRATION.

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

"Subchapter J—Precision Medicine

"SEC. 591. GENERAL AGENCY GUIDANCE ON PRECISION MEDICINE.

''(a) IN GENERAL.—The Secretary shall issue and periodically update guidance to assist sponsors in the development of a precision drug or biological product. Such guidance shall—

''(1) define the term 'precision drug or biological product'; and

''(2) address the topics described in subsection (b).

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

''(1) the evidence needed to support the use of biomarkers (as defined in section 507(e)) that identify subsets of patients as likely responders to thera-

pies in order to streamline the conduct of clinical trials;

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

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

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

''(5) considerations for developing biomarkers that aid prescribing decisions for a drug or biological product, and when information regarding a biomarker may be included in the labeling for a drug or biological product approved under section 505 of this Act or section 351 of the Public Health Service Act.

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

"SEC. 592. PRECISION MEDICINE REGARDING ORPHAN-DRUG AND EXPEDITED-APPROVAL PROGRAMS.

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

"(1) consistent with applicable standards for approval, rely upon data or information previously developed by the sponsor of the precision drug or biological product for a prior approved drug or indication (or that of another sponsor, provided the sponsor of the precision drug or biological product has obtained a contractual right of reference to such other sponsor's data and information) in order to expedite clinical development for a precision drug or indication that is using the same or similar approach as that of the prior approved drug or indication; and

"(2) as appropriate under section 506, consider the application for approval of such precision drug or biological product to be eligible for expedited review, including under section 506(c) (relating to accelerated approval).".

Subtitle D—Modern Trial Design and Evidence Development

SEC. 2061. BROADER APPLICATION OF BAYESIAN STATISTICS AND ADAPTIVE TRIAL DESIGNS.

(a) PROPOSALS FOR USE OF INNOVATIVE STATISTICAL METHODS IN CLINICAL PROTOCOLS FOR DRUGS AND BIOLOGICAL PRODUCTS.—For purposes of assisting sponsors in incorporating adaptive trial design and Bayesian methods into proposed clinical protocols and applications for new drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and biological products under section 351 of the Public Health Service Act (42 U.S.C. 262), the Secretary shall conduct a public meeting and issue guidance in accordance with subsection (b).

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

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

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

(B) issue draft guidance on the use of Bayesian methods in the development and regulatory review and approval or licensure of drugs and biological products.

(2) CONTENTS.—The guidances under paragraph (1) shall address—

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

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

(i) completion of such modeling or simulations; or

(ii) the submission of resulting information to the Secretary;

(C) the types of quantitative and qualitative information that should be submitted for review; and

(D) recommended analysis methodologies.

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

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

(4) SCHEDULE.—The Secretary shall publish—

(A) the final guidance required by paragraph (1)(A) not later than 18 months after the date of the public meeting required by paragraph (3); and

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

SEC. 2062. UTILIZING EVIDENCE FROM CLINICAL EXPERIENCE.

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

"SEC. 505F. UTILIZING EVIDENCE FROM CLINICAL EXPERIENCE.

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

''(1) to help support the approval of a new indication for a drug approved under section 505(b); and

''(2) to help support or satisfy postapproval study requirements.

''(b) EVIDENCE FROM CLINICAL EXPERIENCE DEFINED.—In this section, the term 'evidence from clinical experience' means data regarding the usage, or potential benefits or risks, of a drug derived from sources other than randomized clinical trials, including from observational studies, registries, and therapeutic use.

''(c) PROGRAM FRAMEWORK.—

''(1) IN GENERAL.—Not later than 18 months after the date of enactment of this section, the Secretary shall establish a draft framework for implementation of the program under this section.

''(2) CONTENTS OF FRAMEWORK.—The framework shall include information describing—

''(A) the current sources of data developed through clinical experience, including ongoing

safety surveillance, registry, claims, and patient-centered outcomes research activities;

''(B) the gaps in current data collection activities;

''(C) the current standards and methodologies for collection and analysis of data generated through clinical experience; and

''(D) the priority areas, remaining challenges, and potential pilot opportunities that the program established under this section will address.

''(3) CONSULTATION.—

''(A) IN GENERAL.—In developing the program framework under this subsection, the Secretary shall consult with regulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, disease research foundations, and other interested parties.

''(B) PROCESS.—The consultation under subparagraph (A) may be carried out through approaches such as—

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

''(ii) a contract, grant, or other arrangement, as determined appropriate by the Secretary with such a partnership or an independent research organization.

''(d) PROGRAM IMPLEMENTATION.—The Secretary shall, not later than 24 months after the date of enactment of this section and in accordance with the framework established under subsection (c), implement the program to evaluate the potential use of evidence from clinical experience.

''(e) GUIDANCE FOR INDUSTRY.—The Secretary shall—

''(1) utilize the program established in subsection (d), its activities, and any subsequent pilots or written reports, to inform a guidance for industry on—

''(A) the circumstances under which sponsors of drugs and the Secretary may rely on evidence from clinical experience for the purposes described in subsection (a)(1) or (a)(2); and

''(B) the appropriate standards and methodologies for collection and analysis of evidence from clinical experience submitted for such purposes;

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

''(3) not later than 48 months after the date of enactment of this section, after providing an opportunity for public comment on the draft guidance, issue final guidance.

''(f) RULE OF CONSTRUCTION.—

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

''(2) This section shall not be construed to alter—

''(A) the standards of evidence under—

''(i) subsection (c) or (d) of section 505, including the substantial evidence standard in such subsection (d); or

''(ii) section 351(a) of the Public Health Service Act; or

''(B) the Secretary's authority to require postapproval studies or clinical trials, or the standards of evidence under which studies or trials are evaluated.

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

[“(a) IN GENERAL.—The Secretary shall, in parallel to implementing the program established in section 505F and in order to build capacity for utilizing the evidence from clinical experience described in that section, identify and execute pilot demonstrations to extend existing use of the Sentinel System surveillance infrastructure authorized under section 505(k).]

[“(b) PILOT DEMONSTRATIONS.—]

[“(1) IN GENERAL.—The Secretary—]

[“(A) shall design and implement pilot demonstrations to utilize data captured through the Sentinel System surveillance infrastructure authorized under section 505(k) for purposes of, as appropriate—]

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

“(ii) protecting the public health; or

“(iii) advancing patient-centered care; and

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

and infrastructure the Secretary determines appropriate and necessary.

[“(2) CONSULTATION.—In developing the pilot demonstrations under this subsection, the Secretary shall—]

[“(A) consult with regulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, disease research foundations, and other interested parties through a public process; and]

[“(B) develop a framework to promote appropriate transparency and dialogue about research conducted by the Food and Drug Administration, including by—]

[“(i) providing adequate notice to a sponsor of a drug approved under section 505 or section 351 of the Public Health Service Act of the Secretary’s intent to conduct analyses related to assessing or reassessing the safety of such sponsor’s drug or drugs;]

[“(ii) providing adequate notice of the findings related to analyses described in clause (i) and an opportunity for the spon-

sor of such drug or drugs to comment on such findings; and]

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

[“(3) PUBLIC HEALTH EXEMPTION.—The Secretary may—]

[“(A) deem such pilot demonstrations public health activities, permitting the use and disclosure of protected health information as described in section 164.512(b)(1)(iii) of title 45, Code of Federal Regulations (or any successor regulation) and exempted as a public health activity as described in section 46.101(b)(5) of title 46, Code of Federal Regulations (or any successor regulation); and]

[“(B) deem safety surveillance performed at the request of the Food and Drug Administration or under such jurisdiction by a sponsor with responsibility for a drug approved under this section or section 351 of the Public Health Services Act using the Sentinel System surveil-

lance infrastructure authorized under section 505(k), including use of analytic tools and querying capabilities developed to implement the active postmarket surveillance system described in this section, public health activities as described in section 164.512(b)(1)(iii) of title 45, Code of Federal Regulations (or any successor regulation) and exempted as a public health activity as described in section 46.101(b)(5) of title 46, Code of Federal Regulations (or any successor regulation).]

[''(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section [$_____] for each of fiscal years 2016 through 2019.''.]

SEC. 2063. STREAMLINED DATA REVIEW PROGRAM.

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

''SEC. 505H. STREAMLINED DATA REVIEW PROGRAM.

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

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

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

''(1) the drug has been approved under section 505(c) of this Act or licensed under section 351(a) of the Public Health Service Act for one or more indications, and such approval or licensure remains in effect;

''(2) the supplemental application is for approval or licensure (as applicable) under such section 505(c) or 351(a) of the use of the drug for a new qualified indication under such section 505(c) or 351(a);

''(3) there is an existing database acceptable to the Secretary regarding the safety of the drug developed for one or more indications of the drug approved under such section 505(c) or licensed under such section 351(a);

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

''(5) the full data sets used to develop the qualified data summaries are submitted, if the Secretary determines that the full data sets are required.

''(c) DEFINITIONS.—In this section:

''(1) The term 'qualified indication' means—

''(A) an indication for the treatment of cancer, as determined appropriate by the Secretary; or

''(B) such other types of indications as the Secretary determines to be subject to the streamlined data review program under this section.

''(2) The term 'qualified data summary' means a summary of clinical data intended to demonstrate safety and effectiveness with respect to a qualified indication for use of a drug.''.

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

(1) shall—

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

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

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

(2) in addition to issuing guidance under paragraph (1), may issue such regulations as may be necessary for implementation of the program.

Subtitle E—Expediting Patient Access

SEC. 2081. SENSE OF CONGRESS.

It is the sense of Congress that the Food and Drug Administration should continue to expedite the approval of drugs designated as breakthrough therapies pursuant to section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)) by approving drugs so designated as early as possible in the clinical development process, regardless of the phase of development, provided that the Secretary of Health and Human Services determines that an application for such a drug meets the standards of evidence of safety and effectiveness under section

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

SEC. 2082. EXPANDED ACCESS POLICY.

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

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

(2) by inserting after subsection (c) the following new subsection:

''(d) EXPANDED ACCESS POLICY REQUIRED FOR INVESTIGATIONAL DRUGS.—

''(1) IN GENERAL.—The manufacturer or distributor of one or more investigational drugs for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions shall make publicly available the policy of the sponsor on evaluating and responding to requests submitted under subsection (b) for provision of such a drug. A sponsor may satisfy the requirement of the preceding sentence by posting such policy as generally applicable to all of such sponsor's investigational drugs.

''(2) CONTENT OF POLICY.—A policy described in paragraph (1) shall include making publicly available—

''(A) contact information for the manufacturer or distributor to facilitate communication about requests described in paragraph (1);

''(B) procedures for making such requests;

''(C) the general criteria for the sponsor's consideration or approval of such requests; and

''(D) the length of time the sponsor anticipates will be necessary to acknowledge receipt of such requests.

''(3) NO GUARANTEE OF ACCESS.—The posting of policies by manufacturers and distributors under paragraph (1) shall not serve as a guarantee of access to any specific investigational drug by any individual patient.

''(4) REVISED POLICY.—A manufacturer or distributor that has made a policy publicly available as required by this subsection may revise the policy at any time.

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

''(A) the date that is 60 days after the date of enactment of the 21st Century Cures Act; or

''(B) the first initiation of a phase 2 or phase 3 study (as such terms are defined in section 312.21(b) and (c) of title 21, Code of Federal Regulations (or any successor regulations)) with respect to such a drug.''.

SEC. 2083. FINALIZING DRAFT GUIDANCE ON EXPANDED ACCESS.

(a) IN GENERAL.—Not later than 12 months after the date of enactment of this Act, the Secretary of Health and Human Services shall finalize the draft guidance entitled ''Expanded Access to Investigational Drugs for Treatment Use—Qs & As'' and dated May 2013.

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

Subtitle F—Facilitating Responsible Manufacturer Communications

[SEC. 2101. FACILITATING DISSEMINATION OF HEALTH CARE ECONOMIC INFORMATION.

Section 502(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(a)) is amended—]

[(1) by striking ''(a) If its'' and inserting ''(a)(1) If its'';]

[(2) by striking ''a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations'' and inserting ''a payor, formulary committee, or other similar entity, in the course of the payor, committee, or other similar entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations'';]

[(3) by striking ''directly relates'' and inserting ''relates'';]

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

care economic information provided to such a committee or entity in accordance with this paragraph'' and inserting '', is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any differences between the information and the indication approved under section 505 or under section 351 of the Public Health Service Act. The requirements set forth in section 505(a) or in section 351 of the Public Health Service Act shall not apply to health care economic information provided to such a payor, committee, or entity in accordance with this paragraph''; and]

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

[''(2) For purposes of this paragraph, the term 'health care economic information' means any analysis (including the data, inputs, clinical or other assumptions, methods, results, and other components comprising the analysis) that identifies, measures, or describes the consequences, including the separate or aggregated clinical consequences and costs of the represented health outcomes, of the use of a drug. Such analyses may be comparative to the use of another drug, to another health care intervention, or to no intervention.''.]

SEC. 2102. FACILITATING RESPONSIBLE COMMUNICATION OF SCIENTIFIC AND MEDICAL DEVELOPMENTS.

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

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

Subtitle G—Antibiotic Drug Development

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

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

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

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

''(z) APPROVAL OF CERTAIN ANTIBACTERIAL AND ANTIFUNGAL DRUGS FOR USE IN A LIMITED POPULATION OF PATIENTS.—

''(1) PROCESS.—At the request of the sponsor of an antibacterial or antifungal drug that is intended to treat a serious or life-threatening infection, the Secretary—

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

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

''(C) shall provide the sponsor with an opportunity to request meetings under paragraph (2);

''(D) may approve the drug under subsection (c) for such use—

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

''(ii) based on a streamlined development program; and

''(iii) only if the standards for approval under subsections (c) and (d) of this section or licensure under section 351 of the Public Health Service Act, as applicable, are met; and

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

''(i) traditional endpoints, alternate endpoints, or a combination of traditional and alternate endpoints, and, as appropriate, data sets of a limited size; and

''(ii)(I) additional data, including preclinical, pharmacologic, or pathophysiologic evidence;

''(II) nonclinical susceptibility and pharmacokinetic data;

''(III) data from phase 2 clinical trials; and

''(IV) such other confirmatory evidence as the Secretary determines appropriate to approve the drug.

''(2) FORMAL MEETINGS.—

''(A) IN GENERAL.—To help expedite and facilitate the development and review of a drug for which a sponsor intends to request approval in accordance with this subsection, the Secretary shall, at the request of the sponsor, conduct meetings that provide early consultation, timely advice, and sufficient opportunities to develop an agreement described in paragraph (1)(A) and help the sponsor design and conduct a drug development program as efficiently as possible, including the following types of meetings:

''(i) An early consultation meeting.

''(ii) An assessment meeting.

''(iii) A postapproval meeting.

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

''(C) BREAKTHROUGH THERAPIES.—In the case of a drug designated as a breakthrough therapy under section 506(a), the sponsor of such drug may elect to utilize meetings provided under such section with respect to such drug in lieu of meetings described in subparagraph (A).

''(3) LABELING REQUIREMENT.—The labeling of an antibacterial or antifungal drug approved in accordance with this subsection shall contain the statement 'Limited Population' in a prominent manner and adjacent to, and not more prominent than, the brand name of the product. The prescribing information for such antibacterial or antifungal drug required by section 201.57 of title 21, Code of Federal Regulations (or any successor regulation) shall also include the following statement: 'This drug is indicated for use in a limited and specific population of patients.'.

''(4) PROMOTIONAL MATERIALS.—The provisions of section 506(c)(2)(B) shall apply with respect to approval in accordance with this subsection to the same extent and in the same manner as such provisions apply with respect to accelerated approval in accordance with section 506(c)(1).

''(5) TERMINATION OF REQUIREMENTS OR CONDITIONS.—If a drug is approved in accordance with this subsection for an indication in a limited population of patients and is subsequently approved or licensed under this section or section 351 of the Public Health Service Act, other than in accordance with this subsection, for—

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

''(B) a different indication or condition of use, the Secretary shall not apply the labeling requirements and postmarketing conditions that were made applicable to the drug under this subsection to the subsequent approval of the drug for such different indication or condition of use.

''(6) RELATION TO OTHER PROVISIONS.—Nothing in this subsection shall be construed to prohibit the approval of a drug for use in a limited population of patients in accordance with this subsection, in combination with—

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

"(B) designation and treatment of the drug as a breakthrough therapy under section 506(a);

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

"(D) accelerated approval of the drug in accordance with section 506(c).

"(7) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed—

"(A) to alter the standards of evidence under subsection (c) or (d) (including the substantial evidence standard in subsection (d));

"(B) to waive or otherwise preclude the application of requirements under subsection (o);

"(C) to otherwise, in any way, limit the authority of the Secretary to approve products pursuant to this Act and the Public Health Service Act as authorized prior to the date of enactment of this subsection; or

"(D) to restrict in any manner, the prescribing of antibiotics or other products by

health care providers, or to limit or restrict the practice of health care, including the prescribing of such products by physicians for patients.

''(8) EFFECTIVE IMMEDIATELY.—The Secretary shall have the authorities vested in the Secretary by this subsection beginning on the date of enactment of this subsection, irrespective of when and whether the Secretary promulgates final regulations or guidance.

''(9) DEFINITIONS.—In this subsection:

''(A) EARLY CONSULTATION MEETING.—The term 'early consultation meeting' means a pre-investigational new drug meeting or an end-of-phase 1 meeting that—

''(i) is conducted to review and reach a written agreement—

''(I) on the scope of the streamlined development plan for a drug for which a sponsor intends to request approval in accordance with this subsection; and

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

ical studies early in the development process, including clinical trials whose data are intended to form the primary basis for an effectiveness claim; and

''(ii) provides an opportunity to discuss expectations of the Secretary regarding studies or other information that the Secretary deems appropriate for purposes of applying paragraph (5), relating to the termination of labeling requirements or postmarketing conditions.

''(B) ASSESSMENT MEETING.—The term 'assessment meeting' means an end-of-phase 2 meeting, pre-new drug application meeting, or pre-biologics license application meeting conducted to resolve questions and issues raised during the course of clinical investigations, and details addressed in the written agreement regarding postapproval commitments or expansion of approved uses.

''(C) POSTAPPROVAL MEETING.—The term 'postapproval meeting' means a meeting following initial approval or licensure of the drug for use in a limited population, to discuss any issues identified by the Secretary or the sponsor

regarding postapproval commitments or expansion of approved uses.''.

(c) GUIDANCE.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue draft guidance describing criteria, process, and other general considerations for demonstrating the safety and effectiveness of antibacterial and antifungal drugs to be approved for use in a limited population in accordance with section 505(z) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b).

(d) CONFORMING AMENDMENTS.—

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

(A) by striking ''(j)'' and inserting ''(j)(1)'';

(B) by inserting ''505(z),'' after ''505(p),''; and

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

''(2) In applying section 505(z) of the Federal Food, Drug, and Cosmetic Act to the licensure of biological products under this section—

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

''(B) references to approval of a drug under section 505(c) of such Act shall be construed to refer to a licensure of a biological product under subsection (a) of this section.''.

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

''(dd) If it is a drug approved in accordance with section 505(z) and its labeling does not meet the requirements under paragraph (3) of such subsection, subject to paragraph (5) of such subsection.''.

