21st Century Cures Act

[Public Law 114–255]

[As Amended Through P.L. 117–328, Enacted December 29, 2022]

[Currency: This publication is a compilation of the text of Public Law 114–255. It was last amended by the public law listed in the As Amended Through note above and below at the bottom of each page of the pdf version and reflects current law through the date of the enactment of the public law listed at https://www.govinfo.gov/app/collection/comps/]

[Note: While this publication does not represent an official version of any Federal statute, substantial efforts have been made to ensure the accuracy of its contents. The official version of Federal law is found in the United States Statutes at Large and in the United States Code. The legal effect to be given to the Statutes at Large and the United States Code is established by statute (1 U.S.C. 112, 204).]

AN ACT 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. [42 U.S.C. 201 note] 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:

[1] Does not conform with the section heading for section 1003. See the amendment made by section 1273 of division FF of Public Law 117-328.

[2] Section 1121(c)(2)(B)(ii) of division FF of Public Law 117-328 repealed the item relating to section 6031 in the table of sections. There are no other items remaining in subtitle C.

DIVISION A—21ST CENTURY CURES

SEC. 1000. [42 U.S.C. 201 note] SHORT TITLE.

This Division may be cited as the "21st Century Cures Act".

TITLE I—INNOVATION PROJECTS AND STATE RESPONSES TO OPIOID ABUSE

SEC. 1001. BEAU BIDEN CANCER MOONSHOT AND NIH INNOVATION PROJECTS.

(a) IN GENERAL.—The Director of the National Institutes of Health (referred to in this section as the "Director of NIH") shall use any funds appropriated pursuant to the authorization of appropriations in subsection (b)(3) to carry out the National Institutes of Health innovation projects described in subsection (b)(4) (referred to in this section as the "NIH Innovation Projects").

(b) NATIONAL INSTITUTES OF HEALTH INNOVATION ACCOUNT.—

(1) ESTABLISHMENT OF NIH INNOVATION ACCOUNT.—There is established in the Treasury an account, to be known as the "NIH Innovation Account" (referred to in this subsection as the "Account"), for purposes of carrying out the NIH Innovation Projects described in paragraph (4).

(2) TRANSFER OF DIRECT SPENDING SAVINGS.—

(A) IN GENERAL.—The following amounts shall be transferred to the Account from the general fund of the Treasury:

(i) For fiscal year 2017, $352,000,000.
(ii) For fiscal year 2018, $496,000,000.
(iii) For fiscal year 2019, $711,000,000.
(iv) For fiscal year 2020, $492,000,000.
(v) For fiscal year 2021, $404,000,000.
(vi) For fiscal year 2022, $496,000,000.
(vii) For fiscal year 2023, $1,085,000,000.
(viii) For fiscal year 2024, $407,000,000.
(ix) For fiscal year 2025, $127,000,000.
(x) For fiscal year 2026, $226,000,000.

(B) AMOUNTS DEPOSITED.—Any amounts transferred under subparagraph (A) shall remain unavailable in the Account until such amounts are appropriated pursuant to paragraph (3).

(3) APPROPRIATIONS.—

(A) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2017 through 2026, there is authorized to be appropriated from the Account to the Director of NIH, for the purpose of carrying out the NIH Innovation Projects, an amount not to exceed the total amount transferred to the Account under paragraph (2)(A), to remain available until expended.

(B) OFFSETTING FUTURE APPROPRIATIONS.—For any of fiscal years 2017 through 2026, for any discretionary appropriation under the heading "NIH Innovation Account" provided to the Director of NIH pursuant to the authorization of appropriations under subparagraph (A) for the purpose of carrying out the NIH Innovation Projects, the total amount of such appropriations for the applicable fiscal year (not to exceed the total amount remaining in the Account) shall be subtracted from the estimate of discretionary budget authority and the resulting outlays for any

estimate under the Congressional Budget and Impoundment Control Act of 1974 or the Balanced Budget and Emergency Deficit Control Act of 1985, and the amount transferred to the Account shall be reduced by the same amount.

(4) NIH INNOVATION PROJECTS.—NIH Innovation Projects authorized to be funded under this section shall consist of the following and, of the total amounts authorized to be appropriated under paragraph (3), there are authorized to be appropriated to each such project a total amount not to exceed the following, over the period of fiscal years 2017 through 2026:

(A) For the Precision Medicine Initiative, including for the advancement of a cohort of individuals to support the goals of the Precision Medicine Initiative, not to exceed a total of $1,455,000,000, as follows:

(i) For fiscal year 2017, $40,000,000.
(ii) For fiscal year 2018, $100,000,000.
(iii) For fiscal year 2019, $186,000,000.
(iv) For fiscal year 2020, $149,000,000.
(v) For fiscal year 2021, $109,000,000.
(vi) For fiscal year 2022, $150,000,000.
(vii) For fiscal year 2023, $419,000,000.
(viii) For fiscal year 2024, $235,000,000.
(ix) For fiscal year 2025, $36,000,000.
(x) For fiscal year 2026, $31,000,000.

(B) For the Brain Research through Advancing Innovative Neurotechnologies Initiative (known as the "BRAIN Initiative"), not to exceed a total of $1,511,000,000, as follows:

(i) For fiscal year 2017, $10,000,000.
(ii) For fiscal year 2018, $86,000,000.
(iii) For fiscal year 2019, $115,000,000.
(iv) For fiscal year 2020, $140,000,000.
(v) For fiscal year 2021, $100,000,000.
(vi) For fiscal year 2022, $152,000,000.
(vii) For fiscal year 2023, $450,000,000.
(viii) For fiscal year 2024, $172,000,000.
(ix) For fiscal year 2025, $91,000,000.
(x) For fiscal year 2026, $195,000,000.

(C) To support cancer research, such as the development of cancer vaccines, the development of more sensitive diagnostic tests for cancer, immunotherapy and the development of combination therapies, and research that has the potential to transform the scientific field, that has inherently higher risk, and that seeks to address major challenges related to cancer, not to exceed a total of $1,800,000,000, as follows:

(i) For fiscal year 2017, $300,000,000.
(ii) For fiscal year 2018, $300,000,000.
(iii) For fiscal year 2019, $400,000,000.
(iv) For fiscal year 2020, $195,000,000.
(v) For fiscal year 2021, $195,000,000.
(vi) For fiscal year 2022, $194,000,000.
(vii) For fiscal year 2023, $216,000,000.

(D) For the National Institutes of Health, in coordination with the Food and Drug Administration, to award grants and contracts for clinical research to further the field of regenerative medicine using adult stem cells, including autologous stem cells, for which grants and contracts shall be contingent upon the recipient making available non-Federal contributions toward the costs of such research in an amount not less than $1 for each $1 of Federal funds provided in the award, not to exceed a total of $30,000,000, as follows:

(i) For fiscal year 2017, $2,000,000.

(ii) For each of fiscal years 2018 and 2019, $10,000,000.

(iii) For fiscal year 2020, $8,000,000.

(iv) For each of fiscal years 2021 through 2026, $0.

(c) ACCOUNTABILITY AND OVERSIGHT.—

(1) WORK PLAN.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Director of NIH shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a work plan including the proposed allocation of funds authorized to be appropriated pursuant to subsection (b)(3) for each of fiscal years 2017 through 2026 for the NIH Innovation Projects and the contents described in subparagraph (B).

(B) CONTENTS.—The work plan submitted under subparagraph (A) shall include—

(i) recommendations from the Advisory Committee described in subparagraph (C);

(ii) the amount of money to be obligated or expended in each fiscal year for each NIH Innovation Project;

(iii) a description and justification of each such project; and

(iv) a description of how each such project supports the strategic research priorities identified in the NIH Strategic Plan under subsection (m) of section 402 of the Public Health Service Act (42 U.S.C. 282), as added by section 2031.

(C) RECOMMENDATIONS.—Prior to submitting the work plan under this paragraph, the Director of NIH shall seek recommendations from the Advisory Committee to the Director of NIH appointed under section 222 of the Public Health Service Act (42 U.S.C. 217a) on—

(i) the allocations of funds appropriated pursuant to the authorization of appropriations under subsection (b)(3) for each of fiscal years 2017 through 2026; and

(ii) on the contents of the proposed work plan.

(2) REPORTS.—

(A) ANNUAL REPORTS.—Not later than October 1 of each of fiscal years 2018 through 2027, the Director of NIH shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a report including—

(i) the amount of money obligated or expended in the prior fiscal year for each NIH Innovation Project;

(ii) a description of any such project using funds provided pursuant to the authorization of appropriations under subsection (b)(3); and

(iii) whether such projects are advancing the strategic research priorities identified in the NIH Strategic Plan under subsection (m) of section 402 of the Public Health Service Act (42 U.S.C. 282), as added by section 2031.

(B) ADDITIONAL REPORTS.—At the request of the Committee on Health, Education, Labor, and Pensions or the Committee on Appropriations of the Senate, or the Committee on Energy and Commerce or the Committee on Appropriations of the House of Representatives, the Director of NIH shall provide an update in the form of testimony and any additional reports to the respective congressional committee regarding the allocation of funding under this section or the description of the NIH Innovation Projects.

(d) LIMITATIONS.—Notwithstanding any transfer authority authorized by this Act or any appropriations Act, any funds made available pursuant to the authorization of appropriations under subsection (b)(3) may not be used for any purpose other than a NIH Innovation Project.

(e) SUNSET.—This section shall expire on September 30, 2026.

SEC. 1002. FDA INNOVATION PROJECTS.

(a) IN GENERAL.—The Commissioner of Food and Drugs (referred to in this section as the "Commissioner") shall use any funds appropriated pursuant to the authorization of appropriations under subsection (b)(3) to carry out the activities described in subsection (b)(4).

(b) FDA INNOVATION ACCOUNT.—

(1) ESTABLISHMENT OF FDA INNOVATION ACCOUNT.—There is established in the Treasury an account, to be known as the "FDA Innovation Account" (referred to in this subsection as the "Account"), for purposes of carrying out the activities described in paragraph (4).

(2) TRANSFER OF DIRECT SPENDING SAVINGS.—

(A) IN GENERAL.—For each of fiscal years 2017 through 2025, the following amounts shall be transferred to the Account from the general fund of the Treasury:

(i) For fiscal year 2017, $20,000,000.

(ii) For fiscal year 2018, $60,000,000.

(iii) For fiscal year 2019, $70,000,000.

(iv) For fiscal year 2020, $75,000,000.

(v) For fiscal year 2021, $70,000,000.

(vi) For fiscal year 2022, $50,000,000.
(vii) For fiscal year 2023, $50,000,000.
(viii) For fiscal year 2024, $50,000,000.
(ix) For fiscal year 2025, $55,000,000.

(B) AMOUNTS DEPOSITED.—Any amounts transferred under subparagraph (A) shall remain unavailable in the Account until such amounts are appropriated pursuant to paragraph (3).

(3) APPROPRIATIONS.—

(A) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2017 through 2025, there is authorized to be appropriated from the Account to the Commissioner, for the purpose of carrying out the activities described in paragraph (5), an amount not to exceed the total amount transferred to the Account under paragraph (2)(A), to remain available until expended.

(B) OFFSETTING FUTURE APPROPRIATIONS.—For any of fiscal years 2017 through 2025, for any discretionary appropriation under the heading "FDA Innovation Account" provided to the Commissioner pursuant to the authorization of appropriations under subparagraph (A) for the purpose of carrying out the projects activities described in paragraph (4), the total amount of such appropriations in the applicable fiscal year (not to exceed the total amount remaining in the Account) shall be subtracted from the estimate of discretionary budget authority and the resulting outlays for any estimate under the Congressional Budget and Impoundment Control Act of 1974 or the Balanced Budget and Emergency Deficit Control Act of 1985, and the amount transferred to the Account shall be reduced by the same amount.

(4) FDA ACTIVITIES.—The activities authorized to be funded under this section are the activities under subtitles A through F (including the amendments made by such subtitles) of title III of this Act and section 1014 of the Federal Food, Drug, and Cosmetic Act, as added by section 3073 of this Act.

(c) ACCOUNTABILITY AND OVERSIGHT.—

(1) WORK PLAN.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Commissioner shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a work plan including the proposed allocation of funds appropriated pursuant to the authorization of appropriations under subsection (b)(3) for each of fiscal years 2017 through 2025 and the contents described in subparagraph (B).

(B) CONTENTS.—The work plan submitted under subparagraph (A) shall include—

(i) recommendations from the Advisory Committee described in subparagraph (C);

(ii) the amount of money to be obligated or expended in each fiscal year for each activity described in subsection (b)(4); and

(iii) a description and justification of each such project activity.

(C) RECOMMENDATIONS.—Prior to submitting the work plan under this paragraph, the Commissioner shall seek recommendations from the Science Board to the Food and Drug Administration, on the proposed allocation of funds appropriated pursuant to the authorization of appropriations under subsection (b)(3) for each of fiscal years 2017 through 2025 and on the contents of the proposed work plan.

(2) REPORTS.—

(A) ANNUAL REPORTS.—Not later than October 1 of each of fiscal years 2018 through 2026, the Commissioner shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a report including—

(i) the amount of money obligated or expended in the prior fiscal year for each activity described in subsection (b)(4);

(ii) a description of all such activities using funds provided pursuant to the authorization of appropriations under subsection (b)(3); and

(iii) how the activities are advancing public health.

(B) ADDITIONAL REPORTS.—At the request of the Committee on Health, Education, Labor, and Pensions or the Committee on Appropriations of the Senate, or the Committee on Energy and Commerce or the Committee on Appropriations of the House of Representatives, the Commissioner shall provide an update in the form of testimony and any additional reports to the respective congressional committee regarding the allocation of funding under this section or the description of the activities undertaken with such funding.

(d) LIMITATIONS.—Notwithstanding any transfer authority authorized by this Act or any appropriations Act, any funds made available pursuant to the authorization of appropriations in subsection (b)(3) shall not be used for any purpose other than an activity described in subsection (b)(4).

(e) SUNSET.—This section shall expire on September 30, 2025.

SEC. 1003. [42 U.S.C. 290ee-3a] GRANT PROGRAM FOR STATE AND TRIBAL RESPONSE TO OPIOID USE DISORDERS.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall carry out the grant program described in subsection (b) for purposes of addressing opioid misuse and use disorders and, as applicable and appropriate, stimulant misuse and use disorders, within States, Indian Tribes, and populations served by Tribal organizations and Urban Indian organizations.

(b) GRANTS PROGRAM.—

(1) IN GENERAL.—Subject to the availability of appropriations, the Secretary shall award grants to the single State agency responsible for administering the substance use prevention, treatment, and recovery services block grant under subpart II of part B of title XIX of the Public Health Service Act (42 U.S.C. 300x–21 et seq.), Indian Tribes, and Tribal organizations for the purpose of addressing opioid misuse and use disorders, and as applicable and appropriate, stimulant misuse and use disorders, within such States, such Indian Tribes, and populations served by such Tribal organizations, in accordance with paragraph (2). Indian Tribes or Tribal organizations may also apply for an award as part of a consortia or may include in an application a partnership with an Urban Indian organization.

(2) MINIMUM ALLOCATIONS.—Notwithstanding subsection (i)(3), in determining grant amounts for each recipient of a grant under paragraph (1), the Secretary shall ensure that each State and the District of Columbia receive not less than $4,000,000 and ensure that each Territory receives not less than $250,000.

(3) FORMULA METHODOLOGY.—

(A) IN GENERAL.—At least 30 days before publishing a funding opportunity announcement with respect to grants under this section, the Secretary shall—

(i) develop a formula methodology to be followed in allocating grant funds awarded under this section among grantees, which, where applicable and appropriate based on populations being served by the relevant entity—

(I) with respect to allocations for States, gives preference to States whose populations have a prevalence of opioid misuse and use disorders or drug overdose deaths that is substantially higher relative to the populations of other States;

(II) with respect to allocations for Tribes and Tribal organizations, gives preferences to Tribes and Tribal organizations (including those applying in partnership with an Urban Indian organization) serving populations with demonstrated need with respect to opioid misuse and use disorders or drug overdose deaths;

(III) includes performance assessments for continuation awards; and

(IV) ensures that the formula avoids a funding cliff between States with similar overdose mortality rates to prevent funding reductions when compared to prior year allocations, as determined by the Secretary; and

(ii) not later than 30 days after developing the formula methodology under clause (i), submit the formula methodology to—

(I) the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate; and

(II) the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives.

(B) REPORT.—Not later than two years after the date of the enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that—

(i) assesses how grant funding is allocated to States under this section and how such allocations have changed over time;

(ii) assesses how any changes in funding under this section have affected the efforts of States to address opioid misuse and use disorders and, as applicable and appropriate, stimulant misuse and use disorders; and

(iii) assesses the use of funding provided through the grant program under this section and other similar grant programs administered by the Substance Abuse and Mental Health Services Administration.