(e) EVALUATION.—

(1) ASSESSMENT.—Not later than 48 months after the date of enactment of this Act, the Secretary of Health and Human Services shall publish for public comment an assessment of the program established under section 505(z) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b). Such assessment shall determine if the

limited-use pathway established under such section 505(z) has improved or is likely to improve patient access to novel antibacterial or antifungal treatments and assess how the pathway could be expanded to cover products for serious or life-threatening diseases or conditions beyond bacterial and fungal infections.

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

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

section, the Secretary may expand such limited-use pathway in accordance with such a determination. The approval of any drugs under any such expansion shall be subject to the considerations and requirements described in such section 505 for purposes of expansion to other serious or life-threatening diseases or conditions.

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

"SEC. 317U. MONITORING ANTIBACTERIAL AND ANTIFUNGAL DRUG USE AND RESISTANCE.

''(a) MONITORING.—The Secretary shall use an appropriate monitoring system to monitor—

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

''(2) changes in bacterial and fungal resistance to drugs.

''(b) PUBLIC AVAILABILITY OF DATA.—The Secretary shall make summaries of the data derived from monitoring under this section publicly available for the purposes of—

''(1) improving the monitoring of important trends in antibacterial and antifungal resistance; and

''(2) ensuring appropriate stewardship of antibacterial and antifungal drugs, including those receiving approval or licensure for a limited population pursuant to section 505(z) of the Federal Food, Drug, and Cosmetic Act.''.

SEC. 2122. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS.

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

''SEC. 511. IDENTIFYING AND UPDATING SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS.

''(a) PURPOSE; IDENTIFICATION OF CRITERIA.—

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

''(A) clearance or premarket approval of antimicrobial susceptibility testing devices utilizing updated, recognized susceptibility test interpretive criteria to characterize the in vitro susceptibility of particular bacteria, fungi, or

other microorganisms to antimicrobial drugs; and

''(B) providing public notice of the availability of recognized interpretive criteria to meet premarket submission requirements or other requirements under this Act for antimicrobial susceptibility testing devices.

''(2) IN GENERAL.—The Secretary shall identify appropriate susceptibility test interpretive criteria with respect to antimicrobial drugs—

''(A) if such criteria are available on the date of approval of the drug under section 505 of this Act or licensure of the drug under section 351 of the Public Health Service Act (as applicable), upon such approval or licensure; or

''(B) if such criteria are unavailable on such date, on the date on which such criteria are available for such drug.

''(3) BASES FOR INITIAL IDENTIFICATION.—The Secretary shall identify appropriate susceptibility test interpretive criteria under paragraph (2), based on the Secretary's review of, to the extent available and relevant—

''(A) preclinical and clinical data, including pharmacokinetic, pharmacodynamic, and epidemiological data;

''(B) Bayesian and pharmacometric statistical methodologies; and

''(C) such other evidence and information as the Secretary considers appropriate.

''(b) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA WEBSITE.—

''(1) IN GENERAL.—Not later than 1 year after the date of the enactment of the 21st Century Cures Act, the Secretary shall establish, and maintain thereafter, on the website of the Food and Drug Administration, a dedicated website that contains a list of any appropriate new or updated susceptibility test interpretive criteria standards in accordance with paragraph (2) (referred to in this section as the 'Interpretive Criteria Website').

''(2) LISTING OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA STANDARDS.—

''(A) IN GENERAL.—The list described in paragraph (1) shall consist of any new or updated susceptibility test interpretive criteria standards that are—

''(i) established by a nationally or internationally recognized standard development organization that—

''(I) establishes and maintains procedures to address potential conflicts of interest and ensure transparent decisionmaking;

''(II) holds open meetings to ensure that there is an opportunity for public input by interested parties, and establishes and maintains processes to ensure that such input is considered in decisionmaking; and

''(III) permits its standards to be made publicly available, through the National Library of Medicine or another similar source acceptable to the Secretary; and

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

''(B) OTHER LIST.—The Interpretive Criteria Website shall, in addition to the list described in subparagraph (A), include a list of interpretive criteria, if any, that the Secretary has determined to be appropriate with respect

to legally marketed antimicrobial drugs, where—

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

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

''(iii) the Secretary approves an application under section 505 of this Act or section 351 of the Public Health Service Act, as applicable, with respect to marketing of such a drug for which there are no relevant interpretive criteria included in a standard recognized by the Secretary under subsection (c); or

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

''(I) differ from otherwise applicable interpretive criteria included in a standard listed under subparagraph

(A) or interpretive criteria otherwise listed under this subparagraph; and

''(II) are determined to be appropriate for the drug.

''(C) REQUIRED STATEMENTS ON LIMITATIONS OF INFORMATION.—The Interpretive Criteria Website shall include the following:

''(i) A statement that—

''(I) the website provides information about the susceptibility of bacteria, fungi, or other microorganisms to a certain drug (or drugs); and

''(II) the safety and efficacy of the drug in treating clinical infections due to such bacteria, fungi, or other microorganisms may not have been established in adequate and well-controlled clinical trials and the clinical significance of such susceptibility information in such trials is unknown.

''(ii) A statement that directs health care practitioners to consult the approved product labeling for specific drugs to determine the uses for which the Food and

Drug Administration has approved the product.

''(iii) Any other statement that the Secretary determines appropriate to adequately convey the limitations of the data supporting susceptibility test interpretive criteria standard listed on the website.

''(3) NOTICE.—Not later than the date on which the Interpretive Criteria Website is established, the Secretary shall publish a notice of that establishment in the Federal Register.

''(4) INAPPLICABILITY OF MISBRANDING PROVISION.—The inclusion in the approved labeling of an antimicrobial drug of a reference or hyperlink to the Interpretive Criteria Website, in and of itself, shall not cause the drug to be misbranded in violation of section 502, or the regulations promulgated thereunder.

''(5) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code.

''(c) RECOGNITION OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FROM STANDARD DEVELOPMENT ORGANIZATIONS.—

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

''(A) evaluate any appropriate new or updated susceptibility test interpretive criteria standards established by a nationally or internationally recognized standard development organization described in subsection (b)(2)(A)(i); and

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

''(i) withdrawing recognition of any different susceptibility test interpretive criteria standard, in whole or in part;

''(ii) recognizing the new or updated standards;

''(iii) recognizing one or more parts of the new or updated interpretive criteria specified in such a standard and declining to recognize the remainder of such standard; and

''(iv) making any necessary updates to the lists under subsection (b)(2).

''(2) BASES FOR UPDATING INTERPRETIVE CRITERIA STANDARDS.—In evaluating new or updated susceptibility test interpretive criteria standards under paragraph (1)(A), the Secretary may consider—

''(A) the Secretary's determination that such a standard is not applicable to a particular drug because the characteristics of the drug differ from other drugs with the same active ingredient;

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

''(C) any bases used to identify susceptibility test interpretive criteria under subsection (a)(2); and

''(D) such other information or factors as the Secretary determines appropriate.

''(3) ANNUAL COMPILATION OF NOTICES.—Each year, the Secretary shall compile the notices published under paragraph (1)(B) and publish such compilation in the Federal Register and provide for

public comment. If the Secretary receives comments, the Secretary will review such comments and, if the Secretary determines appropriate, update pursuant to this subsection susceptibility test interpretive criteria standards—

"(A) recognized by the Secretary under this subsection; or

"(B) otherwise listed on the Interpretive Criteria Website under subsection (b)(2).

"(4) RELATION TO SECTION 514(c).—Any susceptibility test interpretive standard recognized under this subsection or any criteria otherwise listed under subsection (b)(2)(B) shall be deemed to be recognized as a standard by the Secretary under section 514(c)(1).

"(5) VOLUNTARY USE OF INTERPRETIVE CRITERIA.—Nothing in this section prohibits a person from seeking approval or clearance of a drug or device, or changes to the drug or the device, on the basis of susceptibility test interpretive criteria standards which differ from those recognized pursuant to paragraph (1).

"(d) ANTIMICROBIAL DRUG LABELING.—

"(1) DRUGS MARKETED PRIOR TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—With

respect to an antimicrobial drug lawfully introduced or delivered for introduction into interstate commerce for commercial distribution before the establishment of the Interpretive Criteria Website, a holder of an approved application under section 505 or section 351 of the Public Health Service Act, as applicable, for each such drug—

''(A) not later than 1 year after establishment of the Interpretive Criteria Website, shall submit to the Secretary a supplemental application for purposes of changing the drug's labeling to substitute a reference or hyperlink to such Website for any susceptibility test interpretive criteria and related information; and

''(B) may begin distribution of the drug involved upon receipt by the Secretary of the supplemental application for such change.

''(2) DRUGS MARKETED SUBSEQUENT TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—With respect to antimicrobial drugs lawfully introduced or delivered for introduction into interstate commerce for commercial distribution on or after the date of the establishment of the Interpretive Criteria Website, the labeling for such a drug shall include, in lieu of susceptibility test interpretive

criteria and related information, a reference to such Website.

''(e) SPECIAL CONDITION FOR MARKETING OF ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

''(1) IN GENERAL.—Notwithstanding sections 501, 502, 510, 513, and 515, if the conditions specified in paragraph (2) are met (in addition to other applicable provisions under this chapter) with respect to an antimicrobial susceptibility testing device described in subsection (f)(1), the Secretary may authorize the marketing of such device for a use described in such subsection.

''(2) CONDITIONS APPLICABLE TO ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—The conditions specified in this paragraph are the following:

''(A) The device is used to make a determination of susceptibility using susceptibility test interpretive criteria that are—

''(i) included in a standard recognized by the Secretary under subsection (c); or

''(ii) otherwise listed on the Interpretive Criteria Website under subsection (b)(2).

''(B) The labeling of such device prominently and conspicuously—

''(i) includes a statement that—

''(I) the device provides information about the susceptibility of bacteria and fungi to certain drugs; and

''(II) the safety and efficacy of such drugs in treating clinical infections due to such bacteria or fungi may not have been established in adequate and well-controlled clinical trials and the clinical significance of such susceptibility information in those instances is unknown;

''(ii) includes a statement directing health care practitioners to consult the approved labeling for drugs tested using such a device, to determine the uses for which the Food and Drug Administration has approved such drugs; and

''(iii) includes any other statement the Secretary determines appropriate to adequately convey the limitations of the data supporting the interpretive criteria described in subparagraph (A).

''(f) DEFINITIONS.—In this section:

''(1) The term 'antimicrobial susceptibility testing device' means a device that utilizes susceptibility test interpretive criteria to determine and report the in vitro susceptibility of certain microorganisms to a drug (or drugs).

''(2) The term 'qualified infectious disease product' means a qualified infectious disease product designated under section 505E(d).

''(3) The term 'susceptibility test interpretive criteria' means—

''(A) one or more specific numerical values which characterize the susceptibility of bacteria or other microorganisms to the drug tested; and

''(B) related categorizations of such susceptibility, including categorization of the drug as susceptible, intermediate, resistant, or such other term as the Secretary determines appropriate.

''(4)(A) The term 'antimicrobial drug' means, subject to subparagraph (B), a systemic antibacterial or antifungal drug that—

''(i) is intended for human use in the treatment of a disease or condition caused by a bacterium or fungus;

''(ii) may include a qualified infectious disease product designated under section 505E(d); and

''(iii) is subject to section 503(b)(1).

''(B) If provided by the Secretary through regulations, such term may include—

''(i) drugs other than systemic antibacterial and antifungal drugs; and

''(ii) biological products (as such term is defined in section 351 of the Public Health Service Act) to the extent such products exhibit antimicrobial activity.

''(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

''(1) to alter the standards of evidence—

''(A) under subsection (c) or (d) of section 505, including the substantial evidence standard in section 505(d), or under section 351 of the Public Health Service Act (as applicable); or

''(B) with respect to marketing authorization for devices, under section 510, 513, or 515;

''(2) to apply with respect to any drug, device, or biological product, in any context other than—

"(A) the use of such drug or product as an antimicrobial drug; or

"(B) the use of an antimicrobial susceptibility testing device to characterize and report the in vitro susceptibility of certain bacteria, fungi, or other microorganisms to antimicrobial drugs in accordance with this section; or

"(3) unless specifically stated, to have any effect on authorities provided under other sections of this Act, including any regulations issued under such sections.".

(b) CONFORMING AMENDMENTS.—

(1) REPEAL OF RELATED AUTHORITY.—Section 1111 of the Food and Drug Administration Amendments Act of 2007 (42 U.S.C. 247d–5a; relating to identification of clinically susceptible concentrations of antimicrobials) is repealed.

(2) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352), as amended by section 2121, is further amended by adding at the end the following:

"(ee) If it is an antimicrobial drug and its labeling fails to conform with the requirements under section 511(d).".

(3) RECOGNITION OF INTERPRETIVE CRITERIA AS DEVICE STANDARD.—Section 514(c)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)(1)(A)) is amended by inserting after ''the Secretary shall, by publication in the Federal Register'' the following: ''(or, with respect to susceptibility test interpretive criteria or standards recognized or otherwise listed under section 511, by posting on the Interpretive Criteria Website in accordance with such section)''.

(c) REPORT TO CONGRESS.—Not later than two years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report on the progress made in implementing section 511 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a), as amended by this section.

(d) REQUESTS FOR UPDATES TO INTERPRETIVE CRITERIA WEBSITE.—Chapter 35 of title 44, United States Code, shall not apply to the collection of information from interested parties regarding the updating of lists under paragraph (2) of subsection (b) section 511 of the Federal Food, Drug, and Cosmetic Act (as amended by subsection

(a)) and posted on the Interpretive Criteria Website established under paragraph (1) of such subsection (b).

(e) NO EFFECT ON HEALTH CARE PRACTICE.—Nothing in this subtitle (including the amendments made by this subtitle) shall be construed to restrict, in any manner, the prescribing or administering of antibiotics or other products by health care practitioners, or to limit the practice of health care.

[SEC. 2123. ENCOURAGING THE DEVELOPMENT AND RESPONSIBLE USE OF NEW ANTIMICROBIAL DRUGS.

[(a) ADDITIONAL PAYMENT FOR NEW ANTIMICROBIAL DRUGS UNDER MEDICARE.—Section 1886(d)(5) of the Social Security Act (42 U.S.C. 1395ww(d)(5)) is amended by adding at the end the following new subparagraph:]

[''(M)(i) Effective for discharges beginning on or after October 1, 2015, the Secretary shall, after notice and opportunity for public comment (in the publications required by subsection (e)(5) for a fiscal year or otherwise), recognize the costs of new antimicrobial drugs under the payment system established under this subparagraph.]

[“(ii) Pursuant to clause (i), the Secretary shall provide for additional payment to be made under this subsection with respect to discharges involving new antimicrobial drugs in the amount provided for under section 1847A for drugs and biological products that are described in section 1842(o)(1)(C).]

[“(iii) For purposes of this subparagraph, the term ‘new antimicrobial drug’ means a product that is approved for use, or a product for which an indication is first approved for use, by the Food and Drug Administration on or after January 1, 2015, and—]

[“(I)(aa) is intended to treat an infection caused by, or likely to be caused by, a qualifying pathogen (as defined under section 505E(f) of the Federal Food, Drug, and Cosmetic Act); or]

[“(bb) meets the definition of a qualified infectious disease product under section 505E(g) of the Federal Food, Drug, and Cosmetic Act;]

[“(II) for which there is an ‘unmet medical need’ as determined by the Food and Drug Administration;]

[“(III) which is associated with high rates of mortality or significant patient morbidity, as determined by the Secretary, in consultation with the Director of the Centers for Disease Control and Prevention and the infectious disease professional community; and]

[“(IV) is used in facilities that participate in the National Healthcare Safety Network of the Centers for Disease Control and Prevention (or, to the extent a similar reporting program relating to antimicrobial drugs is determined by the Secretary to be available to such facilities, such similar reporting program as the Secretary may specify).]

[“(iv)(I) The manufacturer or sponsor of a drug may request the Secretary to designate a drug as a new antimicrobial drug at any time before or after the submission of an application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act for such drug. The Secretary shall, not later than 60 days after the submission of such a request, deter-

mine whether the drug is a new antimicrobial drug.]

[''(II) Except as provided in subclause (III), a designation under this subsection shall not be withdrawn for any reason.]

[''(III) The Secretary may revoke a designation of a drug as a new antimicrobial drug product if the Secretary finds that the request for such designation contained an untrue statement of material fact.]

[''(v) Not later than July 1, 2015, the Secretary shall first publish in the Federal Register a list of the new antimicrobial drugs.''.]

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

[(1) STUDY.—The Comptroller General of the United States shall, in consultation with the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the Director of the Centers for Disease Control and Prevention, conduct a study to—]

[(A) identify and examine the barriers that prevent the development of new antimicrobial drugs, as defined in section

1886(d)(5)(M)(iii) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(M)(iii)); and]

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

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

Subtitle H—Vaccine Access, Certainty, and Innovation

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

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

''(10) ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.—

''(A) STANDARD PERIODS OF TIME FOR MAKING RECOMMENDATIONS.—Upon the licensure of any vaccine or any new indication for a vaccine, the Director of the Program shall direct the Advisory Committee on Immunization Practices, at its next regularly scheduled meeting, to consider the use of the vaccine.

"(B) EXPEDITED REVIEW PURSUANT TO REQUEST BY SPONSOR OR MANUFACTURER.—If the Advisory Committee does not make recommendations with respect to the use of a vaccine at the Advisory Committee's first regularly scheduled meeting after the licensure of the vaccine or any new indication for the vaccine, the Advisory Committee, at the request of the sponsor of the vaccine, shall make such recommendations on an expedited basis.

"(C) EXPEDITED REVIEW FOR BREAKTHROUGH THERAPIES AND FOR USE DURING PUBLIC HEALTH EMERGENCIES.—If a vaccine is designated as a breakthrough therapy under section 506 of the Federal Food, Drug, and Cosmetic Act and is licensed under section 351 of this Act, the Advisory Committee shall make recommendations with respect to the use of the vaccine on an expedited basis.

"(D) DEFINITION.—In this paragraph, the terms 'Advisory Committee on Immunization Practices' and 'Advisory Committee' mean the advisory committee on immunization practices established by the Secretary pursuant to section

222, acting through the Director of the Centers for Disease Control and Prevention.''.

SEC. 2142. REVIEW OF PROCESSES AND CONSISTENCY OF ACIP RECOMMENDATIONS.

(a) REVIEW.—The Director of the Centers for Disease Control and Prevention shall conduct a review of the process used by the Advisory Committee on Immunization Practices to evaluate the consistency of the Advisory Committee in formulating and issuing recommendations pertaining to vaccines.

(b) CONSIDERATIONS.—The review under subsection (a) shall include assessment of—

(1) the criteria used to evaluate new and existing vaccines;

(2) the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach to the review and analysis of scientific and economic data, including the scientific basis for such approach; and

(3) the extent to which the processes used by the working groups of the Advisory Committee on Immunization Practices are consistent among groups.

(c) STAKEHOLDERS.—In carrying out the review under subsection (a), the Director of the Centers for Dis-

ease Control and Prevention shall solicit input from vaccine stakeholders.