(4) USE OF FUNDS.—Grants awarded under this subsection shall be used for carrying out activities that supplement activities pertaining to opioid misuse and use disorders and, as applicable and appropriate, stimulant misuse and use disorders (including co-occurring substance misuse and use disorders), undertaken by the entities described in paragraph (1), which may include public health-related activities such as the following:

(A) Implementing substance use disorder and overdose prevention activities, including primary prevention activities, and evaluating such activities to identify effective strategies to prevent substance use disorders and overdoses, which may include drugs or devices approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act.

(B) Establishing or improving prescription drug monitoring programs.

(C) Training for health care practitioners, such as best practices for prescribing opioids, pain management, recognizing potential cases of substance use disorders, referral of patients to treatment programs, preventing diversion of controlled substances, and overdose prevention.

(D) Supporting access to and the provision of substance use disorder-related health care services, including—

(i) services provided by federally certified opioid treatment programs;

(ii) services provided in outpatient and residential substance use disorder treatment programs or facili-

ties, including those that utilize medication-assisted treatment, as appropriate; or

(iii) services provided by other appropriate health care providers to treat substance use disorders, including crisis services and services provided in integrated health care settings by appropriate health care providers that treat substance use disorders.

(E) Recovery support services, including—

(i) community-based services that include education, outreach, and peer supports such as peer support specialists and recovery coaches to help support recovery;

(ii) mutual aid recovery programs that support medication-assisted treatment;

(iii) services to address housing needs; or

(iv) services related to supporting families that include an individual with a substance use disorder.

(F) Other public health-related activities, as such entity determines appropriate, related to addressing opioid misuse and use disorders and, as applicable and appropriate, stimulant misuse and use disorders, within such entity, including directing resources in accordance with local needs related to substance use disorders.

(c) ACCOUNTABILITY AND OVERSIGHT.—A State receiving a grant under subsection (b) shall submit to the Secretary a description of—

(1) the purposes for which the grant funds received by the State under such subsection for the preceding fiscal year were expended and a description of the activities of the State under the grant;

(2) the ultimate recipients of amounts provided to the State;

(3) the number of individuals served through the grant; and

(4) such other information as determined appropriate by the Secretary.

(d) LIMITATIONS.—Any funds made available pursuant to subsection (i) shall not be used for any purpose other than the grant program under subsection (b).

(e) INDIAN TRIBES AND TRIBAL ORGANIZATIONS.—The Secretary, in consultation with Indian Tribes and Tribal organizations, shall identify and establish appropriate mechanisms for Indian Tribes and Tribal organizations to demonstrate or report the information as required under subsections (b), (c), and (d).

(f) REPORT TO CONGRESS.—Not later than September 30, 2024, and biennially thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and the Committees on Appropriations of the House of Representatives and the Senate, a report that includes a summary of the information provided to the Secretary in reports made pursuant to subsections (c) and (d), including—

(1) the purposes for which grant funds are awarded under this section;

(2) the activities of the grant recipients; and

(3) each entity that receives a grant under this section, including the funding level provided to such recipient.

(g) TECHNICAL ASSISTANCE.—The Secretary, including through the Tribal Training and Technical Assistance Center of the Substance Abuse and Mental Health Services Administration, as applicable, shall provide entities described in subsection (b)(1) with technical assistance concerning grant application and submission procedures under this section, award management activities, and enhancing outreach and direct support to rural and underserved communities and providers in addressing substance use disorders.

(h) DEFINITIONS.—In this section:

(1) INDIAN TRIBE.—The term "Indian Tribe" has the meaning given the term "Indian tribe" in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

(2) TRIBAL ORGANIZATION.—The term "Tribal organization" has the meaning given the term "tribal organization" in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

(3) STATE.—The term "State" has the meaning given such term in section 1954(b) of the Public Health Service Act (42 U.S.C. 300x–64(b)).

(4) URBAN INDIAN ORGANIZATION.—The term "Urban Indian organization" has the meaning given such term in section 4 of the Indian Health Care Improvement Act.

(i) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For purposes of carrying out the grant program under subsection (b), there is authorized to be appropriated $1,750,000,000 for each of fiscal years 2023 through 2027.

(2) FEDERAL ADMINISTRATIVE EXPENSES.—Of the amounts made available for each fiscal year to award grants under subsection (b), the Secretary shall not use more than 2 percent for Federal administrative expenses, training, technical assistance, and evaluation.

(3) SET ASIDE.—Of the amounts made available for each fiscal year to award grants under subsection (b) for a fiscal year, the Secretary shall—

(A) award not more than 5 percent to Indian Tribes and Tribal organizations; and

(B) of the amount remaining after application of subparagraph (A), set aside up to 15 percent for awards to States with the highest age-adjusted rate of drug overdose death based on the ordinal ranking of States according to the Director of the Centers for Disease Control and Prevention.

SEC. 1004. BUDGETARY TREATMENT.

(a) STATUTORY PAYGO SCORECARDS.—The budgetary effects of division A of this Act shall not be entered on either PAYGO scorecard maintained pursuant to section 4(d) of the Statutory Pay-As-You-Go Act of 2010.

(b) SENATE PAYGO SCORECARDS.—The budgetary effects of division A of this Act shall not be entered on any PAYGO scorecard maintained for purposes of section 201 of S. Con. Res. 21 (110th Congress).

(c) RESERVATION OF SAVINGS.—None of the funds in the NIH Innovation Accountor the FDA Innovation Account established by this title shall be made available except to the extent provided in advance in appropriations Acts, and legislation or an Act that rescinds or reduces amounts in such accounts shall not be estimated as a reduction in direct spending under the Congressional Budget and Impoundment Control Act of 1974 or the Balanced Budget and Emergency Deficit Control Act of 1985.

TITLE II—DISCOVERY

Subtitle A—National Institutes of Health Reauthorization

SEC. 2001. 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 "and" at the end;

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

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

"(D) $34,851,000,000 for fiscal year 2018;

"(E) $35,585,871,000 for fiscal year 2019; and

"(F) $36,472,442,775 for fiscal year 2020.".

SEC. 2002. [42 U.S.C. 283q] EUREKA PRIZE COMPETITIONS.

(a) IN GENERAL.—Pursuant to the authorities and processes established under section 24 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3719), the Director of the National Institutes of Health shall support prize competitions for one or both of the following goals:

(1) Identifying and funding areas of biomedical science that could realize significant advancements through a prize competition.

(2) Improving health outcomes, particularly with respect to human diseases and conditions—

(A) for which public and private investment in research is disproportionately small relative to Federal Government expenditures on prevention and treatment activities with respect to such diseases and conditions, such that Federal expenditures on health programs would be reduced;

(B) that are serious and represent a significant disease burden in the United States; or

(C) for which there is potential for significant return on investment to the United States.

(b) TRACKING; REPORTING.—The Director of the National Institutes of Health shall—

(1) collect information on—

(A) the effect of innovations funded through the prize competitions under this section in advancing biomedical science or improving health outcomes pursuant to subsection (a); and

(B) the effect of the innovations on Federal expenditures; and

(2) include the information collected under paragraph (1) in the triennial report under section 403 of the Public Health Service Act (42 U.S.C. 283) (as amended by section 2032).

Subtitle B—Advancing Precision Medicine

SEC. 2011. [42 U.S.C. 289g-5] PRECISION MEDICINE INITIATIVE.

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. PRECISION MEDICINE INITIATIVE

"(a) IN GENERAL.—The Secretary is encouraged to establish and carry out an initiative, to be known as the 'Precision Medicine Initiative' (in this section referred to as the 'Initiative'), to augment efforts to address disease prevention, diagnosis, and treatment.

"(b) COMPONENTS.—The Initiative described under subsection (a) may include—

"(1) developing a network of scientists to assist in carrying out the purposes of the Initiative;

"(2) developing new approaches for addressing scientific, medical, public health, and regulatory science issues;

"(3) applying genomic technologies, such as whole genomic sequencing, to provide data on the molecular basis of disease;

"(4) collecting information voluntarily provided by a diverse cohort of individuals that can be used to better understand health and disease; and

"(5) other activities to advance the goals of the Initiative, as the Secretary determines appropriate.

"(c) AUTHORITY OF THE SECRETARY.—In carrying out this section, the Secretary may—

"(1) coordinate with the Secretary of Energy, private industry, and others, as the Secretary determines appropriate, to identify and address the advanced supercomputing and other advanced technology needs for the Initiative;

"(2) develop and utilize public-private partnerships; and

"(3) leverage existing data sources.

"(d) REQUIREMENTS.—In the implementation of the Initiative under subsection (a), the Secretary shall—

"(1) ensure the collaboration of the National Institutes of Health, the Food and Drug Administration, the Office of the National Coordinator for Health Information Technology, and the Office for Civil Rights of the Department of Health and Human Services;

"(2) comply with existing laws and regulations for the protection of human subjects involved in research, including the protection of participant privacy;

"(3) implement policies and mechanisms for appropriate secure data sharing across systems that include protections for privacy and security of data;

"(4) consider the diversity of the cohort to ensure inclusion of a broad range of participants, including consideration of biological, social, and other determinants of health that contribute to health disparities;

"(5) ensure that only authorized individuals may access controlled or sensitive, identifiable biological material and associated information collected or stored in connection with the Initiative; and

"(6) on the appropriate Internet website of the Department of Health and Human Services, identify any entities with access to such information and provide information with respect to the purpose of such access, a summary of the research project for which such access is granted, as applicable, and a description of the biological material and associated information to which the entity has access.

"(e) REPORT.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall submit a report on the relevant data access policies and procedures to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives. Such report shall include steps the Secretary has taken to consult with experts or other heads of departments or agencies of the Federal Government in the development of such policies.".

SEC. 2012. PRIVACY PROTECTION FOR HUMAN RESEARCH SUBJECTS.

(a) IN GENERAL.—Subsection (d) of section 301 of the Public Health Service Act (42 U.S.C. 241) is amended to read as follows:

"(d)(1)(A) If a person is engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs), the Secretary, in coordination with other agencies, as applicable—

"(i) shall issue to such person a certificate of confidentiality to protect the privacy of individuals who are the subjects of such research if the research is funded wholly or in part by the Federal Government; and

"(ii) may, upon application by a person engaged in research, issue to such person a certificate of confidentiality to protect the privacy of such individuals if the research is not so funded.

"(B) Except as provided in subparagraph (C), any person to whom a certificate is issued under subparagraph (A) to protect the privacy of individuals described in such subparagraph shall not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

"(C) The disclosure prohibition in subparagraph (B) shall not apply to disclosure or use that is—

"(i) required by Federal, State, or local laws, excluding instances described in subparagraph (D);

"(ii) necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

"(iii) made with the consent of the individual to whom the information, document, or biospecimen pertains; or

"(iv) made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

"(D) Any person to whom a certificate is issued under subparagraph (A) to protect the privacy of an individual described in such subparagraph shall not, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, disclose or provide the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, except in the circumstance described in subparagraph (C)(iii).

"(E) Identifiable, sensitive information protected under subparagraph (A), and all copies thereof, shall be immune from the legal process, and shall not, without the consent of the individual to whom the information pertains, be admissible as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding.

"(F) Identifiable, sensitive information collected by a person to whom a certificate has been issued under subparagraph (A), and all copies thereof, shall be subject to the protections afforded by this section for perpetuity.

"(G) The Secretary shall take steps to minimize the burden to researchers, streamline the process, and reduce the time it takes to comply with the requirements of this subsection.

"(2) The Secretary shall coordinate with the heads of other applicable Federal agencies to ensure that such departments have policies in place with respect to the issuance of a certificate of confidentiality pursuant to paragraph (1) and other requirements of this subsection.

"(3) Nothing in this subsection shall be construed to limit the access of an individual who is a subject of research to information about himself or herself collected during such individual's participation in the research.

"(4) For purposes of this subsection, the term 'identifiable, sensitive information' means information that is about an individual and that is gathered or used during the course of research described in paragraph (1)(A) and—

"(A) through which an individual is identified; or

"(B) for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.".

(b) [42 U.S.C. 241 note]

[42 U.S.C. 241 note] APPLICABILITY.—Beginning 180 days after the date of enactment of this Act, all persons engaged in research and authorized by the Secretary of Health and Human Services to protect information under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) prior to the date of enactment of this Act shall be subject to the requirements of such section (as amended by this Act).

SEC. 2013. PROTECTION OF IDENTIFIABLE AND SENSITIVE INFORMATION.

Section 301 of the Public Health Service Act (42 U.S.C. 241) is amended by adding at the end the following:

"(f)(1) The Secretary may exempt from disclosure under section 552(b)(3) of title 5, United States Code, biomedical information that is about an individual and that is gathered or used during the course of biomedical research if—

"(A) an individual is identified; or

"(B) there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources could be used to deduce the identity of an individual.

"(2)(A) Each determination of the Secretary under paragraph (1) to exempt information from disclosure shall be made in writing and accompanied by a statement of the basis for the determination.

"(B) Each such determination and statement of basis shall be available to the public, upon request, through the Office of the Chief FOIA Officer of the Department of Health and Human Services.

"(3) Nothing in this subsection shall be construed to limit a research participant's access to information about such participant collected during the participant's participation in the research.".

SEC. 2014. DATA SHARING.

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

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

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

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

"(25) may require recipients of National Institutes of Health awards to share scientific data, to the extent feasible, generated from such National Institutes of Health awards in a manner that is consistent with all applicable Federal laws and regulations, including such laws and regulations for the protection of—

"(A) human research participants, including with respect to privacy, security, informed consent, and protected health information; and

"(B) proprietary interests, confidential commercial information, and the intellectual property rights of the funding recipient.".

(b) [42 U.S.C. 282 note]

[42 U.S.C. 282 note] CONFIDENTIALITY.—Nothing in the amendments made by subsection (a) authorizes the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code, or be construed to require recipients of grants or

cooperative agreements through the National Institutes of Health to share such information.

Subtitle C—Supporting Young Emerging Scientists

SEC. 2021. INVESTING IN THE NEXT GENERATION OF RESEARCHERS.

(a) IN GENERAL.—Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following:

"SEC. 404M. [42 U.S.C. 283o]

[42 U.S.C. 283o] NEXT GENERATION OF RESEARCHERS

"(a) NEXT GENERATION OF RESEARCHERS INITIATIVE.—There shall be established within the Office of the Director of the National Institutes of Health, the Next Generation of Researchers Initiative (referred to in this section as the 'Initiative'), through which the Director shall coordinate all policies and programs within the National Institutes of Health that are focused on promoting and providing opportunities for new researchers and earlier research independence.

"(b) ACTIVITIES.—The Director of the National Institutes of Health, through the Initiative shall—

"(1) promote policies and programs within the National Institutes of Health that are focused on improving opportunities for new researchers and promoting earlier research independence, including existing policies and programs, as appropriate;

"(2) develop, modify, or prioritize policies, as needed, within the National Institutes of Health to promote opportunities for new researchers and earlier research independence, such as policies to increase opportunities for new researchers to receive funding, enhance training and mentorship programs for researchers, and enhance workforce diversity;

"(3) coordinate, as appropriate, with relevant agencies, professional and academic associations, academic institutions, and others, to improve and update existing information on the biomedical research workforce in order to inform programs related to the training, recruitment, and retention of biomedical researchers; and

"(4) carry out other activities, including evaluation and oversight of existing programs, as appropriate, to promote the development of the next generation of researchers and earlier research independence.".

(b) CONSIDERATION OF RECOMMENDATIONS.—In carrying out activities under section 404M(b) of the Public Health Service Act, the Director of the National Institutes of Health shall take into consideration the recommendations made by the National Academies of Sciences, Engineering, and Medicine as part of the comprehensive study on policies affecting the next generation of researchers under the Department of Health and Human Services Appropriations Act, 2016 (Public Law 114-113), and submit a report to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, and the Committee on Energy and Commerce and the Committee on Appropriations of the House of

Representatives, with respect to any actions taken by the National Institutes of Health based on the recommendations not later than 2 years after the completion of the study required pursuant to the Department of Health and Human Services Appropriations Act, 2016.

SEC. 2022. IMPROVEMENT OF LOAN REPAYMENT PROGRAM.

(a) INTRAMURAL LOAN REPAYMENT PROGRAM.—Section 487A of the Public Health Service Act (42 U.S.C. 288-1) is amended—

(1) by amending the section heading to read as follows: "**intramural loan repayment program**";

(2) in subsection (a)—

(A) by striking "The Secretary shall carry out a program" and inserting "The Director of the National Institutes of Health shall, as appropriate and based on workforce and scientific priorities, carry out a program through the subcategories listed in subsection (b)(1) (or modified subcategories as provided for in subsection (b)(2))";

(B) by striking "conduct" and inserting "conduct research";

(C) by striking "research with respect to acquired immune deficiency syndrome"; and

(D) by striking "$35,000" and inserting "$50,000";

(3) by redesignating subsection (b) as subsection (d);

(4) by inserting after subsection (a), the following:

"(b) SUBCATEGORIES OF RESEARCH.—

"(1) IN GENERAL.—In carrying out the program under subsection (a), the Director of the National Institutes of Health—

"(A) shall continue to focus on—

"(i) general research;

"(ii) research on acquired immune deficiency syndrome; and

"(iii) clinical research conducted by appropriately qualified health professional who are from disadvantaged backgrounds; and

"(B) may focus on an area of emerging scientific or workforce need.