(d) REPORT.—Not later than 18 months after the date of enactment of this Act, the Director of the Centers for Disease Control and Prevention shall submit to the appropriate committees of the Congress and make publicly available a report on the results of the review under subsection (a), including recommendations on improving the consistency of the process described in such subsection.

(e) DEFINITION.—In this section, the term ''Advisory Committee on Immunization Practices'' means the advisory committee on immunization practices established by the Secretary of Health and Human Services pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a), acting through the Director of the Centers for Disease Control and Prevention.

SEC. 2143. MEETINGS BETWEEN CDC AND VACCINE DEVELOPERS.

Section 310 of the Public Health Service Act (42 U.S.C. 242o) is amended by adding at the end the following:

''(c)(1) In this subsection, the term 'vaccine developer' means a nongovernmental entity engaged in—

''(A)(i) the development of a vaccine with the intent to pursue licensing of the vaccine by the Food and Drug Administration; or

''(ii) the production of a vaccine licensed by the Food and Drug Administration; and

''(B) vaccine research.

''(2)(A) Upon the submission of a written request for a meeting by a vaccine developer, that includes a justification for the meeting, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall convene a meeting of representatives of the vaccine developer and experts from the Centers for Disease Control and Prevention in immunization programs, epidemiology, and other relevant areas at which the Director (or the Director's designee), for the purpose of informing the vaccine developer's understanding of public health needs and priorities, shall provide the perspectives of the Centers for Disease Control and Prevention and other relevant Federal agencies regarding—

''(i) public health needs, epidemiology, and implementation considerations with regard to a vaccine developer's potential vaccine profile; and

''(ii) potential implications of such perspectives for the vaccine developer's vaccine research and development planning.

''(B) In addition to the representatives specified in subparagraph (A), the Secretary may, with the agreement of the vaccine developer requesting a meeting under such subparagraph, include in such meeting representatives of—

''(i) the Food and Drug Administration; and

''(ii) the National Vaccine Program.

''(C) The Secretary shall convene a meeting requested under subparagraph (A) not later than 120 days after receipt of the request for the meeting.

''(3)(A) Upon the submission of a written request by a vaccine developer, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall provide to the vaccine developer any age-based or other demographically assessed disease epidemiological analyses or data that—

''(i) are specified in the request;

''(ii) have been published;

''(iii) have been performed by or are in the possession of the Centers;

''(iv) are not a trade secret or commercial or financial information that is privileged or confidential and subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code; and

''(v) do not contain individually identifiable information.

''(B) The Secretary shall provide analyses requested by a vaccine manufacturer under subparagraph (A) not later than 90 calendar days after receipt of the request for the analyses.

''(4) The Secretary shall promptly notify a vaccine developer if—

''(A) the Secretary becomes aware of any change to information that was—

''(i) shared by the Secretary with the vaccine developer during a meeting under paragraph (2); or

''(ii) provided by the Secretary to the vaccine developer in one or more analyses under paragraph (3); and

''(B) the change may have implications for the vaccine developer's vaccine research and development.''.

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.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by section 2063, is further amended by inserting after section 505F of such Act the following:

"SEC. 505G. EXTENSION OF EXCLUSIVITY PERIODS FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.

"(a) DESIGNATION.—

"(1) IN GENERAL.—The Secretary shall designate a drug as a drug approved for a new indication to prevent, diagnose, or treat a rare disease or condition for purposes of granting the extensions under subsection (b) if—

"(A) prior to approval of an application or supplemental application for the new indication, the drug was approved or licensed for marketing under section 505(c) of this Act or section 351(a) of the Public Health Service Act,

but was not so approved or licensed for the new indication;

''(B)(i) the sponsor of the approved or licensed drug files an application or a supplemental application for approval of the new indication for use of the drug to prevent, diagnose, or treat the rare disease or condition; and

''(ii) the Secretary approves the application or supplemental application; and

''(C) the application or supplemental application for the new indication contains the consent of the applicant to notice being given by the Secretary under paragraph (4) respecting the designation of the drug.

''(2) REVOCATION OF DESIGNATION.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), a designation under this subsection shall not be revoked for any reason.

''(B) EXCEPTION.—The Secretary may revoke a designation of a drug under paragraph (1) if the Secretary finds that the application or supplemental application resulting in such designation contained an untrue statement of material fact.

''(3) NOTIFICATION PRIOR TO DISCONTINUANCE OF PRODUCTION FOR SOLELY COMMERCIAL REASONS.—A designation of a drug under paragraph (1) shall be subject to the condition that the sponsor of the drug will notify the Secretary of any discontinuance of the production of the drug for solely commercial reasons at least one year before such discontinuance.

''(4) NOTICE TO PUBLIC.—Notice respecting the designation of a drug under paragraph (1) shall be made available to the public.

''(b) EXTENSION.—If the Secretary designates a drug as a drug approved for a new indication for a rare disease or condition, as described in subsection (a)(1)—

''(1)(A) the 4-, 5-, and 7 ½-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 505, and the 7-year period described in section 527, as applicable, shall be extended by 6 months; or

''(B) the 4- and 12-year periods described in subparagraphs (A) and (B) of section 351(k)(7) of the Public Health Service Act and the 7-year period

described in section 527, as applicable, shall be extended by 6 months; and

''(2)(A) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 or a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of 6 months after the date the patent expires (including any patent extensions); or

''(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of 6 months after the date the patent expires (including any patent extensions).

''(c) RELATION TO PEDIATRIC AND QUALIFIED INFECTIOUS DISEASE PRODUCT EXCLUSIVITY.—Any extension under subsection (b) of a period shall be in addition to any extension of the periods under sections 505A and 505E of this Act and section 351(m) of the Public Health Service Act, as applicable, with respect to the drug.

''(d) LIMITATIONS.—The extension described in subsection (b) shall not apply if the drug designated under subsection (a)(1) has previously received an extension by operation of subsection (b).

''(e) REGULATIONS.—

''(1) IN GENERAL.—Not later than 2 years after the date of enactment of this section, the Secretary shall adopt final regulations implementing this section.

''(2) PROCEDURE.—In promulgating a regulation implementing this section, the Secretary shall—

''(A) issue a notice of proposed rulemaking that includes the proposed regulation;

''(B) provide a period of not less than 60 days for comments on the proposed regulation; and

''(C) publish the final regulation not less than 30 days before the effective date of the regulation.

''(3) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2), except that the Secretary may issue interim guidance for sponsors seeking to submit an application or supplemental application described in subsection (a) prior to the promulgation of such regulations.

''(4) DESIGNATION PRIOR TO REGULATIONS.—The Secretary shall designate drugs under subsection (a) prior to the promulgation of regulations under this subsection, if such drugs meet the criteria described in subsection (a).

''(f) DEFINITION.—In this section, the term 'rare disease or condition' has the meaning given to such term in section 526(a)(2).''.

(b) APPLICATION.—Section 505G of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to a drug for which an application or supplemental application described in subsection (a)(1)(B)(i) of such section 505G is first approved under section 505(c) of such Act (21 U.S.C. 355(c)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) on or after the date of the enactment of this Act.

(c) CONFORMING AMENDMENTS.—

(1) RELATION TO PEDIATRIC EXCLUSIVITY FOR DRUGS.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(A) in subsection (b), by adding at the end the following:

''(3) RELATION TO EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in subsection (b)(1) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in subsection (b)(1) shall be in addition to any extensions under section 505G.''; and

(B) in subsection (c), by adding at the end the following:

''(3) RELATION TO EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in subsection (c)(1) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in subsection (c)(1) shall be in addition to any extensions under section 505G.''.

(2) RELATION TO EXCLUSIVITY FOR NEW QUALIFIED INFECTIOUS DISEASE PRODUCTS THAT

ARE DRUGS.—Subsection (b) of section 505E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355f) is amended—

(A) by amending the subsection heading to read as follows: ''RELATION TO PEDIATRIC EXCLUSIVITY AND EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION''; and

(B) by striking ''any extension of the period under section 505A'' and inserting ''any extension of the periods under sections 505A and 505G, as applicable,''.

(3) RELATION TO PEDIATRIC EXCLUSIVITY FOR BIOLOGICAL PRODUCTS.—Section 351(m) of the Public Health Service Act (42 U.S.C. 262(m)) is amended by adding at the end the following:

''(5) RELATION TO EXCLUSIVITY FOR A BIOLOGICAL PRODUCT APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in paragraphs (2)(A), (2)(B), (3)(A), and (3)(B) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in such paragraphs shall be in addition to any extensions under section 505G.''.

[SEC. 2152. REAUTHORIZATION OF RARE PEDIATRIC DISEASE PRIORITY REVIEW VOUCHER INCENTIVE PROGRAM.

Section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) is amended—]

[(1) in subsection (a)—]

[(A) in paragraph (3), by amending subparagraph (A) to read as follows:]

[''(A) The disease is a serious and life-threatening disease in which the serious and life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents.''; and]

[(B) in paragraph (4)(A)—]

[(i) in subparagraph (E), by striking ''and'';]

[(ii) in subparagraph (F), by striking the period and inserting ''; and''; and]

[(iii) by adding at the end the following:]

[''(G) is for a drug or biological product for which a priority review voucher has not been issued under section 524 (relating to tropical disease products).''; and]

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

[''(5) TERMINATION OF AUTHORITY.—The Secretary may not award any priority review vouchers under paragraph (1) after June 30, 2022.''.]

Subtitle J—Domestic Manufacturing and Export Efficiencies

SEC. 2161. GRANTS FOR STUDYING THE PROCESS OF CONTINUOUS DRUG MANUFACTURING.

(a) IN GENERAL.—The Commissioner of Food and Drugs may award grants to institutions of higher education and nonprofit organizations for the purpose of studying and recommending improvements to the process of continuous manufacturing of drugs and biological products and similar innovative monitoring and control techniques.

(b) DEFINITIONS.—In this section:

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

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

(3) The term ''institution of higher education'' has the meaning given to such term in section 101

of the Higher Education Act of 1965 (20 U.S.C. 1001).

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

SEC. 2162. RE-EXPORTATION AMONG MEMBERS OF THE EUROPEAN ECONOMIC AREA.

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

(1) in paragraph (5)—

(A) by striking ''(5)'' and inserting ''(5)(A)'';

(B) by inserting '', except that the controlled substance may be exported from the second country to another country that is a member of the European Economic Area'' before the period at the end; and

(C) by adding at the end the following:

''(B) Subsequent to any re-exportation described in subparagraph (A), a controlled substance may continue to be exported from any country that is a member of the European Economic Area to any other such country, provided that—

''(i) the conditions applicable with respect to the first country under paragraphs (1), (2),

(3), (4), (6), and (7) are met by each subsequent country from which the controlled substance is exported pursuant to this paragraph; and

''(ii) the conditions applicable with respect to the second country under such paragraphs are met by each subsequent country to which the controlled substance is exported pursuant to this paragraph.''; and

(2) by adding at the end the following:

''(g) LIMITATION.—The Attorney General shall not promulgate nor enforce any regulation, subregulatory guidance, or enforcement policy which impedes re-exportation among European Economic Area countries (as provided in subsection (f)(5)), including by promulgating or enforcing any requirement that—

''(1) re-exportation from the first country to the second country or re-exportation from the second country to another country (as such terms are used in subsection (f)) occur within a specified period of time; or

''(2) information concerning the consignee, country, and product be provided prior to exportation of the controlled substance from the United States.''.

Subtitle K—Enhancing Combination Products Review

SEC. 2181. ENHANCING COMBINATION PRODUCTS REVIEW.

Section 503(g)(4)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)(4)(C)) is amended by adding at the end the following new clause:

''(iii) Not later than 18 months after the date of the enactment of the 21st Century Cures Act, the Secretary shall issue final guidance that describes the responsibilities of each agency center regarding its review of combination products. The Secretary shall, after soliciting public comment, review and update the guidance periodically.''.

Subtitle L—Priority Review for Breakthrough Devices

SEC. 2201. PRIORITY REVIEW FOR BREAKTHROUGH DEVICES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 515(d)—

(A) by striking paragraph (5); and

(B) by redesignating paragraph (6) as paragraph (5); and

(2) by inserting after section 515A (21 U.S.C. 360e–1) the following:

"SEC. 515B. PRIORITY REVIEW FOR BREAKTHROUGH DEVICES.

''(a) IN GENERAL.—In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, the Secretary shall establish a program to provide priority review for devices—

''(1) representing breakthrough technologies;

''(2) for which no approved alternatives exist;

''(3) offering significant advantages over existing approved or cleared alternatives, including the potential to, compared to existing approved or cleared alternatives, reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

''(4) the availability of which is in the best interest of patients.

''(b) REQUEST FOR DESIGNATION.—A sponsor of a device may request that the Secretary designate the device for priority review under this section. Any such request for designation may be made at any time prior to the submission of an application under section 515(c), a petition for classification under section 513(f)(2), or a notification under section 510(k).

''(c) DESIGNATION PROCESS.—

''(1) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under subsection (b), the Secretary shall determine whether the device that is the subject of the request meets the criteria described in subsection (a). If the Secretary determines that the device meets the criteria, the Secretary shall designate the device for priority review.

''(2) REVIEW.—Review of a request under subsection (b) shall be undertaken by a team that is composed of experienced staff and managers of the Food and Drug Administration and is chaired by a senior manager.

''(3) DESIGNATION DETERMINATION.—A determination approving or denying a request under subsection (b) shall be considered a significant decision under section 517A and the Secretary shall provide a written, substantive summary of the basis for the determination in accordance with section 517A(a).

''(4) RECONSIDERATION.—

''(A) REQUEST FOR RECONSIDERATION.—Any person whose request under subsection (b) is denied may, within 30 days of the denial, request reconsideration of the denial in accordance with section 517A(b)—

"(i) based upon the submission of documents by such person; or

"(ii) based upon such documents and a meeting or teleconference.

"(B) RESPONSE.—Reconsideration of a designation determination under this paragraph shall be conducted in accordance with section 517A(b).

"(5) WITHDRAWAL.—If the Secretary approves a priority review designation for a device under this section, the Secretary may not withdraw the designation based on the fact that the criteria specified in subsection (a) are no longer met because of the subsequent clearance or approval of another device that was designated under—

"(A) this section; or

"(B) section 515(d)(5) (as in effect immediately prior to the enactment of the 21st Century Cures Act).

"(d) PRIORITY REVIEW.—

"(1) ACTIONS.—For purposes of expediting the development and review of devices designated under subsection (c), the Secretary shall—

"(A) assign a team of staff, including a team leader with appropriate subject matter ex-

pertise and experience, for each device for which a request is submitted under subsection (b);

''(B) provide for oversight of the team by senior agency personnel to facilitate the efficient development of the device and the efficient review of any submission described in subsection (b) for the device;

''(C) adopt an efficient process for timely dispute resolution;

''(D) provide for interactive communication with the sponsor of the device during the review process;

''(E) expedite the Secretary's review of manufacturing and quality systems compliance, as applicable;

''(F) disclose to the sponsor in advance the topics of any consultation concerning the sponsor's device that the Secretary intends to undertake with external experts or an advisory committee and provide the sponsor an opportunity to recommend such external experts;

''(G) for applications submitted under section 515(c), provide for advisory committee input, as the Secretary determines appropriate

(including in response to the request of the sponsor); and

''(H) assign staff to be available within a reasonable time to address questions by institutional review committees concerning the conditions and clinical testing requirements applicable to the investigational use of the device pursuant to an exemption under section 520(g).

''(2) ADDITIONAL ACTIONS.—In addition to the actions described in paragraph (1), for purposes of expediting the development and review of devices designated under subsection (c), the Secretary, in collaboration with the device sponsor, may, as appropriate—

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

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

''(C) facilitate, to the extent scientifically appropriate, expedited and efficient develop-

ment and review of the device through utilization of timely postmarket data collection, with regard to applications for approval under section 515(c); and

''(D) agree to clinical protocols that the Secretary will consider binding on the Secretary and the sponsor, subject to—

''(i) changes agreed to by the sponsor and the Secretary;

''(ii) changes that the Secretary determines are required to prevent an unreasonable risk to the public health; or

''(iii) the identification of a substantial scientific issue determined by the Secretary to be essential to the safety or effectiveness of the device involved.

''(e) PRIORITY REVIEW GUIDANCE.—

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

''(A) The process for a person to seek a priority review designation.

''(B) A template for requests under subsection (b).

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

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

''(2) PROCESS.—Prior to finalizing the guidance under paragraph (1), the Secretary shall propose such guidance for public comment.

''(f) CONSTRUCTION.—

''(1) PURPOSE.—This section is intended to encourage the Secretary and provide the Secretary sufficient authorities to apply efficient and flexible approaches to expedite the development of, and prioritize the agency's review of, devices that represent breakthrough technologies.

''(2) CONSTRUCTION.—Nothing in this section shall be construed to alter the criteria and standards for evaluating an application pursuant to section 515(c), a report and request for classification under section 513(f)(2), or a report under section 510(k), including the recognition of valid scientific evidence as described in section 513(a)(3)(B), and consideration of the least burdensome means of evaluating

device effectiveness or demonstrating substantial equivalence between devices with differing technological characteristics, as applicable. Nothing in this section alters the authority of the Secretary to act on an application pursuant to section 515(d) before completion of an establishment inspection, as the Secretary deems appropriate.''.

(b) CONFORMING AMENDMENT RELATED TO DESIGNATION DETERMINATIONS.—Section 517A(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–1(a)(1)) is amended by inserting ''a request for designation under section 515B,'' after ''an application under section 515,''.

Subtitle M—Medical Device Regulatory Process Improvements

SEC. 2221. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.

(a) ESTABLISHMENT OF THIRD-PARTY QUALITY SYSTEM ASSESSMENT PROGRAM.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 524A (21 U.S.C. 360n–1) the following new section:

''SEC. 524B. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.

''(a) ACCREDITATION AND ASSESSMENT.—

''(1) IN GENERAL; CERTIFICATION OF DEVICE QUALITY SYSTEM.—The Secretary shall, in accord-

ance with this section, establish a third-party quality system assessment program—

"(A) to accredit persons to assess whether a requestor's quality system, including its design controls, can reasonably assure the safety and effectiveness of in-scope devices subject to device-related changes (as defined in paragraph (2));

"(B) under which accredited persons shall, as applicable, certify that a requestor's quality system meets the criteria issued under paragraph (5) with respect to the in-scope devices at issue; and

"(C) under which the Secretary shall rely on such certifications for purposes of determining the safety and effectiveness of in-scope devices subject to the device-related changes involved, in lieu of compliance with the following submission requirements:

"(i) A thirty-day notice (as defined in paragraph (2)).

"(ii) A Special PMA supplement (as defined in paragraph (2)).

"(2) DEFINITIONS.—For purposes of this section—

''(A) the term 'device-related changes' means changes made by a requestor with respect to in-scope devices, which are—

''(i) manufacturing changes subject to a 30-day notice;

''(ii) changes that qualify for a Special PMA supplement; and

''(iii) such other changes relating to the devices or the device manufacturing process as the Secretary determines appropriate;

''(B) the term 'in-scope device' means a device within the scope of devices agreed to by the requestor and the accredited person for purposes of a request for certification under this section;

''(C) the term 'quality system' means a quality system described in section 520(f);

''(D) the term 'requestor' means a device manufacturer that is seeking certification under this section of a quality system used by such manufacturer;

''(E) the term 'Special PMA' means a Special PMA supplement under section 814.39(d)

of title 21, Code of Federal Regulations (or any successor regulations); and

''(F) the term 'thirty-day notice' means a notice described in section 515(d)(6).

''(3) ACCREDITATION PROCESS; ACCREDITATION RENEWAL.—Except as inconsistent with this section, the process and qualifications for accreditation of persons and renewal of such accreditation under section 704(g) shall apply with respect to accreditation of persons and renewal of such accreditation under this section.

''(4) USE OF ACCREDITED PARTIES TO CONDUCT ASSESSMENTS.—

''(A) INITIATION OF ASSESSMENT SERVICES.—

''(i) DATE ASSESSMENTS AUTHORIZED.—Beginning after issuance of the final guidance under paragraph (5), an accredited person may conduct an assessment under this section.

''(ii) INITIATION OF ASSESSMENTS.—Use of one or more accredited persons to assess a requestor's quality system under this section with respect to in-scope devices shall be at the initiation of the person who

registers and lists the devices at issue under section 510.

''(B) COMPENSATION.—Compensation for such accredited persons shall—

''(i) be determined by agreement between the accredited person and the person who engages the services of the accredited person; and

''(ii) be paid by the person who engages such services.

''(C) ACCREDITED PERSON SELECTION.—Each person who chooses to use an accredited person to assess a requestor's quality system, as described in this section, shall select the accredited person from a list of such persons published by the Secretary in accordance with section 704(g)(4).

''(5) GUIDANCE; CRITERIA FOR CERTIFICATION.—

''(A) IN GENERAL.—The criteria for certification of a quality system under this section shall be as specified by the Secretary in guidance issued under this paragraph.

"(B) CONTENTS; CERTIFICATION CRITERIA.—The guidance under this paragraph shall include specification of—

"(i) evaluative criteria to be used by an accredited person to assess and as applicable certify a requestor's quality system under this section with respect to in-scope devices ; and

"(ii) criteria for accredited persons to apply a waiver of and exemptions from the certification criteria under clause (i).

"(C) TIMEFRAME FOR ISSUING GUIDANCE.—The Secretary shall issue under this paragraph—

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

"(ii) final guidance not later than 12 months after issuance of the draft guidance under clause (i).

"(b) USE OF THIRD-PARTY ASSESSMENT.—

"(1) ASSESSMENT SUMMARY; CERTIFICATION.—

"(A) SUBMISSION OF ASSESSMENT TO SECRETARY.—An accredited person who assesses a

requestor's quality system under subsection (a) shall submit to the Secretary a summary of the assessment—

"(i) within 30 days of the assessment; and

"(ii) which as applicable shall include—

"(I) the accredited person's certification that the requestor has satisfied the criteria issued under subsection (a)(5) for quality system certification with respect to the in-scope devices at issue; and

"(II) any waivers or exemptions from such criteria applied by the accredited person.

"(B) TREATMENT OF ASSESSMENTS.—Subject to action by the Secretary under subparagraph (C), with respect to assessments which include a certification under this section—

"(i) the Secretary's review of the assessment summary shall be deemed complete on the day that is 30 days after the

date on which the Secretary receives the summary under subparagraph (A); and

''(ii) the assessment summary and certification of the requestor shall be deemed accepted by the Secretary on such 30th day.

''(C) ACTIONS BY SECRETARY.—

''(i) IN GENERAL.—Within 30 days of receiving an assessment summary and certification under subparagraph (A), the Secretary may, by written notice to the accredited person submitting such assessment certification, deem any such certification to be provisional beyond such 30-day period, suspended pending further review by the Secretary, or otherwise qualified or cancelled, based on the Secretary's determination that (as applicable)—

''(I) additional information is needed to support such certification;

''(II) such assessment or certification is unwarranted; or

''(III) such action with regard to the certification is otherwise justified

according to such factors and criteria as the Secretary finds appropriate.

''(ii) ACCEPTANCE OF CERTIFICATION.—If following action by the Secretary under clause (i) with respect to a certification, the Secretary determines that such certification is acceptable, the Secretary shall issue written notice to the applicable accredited person indicating such acceptance.

''(2) NOTIFICATIONS TO SECRETARY BY CERTIFIED MANUFACTURERS FOR PROGRAM EVALUATION PURPOSES.—

''(A) PERIODIC NOTIFICATION FOR MANUFACTURING CHANGES OTHERWISE SUBJECT TO THIRTY-DAY NOTICE.—A requestor certified under this section that effectuates device-related changes with respect to in-scope devices, without prior submission of a thirty-day notice, shall provide notification to the Secretary of such changes in the requestor's next periodic report under section 814.84(b) of title 21, Code of Federal Regulations (or any successor regulation). Such notification shall—

''(i) describe the changes made; and

''(ii) indicate the effective dates of such changes.

''(B) PERIODIC NOTIFICATION FOR DEVICE-RELATED CHANGES OTHERWISE SUBJECT TO SPECIAL PMA SUPPLEMENT.—A requestor certified under this section that effectuates device-related changes with respect to in-scope devices, without prior submission of a Special PMA Supplement, shall provide notification to the Secretary of such changes in the requestor's next periodic report under section 814.84(b) of title 21, Code of Federal Regulations (or any successor regulation). Such notification shall—

''(i) describe the changes made, including a full explanation of the basis for the changes; and

''(ii) indicate the effective dates of such changes.

''(C) USE OF NOTIFICATIONS FOR PROGRAM EVALUATION PURPOSES.—Information submitted to the Secretary under subparagraphs (A) and (B) shall be used by the Secretary for purposes of the program evaluation under subsection (d).

''(c) DURATION AND EFFECT OF CERTIFICATION.—A certification under this section—

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

''(2) may be renewed through the process described in subsection (a)(3);

''(3) shall continue to apply with respect to device-related changes made during such 2-year period, provided the certification remains in effect, irrespective of whether such certification is renewed after such 2-year period;

''(4) shall have no effect on the need to comply with applicable submission requirements specified in subsection (a)(1)(C) with respect to any change pertaining to in-scope devices which is not a device-related change under subsection (a)(2);

''(5) shall have no effect on the authority of the Secretary to conduct an inspection or otherwise determine the requestor's conformance with the applicable requirements of this Act; and

''(6) shall be considered to be revoked if the Secretary provides written notification to the certified requestor that its quality system does not satisfy the certification criteria issued under subsection

(a)(5) with respect to the in-scope devices at issue, such that the applicable submission requirements specified in subsection (a)(1)(C) must be met for changes made after receipt of such written notification, with respect to such devices.

''(d) PROGRAM EVALUATION; SUNSET.—

''(1) PROGRAM EVALUATION AND REPORT.—

''(A) EVALUATION.—The Secretary shall complete an evaluation of the third-party quality system assessment program under this section no later than January 31, 2021, based on—

''(i) analysis of information from a representative group of device manufacturers obtained from notifications provided by certified requestors under subsection (b)(2); and

''(ii) such other available information and data as the Secretary determines appropriate.

''(B) REPORT.—No later than 1 year after completing the evaluation under subparagraph (A), the Secretary shall issue a report of the evaluation's findings on the website of the Food and Drug Administration, which shall include

the Secretary's recommendations with respect to continuation and as applicable expansion of the program under this section to include additional types of submissions and additional types of changes beyond those identified in subsection (a)(1)(C), including changes to devices cleared under section 510(k). At the discretion of the Secretary, the program may be expanded prior to January 31, 2021.

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

''(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the authority of the Secretary to request and review the complete assessment of a certified requestor under this section on a for-cause basis.''.

(b) CONFORMING AMENDMENTS.—

(1) REQUIREMENTS FOR PREMARKET APPROVAL SUPPLEMENTS.—Section 515(d)(6)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)(6)(A)(i)) is amended by inserting '', subject to section 524B,'' after ''that affects safety or effectiveness''.

(2) REQUIREMENTS FOR THIRTY-DAY NOTICE.—Section 515(d)(6)(A)(ii) of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)(6)(A)(ii)) is amended by inserting ", subject to section 524B," after "the date on which the Secretary receives the notice".

SEC. 2222. VALID SCIENTIFIC EVIDENCE.

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

(1) by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively;

(2) by striking "(B) If the Secretary" and inserting "(B)(i) If the Secretary"; and

(3) by adding at the end the following:

"(ii) Valid scientific evidence for purposes of clause (i) may include:

"(I) evidence described in well-documented case histories, including registry data, that are collected and monitored under an acceptable protocol;

"(II) studies published in peer-reviewed journals; and

"(III) data collected in countries other than the United States so long as such data otherwise meets the criteria specified in this subparagraph.

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

''(I) the Secretary, in making such request, complies with the requirement of subparagraph (D)(ii) to consider the least burdensome appropriate means of evaluating device effectiveness or subsection (i)(1)(D) to consider the least burdensome means of determining substantial equivalence, as applicable;

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

''(III) if the requested underlying data for such a study are unavailable, the Secretary shall consider such study to be part of the totality of the evidence with respect to the device, as the Secretary determines appropriate.''.

SEC. 2223. TRAINING AND OVERSIGHT IN LEAST BURDENSOME APPROPRIATE MEANS CONCEPT.

(a) IN GENERAL.— Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by inserting after subsection (i) the following:

''(j) TRAINING AND OVERSIGHT IN LEAST BURDENSOME APPROPRIATE MEANS CONCEPT.—

''(1) TRAINING.—Each employee of the Food and Drug Administration who is involved in the review of premarket submissions under section 515 or section 510(k), including supervisors, shall receive training regarding the meaning and implementation of the least burdensome appropriate means concept in the context of the use of that term in subsections (a)(3)(D) and (i)(1)(D) of this section and in section 515(c)(5).

''(2) GUIDANCE DOCUMENTS.—

''(A) DRAFT UPDATED GUIDANCE.—Not later than 12 months after the date of enactment of the 21st Century Cures Act, the Secretary shall issue a draft guidance document updating the October 4, 2002, guidance document entitled 'The Least Burdensome Provision of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry'.

''(B) MEETING OF STAKEHOLDERS.—In developing such draft guidance document, the Secretary shall convene a meeting of stakeholders to ensure a full record to support the publication of such document.

''(3) OMBUDSMAN AUDIT.—Not later than 18 months after the date of issuance of final version of the draft guidance under paragraph (2), the ombudsman for the organizational unit of the Food and Drug Administration responsible for the premarket review of devices shall—

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

''(B) include in such audit interviews with a representative sample of persons from industry regarding their experience in the device premarket review process.''.

(b) ADDITIONAL INFORMATION REGARDING PREMARKET APPLICATIONS.—Subsection (c) of section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S. C. 29 360e) is amended by adding at the end the follows:

''(5)(A) Whenever the Secretary requests additional information from an applicant regarding an application under paragraph (1), the Secretary shall consider the least burdensome appropriate means necessary to demonstrate

device safety and effectiveness, and request information accordingly.

''(B) For purposes of subparagraph (A), the term 'necessary' means the minimum required information that would support a determination by the Secretary that an application provides a reasonable assurance of the safety and effectiveness of the device.

''(C) Nothing in this paragraph alters the standards for premarket approval of a device.''.

SEC. 2224. RECOGNITION OF STANDARDS.

Section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)) is amended—

(1) in paragraph (1), by inserting after subparagraph (B) the following new subparagraphs:

''(C)(i) Any person may submit a request for recognition under subparagraph (A) of all or part of an appropriate standard established by a nationally or internationally recognized standard organization.

''(ii) Not later than 60 days after the Secretary receives such a request, the Secretary shall—

''(I) make a determination to recognize all, part, or none of the standard that is the subject of the request; and

''(II) issue to the person who submitted such request a respond in writing that states the Secretary's rationale for that determination, including the scientific, technical, regulatory, or other basis for such determination;

''(iii) The Secretary make a response issued under clause (ii)(II) publicly available, in such manner as the Secretary determines appropriate.

''(iv) The Secretary shall take such actions as may be necessary to implement all or part of a standard recognized under subclause (I), in accordance with subparagraph (A).

''(D) The Secretary shall make publicly available, in such manner as the Secretary determines appropriate, the rationale for recognition under subparagraph (A) of part of a standard, including the scientific, technical, regulatory, or other basis for such recognition.''; and

(2) by adding at the end the following new paragraphs:

''(4) TRAINING ON USE OF STANDARDS.—The Secretary shall provide to all employees of the Food

and Drug Administration who review premarket submissions for devices periodic training on the concept and use of recognized standards for purposes of meeting a premarket submission requirement or other applicable requirement under this Act, including standards relevant to an employee's area of device review.

''(5) GUIDANCE.—

''(A) DRAFT GUIDANCE.—The Secretary shall publish guidance identifying the principles for recognizing standards under this section. In publishing such guidance, the Secretary shall consider the experience with, and reliance on, a standard by other Federal regulatory authorities and the device industry, and whether recognition of a standard will promote harmonization among regulatory authorities in the regulation of devices.

''(B) TIMING.—The Secretary shall publish—

''(i) draft guidance under subparagraph (A) not later than 12 months after the date of the enactment of the 21st Century Cures Act; and

''(ii) final guidance not later than 12 months of the close of the public comment period for the draft guidance under clause (i).''.

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

(a) CLASS I DEVICES.—Section 510(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is amended—

(1) by striking ''A report under subsection (k)'' and inserting ''(1) A report under subsection (k)''; and

(2) by adding at the end the following new paragraph:

''(2) Not later than 120 days after the date of the enactment of the 21st Century Cures Act, the Secretary shall identify, through publication in the Federal Register, any type of class I device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Upon such publication—

''(A) each type of class I device so identified shall be exempt from the requirement for a report under subsection (k); and

''(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.''.

(b) CLASS II DEVICES.—Section 510(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)) is amended—

(1) by striking paragraph (1) and inserting the following new paragraph:

''(1) The Secretary shall—

''(A) not later than 60 days after the date of the enactment of the 21st Century Cures Act—

''(i) publish in the Federal Register a notice that contains a list of each type of class II device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness; and

''(ii) provide for a period of not less than 60 days for public comment beginning on the date of the publication of such notice; and

''(B) not later than 180 days after the date of the enactment of 21st Century Cures Act, publish in the Federal Register a list representing the Secretary's final determination with respect to the de-

vices contained in the list published under subparagraph (A).'';

(2) in paragraph (2)—

(A) by striking ''1 day after the date of publication of a list under this subsection,'' and inserting ''1 day after the date of publication of the final list under paragraph (1)(B),''; and

(B) by striking ''30-day period'' and inserting ''60-day period''; and

(3) by adding at the end the following new paragraph:

''(3) Upon the publication of the final list under paragraph (1)(B)—

''(A) each type of class II device so listed shall be exempt from the requirement for a report under subsection (k); and

''(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.''.

SEC. 2226. ADVISORY COMMITTEE PROCESS.

(a) CLASSIFICATION PANELS.—Paragraph (5) of section 513(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)) is amended—

(1) by striking ''(5)'' and inserting ''(5)(A)''; and

(2) by adding at the end the following:

''(B) For review by a classification panel of a premarket submission for a device, the Secretary shall—

''(i) provide an opportunity for the person whose premarket submission is subject to panel review to provide recommendations on the expertise needed among the voting members of the panel; and

''(ii) give due consideration to such recommendations and ensure that adequate expertise is represented on advisory panels to assess—

''(I) the disease or condition for which the device is intended to cure, treat, mitigate, prevent, or diagnose; and

''(II) the technology of the device.

''(C) For purposes of subparagraph (B)(ii), the term 'adequate expertise' means that the membership of the classification panel reviewing a premarket submission includes—

''(i) two or more voting members, with a specialty or other expertise clinically relevant to the device under review; and

''(ii) at least one voting member who is knowledgeable about the technology of the device.''.

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

(1) in subparagraph (A)(iii), by inserting before the period at the end '', including by designating a representative who will be provided a time during the panel meeting to address the panel individually (or accompanied by experts selected by such representative) for the purpose of correcting misstatements of fact or providing clarifying information, subject to the discretion of panel chairperson.''.

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

''(B)(i) Any meeting of a classification panel with respect to the review of a premarket submission for a device shall—

''(I) provide adequate time for initial presentations by the person whose pre-

market submission is specifically the subject of such review and by the Secretary; and

''(II) encourage free and open participation by all interested persons.

''(ii) Following the initial presentations described in clause (i), the panel may—

''(I) pose questions to a designated representative described in subparagraph (A)(iii); and

''(II) consider the responses to such questions in the panel's review of the premarket submission.''.

SEC. 2227. HUMANITARIAN DEVICE EXEMPTION APPLICATION.

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

(1) in paragraph (1) by striking ''fewer than 4,000'' and inserting ''not more than 8,000'';

(2) in paragraph (2)(A) by striking ''fewer than 4,000'' and inserting ''not more than 8,000''; and

(3) in paragraph (6)(A)(ii), by striking ''4,000'' and inserting ''8,000''

(b) GUIDANCE DOCUMENT ON PROBABLE BENEFIT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a draft guidance document that defines the criteria for establishing ''probable benefit'' as that term is used in section 520(m)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)(C)).

SEC. 2228. CLIA WAIVER STUDY DESIGN GUIDANCE FOR IN VITRO DIAGNOSTICS.

(a) DRAFT REVISED GUIDANCE.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall publish a draft guidance that—

(1) revises section V ''Demonstrating Insignificant Risk of an Erroneous Result—'Accuracy' '' of the guidance entitled ''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices'' and dated January 30, 2008; and

(2) includes guidance on the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy.

(b) FINAL REVISED GUIDANCE.—The Secretary of Health and Human Services shall finalize the draft guidance published under subsection (a) not later than 12 months after the comment period for such draft guidance closes.

Subtitle N—Sensible Oversight for Technology Which Advances Regulatory Efficiency

SEC. 2241. HEALTH SOFTWARE.

Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(ss)(1) The term 'health software' means software that does not, through use of an in vitro diagnostic device or signal acquisition system, acquire, process, or analyze an image or physiological signal, is not an accessory, is not an integral part of a device necessary to support the use of the device, and—

''(A) is intended for use for administrative or operational support or the processing and maintenance of financial records;

''(B) is intended for use in clinical, laboratory, or administrative workflow and related recordkeeping;

''(C)(i) is intended for use solely in the transfer, aggregation, conversion (in accordance with a present specification), storage, management, retrieval, or transmission of data or information;

''(ii) utilizes a connectivity software platform, electronic or electrical hardware, or a physical communications infrastructure; and

''(iii) is not intended for use—

''(I) in active patient monitoring; or

''(II) in controlling or altering the functions or parameters of a device that is connected to such software;

''(D) is intended for use to organize and present information for health or wellness education or for use in maintaining a healthy lifestyle, including medication adherence and health management tools;

''(E) is intended for use to analyze information to provide general health information that does not include patient-specific recommended options to consider in the prevention, diagnosis, treatment, cure, or mitigation of a particular disease or condition; or

''(F) is intended for use to analyze information to provide patient-specific recommended options to consider in the prevention, diagnosis, treatment, cure, or mitigation of a particular disease or condition.