"(2) ELIMINATION OR ESTABLISHMENT OF SUBCATEGORIES.—The Director of the National Institutes of Health may eliminate one or more subcategories provided for in paragraph (1) due to changes in workforce or scientific needs related to biomedical research. The Director may establish other subcategory areas based on workforce and scientific priorities if the total number of subcategories does not exceed the number of subcategories listed in paragraph (1).

"(c) LIMITATION.—The Director of the National Institutes of Health may not enter into a contract with a health professional pursuant to subsection (a) unless such professional has a substantial amount of education loans relative to income (as determined pursuant to guidelines issued by the Director)."; and

(5) by adding at the end the following:

"(e) AVAILABILITY OF APPROPRIATIONS.—Amounts available for carrying out this section shall remain available until the expiration

of the second fiscal year beginning after the fiscal year for which such amounts are made available.".

(b) EXTRAMURAL LOAN REPAYMENT PROGRAM.—Section 487B of the Public Health Service Act (42 U.S.C. 288-2) is amended—

(1) by amending the section heading to read as follows: "**extramural loan repayment program**";

(2) in subsection (a)—

(A) by striking "The Secretary, in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, shall establish a program" and inserting "In General.—The Director of the National Institutes of Health shall, as appropriate and based on workforce and scientific priorities, carry out a program through the subcategories listed in subsection (b)(1) (or modified subcategories as provided for in subsection (b)(2)),";

(B) by striking "(including graduate students)";

(C) by striking "with respect to contraception, or with respect to infertility,"; and

(D) by striking "service, not more than $35,000" and inserting "research, not more than $50,000";

(3) by redesignating subsections (b) and (c) as subsections (d) and (e), respectively;

(4) by inserting after subsection (a), the following:

"(b) SUBCATEGORIES OF RESEARCH.—

"(1) IN GENERAL.—In carrying out the program under subsection (a), the Director of the National Institutes of Health—

"(A) shall continue to focus on—

"(i) contraception or infertility research;

"(ii) pediatric research, including pediatric pharmacological research;

"(iii) minority health disparities research;

"(iv) clinical research; and

"(v) clinical research conducted by appropriately qualified health professional who are from disadvantaged backgrounds; and

"(B) may focus on an area of emerging scientific or workforce need.

"(2) ELIMINATION OR ESTABLISHMENT OF SUBCATEGORIES.—The Director of the National Institutes of Health may eliminate one or more subcategories provided for in paragraph (1) due to changes in workforce or scientific needs related to biomedical research. The Director may establish other subcategory areas based on workforce and scientific priorities if the total number of subcategories does not exceed the number of subcategories listed in paragraph (1).

"(c) LIMITATION.—The Director of the National Institutes of Health may not enter into a contract with a health professional pursuant to subsection (a) unless such professional has a substantial amount of education loans relative to income (as determined pursuant to guidelines issued by the Director).";

(5) in subsection (d) (as so redesignated), by striking "The provisions" and inserting "Applicability of Certain Provisions Regarding Obligated Service.—The provisions"; and

(6) in subsection (e) (as so redesignated), by striking "Amounts" and inserting "Availability of Appropriations.—Amounts".

(c) TECHNICAL AND CONFORMING AMENDMENTS.—Title IV of the Public Health Service Act is amended—

(1) by striking section 464z-5 (42 U.S.C. 285t-2);

(2) by striking section 487C (42 U.S.C. 288-3);

(3) by striking section 487E (42 U.S.C. 288-5);

(4) by striking section 487F (42 U.S.C. 288-5a), as added by section 205 of Public Law 106-505, relating to loan repayment for clinical researchers; and

(5) by striking section 487F (42 U.S.C. 288-6), as added by section 1002(b) of Public Law 106-310 relating to pediatric research loan repayment.

(d) GAO REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the efforts of the National Institutes of Health to attract, retain, and develop emerging scientists, including underrepresented individuals in the sciences, such as women, racial and ethnic minorities, and other groups. Such report shall include an analysis of the impact of the additional authority provided to the Secretary of Health and Human Services under this Act to address workforce shortages and gaps in priority research areas, including which centers and research areas offered loan repayment program participants the increased award amount.

Subtitle D—National Institutes of Health Planning and Administration

SEC. 2031. NATIONAL INSTITUTES OF HEALTH STRATEGIC PLAN.

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

(1) in subsection (b)(5), by inserting before the semicolon the following: ", and through the development, implementation, and updating of the strategic plan developed under subsection (m)"; and

(2) by adding at the end the following:

"(m) NATIONAL INSTITUTES OF HEALTH STRATEGIC PLAN.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the 21st Century Cures Act, and at least every 6 years thereafter, the Director of the National Institutes of Health shall develop and submit to the appropriate committees of Congress and post on the Internet website of the National Institutes of Health, a coordinated strategy (to be known as the 'National Institutes of Health Strategic Plan') to provide direction to the biomedical research investments made by the National Institutes of Health, to facilitate collaboration across the institutes and centers, to leverage scientific opportunity, and to advance biomedicine.

"(2) REQUIREMENTS.—The strategy under paragraph (1) shall—

"(A) identify strategic research priorities and objectives across biomedical research, including—

"(i) an assessment of the state of biomedical and behavioral research, including areas of opportunity with respect to basic, clinical, and translational research;

"(ii) priorities and objectives to advance the treatment, cure, and prevention of health conditions;

"(iii) emerging scientific opportunities, rising public health challenges, and scientific knowledge gaps; and

"(iv) the identification of near-, mid-, and long-term scientific needs;

"(B) consider, in carrying out subparagraph (A)—

"(i) disease burden in the United States and the potential for return on investment to the United States;

"(ii) rare diseases and conditions;

"(iii) biological, social, and other determinants of health that contribute to health disparities; and

"(iv) other factors the Director of National Institutes of Health determines appropriate;

"(C) include multi-institute priorities, including coordination of research among institutes and centers;

"(D) include strategic priorities for funding research through the Common Fund, in accordance with section 402A(c)(1)(C);

"(E) address the National Institutes of Health's proposed and ongoing activities related to training and the biomedical workforce; and

"(F) describe opportunities for collaboration with other agencies and departments, as appropriate.

"(3) USE OF PLANS.—Strategic plans developed and updated by the national research institutes and national centers of the National Institutes of Health shall be prepared regularly and in such a manner that such plans will be informed by the strategic plans developed and updated under this subsection. Such plans developed by and updated by the national research institutes and national centers shall have a common template.

"(4) CONSULTATION.—The Director of National Institutes of Health shall develop the strategic plan under paragraph (1) in consultation with the directors of the national research institutes and national centers, researchers, patient advocacy groups, and industry leaders.".

(b) CONFORMING AMENDMENT.—Section 402A(c)(1)(C) of the Public Health Service Act (42 U.S.C. 282a(c)(1)(C)) is amended by striking "Not later than June 1, 2007, and every 2 years thereafter," and inserting "As part of the National Institutes of Health Strategic Plan required under section 402(m),".

(c) STRATEGIC PLAN.—Section 492B(a) of the Public Health Service Act (42 U.S.C. 289a-2(a)) is amended by adding at the end the following:

"(3) STRATEGIC PLANNING.—

"(A) IN GENERAL.—The directors of the national institutes and national centers shall consult at least once annually with the Director of the National Institute on Minority Health and Health Disparities and the Director of the Office of Research on Women's Health regarding objectives of the national institutes and national centers to ensure that future activities by such institutes and centers take into account women and minorities and are focused on reducing health disparities.

"(B) STRATEGIC PLANS.—Any strategic plan issued by a national institute or national center shall include details on the objectives described in subparagraph (A).".

SEC. 2032. TRIENNIAL REPORTS.

Section 403 of the Public Health Service Act (42 U.S.C. 283) is amended—

(1) in the section heading, by striking "**biennial**" and inserting "**triennial**"; and

(2) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "biennial" and inserting "triennial";

(B) by amending paragraph (3) to read as follows:

"(3) A description of intra-National Institutes of Health activities, including—

"(A) identification of the percentage of funds made available by each national research institute and national center with respect to each applicable fiscal year for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers; and

"(B) recommendations for promoting coordination of information among the centers of excellence.";

(C) in paragraph (4)—

(i) in subparagraph (B), by striking "demographic variables and other variables" and inserting "demographic variables, including biological and social variables and relevant age categories (such as pediatric subgroups), and determinants of health,"; and

(ii) in subparagraph (C)(v)—

(I) by striking "demographic variables and such" and inserting "demographic variables, including relevant age categories (such as pediatric subgroups), information submitted by each national research institute and national center to the Director of National Institutes of Health under section 492B(f), and such"; and

(II) by striking "(regarding inclusion of women and minorities in clinical research)" and inserting "and other applicable requirements regarding inclusion of demographic groups"; and

(D) in paragraph (6)—

(i) in the matter preceding subparagraph (A), by striking "the following:" and inserting "the following—";

(ii) in subparagraph (A)—

(I) by striking "An evaluation" and inserting "an evaluation"; and

(II) by striking the period and inserting "; and";

(iii) by striking subparagraphs (B) and (D);

(iv) by redesignating subparagraph (C) as subparagraph (B); and

(v) in subparagraph (B), as redesignated by clause (iv), by striking "Recommendations" and inserting "recommendations".

SEC. 2033. 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.—

"(1) IN GENERAL.—The Director of the National Cancer Institute shall be appointed by the President, and the Directors of the other national research institutes and national centers shall be appointed by the Secretary, acting through the Director of National Institutes of Health. Each Director of a national research institute or national center shall report directly to the Director of National Institutes of Health.

"(2) APPOINTMENT.—

"(A) TERM.—A Director of a national research institute or national center who is appointed by the Secretary, acting through the Director of National Institutes of Health, shall be appointed for 5 years.

"(B) REAPPOINTMENT.—At the end of the term of a Director of a national research institute or national center, the Director may be reappointed in accordance with standards applicable to the relevant appointment mechanism. There shall be no limit on the number of terms that a Director may serve.

"(C) 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.

"(D) CURRENT DIRECTORS.—Each Director of a national research institute or national center who is serving on the date of enactment of the 21st Century Cures Act shall be deemed to be appointed for a 5-year term under this subsection beginning on such date of enactment.

"(E) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the authority of the Secretary or the Director of National Institutes of Health to terminate the appointment of a director referred to in subparagraph (A) before the expiration of such director's 5-year term.

"(F) NATURE OF APPOINTMENT.—Appointments and reappointments under this subsection shall be made on the

basis of ability and experience as it relates to the mission of the National Institutes of Health and its components, including compliance with any legal requirement that the Secretary or Director of National Institutes of Health determines relevant.

"(3) NONAPPLICATION OF CERTAIN PROVISION.—The restrictions contained in 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) related to consultants and individual scientists appointed for limited periods of time shall not apply to Directors appointed under this subsection.".

(b) 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 noncompetitive renewal of such a grant, or a noncompetitive administrative supplement to such a grant, the Director of such national research institute or national center shall, consistent with the peer review process—

"(A) review and make the final decision with respect to making the award; and

"(B) take into consideration, as appropriate—

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

"(ii) programs or projects funded by other agencies on similar research topics; and

"(iii) advice by staff and the advisory council or board of such national research institute or national center.".

(c) REPORT ON DUPLICATION IN FEDERAL BIOMEDICAL RESEARCH.—The Secretary of Health and Human Services (referred to in this subsection as the "Secretary"), shall, not later than 2 years after the date of enactment of this Act, submit a report to Congress on efforts to prevent and eliminate duplicative biomedical research that is not necessary for scientific purposes. Such report shall—

(1) describe the procedures in place to identify such duplicative research, including procedures for monitoring research applications and funded research awards to prevent unnecessary duplication;

(2) describe the steps taken to improve the procedures described in paragraph (1), in response to relevant recommendations made by the Comptroller General of the United States;

(3) describe how the Secretary operationally distinguishes necessary and appropriate scientific replication from unnecessary duplication; and

(4) provide examples of instances where the Secretary has identified unnecessarily duplicative research and the steps taken to eliminate the unnecessary duplication.

SEC. 2034. [42 U.S.C. 3501 note] REDUCING ADMINISTRATIVE BURDEN FOR RESEARCHERS.

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

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall—

(A) lead a review by research funding agencies of all regulations and policies related to the disclosure of financial conflicts of interest, including the minimum threshold for reporting financial conflicts of interest;

(B) make revisions, as appropriate, to harmonize existing policies and reduce administrative burden on researchers while maintaining the integrity and credibility of research findings and protections of human participants; and

(C) confer with the Office of the Inspector General about the activities of such office related to financial conflicts of interest involving research funding agencies.

(2) CONSIDERATIONS.—In updating policies under paragraph (1)(B), the Secretary shall consider—

(A) modifying the timelines for the reporting of financial conflicts of interest to just-in-time information by institutions receiving grant or cooperative agreement funding from the National Institutes of Health;

(B) ensuring that financial interest disclosure reporting requirements are appropriate for, and relevant to, awards that will directly fund research, which may include modification of the definition of the term "investigator" for purposes of the regulations and policies described in subparagraphs (A) and (B) of paragraph (1); and

(C) updating any applicable training modules of the National Institutes of Health related to Federal financial interest disclosure.

(b) MONITORING OF SUBRECIPIENTS OF FUNDING FROM THE NATIONAL INSTITUTES OF HEALTH.—The Director of the National Institutes of Health (referred to in this section as the "Director of National Institutes of Health") shall implement measures to reduce the administrative burdens related to monitoring of subrecipients of grants by primary awardees of funding from the National Institutes of Health, which may incorporate findings and recommendations from existing and ongoing activities. Such measures may include, as appropriate—

(1) an exemption from subrecipient monitoring requirements, upon request from the primary awardees, provided that—

(A) the subrecipient is subject to Federal audit requirements pursuant to the Uniform Guidance of the Office of Management and Budget;

(B) the primary awardee conducts, pursuant to guidance of the National Institutes of Health, a pre-award evaluation of each subrecipient's risk of noncompliance with Federal statutes and regulations, the conditions of the subaward, and any recurring audit findings; and

(C) such exemption does not absolve the primary awardee of liability for misconduct by subrecipients; and

(2) the implementation of alternative grant structures that obviate the need for subrecipient monitoring, which may include collaborative grant models allowing for multiple primary awardees.

(c) REPORTING OF FINANCIAL EXPENDITURES.—The Secretary, in consultation with the Director of National Institutes of Health, shall evaluate financial expenditure reporting procedures and requirements for recipients of funding from the National Institutes of Health and take action, as appropriate, to avoid duplication between department and agency procedures and requirements and minimize burden to funding recipients.

(d) ANIMAL CARE AND USE IN RESEARCH.—Not later than 2 years after the date of enactment of this Act, the Director of National Institutes of Health, in collaboration with the Secretary of Agriculture and the Commissioner of Food and Drugs, shall complete a review of applicable regulations and policies for the care and use of laboratory animals and make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals. In carrying out this effort, the Director of the National Institutes of Health shall seek the input of experts, as appropriate. The Director of the National Institutes of Health shall—

(1) identify ways to ensure such regulations and policies are not inconsistent, overlapping, or unnecessarily duplicative, including with respect to inspection and review requirements by Federal agencies and accrediting associations;

(2) take steps to eliminate or reduce identified inconsistencies, overlap, or duplication among such regulations and policies; and

(3) take other actions, as appropriate, to improve the coordination of regulations and policies with respect to research with laboratory animals.

(e) DOCUMENTATION OF PERSONNEL EXPENSES.—The Secretary shall clarify the applicability of the requirements under the Office of Management and Budget Uniform Guidance for management and certification systems adopted by entities receiving Federal research grants through the Department of Health and Human Services regarding documentation of personnel expenses, including clarification of the extent to which any flexibility to such requirements specified in such Uniform Guidance applies to entities receiving grants through the Department of Health and Human Services.

(f) RESEARCH POLICY BOARD.—

(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this Act, the Director of the Office of Management and Budget shall establish an advisory committee, to be known as the "Research Policy Board" (referred to in this subsection as the "Board"), to provide Federal Government officials with information on the effects of regulations related to Federal research requirements.

(2) MEMBERSHIP.—

(A) IN GENERAL.—The Board shall include not more than 10 Federal members, including each of the following Federal members or their designees:

(i) The Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget.

(ii) The Director of the Office of Science and Technology Policy.