''(2) The term 'accessory' means a product that—

''(A) is intended for use with one or more parent devices;

''(B) is intended to support, supplement, or augment the performance of one or more parent devices; and

''(C) shall be classified by the Secretary—

''(i) according to its intended use; and

''(ii) independently of any classification of any parent device with which it is used.''.

SEC. 2242. APPLICABILITY AND INAPPLICABILITY OF REGULATION.

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

''SEC. 524B. HEALTH SOFTWARE.

''(a) INAPPLICABILITY OF REGULATION TO HEALTH SOFTWARE.—Subject to subsection (b), health software shall not be subject to regulation under this Act.

''(b) EXCEPTION.—Subsection (a) shall not apply in the case of a software product of a type described in subparagraph (F) of section 201(ss)(1) that the Secretary determines poses a significant risk to patient safety. In making such a determination for such product, the Secretary shall consider the following:

''(1) The likelihood and severity of patient harm if the product were to not perform as intended.

''(2) The extent to which the product is intended to support the clinical judgment of a medical professional.

''(3) Whether there is a reasonable opportunity for a medical professional to review the basis of the information or treatment recommendation provided by the product.

''(4) The intended use of the product, including the intended user and user environment, such as whether a medical professional will use a software product of a type described in subparagraph (F) of section 201(ss)(1).

''(c) DELEGATION.—The Secretary shall delegate primary jurisdiction for regulating a software product determined under subsection (b) to be subject to regulation

under this Act to the center at the Food and Drug Administration charged with regulating devices.

''(d) REGULATION OF SOFTWARE.—

''(1) IN GENERAL.—The Secretary shall review existing regulations and guidance regarding the regulation of software under this Act. The Secretary may implement a new framework for the regulation of software and shall, as appropriate, modify such regulations and guidance or issue new regulations or guidance.

''(2) ISSUANCE BY ORDER.—Notwithstanding subchapter II of chapter 5 of title 5, United States Code, the Secretary may modify or issue regulations for the regulation of software under this Act by administrative order published in the Federal Register following the publication of a proposed order.

''(3) AREAS UNDER REVIEW.—The review of existing regulations and guidance under paragraph (1) may include review of the following areas:

''(A) Classification of software.

''(B) Standards for development of software.

''(C) Standards for validation and verification of software.

''(D) Review of software.

''(E) Modifications to software.

''(F) Manufacturing of software.

''(G) Quality systems for software.

''(H) Labeling requirements for software.

''(I) Postmarketing requirements for reporting of adverse events.

''(4) PROCESS FOR ISSUING PROPOSED REGULATIONS, ADMINISTRATIVE ORDER, AND GUIDANCE.—Not later than 18 months after the date of enactment of this section, the Secretary shall consult with external stakeholders (including patients, industry, health care providers, academia, and government) to gather input before issuing regulations, an administrative order, and guidance under this subsection.''.

SEC. 2243. EXCLUSION FROM DEFINITION OF DEVICE.

Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended—

(1) in subparagraph (2), by striking ''or'' after ''or other animals,'';

(2) in subparagraph (3), by striking ''and'' and inserting ''or''; and

(3) by inserting after subparagraph (3) the following:

''(4) is not health software (other than software determined to be a risk to patient safety under section 524B(b)), and''.

Subtitle O—Streamlining Clinical Trials

[SEC. 2261. PROTECTION OF HUMAN SUBJECTS IN RESEARCH; APPLICABILITY OF RULES.

Part H of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by inserting after section 491 the following section:]

["SEC. 491A. PROTECTION OF HUMAN SUBJECTS IN RESEARCH; APPLICABILITY OF RULES.

[''(a) PROTECTION OF HUMAN SUBJECTS.—]

[''(1) IN GENERAL.—All human subject research described in paragraph (2)(A) shall be conducted in accordance with the HHS Human Subject Regulations, and as applicable to the human subjects involved in such research, with the vulnerable-populations rules.]

[''(2) APPLICABILITY.—]

[''(A) IN GENERAL.—This section applies to human subject research that is—]

[''(i) conducted or supported by the Department of Health and Human Services; or]

[“(ii) otherwise subject to regulation by the Department under a provision of Federal law (other than this section).]

[“(B) OTHER FEDERAL DEPARTMENTS AND AGENCIES.—The Secretary shall make available assistance to any Federal department or agency seeking—]

[“(i) to improve the regulation or oversight of human subject research; or]

[“(ii) to apply the HHS Human Subject Regulations or the vulnerable-populations rules to human subject research that is conducted, supported, or regulated by such department or agency.]

[“(b) HHS HUMAN SUBJECT REGULATIONS; OTHER DEFINITIONS.—]

[“(1) HHS HUMAN SUBJECT REGULATIONS; VULNERABLE-POPULATIONS RULES.—For purposes of this section:]

[“(A) The term ‘HHS Human Subject Regulations’—]

[“(i) subject to clause (ii), means the provisions of subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations); or]

[“(ii) in the case of human subject research that is subject to the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act, means the provisions of parts 50, 56, 312, and 812 of title 21, Code of Federal Regulations (or any successor regulations).]

[“(B) The term ‘vulnerable-populations rules’—]

[“(i) subject to clause (ii), means the provisions of subparts B through D of such part 46 (or any successor regulations); or]

[“(ii) as applicable to the human subjects involved in research described in subparagraph (A), means the provisions applicable to vulnerable populations under part 56 of such title 21 (or any successor regulations) and subpart D of part 50 of such title 21 (or any successor regulations).]

[“(2) HUMAN SUBJECT RESEARCH.—For purposes of this section:]

[“(A) Except as provided in subparagraph (B), the term ‘human subject research’ means research, as defined in subpart A of part 46 of

title 45, Code of Federal Regulations (or any successor regulations), that involves a human subject, as defined in such subpart A (or any successor regulations).]

[“(B) In the case of an investigation that is subject to the provisions of part 50 of title 21, Code of Federal Regulations (or any successor regulations), the term ‘human subject’ has the meaning given such term in such part 50, and the term ‘human subject research’ means a clinical investigation as defined in such part 50.]

[“(3) OTHER DEFINITIONS.—For purposes of this section:]

[“(A) The term ‘institutional review board’ has the meaning that applies to the term ‘institutional review board’ under the HHS Human Subject Regulations.]

[“(B) The term ‘lead institutional review board’ means an institutional review board that otherwise meets the requirements of the HHS Human Subject Regulations and enters into a written agreement with an institution, another institutional review board, a sponsor, or a principal investigator to approve and oversee human

subject research that is conducted at multiple locations. References to an institutional review board include an institutional review board that serves a single institution as well as a lead institutional review board.]

[“(c) SCOPE OF AUTHORITY OF SECRETARY.—]

[“(1) IN GENERAL.—The HHS Human Subject Regulations (including provisions regarding exemptions) and the vulnerable-populations rules, as in effect on the day before the date of the enactment of the 21st Century Cures Act, continue to be in effect on and after such date, subject to paragraph (2).]

[“(2) MODIFICATIONS.—]

[“(A) COMPLIANCE WITH LAW.—Promptly after the date of the enactment of the Act referred to in paragraph (1), the Secretary shall promulgate regulations to make such modifications to the provisions of the HHS Human Subject Regulations as may be necessary to ensure that such provisions implement, and do not conflict with, this section.]

[“(B) OTHER MODIFICATIONS.—This section may not be construed as affecting the authority of the Secretary to modify the provisions of the HHS Human Subject Regulations or the

vulnerable-populations rules, except to the extent that any such modification is in conflict with this section. Any such modification shall be made by regulation or guidance, as applicable.]

[''(d) AVOIDING REGULATORY DUPLICATION AND UNNECESSARY DELAYS.—]

[''(1) IN GENERAL.—The Secretary shall—]

[''(A) make such modifications to the provisions of the HHS Human Subject Regulations and the vulnerable-populations rules as may be necessary—]

[''(i) to reduce regulatory duplication and unnecessary delays;]

[''(ii) to modernize such provisions in the context of multisite and cooperative research projects;]

[''(iii) to incorporate local considerations, community values, and mechanisms to protect vulnerable populations; and]

[''(iv) to ensure that human subject research that is subject to the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act, and is therefore subject to parts 50, 56, 312, and 812 of title

21, Code of Federal Regulations (or any successor regulations), is not subject to subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations); and]

[“(B) ensure that human subject research that is described in subparagraph (A)(iv), or is cooperative research as such term is defined in section 46.114 of title 45, Code of Federal Regulations (or any successor regulations), may—]

[“(i) use joint or shared review;]

[“(ii) rely upon the review of—]

[“(I) an independent institutional review board; or]

[“(II) an institutional review board of an entity other than the sponsor of the research; or]

[“(iii) use similar arrangements to avoid duplication of effort.]

[“(2) REGULATIONS AND GUIDANCE.—Not later than 12 months after the date of enactment of the 21st Century Cures Act, the Secretary, acting through the relevant agencies and offices of the Department of Health and Human Services, including

the Office for Human Research Protections and relevant agencies and offices of the Food and Drug Administration, shall issue such regulations and guidance and take such other actions as may be necessary to implement this subsection. Such regulations and guidance shall include clarification of requirements and policies relating to the following:]

[''(A) Arrangements to avoid duplication described in paragraph (1)(C), including—]

[''(i) delineating the roles of institutional review boards in multisite or cooperative, multisite studies where one or more local institutional review boards are relied upon, or similar arrangements are used;]

[''(ii) the risks and benefits to human subjects;]

[''(iii) standardization of informed consent and other processes and legal documents; and]

[''(iv) incorporating community values through the use of local institutional review boards while continuing to use central or lead institutional review boards.]

[''(B) Concerns about regulatory and legal liability contributing to decisions by the spon-

sors of research to rely on local institutional review boards for multisite research.]

[''(3) CONSULTATION.—In issuing regulations or guidance pursuant to paragraph (2), the Secretary shall consult with stakeholders (including researchers, academic organizations, hospitals, institutional research boards, pharmaceutical, biotechnology and medical device developers, clinical research organizations, patient groups, and others).''.]

SEC. 2262. USE OF NON-LOCAL INSTITUTIONAL REVIEW BOARDS FOR REVIEW OF INVESTIGATIONAL DEVICE EXEMPTIONS AND HUMAN DEVICE EXEMPTIONS.

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

(1) in subsection (g)(3)—

(A) by striking ''local'' each place it appears; and

(B) in subparagraph (A)(i), by striking ''which has been''; and

(2) in subsection (m)(4)—

(A) by striking ''local'' each place it appears; and

(B) by striking subparagraph (A) and inserting the following new subparagraph:

''(A) in facilities in which clinical testing of devices is supervised by an institutional review committee established in accordance with the regulations of the Secretary, and''.

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

SEC. 2263. ALTERATION OR WAIVER OF INFORMED CONSENT FOR CLINICAL INVESTIGATIONS.

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

(1) in subparagraph (D), by striking ''except where subject to such conditions as the Secretary may prescribe, the investigator'' and inserting the following: ''except where, subject to such conditions as the Secretary may prescribe—

''(i) the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject; or

''(ii) the investigator''; and

(2) in the matter following subparagraph (D), by striking ''subparagraph (D)'' and inserting ''subparagraph (D)(ii)''.

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

Subtitle P—Improving Scientific Expertise and Outreach at FDA

SEC. 2281. SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH SERVICE.

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

(1) in the section heading, by inserting ''AND BIOMEDICAL PRODUCT ASSESSMENT'' after ''RESEARCH'';

(2) in subsection (a)(1), by striking ''Silvio O. Conte Senior Biomedical Research Service, not to

exceed 500 members'' and inserting ''Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service (in this section referred to as the 'Service'), the purpose of which is to recruit and retain competitive and qualified scientific and technical experts outstanding in the field of biomedical research, clinical research evaluation, and biomedical product assessment'';

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

''(2) The authority established in paragraph (1) may not be construed to require the Secretary to reduce the number of employees serving under any other employment system in order to offset the number of members serving in the Service.'';

(4) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking ''or clinical research evaluation'' and inserting '', clinical research evaluation or biomedical product assessment'' after ''evaluation''; and

(B) in paragraph (1), by inserting ''or a master's level degree in engineering, bioinformatics, or a related or emerging field,'' after the comma;

(5) in subsection (d), by striking ''and shall not exceed the rate payable for level I of the Executive Schedule unless approved by the President under section 5377(d)(2) of title 5, United States Code'' and inserting ''and shall not exceed the rate payable for the President'';

(6) by striking subsection (e); and

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

(b) REPORT.—Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit, and publish on the website of the Department of Health and Human Services a report on the implementation of the amendments made by subsection (a), including whether the amendments have improved the ability of the Food and Drug Administration to hire and retain qualified experts to fulfill obligations specified under user fee agreements.

SEC. 2282. ENABLING FDA SCIENTIFIC ENGAGEMENT.

It is the sense of Congress that participation in or sponsorship of scientific conferences and meetings is essential to the mission of the Food and Drug Administration.

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

(a) BOARD OF DIRECTORS.—

(1) COMPOSITION AND SIZE.—Section 770(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(C)) is amended—

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

(B) by inserting after clause (i) the following:

"(ii) ADDITIONAL MEMBERS.—The Board, through amendments to the bylaws of the Foundation, may provide that the number of voting members of the Board shall be a number (to be specified in such amendment) greater than 14. Any Board positions that are established by any such amendment shall be appointed (by majority vote) by the individuals who, as of the date of such amendment, are voting members of the Board and persons so appointed may represent any of the categories specified in subclauses (I) through (V) of clause (i), so long as no more than 30 percent of the total voting members of the Board (including members whose positions are estab-

lished by such amendment) are representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries.''; and

(C) in clause (iii)(I), as redesignated by subparagraph (A), by striking ''The ex officio members shall ensure'' and inserting ''The ex officio members, acting pursuant to clause (i), and the Board, acting pursuant to clause (ii), shall ensure''.

(2) FEDERAL EMPLOYEES ALLOWED TO SERVE ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(C)), as redesignated by paragraph (1)(A), is amended by adding at the end the following: ''For purposes of this section, the term 'employee of the Federal Government' does not include a 'special Government employee', as that term is defined in section 202(a) of title 18, United States Code.''.

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

''(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C)(i), and the term of office of any member of the Board whose position is established pursuant to paragraph (1)(C)(ii), shall be 4 years, except that—

''(i) the terms of offices for the members of the Board initially appointed under paragraph (1)(C)(i) shall expire on a staggered basis as determined by the ex officio members; and

''(ii) the terms of office for the persons initially appointed to positions established pursuant to paragraph (1)(C)(ii) may be made to expire on a staggered basis, as determined by the individuals who, as of the date of the amendment establishing such positions, are members of the Board.''.

(b) EXECUTIVE DIRECTOR COMPENSATION.—Section 770(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(g)(2)) is amended by striking ''but shall not be greater than the compensation of the Commissioner''.

(c) SEPARATION OF FUNDS.—Section 770(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(m)) is amended by striking ''are held in separate accounts from funds received from entities under subsection (i)'' and inserting ''are managed as individual programmatic funds under subsection (i), according to best accounting practices''.

SEC. 2284. COLLECTION OF CERTAIN VOLUNTARY INFORMATION EXEMPTED FROM PAPERWORK REDUCTION ACT.

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

''SEC. 708A. COLLECTION OF CERTAIN VOLUNTARY INFORMATION EXEMPTED FROM PAPERWORK REDUCTION ACT.

''Chapter 35 of title 44, United States Code, shall not apply to the collection from patients, industry, academia, and other stakeholders, of voluntary information such as through voluntary surveys or questionnaires, initiated by the Secretary.''.

TITLE III—DELIVERY

Subtitle A—Interoperability

SEC. 3001. ENSURING INTEROPERABILITY.

(a) DEVELOPMENT OF AND RECOMMENDATIONS FOR METHODS TO MEASURE INTEROPERABILITY.—Subtitle A of title XXX of the Public Health Service Act (42 U.S.C. 300jj–11 et seq.) is amended by adding at the end the following new section:

"SEC. 3010. ENSURING INTEROPERABILITY OF [QUALIFIED ELECTRONIC HEALTH RECORDS]/[HEALTH INFORMATION TECHNOLOGY].

''(a) INTEROPERABILITY.—In order for [qualified electronic health record]/[health information technology] to be considered interoperable, such [record]/[technology] must satisfy the following criteria:

''(1) SECURE TRANSFER.—The [record]/[technology] allows the secure transfer of the entirety of a patient's data from any and all [qualified electronic health records]//[health information technology] for [authorized use].

''(2) COMPLETE ACCESS TO HEALTH DATA.—The [record]/[technology] allows access to the entirety of a patient's data for [authorized use] without special effort, as defined by recommendations adopted in accordance with this section, by the re-

questor of such data unless such data is not disclosable under applicable law.

''(3) NO INFORMATION BLOCKING.—The [record]/[technology] is not [configured, set up, or implemented] to engage in information blocking, as defined in section 3010A(f).

''(b) DETERMINING METHODS BY WHICH TO MEASURE IF [QUALIFIED ELECTRONIC HEALTH RECORDS]/[HEALTH INFORMATION TECHNOLOGY][ARE]/[IS] INTEROPERABLE.—

''(1) IN GENERAL.—The Secretary shall adopt, in accordance with this section and section 3004(c)—

''(A) methods by which to measure if [qualified electronic health records]/[health information technology] satisfy the criteria described in subsection (a); and

''(B) as appropriate, modifications (including additions) to such methods, that are in accordance with the policies developed by the HIT Policy Committee under section 3002(b)(2)(A) with respect to such methods.

''(2) RULES FOR ADOPTION.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), any method adopted under

section 3004(c) or modification to such a method adopted under subsection (c)(2)(B)(ii), pursuant to this subsection, shall be a method that has been recommended by the Charter Organization established under subsection (c).

''(B) SPECIAL RULES.—

''(i) DIFFERENT METHODS.—The Secretary may adopt a method that is different from any method recommended under subsection (c) by the Charter Organization, if—

''(I) the different method will substantially reduce administrative costs to health care providers and health plans compared to the alternatives; and

''(II) the method is promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of title 5, United States Code.

''(ii) NO METHOD BY CHARTER ORGANIZATION.—If the Charter Organization under subsection (c) has not recommended any method relating to the criteria described in subsection (a)—

''(I) subparagraph (A) shall not apply; and

''(II) paragraph (3) shall apply.

''(C) CONSULTATION REQUIREMENT.—

''(i) IN GENERAL.—The Secretary, in complying with paragraph (3), may not adopt under this subsection a method that has not been recommended by the Charter Organization under subsection (c) unless the Secretary consulted with each of the organizations described in clause (ii) before adopting the method.

''(ii) ORGANIZATIONS DESCRIBED.—The organizations referred to in clause (i) are each of the health care standards development organizations accredited by the American National Standards Institute.

''(D) EFFECTIVE DATE.—Any method adopted under clause (i) or (ii) of paragraph (2)(B) shall be effective 12 months after the date of publication of the final rule to adopt such method.

''(3) ASSISTANCE TO THE SECRETARY.—In complying with the requirements of this subsection, the Secretary shall rely on the recommendations of

the National Committee on Vital and Health Statistics established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k)), and shall consult with appropriate Federal and State agencies and private organizations. The Secretary shall publish in the Federal Register any recommendation of the National Committee on Vital and Health Statistics regarding the adoption of a method under this subsection. Any method adopted pursuant to this paragraph shall be promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of title 5, United States Code.

''(4) APPLICATION TO MODIFICATION OF METHODS.—Paragraphs (2) and (3) shall apply to a modification to a method (including an addition to a method) adopted pursuant to paragraph (1)(B) in the same manner as such paragraphs apply to an initial method adopted pursuant to paragraph (1)(A).

''(c) CHARTER ORGANIZATION.—

''(1) ESTABLISHMENT.—Not later than 180 days after the date of the enactment of this section, the Secretary shall seek to enter into a contract with health care standards development organizations accredited by the American National Standards Insti-

tute to establish a committee to be known as the 'Charter Organization'. Under such contract, the Charter Organization shall provide to the HIT Standards Committee for adoption under this section and section 3004(c), as applicable, recommendations, in accordance with this section, for methods in which to measure if [qualified electronic health records]/[health information technology] satisfy the criteria described in subsection (a) and modifications to such methods, which are in accordance with the policies developed by the HIT Policy Committee under section 3002(b)(2)(A) with respect to such methods.

''(2) RECOMMENDATIONS.—

''(A) INITIAL METHODS.—Not later than one year after the date of the enactment of this section, the Charter Organization shall submit to the HIT Standards Committee recommendations for an initial set of methods described in paragraph (1).

''(B) MODIFICATIONS AND ADDITIONS.—

''(i) EVALUATIONS AND REPORTS.—

''(I) HEARINGS.—Not later than 3 years after the date of the enactment of this section, and not less than

biennially thereafter, the Secretary, acting through the Charter Organization, shall conduct hearings to evaluate and review the methods adopted under section 3004(c) and subsection (b)(2)(B).

''(II) REPORT.—Not later than five years after the date of the enactment of this section, and not less than biennially thereafter, the Charter Organization shall provide recommendations to the HIT Standards Committee for updating and improving such methods, in accordance with the policies developed by the HIT Policy Committee under section 3002(b)(2)(A) with respect to such methods.

''(ii) INTERIM FINAL RULEMAKING.—

''(I) IN GENERAL.—Subject to subclause (III) and subsection (b)(2)(B) and notwithstanding section 3004, any recommendations submitted by the Charter Organization under clause (i)(II) shall be adopted by the

Secretary through promulgation of an interim final rule not later than 90 days after receipt by the Secretary of the organization's submission from the HIT Standards Committee.

"(II) PUBLIC COMMENT.—The Secretary shall accept and consider public comments on any interim final rule published under this clause for 60 days after the date of such publication.

"(III) AUTHORITY NOT TO ADOPT.—The Secretary, after the period of public comment described in subclause (II), may determine not to adopt a recommendation to amend an adopted method. Not later than 90 days after the date of such determination, the Secretary shall publish in the Federal Register the reason for such determination not to adopt such recommendation.

"(IV) EFFECTIVE DATE.—The effective date of any amendment to existing methods that is adopted

through an interim final rule published under this paragraph shall be 12 months following the close of the public comment period described in subclause (II).

''(3) MEMBERSHIP.—The Charter Organization shall consist of one representative from each of the health care standards development organizations accredited by the American National Standards Institute.

''(4) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $10,000,000 for a contract with the Charter Organization entered into under paragraph (1), to remain available until expended.

''(d) HARMONIZATION.—In carrying out this section, the Secretary shall recognize methods, with respect to interoperability of [qualified electronic health records]/[health information technology], from an entity or entities for the purpose of harmonizing or updating methods in order to achieve uniform and consistent implementation of the methods.

''(e) PILOT TESTING OF METHODS.—In the development, harmonization, or recognition of methods under this section, the Secretary shall, as appropriate, provide for the

testing of such methods by the National Institute for Standards and Technology under section 13201(a) of the Health Information Technology for Economic and Clinical Health Act.

''(f) CONSISTENCY.—The methods recommended under this section shall be consistent with the standards for information transactions and data elements adopted pursuant to section 1173 of the Social Security Act.''.

(b) MODIFICATIONS TO HIT POLICY COMMITTEE TO INCORPORATE POLICIES FOR UPDATES TO INTEROPERABILITY METHODS.—Section 3002(b)(2) of the Public Health Service Act (42 U.S.C. 300jj–12(b)(2)) is amended—

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

(A) by striking ''The HIT Policy Committee'' and inserting ''Subject to subparagraph (D), the HIT Policy Committee'';

(B) by inserting ''(and the areas in which modifications and additions to methods to measure if [qualified electronic health records]/[health information] satisfy the criteria described in subsection (a) of section 3010 are needed for the electronic exchange and use of health information for purposes of adoption of such modifications and additions under sub-

section (c)(2)(B) of such section)'' after ''section 3004''; and

(C) by striking ''such standards, specifications, and certification criteria'' and inserting ''such standards, specifications, certification criteria, and methods''; and

(2) by adding at the end the following new subparagraph:

''(D) SPECIAL RULE RELATED TO INTEROPERABILITY.—Any recommendation made by the HIT Policy Committee on or after the date of the enactment of this subparagraph with respect to interoperability of [qualified electronic health records]/[health information technology] shall be consistent with the criteria described in subsection (a) of section 3010.''.

(c) MODIFICATIONS TO HIT STANDARDS COMMITTEE TO INCORPORATE INTEROPERABILITY RECOMMENDATIONS.—Section 3003 of the Public Health Service Act (42 U.S.C. 300jj–13) is amended—

(1) in subsection (a), by inserting before the period at the end the following: ''and, in accordance with subsection (b)(1)(E), to submit to the Secretary methods in which to measure if [qualified electronic health records]/[health information technology] sat-

isfy the criteria described in subsection (a) of section 3010 (and modifications to such methods) that are recommended to the HIT Standards Committee under subsection (c) of such section for adoption under section 3004(c)''; and

(2) in subsection (b)(1), by adding at the end the following new subparagraph:

''(E) METHODS TO MEASURE INTEROPERABILITY.—The HIT Standards Committee shall submit to the Secretary, in accordance with section 3010, recommendations submitted by the Charter Organization under subsection (c) of such section (along with comments by the HIT Standards Committee with respect to such recommendations) for methods in which to measure if [qualified electronic health records]/[health information technology] satisfy the criteria described in subsection (a) of such section (and for modifications to such methods) for adoption by the Secretary under section 3004(c). To the extent that any such recommendation submitted to the Secretary for such adoption is inconsistent with or duplicative of a recommendation under subparagraph (A), the recommendation under this subparagraph

shall supercede the recommendation under subparagraph (A).''.

(d) ADOPTION.—Section 3004 of the Public Health Service Act (42 U.S.C. 300jj–14) is amended—

(1) in subsection (b), by adding at the end the following new paragraph:

''(4) LIMITATION.—The Secretary may not adopt any standards, implementation specifications, or certification criteria under this subsection or subsection (a) that are inconsistent with or duplicative of a method adopted under subsection (c) or section 3010. In the case of a standard, specification, or criterion that has been adopted under this section and is inconsistent or duplicative of a method that is subsequently adopted under subsection (c) or section 3010, such method shall supercede such standard, specification, or criterion and such standard, specification, or criterion shall no longer be considered adopted under this section beginning on the date that such method becomes effective.''; and

(2) by adding at the end the following new subsection:

''(c) ADOPTION OF METHODS TO MEASURE INTEROPERABILITY.—

''(1) REVIEW OF METHODS.—Not later than 90 days after the date of receipt of recommendations for methods, the Secretary, in consultation with the National Coordinator and representatives of other relevant Federal agencies, shall jointly review such methods and shall determine whether or not to propose adoption of such methods.

''(2) DETERMINATION TO ADOPT.—If the Secretary determines—

''(A) to propose adoption of such methods, the Secretary shall, by regulation under section 553 of title 5, United States Code, determine whether or not to adopt such methods; or

''(B) not to propose adoption of such methods, the Secretary shall notify the National Coordinator and the HIT Standards Committee and Charter Organization under section 3010(c) in writing of such determination and the reasons for not proposing the adoption of the recommendation for such methods.

''(3) PUBLICATION.—The Secretary shall provide for publication in the Federal Register of all determinations made by the Secretary under paragraph (1).

''(4) APPLICATION.—Any method adopted under this subsection shall be effective 12 months after the date of publication of the determination to adopt such method.''.

(e) REPORTS AND NOTIFICATIONS.—Section 3010 of the Public Health Service Act, as added by subsection (a), is amended by adding at the end the following new subsection:

''(g) DISSEMINATION OF INFORMATION.—

''(1) INITIAL SUMMARY REPORT.—Not later than July 1, 2016, the Secretary, after consultation with relevant stakeholders, shall submit to Congress and provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of a report on the following:

''(A) The initial set of methods adopted under this section and section 3004(c).

''(B) The strategies for achieving widespread interoperability.

''(C) An overview of the extent to which [qualified electronic health records]/[health information technology] offered as of such date satisfy such initial set.

"(D) Any barriers that are preventing widespread interoperability.

"(E) The plan and milestones, including specific steps, to achieve widespread interoperability.

"(2) FOLLOW-UP DETERMINATION AND REPORT ON WIDESPREAD INTEROPERABILITY.—Not later than [December 31, 2017], the Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of the following:

"(A) A determination by the Secretary whether the goal of widespread interoperability has been achieved.

"(B) A list identifying the vendors of, or other entities offering, [qualified electronic health records]/[health information technology], which categorizes such entities, with respect to such records, as in compliance or not in compliance with the certification criteria described in section 3001(c)(5)(B)(ii) and with the requirements under clause (i) of section 3001(c)(5)(C) (including with the terms of the

attestation and other requirements under such clause).

''(C) Actions that may be taken by entities identified under subparagraph (B) as not being in compliance with such criteria and requirements in order for such entities to become in compliance with such criteria and requirements.

''(D) Penalties described in section 3010A(b) to which entities, with respect to such [qualified electronic health records]/[health information technology], beginning January 1, 2019, are subject if such technology and entities are not in compliance with the certification criteria described in section 3001(c)(5)(B)(ii) and with the requirements under clause (i) of section 3001(c)(5)(C), respectively.

''(3) ONGOING PUBLICATION OF RECOMMENDATIONS.—The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of all recommendations made under this section.''.

(f) CERTIFICATION AND OTHER ENFORCEMENT PROVISIONS.—

(1) CERTIFICATION OF [QUALIFIED ELECTRONIC HEALTH RECORD]/[HEALTH INFORMATION] TECHNOLOGY.—

(A) IN GENERAL.—Section 3007(b) of the Public Health Service Act (42 U.S.C. 300jj–17(b)) is amended by striking ''under section 3001(c)(3) to be in compliance with'' and all that follows through the period at the end and inserting ''under section 3001(c)(3)—

''(1) for certifications made before January 1, 2018, to be in compliance with applicable standards adopted under subsections (a) and (b) of section 3004; and

''(2) for certifications made on or after January 1, 2018, to be in compliance with applicable standards adopted under subsections (a) and (b) of section 3004 and to be interoperable in accordance with section 3010, including as measured by the methods adopted under such section and methods adopted under subsection (c) of section 3004.''.

(B) REQUIREMENTS OF SECRETARY.—Section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj–11(c)(5)) is amended—

(i) by amending subparagraph (B) of such section to read as follows:

"(B) CERTIFICATION CRITERIA DESCRIBED.—In this title, the term 'certification criteria' means, with respect to [qualified electronic health records]—

"(i) for certifications made before January 1, 2018, criteria to establish that the technology meets standards and implementation specifications adopted under subsections (a) and (b) of section 3004 for [qualified electronic health records]/[health information technology]; and

"(ii) for certifications made on or after January 1, 2018, criteria described in clause (i) and criteria to establish that the technology is interoperable, in accordance with section 3010, including as measured by the methods adopted under such section and the methods adopted under subsection (c) of section 3004."; and

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

"(C) ENFORCEMENT; DECERTIFICATIONS.—

"(i) REQUIREMENTS.—Under any program kept or recognized under subpara-

graph (A), the Secretary shall ensure that any vendor of or other entity offering [qualified electronic health records]/[health information technology] seeking a certification of such records under such program on or after January 1, 2018, shall, as a condition of certification (and maintenance of certification) of such records under such program—

"(I) provide to the Secretary an attestation—

"(aa) that the entity, unless for a legitimate purpose specified by the Secretary, has not taken any action, including through any financial, administrative, or technological barrier, which the entity [knows or should know (as defined in section 1128A(i)(7) of the Social Security Act)], is to limit or restrict the exchange of information or to prevent or disincentivize widespread interoperability between any providers using such records or other

[qualified electronic health records]/[health information technology] in connection with such records;

''(bb) on the pricing information on data transmission and other services affiliated with the use of [qualified electronic health records]/[health information technology];

''(cc) that the software with respect to such records have published application programming interfaces for medical records data, search and indexing, semantic harmonization and vocabulary translation, and user interface applications; and

''(dd) that the entity has in place data sharing programs or capabilities based on common data elements through application programming interfaces without the requirement for spe-

cial middleware or vendor-specific interfaces;

''(II) publish application programming interfaces and associated documentation, with respect to such records, for medical records data, search and indexing, semantic harmonization and vocabulary translation, and user interface applications; and

''(III) demonstrate to the satisfaction of the Secretary that data from such records is able to be exchanged through the use of application programming interfaces and used in a manner that allows for exchange and everyday use of such [records]/[technology] by [authorized users].

''(ii) DECERTIFICATION.—Under any program kept or recognized under subparagraph (A), the Secretary shall ensure that beginning January 1, 2019, any [qualified electronic health record]/[health information technology] that does not satisfy the certification criteria described in section 3001(c)(5)(B)(ii) or with respect to which

the vendor or other entity described in clause (i) does not satisfy the requirements under such clause (or is determined to be in violation of the terms of the attestation or other requirements under such clause) shall no longer be considered as certified under such program.

''(iii) ANNUAL PUBLICATION.—For 2019 and each subsequent year, the Secretary shall post on the public Internet website of the Department of Health and Human Services a list of any vendors of or other entities offering [qualified electronic health records]/[health information technology] with respect to which certification has been withdrawn under clause (ii) during such year.

''(iv) PERIODIC REVIEW.—The Secretary shall periodically review and confirm that vendors of and other entities offering [qualified electronic health records]/[health information technology] have publicly published application programming interfaces and associated documentation as required by clause (i)(II) for purposes of

certification and maintaining certification under any program kept or recognized under subparagraph (A).''.

(2) ADDITIONAL ENFORCEMENT PROVISIONS UNDER THE PUBLIC HEALTH SERVICE ACT.—Subtitle A of title XXX of the Public Health Service Act (42 U.S.C. 300jj–11 et seq.), as amended by subsection (a)(1), is further amended by adding at the end the following new section:

''SEC. 3010A. ENFORCEMENT MECHANISMS.

''(a) INSPECTOR GENERAL AUTHORITY.—The Inspector General of the Department of Health and Human Services shall have the authority to investigate claims of—

''(1) vendors of, or other entities offering, [qualified electronic health records]—

''(A) being in violation of an attestation made under section 3001(c)(5)(C)(i)(I), with respect to the use of such [records] by a health care provider under a specified Medicare incentive program; and

''(B) having engaged in information blocking (as defined in subsection (f)), unless for a legitimate purpose specified by the Secretary, with respect to the use of such [records] by a health care provider under such a program;

''(2) health care providers, with respect to the use of such [records] under a specified Medicare incentive program, having, unless for a legitimate purpose specified by the Secretary, engaged in information blocking (as so defined); and

''(3) health information system providers described in subsection (b) having engaged in information blocking (as so defined), unless for a legitimate purpose specified by the Secretary, with respect to the use of such [records] under a specified Medicare incentive program.

''(b) HEALTH INFORMATION SYSTEM PROVIDERS.—The Inspector General of the Department of Health and Human Services shall, in coordination with the Federal Trade Commission, ensure that health information system providers (such as operators of health information exchanges and other systems that facilitate the exchange of information between [qualified electronic health records]) investigate claims of information blocking, with respect to the use of such records under a specified Medicare incentive program.

''(c) INFORMATION SHARING PROVISIONS.—

''(1) IN GENERAL.—The National Coordinator may serve as a technical consultant to the Inspector General of the Department of Health and Human

Services and the Federal Trade Commission for purposes of carrying out this section. As such technical consultant, the National Coordinator may, notwithstanding any other provision of law, share information related to claims or investigations under subsection (a) or (b) with the Inspector General and Federal Trade Commission for purposes of such investigations.

''(2) PROTECTION FROM DISCLOSURE OF INFORMATION.—Any information shared by the National Coordinator under paragraph (1) shall not be subject to the provisions of section 552 of title 5, United States Code (commonly referred to as the Freedom of Information Act). Any information acquired pursuant to paragraph (1) shall be held in confidence and shall not be disclosed to any person except as may be necessary to carry out the purposes of subsection (a).

''(3) NONAPPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code (commonly referred to as the Paperwork Reduction Act of 1995) shall not apply to the National Coordinator or to the Office of the National Coordinator for Health Information Technology with re-

spect to the collection of complaints relating to claims described in subsection (a).

''(d) PENALTY.—Any person or entity determined to have committed an act described in subsection (a), in connection with a specified Medicare incentive program, shall be subject to the provisions of sections 1128, 1128A, and 1128B in the same manner as a person or entity determined to have committed an act described in such respective section. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty applied under this subsection in the same manner as they apply to a civil money penalty or proceeding under section 1128A(a).

''(e) SPECIFIED MEDICARE INCENTIVE PROGRAM.—For purposes of this section, the term 'specified Medicare incentive program' includes the following:

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

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

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

''(4) The incentive payment under paragraph (3) of section 1814(l) of such Act (42 U.S.C. 1395f(l)) and adjustment under paragraph (4) of such section.

''(5) The shared savings program under section 1899 of the Social Security Act (42 U.S.C. 1395jjj).

''(f) INFORMATION BLOCKING.—

''(1) IN GENERAL.—For purposes of this section and section 3010, the term 'information blocking' means, with respect to the use of ▌qualified electronic health records▐ under a specified Medicare incentive program, business, technical, and organizational practices, including practices described in paragraph (2), that—

''(A) interfere with the exchange of electronic health information;

''(B) the actor ▌knows or should know (as defined in section 1128A(i)(7) of the Social Security Act)▐ is likely to interfere with the exchange or use of electronic health information; and

''(C) do not serve to protect patient safety, maintain the privacy and security of individuals' health information or promote competition and consumer welfare.

''(2) PRACTICES DESCRIBED.—For purposes of paragraph (1), the practices described in this paragraph are the following:

''(A) Contract terms, policies, or other business or organizational practices that restrict individuals' access to their electronic health information or restrict the exchange or use of that information for treatment and other permitted purposes.

''(B) Charging prices or fees (such as for data exchange, portability, and interfaces) that make exchanging and using electronic health information cost prohibitive.

''(C) Developing or implementing health information technology in nonstandard ways that are likely to substantially increase the costs, complexity, or burden of sharing electronic health information, especially in cases in which relevant interoperability standards or methods to measure interoperability have been adopted by the Secretary.