(iii) The Secretary of Health and Human Services.

(iv) The Director of the National Science Foundation.

(v) The secretaries and directors of other departments and agencies that support or regulate scientific research, as determined by the Director of the Office of Management and Budget.

(B) NON-FEDERAL MEMBERS.—The Board shall be comprised of not less than 9 and not more than 12 representatives of academic research institutions, other private, nonprofit research institutions, or other nonprofit organizations with relevant expertise. Such members shall be appointed by a formal process, to be established by the Director of the Office of Management and Budget, in consultation with the Federal membership, and that incorporates—

(i) nomination by members of the nonprofit scientific research community, including academic research institutions; and

(ii) procedures to fill membership positions vacated before the end of a member's term.

(3) PURPOSE AND RESPONSIBILITIES.—The Board shall make recommendations regarding the modification and harmonization of regulations and policies having similar purposes across research funding agencies to ensure that the administrative burden of such research policy and regulation is minimized to the greatest extent possible and consistent with maintaining responsible oversight of federally funded research. Activities of the Board may include—

(A) providing thorough and informed analysis of regulations and policies;

(B) identifying negative or adverse consequences of existing policies and making actionable recommendations regarding possible improvement of such policies;

(C) making recommendations with respect to efforts within the Federal Government to improve coordination of regulation and policy related to research;

(D) creating a forum for the discussion of research policy or regulatory gaps, challenges, clarification, or harmonization of such policies or regulation, and best practices; and

(E) conducting ongoing assessment and evaluation of regulatory burden, including development of metrics, periodic measurement, and identification of process improvements and policy changes.

(4) EXPERT SUBCOMMITTEES.—The Board may form temporary expert subcommittees, as appropriate, to develop timely

analysis on pressing issues and assist the Board in anticipating future regulatory challenges, including challenges emerging from new scientific advances.

(5) REPORTING REQUIREMENTS.—Not later than 2 years after the date of enactment of this Act, and once thereafter, the Board shall submit a report to the Director of the Office of Management and Budget, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget, the Director of the Office of Science and Technology Policy, the heads of relevant Federal departments and agencies, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives containing formal recommendations on the conceptualization, development, harmonization, and reconsideration of scientific research policy, including the regulatory benefits and burdens.

(6) SUNSET.—The Board shall terminate on September 30, 2021.

(7) GAO REPORT.—Not later than 4 years after the date of enactment of this Act, the Comptroller General of the United States shall conduct an independent evaluation of the activities carried out by the Board pursuant to this subsection and submit to the appropriate committees of Congress a report regarding the results of the independent evaluation. Such report shall review and assess the Board's activities with respect to the responsibilities described in paragraph (3).

SEC. 2035. EXEMPTION FOR THE NATIONAL INSTITUTES OF HEALTH FROM THE PAPERWORK REDUCTION ACT REQUIREMENTS.

Section 301 of the Public Health Service Act (42 U.S.C. 241), as amended by section 2013, is further amended by adding at the end the following:

"(g) Subchapter I of chapter 35 of title 44, United States Code, shall not apply to the voluntary collection of information during the conduct of research by the National Institutes of Health.".

SEC. 2036. HIGH-RISK, HIGH-REWARD RESEARCH.

(a) IN GENERAL.—Section 402 of the Public Health Service Act (42 U.S.C. 282), as amended by section 2031, is further amended by adding at the end the following:

"(n) UNIQUE RESEARCH INITIATIVES.—

"(1) IN GENERAL.—The Director of NIH may approve, after consideration of a proposal under paragraph (2)(A), requests by the national research institutes and centers, or program officers within the Office of the Director to engage in transactions other than a contract, grant, or cooperative agreement with respect to projects that carry out—

"(A) the Precision Medicine Initiative under section 498E; or

"(B) section 402(b)(7), except that not more than 50 percent of the funds available for a fiscal year through the Common Fund under section 402A(c)(1) for purposes of carrying out such section 402(b)(7) may be used to engage in such other transactions.

"(2) REQUIREMENTS.—The authority provided under this subsection may be used to conduct or support high impact cutting-edge research described in paragraph (1) using the other transactions authority described in such paragraph if the institute, center, or office—

"(A) submits a proposal to the Director of NIH for the use of such authority before conducting or supporting the research, including why the use of such authority is essential to promoting the success of the project;

"(B) receives approval for the use of such authority from the Director of NIH; and

"(C) for each year in which the institute, center, or office has used such authority in accordance with this subsection, submits a report to the Director of NIH on the activities of the institute, center, or office relating to such research.".

(b) REPORT TO CONGRESS.—Not later than September 30, 2020, the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall conduct an evaluation of the activities under subsection (n) of section 402 of the Public Health Service Act (42 U.S.C. 282), as added by subsection (a), and submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the results of such evaluation.

(c) DUTIES OF DIRECTORS OF INSTITUTES.—Section 405(b)(1) of the Public Health Service Act (42 U.S.C. 284(b)(1)) is amended—

(1) by redesignating subparagraphs (C) through (L) as subparagraphs (D) through (M), respectively; and

(2) by inserting after subparagraph (B), the following:

"(C) shall, as appropriate, conduct and support research that has the potential to transform the scientific field, has inherently higher risk, and that seeks to address major current challenges;".

SEC. 2037. NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES.

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

(1) in paragraph (1), by striking "phase IIA" and inserting "phase IIB"; and

(2) in paragraph (2)—

(A) in the matter preceding subparagraph (A), by striking "phase IIB" and inserting "phase III";

(B) in subparagraph (A), by striking "phase IIB" and inserting "phase III";

(C) in subparagraph (B), by striking "phase IIA" and inserting "phase IIB"; and

(D) in subparagraph (C), by striking "phase IIB" and inserting "phase III".

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

(1) in subsection (c)—

(A) in paragraph (4)(D), by striking "and" at the end;

(B) in paragraph (5), by striking the period and inserting a semicolon; and

(C) by adding at the end the following:

"(6) the methods and tools, if any, that have been developed since the last biennial report was prepared; and

"(7) the methods and tools, if any, that have been developed and are being utilized by the Food and Drug Administration to support medical product reviews."; and

(2) by adding at the end the following:

"(d) INCLUSION OF LIST.—The first biennial report submitted under this section after the date of enactment of the 21st Century Cures Act shall include a complete list of all of the methods and tools, if any, which have been developed by research supported by the Center.

"(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret, or other privileged or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.".

SEC. 2038. COLLABORATION AND COORDINATION TO ENHANCE RESEARCH.

(a) RESEARCH PRIORITIES; COLLABORATIVE RESEARCH PROJECTS.—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) by amending paragraph (4) to read as follows:

"(4) shall assemble accurate data to be used to assess research priorities, including—

"(A) information to better evaluate scientific opportunity, public health burdens, and progress in reducing health disparities; and

"(B) data on study populations of clinical research, funded by or conducted at each national research institute and national center, which—

"(i) specifies the inclusion of—

"(I) women;

"(II) members of minority groups;

"(III) relevant age categories, including pediatric subgroups; and

"(IV) other demographic variables as the Director of the National Institutes of Health determines appropriate;

"(ii) is disaggregated by research area, condition, and disease categories; and

"(iii) is to be made publicly available on the Internet website of the National Institutes of Health;"; and

(2) in paragraph (8)—

(A) in subparagraph (A), by striking "and" at the end; and

(B) by adding at the end the following:

"(C) foster collaboration between clinical research projects funded by the respective national research institutes and national centers that—

"(i) conduct research involving human subjects; and

"(ii) collect similar data; and

"(D) encourage the collaboration described in subparagraph (C) to—

"(i) allow for an increase in the number of subjects studied; and

"(ii) utilize diverse study populations, with special consideration to biological, social, and other determinants of health that contribute to health disparities;".

(b) REPORTING.—Section 492B(f) of the Public Health Service Act (42 U.S.C. 289a-2(f)) is amended—

(1) by striking "biennial" each place such term appears and inserting "triennial";

(2) by striking "The advisory council" and inserting the following:

"(1) IN GENERAL.—The advisory council"; and

(3) by adding at the end the following:

"(2) CONTENTS.—Each triennial report prepared by an advisory council of each national research institute as described in paragraph (1) shall include each of the following:

"(A) The number of women included as subjects, and the proportion of subjects that are women, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease, and accounting for single-sex studies.

"(B) The number of members of minority groups included as subjects, and the proportion of subjects that are members of minority groups, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease and accounting for single-race and single-ethnicity studies.

"(C) For the applicable reporting period, the number of projects of clinical research that include women and members of minority groups and that—

"(i) have been completed during such reporting period; and

"(ii) are being carried out during such reporting period and have not been completed.

"(D) The number of studies completed during the applicable reporting period for which reporting has been submitted in accordance with subsection (c)(2)(A).".

(c) COORDINATION.—Section 486(c)(2) of the Public Health Service Act (42 U.S.C. 287d(c)(2)) is amended by striking "designees" and inserting "senior-level staff designees".

(d) IN GENERAL.—Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.), as amended by section 2021, is further amended by adding at the end the following:

"SEC. 404N. [42 U.S.C. 283p]

[42 U.S.C. 283p] POPULATION FOCUSED RESEARCH

"The Director of the National Institutes of Health shall, as appropriate, encourage efforts to improve research related to the health of sexual and gender minority populations, including by—

"(1) facilitating increased participation of sexual and gender minority populations in clinical research supported by the National Institutes of Health, and reporting on such participation, as applicable;

"(2) facilitating the development of valid and reliable methods for research relevant to sexual and gender minority populations; and

"(3) addressing methodological challenges.".

(e) [42 U.S.C. 283p note]

[42 U.S.C. 283p note] REPORTING.—

(1) IN GENERAL.—The Secretary, in collaboration with the Director of the National Institutes of Health, shall as appropriate—

(A) continue to support research for the development of appropriate measures related to reporting health information about sexual and gender minority populations; and

(B) not later than 2 years after the date of enactment of this Act, disseminate and make public such measures.

(2) NATIONAL ACADEMY OF MEDICINE RECOMMENDATIONS.—In developing the measures described in paragraph (1)(A), the Secretary shall take into account recommendations made by the National Academy of Medicine.

(f) IMPROVING COORDINATION RELATED TO MINORITY HEALTH AND HEALTH DISPARITIES.—Section 464z-3 of the Public Health Service Act (42 U.S.C. 285t) is amended—

(1) by redesignating subsection (h), relating to interagency coordination, that follows subsection (j) as subsection (k); and

(2) in subsection (k) (as so redesignated)—

(A) in the subsection heading, by striking "**Interagency**" and inserting "**Intra-National Institutes of Health**";

(B) by striking "as the primary Federal officials" and inserting "as the primary Federal official";

(C) by inserting a comma after "review";

(D) by striking "Institutes and Centers of the National Institutes of Health" and inserting "national research institutes and national centers"; and

(E) by adding at the end the following: "The Director of the Institute may foster partnerships between the national research institutes and national centers and may encourage the funding of collaborative research projects to achieve the goals of the National Institutes of Health that are related to minority health and health disparities.".

(g) [42 U.S.C. 284r]

[42 U.S.C. 284r] BASIC RESEARCH.—

(1) DEVELOPING POLICIES.—Not later than 2 years after the date of enactment of this Act, the Director of the National Institutes of Health (referred to in this section as the "Director of the National Institutes of Health"), taking into consideration the recommendations developed under section 2039, shall develop policies for projects of basic research funded by National Institutes of Health to assess—

(A) relevant biological variables including sex, as appropriate; and

(B) how differences between male and female cells, tissues, or animals may be examined and analyzed.

(2) REVISING POLICIES.—The Director of the National Institutes of Health may update or revise the policies developed under paragraph (1) as appropriate.

(3) CONSULTATION AND OUTREACH.—In developing, updating, or revising the policies under this section, the Director of the National Institutes of Health shall—

(A) consult with—

(i) the Office of Research on Women's Health;

(ii) the Office of Laboratory Animal Welfare; and

(iii) appropriate members of the scientific and academic communities; and

(B) conduct outreach to solicit feedback from members of the scientific and academic communities on the influence of sex as a variable in basic research, including feedback on when it is appropriate for projects of basic research involving cells, tissues, or animals to include both male and female cells, tissues, or animals.

(4) ADDITIONAL REQUIREMENTS.—The Director of the National Institutes of Health shall—

(A) ensure that projects of basic research funded by the National Institutes of Health are conducted in accordance with the policies developed, updated, or revised under this section, as applicable; and

(B) encourage that the results of such research, when published or reported, be disaggregated as appropriate with respect to the analysis of any sex differences.

(h) [42 U.S.C. 289a-2 note]

[42 U.S.C. 289a-2 note] CLINICAL RESEARCH.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Director of the National Institutes of Health, in consultation with the Director of the Office of Research on Women's Health and the Director of the National Institute on Minority Health and Health Disparities, shall update the guidelines established under section 492B(d) of Public Health Service Act (42 U.S.C. 289a-2(d)) in accordance with paragraph (2).

(2) REQUIREMENTS.—The updated guidelines described in paragraph (1) shall—

(A) reflect the science regarding sex differences;

(B) improve adherence to the requirements under section 492B of the Public Health Service Act (42 U.S.C. 289a-2), including the reporting requirements under subsection (f) of such section; and

(C) clarify the circumstances under which studies should be designed to support the conduct of analyses to detect significant differences in the intervention effect due to demographic factors related to section 492B of the Public Health Service Act, including in the absence of prior studies that demonstrate a difference in study outcomes on the basis of such factors and considering the effects of the absence of such analyses on the availability of data related to demographic differences.

(i) [42 U.S.C. 282 note]

[42 U.S.C. 282 note] APPROPRIATE AGE GROUPINGS IN CLINICAL RESEARCH.—

(1) 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 pediatric and older populations to provide input on—

(A) appropriate age groups to be included in research studies involving human subjects; and

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

(2) POLICY UPDATES.—Not later than 180 days after the conclusion of the workshop under paragraph (1), the Director of the National Institutes of Health shall make a determination with respect to whether the policies of the National Institutes of Health on the inclusion of relevant age groups in clinical studies need to be updated, and shall update such policies as appropriate. In making the determination, the Director of the National Institutes of Health shall take into consideration whether such policies—

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

(B) identify the criteria for justification for any age-related exclusions in such research.

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

(A) make the findings and conclusions resulting from the workshop under paragraph (1) and updates to policies in accordance with paragraph (2), as applicable, available to the public on the Internet website of the National Institutes of Health; and

(B) ensure that age-related data reported in the triennial report under section 403 of the Public Health Service Act (42 U.S.C. 283) (as amended by section 2032) are made available to the public on the Internet website of the National Institutes of Health.

SEC. 2039. [42 U.S.C. 282 note] ENHANCING THE RIGOR AND REPRODUCIBILITY OF SCIENTIFIC RESEARCH.

(a) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall convene a working group under the Advisory Committee to the Director of the National Institutes of Health (referred to in this section as the "Advisory Committee"), appointed under section 222 of the Public Health Service Act (42 U.S.C. 217a), to develop and issue recommendations through the Advisory Committee for a formal policy, which may incorporate or be informed by relevant existing and ongoing activities, to enhance rigor and reproducibility of scientific research funded by the National Institutes of Health.

(b) CONSIDERATIONS.—In developing and issuing recommendations through the Advisory Committee under subsection (a), the working group established under such subsection shall consider, as appropriate—

(1) preclinical experiment design, including analysis of sex as a biological variable;

(2) clinical experiment design, including—

(A) the diversity of populations studied for clinical research, with respect to biological, social, and other determinants of health that contribute to health disparities;

(B) the circumstances under which summary information regarding biological, social, and other factors that contribute to health disparities should be reported; and

(C) the circumstances under which clinical studies, including clinical trials, should conduct an analysis of the data collected during the study on the basis of biological, social, and other factors that contribute to health disparities;

(3) applicable levels of rigor in statistical methods, methodology, and analysis;

(4) data and information sharing in accordance with applicable privacy laws and regulations; and

(5) any other matter the working group determines relevant.

(c) POLICIES.—Not later than 18 months after the date of enactment of this Act, the Director of the National Institutes of Health shall consider the recommendations developed by the working group and issued by the Advisory Committee under subsection (a) and develop or update policies as appropriate.

(d) REPORT.—Not later than 2 years after the date of enactment of this Act, the Director of the National Institutes of Health shall issue a report to the Secretary of Health and Human Services, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives regarding recommendations developed under subsection (a) and any subsequent policy changes implemented, to enhance rigor and reproducibility in scientific research funded by the National Institutes of Health.

(e) CONFIDENTIALITY.—Nothing in this section authorizes the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

SEC. 2040. IMPROVING MEDICAL REHABILITATION RESEARCH AT THE NATIONAL INSTITUTES OF HEALTH.