''(D) Developing or implementing health information technology in ways that are likely to lock in users or electronic health information, such as not allowing for the full export of data; lead to fraud, waste, or abuse; or impede innovations and advancements in health information exchange and health information technology-enabled care delivery.

''(g) TREATMENT OF VENDORS WITH RESPECT TO PATIENT SAFETY ORGANIZATIONS.—In applying part C of title IX—

''(1) vendors shall be treated as a provider (as defined in section 921) for purposes of reporting requirements under such part, to the extent that such reports are related to attestation requirements under section 3001(c)(5)(C)(i)(I);

''(2) claims of information blocking described in subsection (a) shall be treated as a patient safety activity under such part for purposes of reporting requirements under such part; and

''(3) health care providers that are not members of patient safety organizations shall be treated in the same manner as health care providers that are such members for purposes of such reporting re-

quirements with respect to claims of information blocking described in subsection (a).''.

(3) DEMONSTRATION REQUIRED FOR MEANINGFUL EHR USE INCENTIVES UNDER MEDICARE.—

(A) INCENTIVES FOR PROFESSIONALS.—

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

''(iii) INTEROPERABILITY.—With respect to EHR reporting periods for payment years beginning with 2018, the means described in clause (i) specified by the Secretary shall include a demonstration, through means such as an attestation, that the professional has not taken any action described in subsection (a)(2) of section 3010A of the Public Health Service Act with respect to which the professional [knows or should know (as defined in section 1128A(i)(7)) about], with respect to the use of any certified EHR technology.''.

(ii) HARDSHIP EXEMPTION IN CASE OF DECERTIFIED EHR.—Subparagraph (B)

of section 1848(a)(7) of the Social Security Act (42 U.S.C. 1395w–4(a)(7)(B)) is amended to read as follows:

"(B) SIGNIFICANT HARDSHIP EXCEPTION.—

"(i) IN GENERAL.—The Secretary may, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment under subparagraph (A) if the Secretary determines, subject to annual renewal, that compliance with the requirement for being a meaningful EHR user would result in a significant hardship, such as in the case of an eligible professional who practices in a rural area without sufficient Internet access.

"(ii) DECERTIFICATION.—

"(I) IN GENERAL.—The Secretary may, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment under subparagraph (A) if the Secretary determines that such professional was determined to not be a meaningful EHR user because the

[qualified electronic health record]/[health information technology] used by such professional was decertified under section 3001(c)(5)(C) of the Public Health Service Act. An exemption under the previous sentence may be applied to an eligible professional only during the first year with respect to which such decertification applies.

''(II) DURATION.—In no case shall an exemption by reason of this clause be for a period of less than 12 months.

''(iii) LIMITATION.—Subject to clause (ii)(II), in no case may an eligible professional be granted an exemption under this subparagraph for more than 5 years.''.

(B) INCENTIVES FOR HOSPITALS.—

(i) IN GENERAL.—Section 1886(o)(1) of the Social Security Act (42 U.S.C. 1395ww(o)(1)) is amended—

(I) in subparagraph (A), by inserting before the period at the end the following: ''and, for performance periods for fiscal year 2018 or a sub-

sequent fiscal year, that provide a demonstration described in subparagraph (D) to the Secretary''; and

(II) by adding at the end the following new subparagraph:

''(D) DEMONSTRATION DESCRIBED.—The demonstration described in this subparagraph is a demonstration, through means such as an attestation, that the hospital has not taken any action described in subsection (a)(2) of section 3010A of the Public Health Service Act with respect to which the hospital [knows or should know (as defined in section 1128A(i)(7) of the Social Security Act) about], with respect to the use of any [certified EHR technology].''.

(ii) HARDSHIP EXEMPTION IN CASE OF DECERTIFIED EHR.—Subclause (II) of section 1886(b)(3)(B)(ix) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(ix)) is amended to read as follows:

''(II)(aa) The Secretary may, on a case-by-case basis, exempt a subsection (d) hospital from the application of subclause (I) with respect to a

fiscal year if the Secretary determines, subject to annual renewal, that requiring such hospital to be a meaningful EHR user during such fiscal year would result in a significant hardship, such as in the case of a hospital in a rural area without sufficient Internet access.

''(bb) The Secretary may, on a case-by-case basis, exempt a subsection (d) hospital from the application of subclause (I) with respect to a fiscal year if the Secretary determines, subject to annual renewal, that such hospital was determined to not be a meaningful EHR user because the [qualified electronic health record]/[health information technology] used by such hospital was decertified under section 3001(c)(5)(C) of the Public Health Service Act. An exemption under the previous sentence may be applied to a subsection (d) hospital only during the first fiscal

year with respect to which such decertification applies.

''(cc) In no case shall an exemption by reason of item (bb) be for a period of less than 12 months.

''(dd) Subject to item (cc), in no case may a hospital be granted an exemption under this subclause for more than 5 years.''.

(C) DEMONSTRATION REQUIRED FOR MEANINGFUL EHR USE INCENTIVES UNDER MEDICAID.—Section 1903(t)(2) of the Social Security Act (42 U.S.C. 1396b(t)(2)) is amended by adding at the end the following: ''An eligible professional shall not qualify as a Medicaid provider under this subsection, with respect to a year beginning with 2018, unless such provider demonstrates to the Secretary, through means such as an attestation, that the provider has not taken any action described in subsection (a)(2) of section 3010A of the Public Health Service Act with respect to which the provider [knows or should know (as defined in section 1128A(i)(7) of the Social Security Act)

about], with respect to the use of any certified EHR technology.''.

(g) DEFINITIONS.—

(1) CERTIFIED EHR TECHNOLOGY.—Paragraph (1) of section 3000 of the Public Health Service Act (42 U.S.C. 300jj) is amended to read as follows:

''(1) CERTIFIED EHR TECHNOLOGY.—The term 'certified EHR technology' means a [qualified electronic health record] that is certified pursuant to section 3001(c)(5) as meeting the certification criteria defined in subparagraph (B) of such section that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals) and, beginning January 1, 2018, with respect to which the vendor or other entity offering such technology is in compliance with the requirements under section 3001(c)(5)(C)(i).''.

(2) WIDESPREAD INTEROPERABILITY.—Section 3000 of the Public Health Service Act (42 U.S.C. 300jj) is amended by adding at the end the following new paragraph:

''(15) WIDESPREAD INTEROPERABILITY.—The term 'widespread interoperability' means that, on a nationwide basis—

''(A) [qualified electronic health records]/[health information technology] are interoperable, in accordance with section 3010, including as measured by the methods adopted under such section; and

''(B) such records are employed by meaningful EHR users under the specified Medicare incentive programs (as defined in section 3010A(e)) and other clinicians and health care providers.''.

(h) CONFORMING AMENDMENTS.—

(1) VOLUNTARY USE OF STANDARDS.—Section 3006 of the Public Health Service Act (42 U.S.C. 300jj–16) is amended—

(A) in subsection (a)—

(i) in paragraph (1), by inserting ''or a method adopted under section 3010 or 3004(c)'' after ''section 3004''; and

(ii) in paragraph (2), by striking ''or implementation specification'' and inserting ''implementation specification, or method''; and

(B) in subsection (b), by inserting ''or the methods adopted under section 3010 and 3004(c)'' after ''section 3004''.

(2) HIPAA PRIVACY AND SECURITY LAW DEFINITION CORRECTION.—Section 3009(a)(2)(A) of the Public Health Service Act (42 U.S.C. 300jj–19(a)(2)(A)) is amended by striking ''title IV'' and inserting ''title XIII''.

(3) COORDINATION OF FEDERAL ACTIVITIES.—Section 13111 of the HITECH Act is amended—

(A) in subsection (a), by inserting before the period at the end the following: ''(and, beginning on January 1, 2018, that are also interoperable under section 3010 of such Act, including as measured by the methods adopted under such section and section 3004(c) of such Act)''; and

(B) in subsection (b)—

(i) by inserting ''(and, beginning on January 1, 2018, a method adopted under section 3010 of such Act or section 3004(c) of such Act)'' before ''the President''; and

(ii) by inserting ''(or method)'' before '', respectively''.

(4) APPLICATION TO PRIVATE ENTITIES.—Section 13112 of the HITECH Act is amended by inserting before the period at the end the following ''(and, beginning on January 1, 2018, that are also interoperable under section 3010 of such Act, including as measured by the methods adopted under such section and under section 3004(c) of such Act)''.

(5) NIST TESTING.—Section 13201(a) of the HITECH Act is amended—

(A) by inserting ''and methods under section 3010 of such Act'' after ''under such section''; and

(B) by striking each place it appears ''such standards and implementation specifications'' and inserting ''such standards, implementation specifications, and methods''.

(6) COORDINATION WITH RECOMMENDATIONS FOR ACHIEVING WIDESPREAD EHR INTEROPERABILITY.—Section 106(b)(1) of the Medicare Access and CHIP Reauthorization Act of 2015 (Public Law 114–10) is amended by adding at the end the following new subparagraph:

''(E) COORDINATION.—Any recommendation submitted under subparagraph (D) shall be

consistent with the criteria specified under subsection (a) of section 3010 of the Public Health Service Act.''.

(i) PATIENT EMPOWERMENT.—It is the sense of Congress that—

(1) patients have the right to the entirety of the health information of such patient, including such information contained in an electronic health record of such patient;

(2) such right extends to both structured and unstructured data; and

(3) to further facilitate patient ownership over health information of such patient—

(A) health care providers should not have the ability to deny a patient's request for access to the entirety of such health information of such patient; and

(B) health care providers do not need the consent of their patients to share personal health information of such patients with other covered entities, in compliance with the HIPAA privacy regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 for the purposes of supporting patient care, except in

situations where consent is specifically required under such regulations, such as in cases related to the psychiatric records of the patient.

Subtitle B—Telehealth

SEC. 3021. TELEHEALTH SERVICES UNDER THE MEDICARE PROGRAM.

(a) PROVISION OF INFORMATION BY CENTERS FOR MEDICARE & MEDICAID SERVICES.—Not later than one year after the date of the enactment of this Act, the Administrator of the Centers for Medicare & Medicaid Services shall provide to the committees of jurisdiction of the House of Representatives and the Senate information on the following:

(1) The populations of Medicare beneficiaries, such as those who are dually eligible for the Medicare program under title XVIII of the Social Security Act and the Medicaid program under title XIX of such Act and those with chronic conditions, whose care may be improved most in terms of quality and efficiency by the expansion, in a manner that meets or exceeds the existing in-person standard of care under the Medicare program under title XVIII of such Act, of telehealth services under section 1834(m)(4) of such Act (42 U.S.C. 1395m(m)(4)).

(2) Activities by the Center for Medicare and Medicaid Innovation which examine the use of telehealth services in models, projects, or initiatives funded through section 1115A of the Social Security Act (42 U.S.C. 1315a).

(3) The types of high volume procedures codes or diagnoses under such title XVIII which might be suitable to the furnishing of services via telehealth.

(4) Barriers that might prevent the expansion of telehealth services under section 1834(m)(4) of the Social Security Act (42 U.S.C. 1395m(m)(4)) beyond such services that are in effect as of the date of the enactment of this Act.

(b) PROVISION OF INFORMATION BY MEDPAC.—Not later than one year after the date of the enactment of this Act, the Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6) shall, using data from the Medicare Advantage program under part C of title XVIII of such Act, provide information to the committees of jurisdiction of the House of Representatives and the Senate that identifies—

(1) services—

(A) for which payment could not be made, as of the date of the enactment of this Act,

under the fee-for-service program under parts A and B of such title by reason of any limitation imposed under section 1834(m) of such Act (42 U.S.C. 1395m(m)); and

(B) that are services that are recommended by the Commission to be included as telehealth services for which payment may be made under the fee-for-service program under parts A and B of such title; and

(2) barriers to furnishing telehealth services for which payment may be made under such title XVIII and solutions to address such barriers.

(c) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) States should collaborate, through the use of State medical board compacts or other mechanisms, to create common licensure requirements for providing telehealth services in order to facilitate multistate practices and allow for health care providers to provide such services across State lines;

(2) eligible originating sites should be expanded beyond those originating sites described in section 1834(m)(4)(C) of the Social Security Act (42 U.S.C. 1395m(m)(4)(C)); and

(3) any expansion of telehealth services under the Medicare program should—

(A) recognize that telemedicine is the delivery of safe, effective, quality health care services, by a health care provider, using technology as the mode of care delivery;

(B) meet or exceed the conditions of coverage and payment with respect to the Medicare program under title XVIII unless specifically address in subsequent statute, of such Act if the service were furnished in person, including standards of care; and

(C) involve clinically appropriate means to furnish such services.

Subtitle C—Encouraging Continuing Medical Education for Physicians

SEC. 3041. EXEMPTING FROM MANUFACTURER TRANSPARENCY REPORTING CERTAIN TRANSFERS USED FOR EDUCATIONAL PURPOSES.

(a) IN GENERAL.—Section 1128G(e)(10)(B) of the Social Security Act (42 U.S.C. 1320a–7h(e)(10)(B)) is amended—

(1) in clause (iii), by inserting ", including peer-reviewed journals, journal reprints, journal sup-

plements, medical conference reports, and medical textbooks'' after ''patient use''; and

(2) by adding at the end the following new clause:

''(xiii) In the case of a covered recipient who is a physician, an indirect payment or transfer of value to the covered recipient—

''(I) for speaking at, or preparing educational materials for, an educational event for physicians or other health care professionals that does not commercially promote a covered drug, device, biological, or medical supply; or

''(II) that serves the sole purpose of providing the covered recipient with medical education, such as by providing the covered recipient with the tuition required to attend an educational event or with materials provided to physicians at an educational event.''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to transfers of value made on or after the date of the enactment of this Act.

Subtitle D—Disposable Medical Technologies

[SEC. 3061. TREATMENT OF CERTAIN ITEMS AND DEVICES.

[(a) PAYMENT FOR DURABLE MEDICAL ITEMS (DMI).—]

[(1) IN GENERAL.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) is amended—]

[(A) in subparagraph (EE), by striking ''and'' at the end;]

[(B) in subparagraph (FF), by adding ''and'' at the end; and]

[(C) by adding at the end the following new subparagraph:]

[''(GG) a durable medical item that administers a drug described in section 1927(k)(2)(C) that would otherwise be self-administered multiple times per day and includes a disposable component and at least one component that can withstand repeated use, and supplies used in conjunction with such item (including the drug administered by such item);''.]

[(2) PAYMENT.—

[(A) PAYMENT AMOUNT FOR DMI.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:]

[''(r) PAYMENT METHODOLOGY FOR DURABLE MEDICAL ITEMS (DMI).—The Secretary shall establish a payment methodology for a durable medical item described in section 1861(s)(2)(GG) and supplies used in conjunction with such item (other than a drug administered by such item) such that the estimated average total payment per individual for a period for such items and supplies does not exceed the estimated average total payment per individual for such period that would otherwise be made (taking into account the application of section 1847) for the durable medical equipment for which it is a substitute and for supplies used in conjunction with such equipment (other than such a drug) as determined appropriate by the Secretary.''.]

[(B) PAYMENT FOR DRUG.—Section 1842(o)(1)(D) of the Social Security Act (42 U.S.C. 1395u(o)(1)(D)) is amended—]

[(i) in clause (i), by inserting ''or drugs administered by a durable medical item covered under section 1861(s)(2)(GG)

on or after January 1, 2017,'' after ''after January 1, 2004,''; and]

[(ii) in clause (ii), by striking ''infusion''.]

[(C) COMPETITIVE ACQUISITION.—Section 1847(a)(2) of the Social Security Act (42 U.S.C. 1395w–3(a)(2)) is amended by adding at the end the following new subparagraph:]

[''(D) DURABLE MEDICAL ITEM.—A durable medical item and supplies used in conjunction with such item, described in section 1861(s)(2)(GG).''.]

[(3) CONFORMING AMENDMENT.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)) is amended—]

[(A) by striking ''and'' before ''(Z)''; and]

[(B) by inserting before the semicolon at the end the following: '', and (AA) with respect to durable medical items described in section 1861(s)(2)(GG), the amount paid shall be equal to 80 percent of the lesser of the actual charge or the amount determined under section 1834(r)''.]

(4) EFFECTIVE DATE.—The amendments made by this subsection shall apply to items furnished on or after January 1, 2017.

[(b) PAYMENT FOR CERTAIN DISPOSABLE DEVICES.—]

[(1) IN GENERAL.—Section 1834 of the Social Security Act (42 U.S.C. 1395m), as amended by subsection (a)(2), is further amended by adding at the end the following new subsection:]

[''(s) PAYMENT FOR CERTAIN DISPOSABLE DEVICES.—]

[''(1) IN GENERAL.—The Secretary shall make separate payment in the amount established under paragraph (3) to a home health agency for a device described in paragraph (2) when furnished to an individual who receives home health services for which payment is made under section 1895(b).]

[''(2) DEVICE DESCRIBED.—For purposes of paragraph (1), a device described in this paragraph is a disposable device for which, as of January 1, 2015, there is—]

[''(A) a Level I Healthcare Common Procedure Coding System (HCPCS) code for which the description for a professional service includes the furnishing of such device; and]

[“(B) a separate Level I HCPCS code for a professional service that uses durable medical equipment instead of such device.]

[“(3) PAYMENT AMOUNT.—The Secretary shall establish the separate payment amount for such a device such that such amount does not exceed the payment that would be made for the HCPCS code described in paragraph (2)(A) under section 1833(t) (relating to payment for covered OPD services).”.]

(2) CONFORMING AMENDMENT.—Section 1861(m)(5) of the Social Security Act (42 U.S.C. 1395x(m)(5)) is amended by inserting “and devices described in section 1834(s)(2)” after “durable medical equipment”.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to devices furnished on or after January 1, 2017.

Subtitle E—Local Coverage Decision Reforms

SEC. 3081. IMPROVEMENTS IN THE MEDICARE LOCAL COVERAGE DETERMINATION (LCD) PROCESS.

(a) IN GENERAL.—Section 1862(l)(5) of the Social Security Act (42 U.S.C. 1395y(l)(5)) is amended by adding at the end the following new subparagraph:

''(D) LOCAL COVERAGE DETERMINATIONS.—The Secretary shall require each medicare administrative contractor that develops a local coverage determination to make available on the website of such contractor and in the coverage database on the Medicare website, at least 45 days before the effective date of such determination, the following information:

''(i) Such determination in its entirety.

''(ii) Where and when the proposed determination was first made public.

''(iii) Links to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.

''(iv) A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence.

''(v) An explanation of the rationale that supports such determination.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to local coverage determinations that are proposed or revised on or after

the date that is 180 days after the date of the enactment of this Act.

Subtitle F—Medicare Pharmaceutical and Technology Ombudsman

SEC. 3101. MEDICARE PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN.

Section 1808(c) of the Social Security Act (42 U.S.C. 1395b–9(c)) is amended by adding at the end the following new paragraph:

''(4) PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN.—Not later than 12 months after the date of the enactment of this paragraph, the Secretary shall provide for a pharmaceutical and technology ombudsman within the Centers for Medicare & Medicaid Services who shall receive and respond to complaints, grievances, and requests that—

''(A) are from entities that manufacture pharmaceutical, biotechnology, medical device, or diagnostic products that are covered or for which coverage is being sought under this title; and

''(B) regard coverage, coding, or payment under this title for such products.''.

Subtitle G—Medicare Site-of-Service Price Transparency

SEC. 3121. MEDICARE SITE-OF-SERVICE PRICE TRANSPARENCY.

Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

''(r) SITE-OF-SERVICE PRICE TRANSPARENCY.—

''(1) IN GENERAL.—In order to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or to an ambulatory surgery center under this title, the Secretary shall, for 2017 and each year thereafter, make available to the public via a searchable website, with respect to an appropriate number of such items and services—

''(A) the estimated payment amount for such items and services under the outpatient department fee schedule under subsection (t) of section 1833 and the ambulatory surgical center payment system under subsection (i) of such section; and

''(B) the estimated amount of beneficiary liability applicable to such an item or service.

''(2) CALCULATION OF ESTIMATED BENEFICIARY LIABILITY.—For purposes of paragraph (1)(B), the estimated amount of beneficiary liability, with respect to an item or service, is the amount for such item or service for which an individual who does not have coverage under a medicare supplemental policy certified under section 1882 or any other supplemental insurance coverage is responsible.

''(3) IMPLEMENTATION.—In carrying out this subsection, the Secretary—

''(A) shall include in the notice described in section 1804(a) a notification of the availability of the estimated amounts made available under paragraph (1); and

''(B) may utilize existing mechanisms, such as the portion of the website of the Centers for Medicare & Medicaid Services on which information comparing physician performance is posted (commonly referred to as the Physician Compare website), to make available such estimated amounts under such paragraph.

''(4) FUNDING.—For purposes of implementing this subsection, the Secretary shall provide for the transfer, from the Supplemental Medical Insurance

Trust Fund under section 1841 to the Centers for Medicare & Medicaid Services Program Management Account, of $6,000,000 for fiscal year 2015, to remain available until expended.''.

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.

(a) DRUG MANAGEMENT PROGRAM FOR AT-RISK BENEFICIARIES.—

(1) IN GENERAL.—Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–10(c)) is amended by adding at the end the following:

''(5) DRUG MANAGEMENT PROGRAM FOR AT-RISK BENEFICIARIES.—

''(A) AUTHORITY TO ESTABLISH.—A PDP sponsor may establish a drug management program for at-risk beneficiaries under which, subject to subparagraph (B), the PDP sponsor may, in the case of an at-risk beneficiary for prescription drug abuse who is an enrollee in a prescription drug plan of such PDP sponsor, limit such beneficiary's access to coverage for frequently abused drugs under such plan to fre-

quently abused drugs that are prescribed for such beneficiary by a prescriber selected under subparagraph (D), and dispensed for such beneficiary by a pharmacy selected under such subparagraph.

''(B) REQUIREMENT FOR NOTICES.—

''(i) IN GENERAL.—A PDP sponsor may not limit the access of an at-risk beneficiary for prescription drug abuse to coverage for frequently abused drugs under a prescription drug plan until such sponsor—

''(I) provides to the beneficiary an initial notice described in clause (ii) and a second notice described in clause (iii); and

''(II) verifies with the providers of the beneficiary that the beneficiary is an at-risk beneficiary for prescription drug abuse.

''(ii) INITIAL NOTICE.—An initial notice described in this clause is a notice that provides to the beneficiary—

''(I) notice that the PDP sponsor has identified the beneficiary as po-

tentially being an at-risk beneficiary for prescription drug abuse;

''(II) information describing all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health services and other counseling services;

''(III) notice of, and information about, the right of the beneficiary to appeal such identification under subsection (h) and the option of an automatic escalation to external review;

''(IV) a request for the beneficiary to submit to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would prefer the PDP sponsor to select under subparagraph (D) in the case that the beneficiary is identified as an at-risk beneficiary for prescription drug abuse as described in clause (iii)(I);

''(V) an explanation of the meaning and consequences of the identi-

fication of the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse, including an explanation of the drug management program established by the PDP sponsor pursuant to subparagraph (A);

''(VI) clear instructions that explain how the beneficiary can contact the PDP sponsor in order to submit to the PDP sponsor the preferences described in subclause (IV) and any other communications relating to the drug management program for at-risk beneficiaries established by the PDP sponsor; and

''(VII) contact information for other organizations that can provide the beneficiary with assistance regarding such drug management program (similar to the information provided by the Secretary in other standardized notices provided to part D eligible individuals enrolled in prescription drug plans under this part).

''(iii) SECOND NOTICE.—A second notice described in this clause is a notice that provides to the beneficiary notice—

''(I) that the PDP sponsor has identified the beneficiary as an at-risk beneficiary for prescription drug abuse;

''(II) that such beneficiary is subject to the requirements of the drug management program for at-risk beneficiaries established by such PDP sponsor for such plan;

''(III) of the prescriber and pharmacy selected for such individual under subparagraph (D);

''(IV) of, and information about, the beneficiary's right to appeal such identification under subsection (h) and the option of an automatic escalation to external review;

''(V) that the beneficiary can, in the case that the beneficiary has not previously submitted to the PDP sponsor preferences for which prescribers and pharmacies the bene-

ficiary would prefer the PDP sponsor select under subparagraph (D), submit such preferences to the PDP sponsor; and

''(VI) that includes clear instructions that explain how the beneficiary can contact the PDP sponsor.

''(iv) TIMING OF NOTICES.—

''(I) IN GENERAL.—Subject to subclause (II), a second notice described in clause (iii) shall be provided to the beneficiary on a date that is not less than 60 days after an initial notice described in clause (ii) is provided to the beneficiary.

''(II) EXCEPTION.—In the case that the PDP sponsor, in conjunction with the Secretary, determines that concerns identified through rulemaking by the Secretary regarding the health or safety of the beneficiary or regarding significant drug diversion activities require the PDP sponsor to provide a second notice described in clause (iii) to the beneficiary on a

date that is earlier than the date described in subclause (II), the PDP sponsor may provide such second notice on such earlier date.

''(C) AT-RISK BENEFICIARY FOR PRESCRIPTION DRUG ABUSE.—

''(i) IN GENERAL.—For purposes of this paragraph, the term 'at-risk beneficiary for prescription drug abuse' means a part D eligible individual who is not an exempted individual described in clause (ii) and—

''(I) who is identified through the use of clinical guidelines developed by the Secretary in consultation with PDP sponsors and other stakeholders described in section 3151(f)(2)(A) of the 21st Century Cures Act; or

''(II) with respect to whom the PDP sponsor of a prescription drug plan, upon enrolling such individual in such plan, received notice from the Secretary that such individual was identified under this paragraph to be an at-risk beneficiary for prescription

drug abuse under the prescription drug plan in which such individual was most recently previously enrolled and such identification has not been terminated under subparagraph (F).

''(ii) EXEMPTED INDIVIDUAL DESCRIBED.—An exempted individual described in this clause is an individual who—

''(I) an individual who receives hospice care under this title; or

''(II) an individual, such as an individual who is a resident of a long-term care facility, who the Secretary elects to treat as an exempted individual for purposes of clause (i).

''(D) SELECTION OF PRESCRIBERS.—

''(i) IN GENERAL.—With respect to each at-risk beneficiary for prescription drug abuse enrolled in a prescription drug plan offered by such sponsor, a PDP sponsor shall, based on the preferences submitted to the PDP sponsor by the beneficiary pursuant to clauses (ii)(IV) and (iii)(V) of subparagraph (B), select—

''(I) one or more individuals who are authorized to prescribe frequently abused drugs (referred to in this paragraph as 'prescribers') who may write prescriptions for such drugs for such beneficiary; and

''(II) one or more pharmacies that may dispense such drugs to such beneficiary.

''(ii) REASONABLE ACCESS.—In making the selection under this subparagraph, a PDP sponsor shall ensure that the beneficiary continues to have reasonable access to drugs described in subparagraph (G), taking into account geographic location, beneficiary preference, impact on cost-sharing, and reasonable travel time.

''(iii) BENEFICIARY PREFERENCES.—

''(I) IN GENERAL.—If an at-risk beneficiary for prescription drug abuse submits preferences for which in-network prescribers and pharmacies the beneficiary would prefer the PDP sponsor select in response to a notice

under subparagraph (B), the PDP sponsor shall—

"(aa) review such preferences;

"(bb) select or change the selection of a prescriber or pharmacy for the beneficiary based on such preferences; and

"(cc) inform the beneficiary of such selection or change of selection.

"(II) EXCEPTION.—In the case that the PDP sponsor determines that a change to the selection of a prescriber or pharmacy under item (bb) by the PDP sponsor is contributing or would contribute to prescription drug abuse or drug diversion by the beneficiary, the PDP sponsor may change the selection of a prescriber or pharmacy for the beneficiary without regard to the preferences of the beneficiary described in subclause (I).

"(iv) CONFIRMATION.—Before selecting a prescriber or pharmacy under this

subparagraph, a PDP sponsor must request and receive confirmation from the prescriber or pharmacy acknowledging and accepting that the beneficiary involved is in the drug management program for at-risk beneficiaries.

''(E) TERMINATIONS AND APPEALS.—The identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph, a coverage determination made under a drug management program for at-risk beneficiaries, and the selection of a prescriber or pharmacy under subparagraph (D) with respect to such individual shall be subject to reconsideration and appeal under subsection (h) and the option of an automatic escalation to external review to the extent provided by the Secretary.

''(F) TERMINATION OF IDENTIFICATION.—

''(i) IN GENERAL.—The Secretary shall develop standards for the termination of identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph. Under such stand-

ards such identification shall terminate as of the earlier of—

"(I) the date the individual demonstrates that the individual is no longer likely, in the absence of the restrictions under this paragraph, to be an at-risk beneficiary for prescription drug abuse described in subparagraph (C)(i); or

"(II) the end of such maximum period of identification as the Secretary may specify.

"(ii) RULE OF CONSTRUCTION.—Nothing in clause (i) shall be construed as preventing a plan from identifying an individual as an at-risk beneficiary for prescription drug abuse under subparagraph (C)(i) after such termination on the basis of additional information on drug use occurring after the date of notice of such termination.

"(G) FREQUENTLY ABUSED DRUG.—For purposes of this subsection, the term 'frequently abused drug' means a drug that is a controlled

substance that the Secretary determines to be frequently abused or diverted.

''(H) DATA DISCLOSURE.—In the case of an at-risk beneficiary for prescription drug abuse whose access to coverage for frequently abused drugs under a prescription drug plan has been limited by a PDP sponsor under this paragraph, such PDP sponsor shall disclose data, including any necessary individually identifiable health information, in a form and manner specified by the Secretary, about the decision to impose such limitations and the limitations imposed by the sponsor under this part.

''(I) EDUCATION.—The Secretary shall provide education to enrollees in prescription drug plans of PDP sponsors and providers regarding the drug management program for at-risk beneficiaries described in this paragraph, including education—

''(i) provided by medicare administrative contractors through the improper payment outreach and education program described in section 1874A(h); and

''(ii) through current education efforts (such as State health insurance assistance

programs described in subsection (a)(1)(A) of section 119 of the Medicare Improvements for Patients and Providers Act of 2008 (42 U.S.C. 1395b–3 note)) and materials directed toward such enrollees.

''(J) APPLICATION UNDER MA–PD PLANS.—Pursuant to section 1860D—21(c)(1), the provisions of this paragraph apply under part D to MA organizations offering MA–PD plans to MA eligible individuals in the same manner as such provisions apply under this part to a PDP sponsor offering a prescription drug plan to a part D eligible individual.''.

(2) INFORMATION FOR CONSUMERS.—Section 1860D–4(a)(1)(B) of the Social Security Act (42 U.S.C. 1395w–104(a)(1)(B)) is amended by adding at the end the following:

''(v) The drug management program for at-risk beneficiaries under subsection (c)(5).''.

(b) UTILIZATION MANAGEMENT PROGRAMS.—Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)), as amended by subsection (a)(1), is further amended—

(1) in paragraph (1), by inserting after subparagraph (D) the following new subparagraph:

''(E) A utilization management tool to prevent drug abuse (as described in paragraph (6)(A)).''; and

(2) by adding at the end the following new paragraph:

''(6) UTILIZATION MANAGEMENT TOOL TO PREVENT DRUG ABUSE.—

''(A) IN GENERAL.—A tool described in this paragraph is any of the following:

''(i) A utilization tool designed to prevent the abuse of frequently abused drugs by individuals and to prevent the diversion of such drugs at pharmacies.

''(ii) Retrospective utilization review to identify—

''(I) individuals that receive frequently abused drugs at a frequency or in amounts that are not clinically appropriate; and

''(II) providers of services or suppliers that may facilitate the abuse or diversion of frequently abused drugs by beneficiaries.

''(iii) Consultation with the contractor described in subparagraph (B) to verify if an individual enrolling in a prescription drug plan offered by a PDP sponsor has been previously identified by another PDP sponsor as an individual described in clause (ii)(I).

''(B) REPORTING.—A PDP sponsor offering a prescription drug plan (and an MA organization offering an MA–PD plan) in a State shall submit to the Secretary and the Medicare drug integrity contractor with which the Secretary has entered into a contract under section 1893 with respect to such State a report, on a monthly basis, containing information on—

''(i) any provider of services or supplier described in subparagraph (A)(ii)(II) that is identified by such plan sponsor (or organization) during the 30-day period before such report is submitted; and

''(ii) the name and prescription records of individuals described in paragraph (5)(C).''.

(c) EXPANDING ACTIVITIES OF MEDICARE DRUG INTEGRITY CONTRACTORS (MEDICS).—

(1) IN GENERAL.—Section 1893 of the Social Security Act (42 U.S.C. 1395ddd) is amended by adding at the end the following new subsection:

''(j) EXPANDING ACTIVITIES OF MEDICARE DRUG INTEGRITY CONTRACTORS (MEDICS).—

''(1) ACCESS TO INFORMATION.—Under contracts entered into under this section with Medicare drug integrity contractors, the Secretary shall authorize such contractors to directly accept prescription and necessary medical records from entities such as pharmacies, prescription drug plans, MA–PD plans, and physicians with respect to an individual in order for such contractors to provide information relevant to the determination of whether such individual is an at-risk beneficiary for prescription drug abuse, as defined in section 1860D–4(c)(5)(C).

''(2) REQUIREMENT FOR ACKNOWLEDGMENT OF REFERRALS.—If a PDP sponsor or MA organization refers information to a contractor described in paragraph (1) in order for such contractor to assist in the determination described in such paragraph, the contractor shall—

''(A) acknowledge to the sponsor or organization receipt of the referral; and

''(B) in the case that any PDP sponsor or MA organization contacts the contractor requesting to know the determination by the contractor of whether or not an individual has been determined to be an individual described such paragraph, shall inform such sponsor or organization of such determination on a date that is not later than 15 days after the date on which the sponsor or organization contacts the contractor.

''(3) MAKING DATA AVAILABLE TO OTHER ENTITIES.—

''(A) IN GENERAL.—For purposes of carrying out this subsection, subject to subparagraph (B), the Secretary shall authorize MEDICs to respond to requests for information from PDP sponsors and MA organizations, State prescription drug monitoring programs, and other entities delegated by such sponsors or organizations using available programs and systems in the effort to prevent fraud, waste, and abuse.

''(B) HIPAA COMPLIANT INFORMATION ONLY.—Information may only be disclosed by a MEDIC under subparagraph (A) if the disclo-

sure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).''.

(2) OIG STUDY AND REPORT ON EFFECTIVENESS OF MEDICS.—

(A) STUDY.—The Inspector General of the Department of Health and Human Services shall conduct a study on the effectiveness of Medicare drug integrity contractors in identifying combating, and preventing fraud under the Medicare program, including under the authority provided under section 1893(j) of the Social Security Act, added by paragraph (1).

(B) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Inspector General shall submit to Congress a report on the study conducted under subparagraph (A). Such report shall include such recommendations for improvements in the effectiveness of such contractors as the Inspector General determines appropriate.

(d) TREATMENT OF CERTAIN COMPLAINTS FOR PURPOSES OF QUALITY OR PERFORMANCE ASSESSMENT.—Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152) is amended by adding at the end the following new subsection:

''(d) TREATMENT OF CERTAIN COMPLAINTS FOR PURPOSES OF QUALITY OR PERFORMANCE ASSESSMENT.—In conducting a quality or performance assessment of a PDP sponsor, the Secretary shall develop or utilize existing screening methods for reviewing and considering complaints that are received from enrollees in a prescription drug plan offered by such PDP sponsor and that are complaints regarding the lack of access by the individual to prescription drugs due to a drug management program for at-risk beneficiaries.''.

(e) SENSE OF CONGRESS REGARDING USE OF TECHNOLOGY TOOLS TO COMBAT FRAUD.—It is the sense of Congress that MA organizations and PDP sponsors should consider using e-prescribing and other health information technology tools to support combating fraud under MA–PD plans and prescription drug plans under parts C and D of the Medicare program.

(f) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by this section shall apply to prescription drug plans

(and MA–PD plans) for plan years beginning more than 1 year after the date of the enactment of this Act.

(2) STAKEHOLDER MEETINGS PRIOR TO EFFECTIVE DATE.—

(A) IN GENERAL.—Not later than January 1, 2016, the Secretary of Health and Human Services shall convene stakeholders, including individuals entitled to benefits under part A of title XVIII of the Social Security Act or enrolled under part B of such title of such Act, advocacy groups representing such individuals, clinicians, plan sponsors, entities delegated by plan sponsors, and biopharmaceutical manufacturers for input regarding the topics described in subparagraph (B).

(B) TOPICS DESCRIBED.—The topics described in this subparagraph are the topics of—

(i) the impact on cost-sharing and ensuring accessibility to prescription drugs for enrollees in prescription drug plans of PDP sponsors, and enrollees in MA–PD plans, who are at-risk beneficiaries for prescription drug abuse (as defined in subparagraph (C) of paragraph (5) of section

1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)));

(ii) the use of an expedited appeals process under which such an enrollee may appeal an identification of such enrollee as an at-risk beneficiary for prescription drug abuse under such paragraph (similar to the processes established under the Medicare Advantage program under part C of title XVIII of the Social Security Act that allow an automatic escalation to external review of claims submitted under such part);

(iii) the types of enrollees that should be treated as exempted individuals, as described in subparagraph (C)(ii) of such paragraph;

(iv) the manner in which terms and definitions in such paragraph should be applied, such as the use of clinical appropriateness in determining whether an enrollee is an at-risk beneficiary for prescription drug abuse as defined in subparagraph (C) of such paragraph;

(v) the information to be included in the notices described in subparagraph (B)

of such paragraph and the standardization of such notices; and

(vi) with respect to a PDP sponsor (or Medicare Advantage organization) that establishes a drug management program for at-risk beneficiaries under such paragraph, the responsibilities of such PDP sponsor (or organization) with respect to the implementation of such program.

(g) RULEMAKING.—The Secretary of Health and Human Services shall promulgate regulations based on the input gathered pursuant to subsection (f)(2)(A).