(a) IN GENERAL.—Section 452 of the Public Health Service Act (42 U.S.C. 285g-4) is amended—

(1) in subsection (b), by striking "conduct and support" and inserting "conduct, support, and coordination";

(2) in subsection (c)(1)(C), by striking "of the Center" and inserting "within the Center";

(3) in subsection (d)—

(A) by striking "(d)(1) In consultation" and all that follows through the end of paragraph (1) and inserting the following:

"(d)(1) The Director of the Center, in consultation with the Director of the Institute, the coordinating committee established under subsection (e), and the advisory board established under sub-

section (f), shall develop a comprehensive plan (referred to in this section as the 'Research Plan') for the conduct, support, and coordination of medical rehabilitation research.";

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "; and" and inserting a semicolon;

(ii) in subparagraph (B), by striking the period and inserting "; and"; and

(iii) by adding at the end the following:

"(C) include goals and objectives for conducting, supporting, and coordinating medical rehabilitation research, consistent with the purpose described in subsection (b).";

(C) by striking paragraph (4) and inserting the following:

"(4) The Director of the Center, in consultation with the Director of the Institute, the coordinating committee established under subsection (e), and the advisory board established under subsection (f), shall revise and update the Research Plan periodically, as appropriate, or not less than every 5 years. Not later than 30 days after the Research Plan is so revised and updated, the Director of the Center shall transmit the revised and updated Research Plan to the President, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives."; and

(D) by adding at the end the following:

"(5) The Director of the Center, in consultation with the Director of the Institute, shall, prior to revising and updating the Research Plan, prepare a report for the coordinating committee established under subsection (e) and the advisory board established under subsection (f) that describes and analyzes the progress during the preceding fiscal year in achieving the goals and objectives described in paragraph (2)(C) and includes expenditures for rehabilitation research at the National Institutes of Health. The report shall include recommendations for revising and updating the Research Plan, and such initiatives as the Director of the Center and the Director of the Institute determine appropriate. In preparing the report, the Director of the Center and the Director of the Institute shall consult with the Director of the National Institutes of Health.";

(4) in subsection (e)—

(A) in paragraph (2), by inserting "periodically host a scientific conference or workshop on medical rehabilitation research and" after "The Coordinating Committee shall"; and

(B) in paragraph (3), by inserting "the Director of the Division of Program Coordination, Planning, and Strategic Initiatives within the Office of the Director of the National Institutes of Health," after "shall be composed of";

(5) in subsection (f)(3)(B)—

(A) by redesignating clauses (ix) through (xi) as clauses (x) through (xii), respectively; and

(B) by inserting after clause (viii) the following:

"(ix) The Director of the Division of Program Coordination, Planning, and Strategic Initiatives."; and

(6) by adding at the end the following:

"(g)(1) The Secretary and the heads of other Federal agencies shall jointly review the programs carried out (or proposed to be carried out) by each such official with respect to medical rehabilitation research and, as appropriate, enter into agreements preventing duplication among such programs.

"(2) The Secretary shall, as appropriate, enter into interagency agreements relating to the coordination of medical rehabilitation research conducted by agencies of the National Institutes of Health and other agencies of the Federal Government.

"(h) For purposes of this section, the term 'medical rehabilitation research' means the science of mechanisms and interventions that prevent, improve, restore, or replace lost, underdeveloped, or deteriorating function.".

(b) CONFORMING AMENDMENT.—Section 3 of the National Institutes of Health Amendments of 1990 (42 U.S.C. 285g-4 note) is amended—

(1) in subsection (a), by striking "In General.—"; and

(2) by striking subsection (b).

SEC. 2041. [42 U.S.C. 289a-2 note] TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN.

(a) TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN.—

(1) ESTABLISHMENT.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall establish a task force, in accordance with the Federal Advisory Committee Act (5 U.S.C. App.), to be known as the "Task Force on Research Specific to Pregnant Women and Lactating Women" (in this section referred to as the "Task Force").

(2) DUTIES.—The Task Force shall provide advice and guidance to the Secretary regarding Federal activities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities.

(3) MEMBERSHIP.—

(A) FEDERAL MEMBERS.—The Task Force shall be composed of each of the following Federal members, or the designees of such members:

(i) The Director of the Centers for Disease Control and Prevention.

(ii) The Director of the National Institutes of Health, the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the directors of such other appropriate national research institutes.

(iii) The Commissioner of Food and Drugs.

(iv) The Director of the Office on Women's Health.

(v) The Director of the National Vaccine Program Office.

(vi) The head of any other research-related agency or department not described in clauses (i) through (v) that the Secretary determines appropriate, which may

include the Department of Veterans Affairs and the Department of Defense.

(B) NON-FEDERAL MEMBERS.—The Task Force shall be composed of each of the following non-Federal members, including—

(i) representatives from relevant medical societies with subject matter expertise on pregnant women, lactating women, or children;

(ii) nonprofit organizations with expertise related to the health of women and children;

(iii) relevant industry representatives; and

(iv) other representatives, as appropriate.

(C) LIMITATIONS.—The non-Federal members described in subparagraph (B) shall—

(i) compose not more than one-half, and not less than one-third, of the total membership of the Task Force; and

(ii) be appointed by the Secretary.

(4) TERMINATION.—

(A) IN GENERAL.—Subject to subparagraph (B), the Task Force shall terminate on the date that is 2 years after the date on which the Task Force is established under paragraph (1).

(B) EXTENSION.—The Secretary may extend the operation of the Task Force for one additional 2-year period following the 2-year period described in subparagraph (A), if the Secretary determines that the extension is appropriate for carrying out the purpose of this section.

(5) MEETINGS.—The Task Force shall meet not less than 2 times each year and shall convene public meetings, as appropriate, to fulfill its duties under paragraph (2).

(6) TASK FORCE REPORT TO CONGRESS.—Not later than 18 months after the date on which the Task Force is established under paragraph (1), the Task Force shall prepare and submit to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report that includes each of the following:

(A) A plan to identify and address gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies.

(B) Ethical issues surrounding the inclusion of pregnant women and lactating women in clinical research.

(C) Effective communication strategies with health care providers and the public on information relevant to pregnant women and lactating women.

(D) Identification of Federal activities, including—

(i) the state of research on pregnancy and lactation;

(ii) recommendations for the coordination of, and collaboration on research related to pregnant women and lactating women;

(iii) dissemination of research findings and information relevant to pregnant women and lactating women to providers and the public; and

(iv) existing Federal efforts and programs to improve the scientific understanding of the health impacts on pregnant women, lactating women, and related birth and pediatric outcomes, including with respect to pharmacokinetics, pharmacodynamics, and toxicities.

(E) Recommendations to improve the development of safe and effective therapies for pregnant women and lactating women.

(b) CONFIDENTIALITY.—Nothing in this section shall authorize the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

(c) UPDATING PROTECTIONS FOR PREGNANT WOMEN AND LACTATING WOMEN IN RESEARCH.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Secretary, considering any recommendations of the Task Force available at such time and in consultation with the heads of relevant agencies of the Department of Health and Human Services, shall, as appropriate, update regulations and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical research.

(2) CRITERIA FOR EXCLUDING PREGNANT OR LACTATING WOMEN.—In updating any regulations or guidance described in paragraph (1), the Secretary shall consider any appropriate criteria to be used by institutional review boards and individuals reviewing grant proposals for excluding pregnant women or lactating women as a study population requiring additional protections from participating in human subject research.

SEC. 2042. STREAMLINING NATIONAL INSTITUTES OF HEALTH REPORTING REQUIREMENTS.

(a) TRANS-NATIONAL INSTITUTES OF HEALTH RESEARCH REPORTING.—Section 402A(c)(2) of the Public Health Service Act (42 U.S.C. 282a(c)(2)) is amended—

(1) by amending subparagraph (B) to read as follows:

"(B) REPORTING.—Not later than 2 years after the date of enactment of 21st Century Cures Act, the head of each national research institute or national center shall submit to the Director of the National Institutes of Health a report, to be included in the triennial report under section 403, on the amount made available by the institute or center for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers."; and

(2) in subparagraphs (D) and (E) by striking "(B)(i)" each place it appears and inserting "(B)".

(b) FRAUD AND ABUSE REPORTING.—Section 403B of the Public Health Service Act (42 U.S.C. 283a-1) is amended—

(1) by striking subsection (b);

(2) by redesignating subsection (c) as subsection (b); and

(3) in subsection (b) (as so redesignated), by striking "subsections (a) and (b)" and inserting "subsection (a)".

(c) DOCTORAL DEGREES REPORTING.—Section 403C(a)(2) of the Public Health Service Act (42 U.S.C. 283a-2(a)(2)) is amended by striking "(not including any leaves of absence)".

(d) VACCINE REPORTING.—Section 404B of the Public Health Service Act (42 U.S.C. 283d) is amended—

(1) by striking subsection (b); and

(2) by striking "(a) Development of New Vaccines.—The Secretary" and inserting "The Secretary".

(e) NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES.—Section 479(c) of the Public Health Service Act (42 U.S.C. 287(c)) is amended—

(1) in the subsection heading, by striking "**Annual**" and inserting "**Biennial**"; and

(2) in the matter preceding paragraph (1), by striking "an annual report" and inserting "a report on a biennial basis".

(f) REVIEW OF CENTERS OF EXCELLENCE.—

(1) REPEAL.—Section 404H of the Public Health Service Act (42 U.S.C. 283j) is repealed.

(2) CONFORMING AMENDMENT.—Section 399EE(c) of the Public Health Service Act (42 U.S.C. 280-4(c)) is amended by striking "399CC, 404H," and inserting "399CC".

(g) RAPID HIV TEST REPORT.—Section 502(a) of the Ryan White CARE Act Amendments of 2000 (42 U.S.C. 300cc note) is amended—

(1) by striking paragraph (2); and

(2) by redesignating paragraph (3) as paragraph (2).

(h) NATIONAL INSTITUTE OF NURSING RESEARCH.—

(1) REPEAL.—Section 464Y of the Public Health Service Act (42 U.S.C. 285q-3) is repealed.

(2) CONFORMING AMENDMENT.—Section 464X(g) of the Public Health Service Act (42 U.S.C. 285q-2(g)) is amended by striking "biennial report made under section 464Y," and inserting "triennial report made under section 403".

SEC. 2043. REIMBURSEMENT FOR RESEARCH SUBSTANCES AND LIVING ORGANISMS.

Section 301 of the Public Health Service Act (42 U.S.C. 241), as amended by section 2035, is further amended—

(1) in the flush matter at the end of subsection (a)—

(A) by redesignating such matter as subsection (h)(1); and

(B) by moving such matter so as to appear at the end of such section; and

(2) in subsection (h) (as so redesignated), by adding at the end the following:

"(2) Where research substances and living organisms are made available under paragraph (1) through contractors, the Secretary may direct such contractors to collect payments on behalf of the Secretary for the costs incurred to make available such substances and organisms and to forward amounts so collected to the Secretary, in the time and manner specified by the Secretary.

"(3) Amounts collected under paragraph (2) shall be credited to the appropriations accounts that incurred the costs to make available the research substances and living organisms involved, and shall remain available until expended for carrying out activities under such accounts.".

SEC. 2044. SENSE OF CONGRESS ON INCREASED INCLUSION OF UNDERREPRESENTED POPULATIONS IN CLINICAL TRIALS.

It is the sense of Congress that the National Institute on Minority Health and Health Disparities should include within its strategic plan under section 402(m) of the Public Health Service Act (42 U.S.C. 282(m)) ways to increase representation of underrepresented populations in clinical trials.

Subtitle E—Advancement of the National Institutes of Health Research and Data Access

SEC. 2051. TECHNICAL UPDATES TO CLINICAL TRIALS DATABASE.

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

(1) in clause (ii)(I), by inserting before the semicolon ", unless the responsible party affirmatively requests that the Director of the National Institutes of Health publicly post such clinical trial information for an applicable device clinical trial prior to such date of clearance or approval"; and

(2) by adding at the end the following:

"(iii) OPTION TO MAKE CERTAIN CLINICAL TRIAL INFORMATION AVAILABLE EARLIER.—The Director of the National Institutes of Health shall inform responsible parties of the option to request that clinical trial information for an applicable device clinical trial be publicly posted prior to the date of clearance or approval, in accordance with clause (ii)(I).

"(iv) COMBINATION PRODUCTS.—An applicable clinical trial for a product that is a combination of drug, device, or biological product shall be considered—

"(I) an applicable drug clinical trial, if the Secretary determines under section 503(g) of the Federal Food, Drug, and Cosmetic Act that the primary mode of action of such product is that of a drug or biological product; or

"(II) an applicable device clinical trial, if the Secretary determines under such section that the primary mode of action of such product is that of a device.".

SEC. 2052. COMPLIANCE ACTIVITIES REPORTS.

(a) DEFINITIONS.—In this section:

(1) APPLICABLE CLINICAL TRIAL.—The term "applicable clinical trial" has the meaning given the term in section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)).

(2) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(b) REPORT ON ACTIVITIES TO ENCOURAGE COMPLIANCE.—Not later than 2 years after the date of enactment of this Act, the Secretary, acting through the Director of the National Institutes of Health and in collaboration with the Commissioner of Food and Drugs, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report that describes education and outreach, guidance, enforcement, and other activities undertaken to encourage compliance with section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)).

(c) REPORTS ON CLINICAL TRIALS.—

(1) IN GENERAL.—Not later than 2 years after the final compliance date under the final rule implementing section 402(j) of the Public Health Service Act, and every 2 years thereafter for the next 4 years, the Secretary, acting through the Director of the National Institutes of Health and in collaboration with the Commissioner of Food and Drugs, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report describing—

(A) the total number of applicable clinical trials with complete data bank registration information registered during the period for which the report is being prepared (broken down by each year of such reporting period);

(B) the total number of applicable clinical trials registered during the period for which the report is being prepared for which results have been submitted to the data bank (broken down by each year of such reporting period);

(C) the activities undertaken by the Secretary to educate responsible persons about data bank registration and results submission requirements, including through issuance of guidance documents, informational meetings, and training sessions; and

(D) the activities described in the report submitted under subsection (b).

(2) ACTIONS TO ENFORCE COMPLIANCE.—After the Secretary has undertaken the educational activities described in paragraph (1)(C), the Secretary shall include in subsequent reports submitted under paragraph (1) the number of actions taken by the Secretary during the period for which the report is being prepared to enforce compliance with data bank registration and results submission requirements.

SEC. 2053. UPDATES TO POLICIES TO IMPROVE DATA.

Section 492B(c) of the Public Health Service Act (42 U.S.C. 289a-2(c)) is amended—

(1) by striking "In the case" and inserting the following:

"(1) IN GENERAL.—In the case"; and

(2) by adding at the end the following:

"(2) REPORTING REQUIREMENTS.—For any new and competing project of clinical research subject to the requirements under this section that receives a grant award 1 year after the

date of enactment of the 21st Century Cures Act, or any date thereafter, for which a valid analysis is provided under paragraph (1)—

"(A) and which is an applicable clinical trial as defined in section 402(j), the entity conducting such clinical research shall submit the results of such valid analysis to the clinical trial registry data bank expanded under section 402(j)(3), and the Director of the National Institutes of Health shall, as appropriate, consider whether such entity has complied with the reporting requirement described in this subparagraph in awarding any future grant to such entity, including pursuant to section 402(j)(5)(A)(ii) when applicable; and

"(B) the Director of the National Institutes of Health shall encourage the reporting of the results of such valid analysis described in paragraph (1) through any additional means determined appropriate by the Director.".

SEC. 2054. CONSULTATION.

Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall consult with relevant Federal agencies, including the Food and Drug Administration, the Office of the National Coordinator for Health Information Technology, and the National Institutes of Health, as well as other stakeholders (including patients, researchers, physicians, industry representatives, and developers of health information technology) to receive recommendations with respect to 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 with respect to usability, functionality, and search capability.

Subtitle F—Facilitating Collaborative Research

SEC. 2061. NATIONAL NEUROLOGICAL CONDITIONS SURVEILLANCE SYSTEM.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by inserting after section 399S the following:

"SEC. 399S-1. [42 U.S.C. 280g-7a] 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 the Secretary determines, shall, as appropriate—

"(1) enhance and expand infrastructure and activities to track the epidemiology of neurological diseases; and

"(2) incorporate information obtained through such activities into an integrated surveillance system, which may consist of or include a registry, to be known as the National Neurological Conditions Surveillance System.

"(b) RESEARCH.—The Secretary shall ensure that the National Neurological Conditions 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 information on neurological diseases, including information related to persons living with neurological diseases who choose to participate, such as—

"(A) demographics, such as age, race, ethnicity, sex, geographic location, family history, and other information, as appropriate;

"(B) risk factors that may be associated with neurological diseases, such as genetic and environmental risk factors and other information, as appropriate; 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 natural history of the diseases;

"(B) the prevention of the diseases;

"(C) the detection, management, and treatment approaches for the diseases; and

"(D) the development of outcomes measures;

"(4) may address issues identified during the consultation process under subsection (d); and

"(5) initially may address a limited number of neurological diseases.

"(d) CONSULTATION.—In carrying out this section, the Secretary shall consult with individuals with appropriate expertise, which may include—

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

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

"(A) focus on neurological diseases; 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—

"(1) make information and analysis in the National Neurological Conditions Surveillance System available, as appropriate—

"(A) to Federal departments and agencies, such as the National Institutes of Health and the Department of Veterans Affairs; and

"(B) to State and local agencies; and

"(2) identify, build upon, leverage, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health infrastructure, wherever practicable.

"(g) PUBLIC ACCESS.—Subject to subsection (h), the Secretary shall ensure that information and analysis in the National Neurological Conditions Surveillance System are available, as appropriate, to the public, including researchers.

"(h) PRIVACY.—The Secretary shall ensure that information and analysis in the National Neurological Conditions Surveillance System are made available only to the extent permitted by applicable Federal and State law, and in a manner that protects personal privacy, to the extent required by applicable Federal and State privacy law, at a minimum.

"(i) REPORTS.—

"(1) REPORT ON INFORMATION AND ANALYSES.—Not later than 1 year after the date on which any system is established under this section, the Secretary shall submit an interim report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding aggregate information collected pursuant to this section and epidemiological analyses, as appropriate. Such report shall be posted on the Internet website of the Department of Health and Human Services and shall be updated biennially.

"(2) IMPLEMENTATION 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—

"(A) the development and maintenance of the National Neurological Conditions Surveillance System;

"(B) the type of information collected and stored in the surveillance system;

"(C) the use and availability of such information, including guidelines for such use; and

"(D) 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 with experience serving the population of individuals with neurological disease and have demonstrated experience in neurological disease research, care, and patient services.

"(k) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $5,000,000 for each of fiscal years 2018 through 2022.".

SEC. 2062. [42 U.S.C. 284s] TICK-BORNE DISEASES.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as "the Secretary") shall continue to conduct or support epidemiological, basic, translational, and clinical research related to vector-borne diseases, including tick-borne diseases.

(b) REPORTS.—The Secretary shall ensure that each triennial report under section 403 of the Public Health Service Act (42 U.S.C. 283) (as amended by section 2032) includes information on actions undertaken by the National Institutes of Health to carry out subsection (a) with respect to tick-borne diseases.

(c) TICK-BORNE DISEASES WORKING GROUP.—

(1) ESTABLISHMENT.—The Secretary shall establish a working group, to be known as the Tick-Borne Disease Working Group (referred to in this section as the "Working Group"), comprised of representatives of appropriate Federal agencies and other non-Federal entities, to provide expertise and to review all efforts within the Department of Health and Human Services related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities.

(2) RESPONSIBILITIES.—The working group shall—

(A) not later than 2 years after the date of enactment of this Act, develop or update a summary of—

(i) ongoing tick-borne disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, duration of illness, and intervention for individuals with tick-borne diseases;

(ii) advances made pursuant to such research;

(iii) Federal activities related to tick-borne diseases, including—

(I) epidemiological activities related to tick-borne diseases; and

(II) basic, clinical, and translational tick-borne disease research related to the pathogenesis, prevention, diagnosis, and treatment of tick-borne diseases;

(iv) gaps in tick-borne disease research described in clause (iii)(II);

(v) the Working Group's meetings required under paragraph (4); and

(vi) the comments received by the Working Group;

(B) make recommendations to the Secretary regarding any appropriate changes or improvements to such activities and research; and

(C) solicit input from States, localities, and nongovernmental entities, including organizations representing patients, health care providers, researchers, and industry regarding scientific advances, research questions, surveillance activities, and emerging strains in species of pathogenic organisms.

(3) MEMBERSHIP.—The members of the working group shall represent a diversity of scientific disciplines and views and shall be composed of the following members:

(A) FEDERAL MEMBERS.—Seven Federal members, consisting of one or more representatives of each of the following:

(i) The Office of the Assistant Secretary for Health.

(ii) The Food and Drug Administration.

(iii) The Centers for Disease Control and Prevention.

(iv) The National Institutes of Health.

(v) Such other agencies and offices of the Department of Health and Human Services as the Secretary determines appropriate.

(B) NON-FEDERAL PUBLIC MEMBERS.—Seven non-Federal public members, consisting of representatives of the following categories:

(i) Physicians and other medical providers with experience in diagnosing and treating tick-borne diseases.

(ii) Scientists or researchers with expertise.

(iii) Patients and their family members.

(iv) Nonprofit organizations that advocate for patients with respect to tick-borne diseases.

(v) Other individuals whose expertise is determined by the Secretary to be beneficial to the functioning of the Working Group.

(4) MEETINGS.—The Working Group shall meet not less than twice each year.

(5) REPORTING.—Not later than 2 years after the date of enactment of this Act, and every 2 years thereafter until termination of the Working Group pursuant to paragraph (7), the Working Group shall—

(A) submit a report on its activities under paragraph (2)(A) and any recommendations under paragraph (2)(B) to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate; and

(B) make such report publicly available on the Internet website of the Department of Health and Human Services.

(6) APPLICABILITY OF FACA.—The Working Group shall be treated as an advisory committee subject to the Federal Advisory Committee Act (5 U.S.C. App.).

(7) SUNSET.—The Working Group under this section shall terminate 6 years after the date of enactment of this Act.

SEC. 2063. [42 U.S.C. 1320d-2 note] ACCESSING, SHARING, AND USING HEALTH DATA FOR RESEARCH PURPOSES.

(a) GUIDANCE RELATED TO REMOTE ACCESS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall issue guidance clarifying that subparagraph (B) of section 164.512(i)(1)(ii) of part 164 of the Rule (prohibiting the re-

moval of protected health information by a researcher) does not prohibit remote access to health information by a researcher for such purposes as described in section 164.512(i)(1)(ii) of part 164 of the Rule so long as—

(1) at a minimum, security and privacy safeguards, consistent with the requirements of the Rule, are maintained by the covered entity and the researcher; and

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

(b) GUIDANCE RELATED TO STREAMLINING AUTHORIZATION.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue guidance on the following:

(1) AUTHORIZATION FOR USE AND DISCLOSURE OF HEALTH INFORMATION.—Clarification of the circumstances under which the authorization for the use or disclosure of protected health information, with respect to an individual, for future research purposes contains a sufficient description of the purpose of the use or disclosure, such as if the authorization—

(A) 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;

(B) either—

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

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

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

(2) REMINDER OF THE RIGHT TO REVOKE.—Clarification of the circumstances under which it is appropriate to provide an individual with an annual notice or reminder that the individual has the right to revoke such authorization.

(3) REVOCATION OF AUTHORIZATION.—Clarification of appropriate mechanisms by which an individual may revoke an authorization for future research purposes, such as described in paragraph (1)(C).

(c) WORKING GROUP ON PROTECTED HEALTH INFORMATION FOR RESEARCH.—

(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this Act, the Secretary shall convene a working group to study and report on the uses and disclosures of protected health information for research purposes, under the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191).

(2) MEMBERS.—The working group shall include representatives of—

(A) relevant Federal agencies, including the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Office for Civil Rights;

(B) the research community;

(C) patients;

(D) experts in civil rights, such as privacy rights;
(E) developers of health information technology;
(F) experts in data privacy and security;
(G) health care providers;
(H) bioethicists; and
(I) other experts and entities, as the Secretary determines appropriate.

(3) REPORT.—Not later than 1 year after the date on which the working group is convened under paragraph (1), the working group shall conduct a review and submit a report to the Secretary containing recommendations on whether the uses and disclosures of protected health information for research purposes should be modified to allow protected health information to be available, as appropriate, for research purposes, including studies to obtain generalizable knowledge, while protecting individuals' privacy rights. In conducting the review and making recommendations, the working group shall—

(A) address, at a minimum—

(i) the appropriate manner and timing of authorization, including whether additional notification to the individual should be required when the individual's protected health information will be used or disclosed for such research;

(ii) opportunities for individuals to set preferences on the manner in which their protected health information is used in research;

(iii) opportunities for patients to revoke authorization;

(iv) notification to individuals of a breach in privacy;

(v) existing gaps in statute, regulation, or policy related to protecting the privacy of individuals, and

(vi) existing barriers to research related to the current restrictions on the uses and disclosures of protected health information; and

(B) consider, at a minimum—

(i) expectations and preferences on how an individual's protected health information is shared and used;

(ii) issues related to specific subgroups of people, such as children, incarcerated individuals, and individuals with a cognitive or intellectual disability impacting capacity to consent;

(iii) relevant Federal and State laws;

(iv) models of facilitating data access and levels of data access, including data segmentation, where applicable;

(v) potential impacts of disclosure and non-disclosure of protected health information on access to health care services; and

(vi) the potential uses of such data.

(4) REPORT SUBMISSION.—The Secretary shall submit the report under paragraph (3) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee

on Energy and Commerce of the House of Representatives, and shall post such report on the appropriate Internet website of the Department of Health and Human Services.

(5) TERMINATION.—The working group convened under paragraph (1) shall terminate the day after the report under paragraph (3) is submitted to Congress and made public in accordance with paragraph (4).

(d) DEFINITIONS.—In this section:

(1) 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).

(2) 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).

Subtitle G—Promoting Pediatric Research

SEC. 2071. 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), 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, may provide for the establishment of" and inserting "in collaboration with the national research institutes and national centers that carry out activities involving pediatric research, shall support"; and

(2) in paragraph (2)(A) and the first sentence of paragraph (2)(E), by striking "may" each place such term appears and inserting "shall".

SEC. 2072. GLOBAL PEDIATRIC CLINICAL STUDY NETWORK.

It is the sense of Congress that—

(1) the National Institutes of Health should encourage a global pediatric clinical study network by providing grants, contracts, or cooperative agreements to support new and early stage investigators who participate in the global pediatric clinical study network;

(2) the Secretary of Health and Human Services (referred to in this section as the "Secretary") should engage with clinical investigators and appropriate authorities outside of the United States, including authorities in the European Union, during the formation of the global pediatric clinical study network to encourage the participation of such investigator and authorities; and

(3) once a global pediatric clinical study network is established and becomes operational, the Secretary should continue to encourage and facilitate the participation of clinical investigators and appropriate authorities outside of the United States, including in the European Union, to participate in the network with the goal of enhancing the global reach of the network.

TITLE III—DEVELOPMENT

Subtitle A—Patient-Focused Drug Development

SEC. 3001. PATIENT EXPERIENCE DATA.

Section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-8c) is amended—

(1) in subsection (a)—

(A) in the subsection heading, by striking "**In General**" and inserting "**Patient Engagement in Drugs and Devices**";

(B) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively, and moving such subparagraphs 2 ems to the right; and

(C) by striking "The Secretary" and inserting the following:

"(1) IN GENERAL.—The Secretary";

(2) by redesignating subsections (b) through (e) as paragraphs (2) through (5), respectively, and moving such paragraphs 2 ems to the right; and

(3) by adding at the end the following:

"(b) STATEMENT OF PATIENT EXPERIENCE.—

"(1) IN GENERAL.—Following the approval of an application that was submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act at least 180 days after the date of enactment of the 21st Century Cures Act, the Secretary shall make public a brief statement regarding the patient experience data and related information, if any, submitted and reviewed as part of such application.

"(2) DATA AND INFORMATION.—The data and information referred to in paragraph (1) are—

"(A) patient experience data;

"(B) information on patient-focused drug development tools; and

"(C) other relevant information, as determined by the Secretary.

"(c) PATIENT EXPERIENCE DATA.—For purposes of this section, the term 'patient experience data' includes data that—

"(1) are collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers, and drug manufacturers); and

"(2) are intended to provide information about patients' experiences with a disease or condition, including—

"(A) the impact of such disease or condition, or a related therapy, on patients' lives; and

"(B) patient preferences with respect to treatment of such disease or condition.".

SEC. 3002. PATIENT-FOCUSED DRUG DEVELOPMENT GUIDANCE.

(a) PUBLICATION OF GUIDANCE DOCUMENTS.—Not later than 180 days after the date of enactment of this Act, the Secretary of

Health and Human Services (referred to in this section as the "Secretary"), acting through the Commissioner of Food and Drugs, shall develop a plan to issue draft and final versions of one or more guidance documents, over a period of 5 years, regarding the collection of patient experience data, and the use of such data and related information in drug development. Not later than 18 months after the date of enactment of this Act, the Secretary shall issue a draft version of at least one such guidance document. Not later than 18 months after the public comment period on the draft guidance ends, the Secretary shall issue a revised draft guidance or final guidance.

(b) PATIENT EXPERIENCE DATA.—For purposes of this section, the term "patient experience data" has the meaning given such term in section 569C of the Federal Food, Drug, and Cosmetic Act (as added by section 3001).

(c) CONTENTS.—The guidance documents described in subsection (a) shall address—

(1) methodological approaches that a person seeking to collect patient experience data for submission to, and proposed use by, the Secretary in regulatory decisionmaking may use, that are relevant and objective and ensure that such data are accurate and representative of the intended population, including methods to collect meaningful patient input throughout the drug development process and methodological considerations for data collection, reporting, management, and analysis;

(2) methodological approaches that may be used to develop and identify what is most important to patients with respect to burden of disease, burden of treatment, and the benefits and risks in the management of the patient's disease;

(3) approaches to identifying and developing methods to measure impacts to patients that will help facilitate collection of patient experience data in clinical trials;

(4) methodologies, standards, and technologies to collect and analyze clinical outcome assessments for purposes of regulatory decisionmaking;

(5) how a person seeking to develop and submit proposed draft guidance relating to patient experience data for consideration by the Secretary may submit such proposed draft guidance to the Secretary;

(6) the format and content required for submissions under this section to the Secretary, including with respect to the information described in paragraph (1);

(7) how the Secretary intends to respond to submissions of information described in paragraph (1), if applicable, including any timeframe for response when such submission is not part of a regulatory application or other submission that has an associated timeframe for response; and

(8) how the Secretary, if appropriate, anticipates using relevant patient experience data and related information, including with respect to the structured risk-benefit assessment framework described in section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)), to inform regulatory decisionmaking.

SEC. 3003. STREAMLINING PATIENT INPUT.

Chapter 35 of title 44, United States Code, shall not apply to the collection of information to which a response is voluntary, that is initiated by the Secretary under section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-8c) (as amended by section 3001) or section 3002.

SEC. 3004. [21 U.S.C. 355 note] REPORT ON PATIENT EXPERIENCE DRUG DEVELOPMENT.

Not later than June 1 of 2021, 2026, and 2031, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall prepare and publish on the Internet website of the Food and Drug Administration a report assessing the use of patient experience data in regulatory decisionmaking, in particular with respect to the review of patient experience data and information on patient-focused drug development tools as part of applications approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

Subtitle B—Advancing New Drug Therapies

SEC. 3011. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506F the following new section:

"SEC. 507. [21 U.S.C. 357]

[21 U.S.C. 357] 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 accepts or declines to accept such letter of intent;

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

"(ii) the Secretary accepts or declines 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 determines whether to accept such qualification package for review; and

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

"(2) ACCEPTANCE AND REVIEW OF SUBMISSIONS.—

"(A) IN GENERAL.—Subparagraphs (B), (C), and (D) shall apply with respect to the treatment of a letter of in-

tent, a qualification plan, or a full qualification package submitted under paragraph (1) (referred to in this paragraph as 'qualification submissions').

"(B) ACCEPTANCE FACTORS; NONACCEPTANCE.—The Secretary shall determine whether to accept a qualification submission based on factors which may include the scientific merit of the qualification submission. A determination not to accept a submission under paragraph (1) shall not be construed as a final determination by the Secretary under this section regarding the qualification of a drug development tool for its proposed context of use.

"(C) PRIORITIZATION OF QUALIFICATION REVIEW.—The Secretary may prioritize the review of a full qualification package submitted under 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 its proposed context of use as a public health priority.

"(D) 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 paragraph (1) or the review of any full qualification package under paragraph (3).

"(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 (3).

"(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 ac-

cordance 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 under subparagraph (A) a determination to qualify a drug development tool, the requestor involved shall, on request, be granted 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 biannual 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;

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

"(iv) submissions from requestors under the qualification process under subsection (a), including any data and evidence contained in such submissions, and any updates to such submissions.

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

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

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

"(E) A comprehensive list of—

"(i) all drug development tools qualified under subsection (a); and

"(ii) all surrogate endpoints which were the basis of 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.

"(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.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information contained in an application submitted under section 505 of this Act or section 351 of the Public Health Service Act 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 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) DEFINITIONS.—In this section:

"(1) BIOMARKER.—The term 'biomarker'—

"(A) 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; and

"(B) includes a surrogate endpoint.

"(2) BIOMEDICAL RESEARCH CONSORTIA.—The term 'biomedical research consortia' means collaborative groups that may take the form of public-private partnerships and may include government agencies, institutions of higher education (as defined in section 101(a) of the Higher Education Act of 1965), patient advocacy groups, industry representatives, clinical and scientific experts, and other relevant entities and individuals.

"(3) CLINICAL OUTCOME ASSESSMENT.—The term 'clinical outcome assessment' means—

"(A) a measurement of a patient's symptoms, overall mental state, or the effects of a disease or condition on how the patient functions; and

"(B) includes a patient-reported outcome.

"(4) CONTEXT OF USE.—The term 'context of use' means, with respect to a drug development tool, 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 is not itself a direct measurement of clinical benefit, and—

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

(b) [21 U.S.C. 357 note]

[21 U.S.C. 357 note] GUIDANCE.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall, in consultation with biomedical research consortia (as defined in subsection (e) of section 507 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) 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) with respect to the qualification process under such section 507—

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

(ii) outlines 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 Sec-

retary in the review of qualification plans and full qualification submissions under such section; and

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

(2) TIMING.—Not later than 3 years after the date of the enactment of this Act, the Secretary shall issue draft guidance under paragraph (1) on the implementation of section 507 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)). 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 2 years 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 1 year after the close of the public comment period.

(c) MEETING AND REPORT.—

(1) MEETING.—Not later than 2 years after the date of the enactment of this Act, the Secretary 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 (a).

(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 (a), 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 507);

(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 subsection (e) of such section 507), respectively;

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

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

(E) the drug development tools qualified through such qualification 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. 3012. TARGETED DRUGS FOR RARE DISEASES.

Subchapter B of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aa et seq.) is amended by inserting after section 529 the following:

"SEC. 529A. [21 U.S.C. 360ff-1] TARGETED DRUGS FOR RARE DISEASES

"(a) PURPOSE.—The purpose of this section, through the approach provided for in subsection (b), is to—

"(1) facilitate the development, review, and approval of genetically targeted drugs and variant protein targeted drugs to address an unmet medical need in one or more patient subgroups, including subgroups of patients with different mutations of a gene, with respect to rare diseases or conditions that are serious or life-threatening; and

"(2) maximize the use of scientific tools or methods, including surrogate endpoints and other biomarkers, for such purposes.

"(b) LEVERAGING OF DATA FROM PREVIOUSLY APPROVED DRUG APPLICATION OR APPLICATIONS.—The Secretary may, consistent with applicable standards for approval under this Act or section 351(a) of the Public Health Service Act, allow the sponsor of an application under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act for a genetically targeted drug or a variant protein targeted drug to rely upon data and information—

"(1) previously developed by the same sponsor (or another sponsor that has provided the sponsor with a contractual right of reference to such data and information); and

"(2) submitted by a sponsor described in paragraph (1) in support of one or more previously approved applications that were submitted under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act,

for a drug that incorporates or utilizes the same or similar genetically targeted technology as the drug or drugs that are the subject of an application or applications described in paragraph (2) or for a variant protein targeted drug that is the same or incorporates or utilizes the same variant protein targeted drug, as the drug or drugs that are the subject of an application or applications described in paragraph (2).

"(c) DEFINITIONS.—For purposes of this section—

"(1) the term 'genetically targeted drug' means a drug that—

"(A) is the subject of an application under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act for the treatment of a rare disease or condition (as such term is defined in section 526) that is serious or life-threatening;

"(B) may result in the modulation (including suppression, up-regulation, or activation) of the function of a gene or its associated gene product; and

"(C) incorporates or utilizes a genetically targeted technology;

"(2) the term 'genetically targeted technology' means a technology comprising non-replicating nucleic acid or analogous compounds with a common or similar chemistry that is intended to treat one or more patient subgroups, including subgroups of patients with different mutations of a gene, with the same disease or condition, including a disease or condition due to other variants in the same gene; and

"(3) the term 'variant protein targeted drug' means a drug that—

"(A) is the subject of an application under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act for the treatment of a rare disease or condition (as such term is defined in section 526) that is serious or life-threatening;

"(B) modulates the function of a product of a mutated gene where such mutation is responsible in whole or in part for a given disease or condition; and

"(C) is intended to treat one or more patient subgroups, including subgroups of patients with different mutations of a gene, with the same disease or condition.

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

"(1) alter the authority of the Secretary to approve drugs pursuant to this Act or section 351 of the Public Health Service Act (as authorized prior to the date of enactment of the 21st Century Cures Act), including the standards of evidence, and applicable conditions, for approval under such applicable Act; or

"(2) confer any new rights, beyond those authorized under this Act or the Public Health Service Act prior to enactment of this section, with respect to the permissibility of a sponsor referencing information contained in another application submitted under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act.".

SEC. 3013. REAUTHORIZATION OF PROGRAM TO ENCOURAGE TREATMENTS FOR RARE PEDIATRIC DISEASES.

(a) IN GENERAL.—Section 529(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff(b)) is amended 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 September 30, 2020, unless the rare pediatric disease product application—

"(A) is for a drug that, not later than September 30, 2020, is designated under subsection (d) as a drug for a rare pediatric disease; and

"(B) is, not later than September 30, 2022, approved under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act.".

(b) REPORT.—The Advancing Hope Act of 2016 (Public Law 114-229) is amended by striking section 3.

SEC. 3014. GAO STUDY OF PRIORITY REVIEW VOUCHER PROGRAMS.

(a) STUDY.—The Comptroller General of the United States (referred to in this section as the "Comptroller General") shall conduct a study addressing the effectiveness and overall impact of the following priority review voucher programs, including any such programs amended or established by this Act:

(1) The neglected tropical disease priority review voucher program under section 524 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n).

(2) The rare pediatric disease priority review voucher program under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff).

(3) The medical countermeasure priority review voucher program under section 565A of the Federal Food, Drug, and Cosmetic Act, as added by section 3086.

(b) ISSUANCE OF REPORT.—Not later than January 31, 2020, the Comptroller General shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing the results of the study under subsection (a).

(c) CONTENTS OF REPORTS.—The report submitted under subsection (b) shall address—

(1) for each drug for which a priority review voucher has been awarded as of initiation of the study—

(A) the indications for which the drug is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), pursuant to an application under section 505(b)(1) of such Act, or licensed under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a));

(B) whether, and to what extent, the voucher impacted the sponsor's decision to develop the drug; and

(C) whether, and to what extent, the approval or licensure of the drug, as applicable and appropriate—

(i) addressed a global unmet need related to the treatment or prevention of a neglected tropical disease, including whether the sponsor of a drug coordinated with international development organizations;

(ii) addressed an unmet need related to the treatment of a rare pediatric disease; or

(iii) affected the Nation's preparedness against a chemical, biological, radiological, or nuclear threat, including naturally occurring threats;

(2) for each drug for which a priority review voucher has been used—

(A) the indications for which such drug is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), pursuant to an application under section 505(b)(1) of such Act, or licensed under section 351(a) of the Public Health Service Act (42 U.S.C. 262);

(B) the value of the voucher, if transferred; and

(C) the length of time between the date on which the voucher was awarded and the date on which the voucher was used; and

(3) an analysis of the priority review voucher programs described in subsection (a), including—

(A) the resources used by the Food and Drug Administration in reviewing drugs for which vouchers were used, including the effect of the programs on the Food and Drug Administration's review of drugs for which priority review vouchers were not awarded or used;

(B) whether any improvements to such programs are necessary to appropriately target incentives for the development of drugs that would likely not otherwise be developed, or developed in as timely a manner, and, as applicable and appropriate—

(i) address global unmet needs related to the treatment or prevention of neglected tropical diseases, including in countries in which neglected tropical diseases are endemic; or

(ii) address unmet needs related to the treatment of rare pediatric diseases; and

(C) whether the sunset of the rare pediatric disease program and medical countermeasure program has had an impact on the program, including any potential unintended consequences.

(d) PROTECTION OF NATIONAL SECURITY.—The Comptroller General shall conduct the study and issue reports under this section in a manner that does not compromise national security.

SEC. 3015. AMENDMENTS TO THE ORPHAN DRUG GRANTS.

Section 5 of the Orphan Drug Act (21 U.S.C. 360ee) is amended—

(1) in subsection (a), by striking paragraph (1) and inserting the following: "(1) defraying the costs of developing drugs for rare diseases or conditions, including qualified testing expenses,"; and

(2) in subsection (b)(1)—

(A) in subparagraph (A)(ii), by striking "and" after the semicolon;

(B) in subparagraph (B), by striking the period and inserting "; and"; and

(C) by adding at the end the following:

"(C) prospectively planned and designed observational studies and other analyses conducted to assist in the understanding of the natural history of a rare disease or condition and in the development of a therapy, including studies and analyses to—

"(i) develop or validate a drug development tool related to a rare disease or condition; or

"(ii) understand the full spectrum of the disease manifestations, including describing genotypic and phenotypic variability and identifying and defining distinct subpopulations affected by a rare disease or condition.".

SEC. 3016. [21 U.S.C. 399h] NATIONAL CENTERS OF EXCELLENCE IN ADVANCED AND CONTINUOUS PHARMACEUTICAL MANUFACTURING.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs—

(1) may, to support the advancement, development, and implementation of advanced and continuous pharmaceutical manufacturing—

(A) solicit requests for designation as National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing (in this section referred to as a "National Center of Excellence");

(B) beginning not later than one year after the date of enactment of the Food and Drug Omnibus Reform Act of 2022, designate as National Centers of Excellence institutions of higher education or consortia of institutions of higher education that—

(i) request such designation; and

(ii) meet the eligibility criteria specified in subsection (c); and

(C) award grants to such institutions or consortia of institutions; and

(2) shall so designate not more than 5 institutions of higher education or consortia of such institutions.

(b) REQUEST FOR DESIGNATION.— A request for designation under subsection (a) shall be made to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(c) ELIGIBILITY CRITERIA FOR DESIGNATION.—To be eligible to receive a designation under this section, an institution of higher education or consortium of institutions of higher education shall include in its request for designation a description of the institution's or consortium's—

(1) physical capacity and technical capabilities to conduct advanced research on, and to develop and implement, advanced and continuous pharmaceutical manufacturing;

(2) collaboration or partnerships with other institutions of higher education, nonprofit organizations, and large and small pharmaceutical manufacturers, including generic and nonprescription manufacturers, contract manufacturers, and other relevant entities;

(3) proven capacity to design, develop, implement, and demonstrate new, highly effective technologies for use in advanced and continuous pharmaceutical manufacturing;

(4) proven ability to facilitate training of a qualified workforce for advanced research on, and development and implementation of, advanced and continuous pharmaceutical manufacturing; and

(5)(A) experience in participating in and leading advanced and continuous pharmaceutical manufacturing technology partnerships with other institutions of higher education, nonprofit organizations, and large and small pharmaceutical manufacturers, including generic and nonprescription manufacturers, contract manufacturers, and other relevant entities to—

(i) support the implementation of advanced or continuous pharmaceutical manufacturing for companies manufacturing or seeking to manufacture in the United States;

(ii) support Federal agencies with technical assistance and workforce training, which may include regulatory and quality metric guidance as applicable, and hands-on training, for advanced and continuous pharmaceutical manufacturing;

(iii) organize and conduct advanced research and development activities, with respect to advanced or continuous pharmaceutical manufacturing, needed to develop new and more effective technology, and to develop and support technological leadership;

(iv) develop best practices for designing, developing, and implementing advanced and continuous pharmaceutical manufacturing processes; and

(v) identify and assess workforce needs for advanced and continuous pharmaceutical manufacturing, and address such workforce needs, which may include the development and implementing of training programs; or

(B) a plan, to be implemented within 2 years, to establish partnerships described in subparagraph (A).

(d) TERMINATION OF DESIGNATION.—The Secretary may terminate the designation of any National Center of Excellence designated under this section if the Secretary determines such National Center of Excellence no longer meets the criteria specified in subsection (c). Not later than 90 days before the effective date of such a termination, the Secretary shall provide written notice to the National Center of Excellence, including the rationale for such termination.

(e) CONDITIONS FOR DESIGNATION.—As a condition of designation as a National Center of Excellence under this section, the Secretary shall require that an institution of higher education or consortium of institutions of higher education enter into an agreement with the Secretary under which the institution or consortium agrees—

(1) to collaborate directly with the Food and Drug Administration to publish the reports required by subsection (g);

(2) to share data with the Food and Drug Administration regarding best practices and research generated through the funding under subsection (f);

(3) to develop, along with industry partners (which may include large and small pharmaceutical manufacturers, including generic and nonprescription manufacturers, and contract research organizations or contract manufacturers that carry out drug development and manufacturing activities) and another institution or consortium designated under this section, if any, a strategic plan for developing an advanced and continuous pharmaceutical manufacturing workforce;

(4) to develop, along with industry partners and other institutions or consortia of such institutions designated under this section, a strategic plan for strengthening existing, and developing new, partnerships with other institutions of higher education or consortia thereof, or nonprofit organizations; and

(5) to provide an annual report to the Food and Drug Administration regarding the designee's activities under this section, including a description of how the designee continues to meet and make progress on the criteria specified in subsection (c).

(f) FUNDING.—

(1) IN GENERAL.—The Secretary shall award funding, through grants, contracts, or cooperative agreements, to the entities designated as National Centers of Excellence under this section for the purposes of supporting the advanced research on, and development and implementation of, advanced and continuous pharmaceutical manufacturing, and recommending improvements to advanced and continuous pharmaceutical manufacturing, including—

(A) expanding capacity for advanced research on, and development of, advanced and continuous pharmaceutical manufacturing; and

(B) implementing advanced research capacity and capabilities in advanced and continuous pharmaceutical manufacturing suitable for accelerating the development of drug products needed to respond to public health threats, mitigate or prevent drug shortages, address drug quality issues and supply chain disruptions, and other circumstances with respect to which the Secretary may determine the rapid development of new products or new manufacturing processes may be appropriate.

(2) CONSISTENCY WITH FDA MISSION.—As a condition on receipt of funding under this subsection, a National Center of Excellence shall consider any input from the Secretary regarding the use of funding related to—

(A) best practices to increase, and provide for the advancement of, advanced and continuous pharmaceutical manufacturing through the National Center of Excellence; and

(B) the extent to which activities conducted by the National Center of Excellence are consistent with the mission of the Food and Drug Administration.

(3) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as precluding a National Center for Excellence designated under this section from receiving funds under any other provision of this Act or any other Federal law.

(g) ANNUAL REVIEW AND REPORTS.—

(1) ANNUAL REPORT TO CONGRESS.—Beginning not later than one year after the date on which the first designation is made under subsection (a), and annually thereafter, the Secretary shall—

(A) submit to Congress a report describing the activities, partnerships and collaborations, Federal policy recommendations, previous and continuing funding, and findings of, and any other applicable information from, the National Centers of Excellence designated under this section;

(B) include in such report an accounting of the Federal administrative expenses described in subsection (i)(2) over the reporting period; and

(C) make such report available to the public in an easily accessible electronic format on the website of the Food and Drug Administration.

(2) CENTER OF EXCELLENCE REPORT.—An entity receiving a grant under this section shall, not later than 1 year after receiving such grant, and annually thereafter for the duration of the grant period, submit to the Secretary a summary of programs and activities funded under the grant.

(3) PERIODIC REVIEW.—The Secretary shall periodically review the National Centers of Excellence designated under this section to ensure that such National Centers of Excellence continue to meet the criteria for designation under this section.

(4) ADDITIONAL REPORT TO CONGRESS.—Not later than 1 year after the date on which the first designation is made under subsection (a), the Secretary, in consultation with the National Centers of Excellence designated under this section, shall submit a report to the Congress on the role of the Food and Drug Administration in supporting advanced and continuous pharmaceutical manufacturing, including—

(A) a national framework of principles related to the implementation of advanced and continuous pharmaceutical manufacturing;

(B) a plan for the development of Federal regulations and guidance to support and facilitate the incorporation of advanced or continuous manufacturing into the development of pharmaceuticals;

(C) a plan for development of Federal regulations or guidance related to the review of advanced and continuous pharmaceutical manufacturing, including how such manufacturing practices may be incorporated into the review of medical product applications; and

(D) a summary of relevant feedback related to improving advanced and continuous pharmaceutical manufacturing solicited from the public, which may include other institutions of higher education, nonprofit organizations, and large and small pharmaceutical manufacturers, including generic and nonprescription manufacturers, and contract manufacturers, and other relevant entities.

(h) DEFINITIONS.—In this section:

(1) ADVANCED AND CONTINUOUS PHARMACEUTICAL MANUFACTURING.—The term "advanced and continuous pharmaceutical manufacturing" refers to a method of pharmaceutical manufacturing, or a combination of pharmaceutical manufacturing methods—

(A) that incorporates a novel technology, or uses an established technique or technology in a new or innovative way, that enhances drug quality or improves the manufacturing process for a drug, including processes that may apply to advanced therapies and the production of biological products, such as cell and gene therapies; or

(B) for which the input materials are continuously fed into and transformed within the process, and the output materials are continuously removed from the system, uti-

lizing an integrated manufacturing process that consists of a series of 2 or more simultaneous unit operations.

(2) BIOLOGICAL PRODUCT.—The term "biological product" has the meaning given such term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(3) DRUG.—The term "drug" has the meaning given such term in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)).

(4) INSTITUTION OF HIGHER EDUCATION.—The term "institution of higher education" has the meaning given such term in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)).

(5) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(i) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There is authorized to be appropriated to carry out this section $100,000,000 for the period of fiscal years 2023 through 2027.

(2) FEDERAL ADMINISTRATIVE EXPENSES.—Of the amounts made available to carry out this section for a fiscal year, the Secretary shall not use more than 8 percent for Federal administrative expenses, including training, technical assistance, reporting, and evaluation.

Subtitle C—Modern Trial Design and Evidence Development

SEC. 3021. [21 U.S.C. 355 note] NOVEL CLINICAL TRIAL DESIGNS.

(a) PROPOSALS FOR USE OF NOVEL CLINICAL TRIAL DESIGNS FOR DRUGS AND BIOLOGICAL PRODUCTS.—For purposes of assisting sponsors in incorporating complex adaptive and other novel trial designs 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 of Health and Human Services (referred to in this section as the "Secretary") shall conduct a public meeting and issue guidance in accordance with subsection (b).

(b) GUIDANCE ADDRESSING USE OF NOVEL CLINICAL TRIAL DESIGNS.—

(1) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall update or issue guidance addressing the use of complex adaptive and other novel trial design in the development and regulatory review and approval or licensure for drugs and biological products.

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

(A) the use of complex adaptive and other novel trial designs, including how such clinical trials proposed or submitted help to 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 issuing the guidance required by paragraph (1), the Secretary shall consult with stakeholders, including representatives of regulated industry, academia, patient advocacy organizations, consumer groups, and disease research foundations, through a public meeting to be held not later than 18 months after the date of enactment of this Act.

(4) TIMING.—The Secretary shall update or issue a draft version of the guidance required by paragraph (1) not later than 18 months after the date of the public meeting required by paragraph (3) and finalize such guidance not later than 1 year after the date on which the public comment period for the draft guidance closes.

SEC. 3022. REAL WORLD EVIDENCE.

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

"SEC. 505F. [21 U.S.C. 355g] UTILIZING REAL WORLD EVIDENCE

"(a) IN GENERAL.—The Secretary shall establish a program to evaluate the potential use of real world evidence—

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

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

"(b) REAL WORLD EVIDENCE DEFINED.—In this section, the term 'real world evidence' means data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than randomized clinical trials.

"(c) PROGRAM FRAMEWORK.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the 21st Century Cures Act, 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 sources of real world evidence, including ongoing safety surveillance, observational studies, registries, claims, and patient-centered outcomes research activities;

"(B) the gaps in data collection activities;

"(C) the standards and methodologies for collection and analysis of real world evidence; 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, consumer 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;

"(ii) a contract, grant, or other arrangement, as the Secretary determines appropriate, with such a partnership or an independent research organization; or

"(iii) public workshops with the entities described in such subparagraph.

"(d) PROGRAM IMPLEMENTATION.—The Secretary shall, not later than 2 years after the date of enactment of the 21st Century Cures Act and in accordance with the framework established under subsection (c), implement the program to evaluate the potential use of real world evidence.

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

"(1) utilize the program established under subsection (a), 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 real world evidence for the purposes described in paragraphs (1) and (2) of subsection (a); and

"(B) the appropriate standards and methodologies for collection and analysis of real world evidence submitted for such purposes;

"(2) not later than 5 years after the date of enactment of the 21st Century Cures Act, issue draft guidance for industry as described in paragraph (1); and

"(3) not later than 18 months after the close of the public comment period for the draft guidance described in paragraph (2), issue revised draft guidance or final guidance.

"(f) RULE OF CONSTRUCTION.—

"(1) IN GENERAL.—Subject to paragraph (2), nothing in this section prohibits the Secretary from using real world evidence for purposes not specified in this section, provided the Secretary determines that sufficient basis exists for any such non-specified use.

"(2) STANDARDS OF EVIDENCE AND SECRETARY'S AUTHORITY.—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. 3023. [42 U.S.C. 289 note] PROTECTION OF HUMAN RESEARCH SUBJECTS.

(a) IN GENERAL.—In order to simplify and facilitate compliance by researchers with applicable regulations for the protection of human subjects in research, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall, to the extent practicable and consistent with other statutory provisions, harmonize differences between the HHS Human Subject Regulations and the FDA Human Subject Regulations in accordance with subsection (b).

(b) AVOIDING REGULATORY DUPLICATION AND UNNECESSARY DELAYS.—The Secretary shall, as appropriate—

(1) make such modifications to the provisions of the HHS Human Subject Regulations, the FDA Human Subject Regulations, and the vulnerable populations rules as may be necessary—

(A) to reduce regulatory duplication and unnecessary delays;

(B) to modernize such provisions in the context of multisite and cooperative research projects; and

(C) to protect vulnerable populations, incorporate local considerations, and support community engagement through mechanisms such as consultation with local researchers and human research protection programs, in a manner consistent with subparagraph (B); and

(2) ensure that human subject research that is subject to the HHS Human Subject Regulations and to the FDA Human Subject Regulations may—

(A) use joint or shared review;

(B) 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

(C) use similar arrangements to avoid duplication of effort.

(c) CONSULTATION.—In harmonizing or modifying regulations or guidance under this section, 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).

(d) TIMING.—The Secretary shall complete the harmonization described in subsection (a) not later than 3 years after the date of enactment of this Act.

(e) PROGRESS REPORT.—Not later than 2 years after the date of enactment of this Act, the Secretary shall submit to Congress a report on the progress made toward completing such harmonization.

(f) DEFINITIONS.—

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

(A) FDA HUMAN SUBJECT REGULATIONS.—The term "FDA Human Subject Regulations" means the provisions of parts 50, 56, 312, and 812 of title 21, Code of Federal Regulations (or any successor regulations).

(B) HHS HUMAN SUBJECT REGULATIONS.—The term "HHS Human Subject Regulations" means the provisions of subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations).

(C) VULNERABLE POPULATION RULES.—The term "vulnerable population rules" means—

(i) except in the case of research described in clause (ii), the provisions of subparts B through D of part 46, Code of Federal Regulations (or any successor regulations); and

(ii) in the case of research that is subject to FDA Human Subject Regulations, the provisions applicable to vulnerable populations under part 56 of title 21, Code of Federal Regulations (or any successor regulations) and subpart D of part 50 of such title 21 (or any successor regulations).

(2) INSTITUTIONAL REVIEW BOARD DEFINED.—In this section, the term "institutional review board" has the meaning that applies to the term "institutional review board" under the HHS Human Subject Regulations.

SEC. 3024. INFORMED CONSENT WAIVER OR ALTERATION 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 D—Patient Access to Therapies and Information

SEC. 3031. SUMMARY LEVEL REVIEW.

(a) FFDCA.—Section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) is amended by adding at the end the following:

"(5)(A) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under subsection (b), if such supplemental application complies with subparagraph (B).

"(B) A supplemental application is eligible for review as described in subparagraph (A) only if—

"(i) there is existing data available and acceptable to the Secretary demonstrating the safety of the drug; and

"(ii) all data used to develop the qualified data summaries are submitted to the Secretary as part of the supplemental application.

"(C) The Secretary shall post on the Internet website of the Food and Drug Administration and update annually—

"(i) the number of applications reviewed solely under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act;

"(ii) the average time for completion of review under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act;

"(iii) the average time for review of supplemental applications where the Secretary did not use review flexibility under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act; and

"(iv) the number of applications reviewed under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act for which the Secretary made use of full data sets in addition to the qualified data summary.

"(D) In this paragraph—

"(i) the term 'qualified indication' means an indication for a drug that the Secretary determines to be appropriate for summary level review under this paragraph; and

"(ii) the term 'qualified data summary' means a summary of clinical data that demonstrates the safety and effectiveness of a drug with respect to a qualified indication.".

(b) PHSA.—Section 351(a)(2) of the Public Health Service Act (42 U.S.C. 262(a)(2)) is amended by adding at the end the following:

"(E)(i) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under this subsection, if such supplemental application complies with the require-

ments of subparagraph (B) of section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act.

"(ii) In this subparagraph, the terms 'qualified indication' and 'qualified data summary' have the meanings given such terms in section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act.".

SEC. 3032. EXPANDED ACCESS POLICY.

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

"SEC. 561A. EXPANDED ACCESS POLICY REQUIRED FOR INVESTIGATIONAL DRUGS

"(a) 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 available the policy of the manufacturer or distributor on evaluating and responding to requests submitted under section 561(b) for provision of such a drug.

"(b) PUBLIC AVAILABILITY OF EXPANDED ACCESS POLICY.—The policies under subsection (a) shall be made public and readily available, such as by posting such policies on a publicly available Internet website. Such policies may be generally applicable to all investigational drugs of such manufacturer or distributor.

"(c) CONTENT OF POLICY.—A policy described in subsection (a) shall include—

"(1) contact information for the manufacturer or distributor to facilitate communication about requests described in subsection (a);

"(2) procedures for making such requests;

"(3) the general criteria the manufacturer or distributor will use to evaluate such requests for individual patients, and for responses to such requests;

"(4) the length of time the manufacturer or distributor anticipates will be necessary to acknowledge receipt of such requests; and

"(5) a hyperlink or other reference to the clinical trial record containing information about the expanded access for such drug that is required under section 402(j)(2)(A)(ii)(II)(gg) of the Public Health Service Act.

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

"(e) REVISED POLICY.—Nothing in this section shall prevent a manufacturer or distributor from revising a policy required under this section at any time.

"(f) APPLICATION.—This section shall apply to a manufacturer or distributor with respect to an investigational drug beginning on the later of—

"(1) the date that is 60 calendar days after the date of enactment of the 21st Century Cures Act; or

"(2) 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 investigational drug.".

SEC. 3033. ACCELERATED APPROVAL FOR REGENERATIVE ADVANCED THERAPIES.

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

(1) by transferring subsection (e) (relating to construction) so that it appears before subsection (f) (relating to awareness efforts); and

(2) by adding at the end the following:

"(g) REGENERATIVE ADVANCED THERAPY.—

"(1) IN GENERAL.—The Secretary, at the request of the sponsor of a drug, shall facilitate an efficient development program for, and expedite review of, such drug if the drug qualifies as a regenerative advanced therapy under the criteria described in paragraph (2).

"(2) CRITERIA.—A drug is eligible for designation as a regenerative advanced therapy under this subsection if—

"(A) the drug is a regenerative medicine therapy (as defined in paragraph (8));

"(B) the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and

"(C) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition.

"(3) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a regenerative advanced therapy concurrently with, or at any time after, 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.

"(4) DESIGNATION.—Not later than 60 calendar days after the receipt of a request under paragraph (3), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (2). If the Secretary determines that the drug meets the criteria, the Secretary shall designate the drug as a regenerative advanced therapy and shall take such actions as are appropriate under paragraph (1). If the Secretary determines that a drug does not meet the criteria for such designation, the Secretary shall include with the determination a written description of the rationale for such determination.

"(5) ACTIONS.—The sponsor of a regenerative advanced therapy shall be eligible for the actions to expedite development and review of such therapy under subsection (a)(3)(B), including early interactions to discuss any potential surrogate or intermediate endpoint to be used to support the accelerated approval of an application for the product under subsection (c).

"(6) ACCESS TO EXPEDITED APPROVAL PATHWAYS.—An application for a regenerative advanced therapy under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act may be—

"(A) eligible for priority review, as described in the Manual of Policies and Procedures of the Food and Drug

Administration and goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012; and

"(B) eligible for accelerated approval under subsection (c), as agreed upon pursuant to subsection (a)(3)(B), through, as appropriate—

"(i) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit; or

"(ii) reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites, as appropriate.

"(7) POSTAPPROVAL REQUIREMENTS.—The sponsor of a regenerative advanced therapy that is granted accelerated approval and is subject to the postapproval requirements under subsection (c) may, as appropriate, fulfill such requirements, as the Secretary may require, through—

"(A) the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence, such as electronic health records;

"(B) the collection of larger confirmatory data sets, as agreed upon pursuant to subsection (a)(3)(B); or

"(C) postapproval monitoring of all patients treated with such therapy prior to approval of the therapy.

"(8) DEFINITION.—For purposes of this section, the term 'regenerative medicine therapy' includes cell therapy, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except for those regulated solely under section 361 of the Public Health Service Act and part 1271 of title 21, Code of Federal Regulations.".

(b) [21 U.S.C. 356 note]

[21 U.S.C. 356 note] RULE OF CONSTRUCTION.—Nothing in this section and the amendments made by this section shall be construed to alter the authority of the Secretary of Health and Human Services—

(1) to approve drugs pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and section 351 of the Public Health Service Act (42 U.S.C. 262) as authorized prior to the date of enactment of the 21st Century Cures Act, including the standards of evidence, and applicable conditions, for approval under such Acts; or

(2) to alter the authority of the Secretary to require postapproval studies pursuant to such Acts, as authorized prior to the date of enactment of the 21st Century Cures Act.

(c) CONFORMING AMENDMENT.—Section 506(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(e)(1)) is amended by inserting "and the 21st Century Cures Act" after "Food and Drug Administration Safety and Innovation Act".

SEC. 3034. [21 U.S.C. 356g note] GUIDANCE REGARDING DEVICES USED IN THE RECOVERY, ISOLATION, OR DELIVERY OF REGENERATIVE ADVANCED THERAPIES.

(a) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue draft guidance clarifying how, in the context of

regenerative advanced therapies, the Secretary will evaluate devices used in the recovery, isolation, or delivery of regenerative advanced therapies. In doing so, the Secretary shall specifically address—

(1) how the Food and Drug Administration intends to simplify and streamline regulatory requirements for combination device and cell or tissue products;

(2) what, if any, intended uses or specific attributes would result in a device used with a regenerative therapy product to be classified as a class III device;

(3) when the Food and Drug Administration considers it is necessary, if ever, for the intended use of a device to be limited to a specific intended use with only one particular type of cell; and

(4) application of the least burdensome approach to demonstrate how a device may be used with more than one cell type.

(b) FINAL GUIDANCE.—Not later than 12 months after the close of the period for public comment on the draft guidance under subsection (a), the Secretary of Health and Human Services shall finalize such guidance.

SEC. 3035. [21 U.S.C. 356 note] REPORT ON REGENERATIVE ADVANCED THERAPIES.

(a) REPORT TO CONGRESS.—Before March 1 of each calendar year, the Secretary of Health and Human Services shall, with respect to the previous calendar year, submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on—

(1) the number and type of applications for approval of regenerative advanced therapies filed, approved or licensed as applicable, withdrawn, or denied; and

(2) how many of such applications or therapies, as applicable, were granted accelerated approval or priority review.

(b) REGENERATIVE ADVANCED THERAPY.—In this section, the term "regenerative advanced therapy" has the meaning given such term in section 506(g) of the Federal Food, Drug, and Cosmetic Act, as added by section 3033 of this Act.

SEC. 3036. STANDARDS FOR REGENERATIVE MEDICINE AND REGENERATIVE ADVANCED THERAPIES.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506F the following:

"SEC. 506G. [21 U.S.C. 356g] STANDARDS FOR REGENERATIVE MEDICINE AND REGENERATIVE ADVANCED THERAPIES

"(a) IN GENERAL.—Not later than 2 years after the date of enactment of the 21st Century Cures Act, the Secretary, in consultation with the National Institute of Standards and Technology and stakeholders (including regenerative medicine and advanced therapies manufacturers and clinical trial sponsors, contract manufacturers, academic institutions, practicing clinicians, regenerative medicine and advanced therapies industry organizations, and standard setting organizations), shall facilitate an effort to coordi-

nate and prioritize the development of standards and consensus definition of terms, through a public process, to support, through regulatory predictability, the development, evaluation, and review of regenerative medicine therapies and regenerative advanced therapies, including with respect to the manufacturing processes and controls of such products.

"(b) ACTIVITIES.—

"(1) IN GENERAL.—In carrying out this section, the Secretary shall continue to—

"(A) identity opportunities to help advance the development of regenerative medicine therapies and regenerative advanced therapies;

"(B) identify opportunities for the development of laboratory regulatory science research and documentary standards that the Secretary determines would help support the development, evaluation, and review of regenerative medicine therapies and regenerative advanced therapies through regulatory predictability; and

"(C) work with stakeholders, such as those described in subsection (a), as appropriate, in the development of such standards.

"(2) REGULATIONS AND GUIDANCE.—Not later than 1 year after the development of standards as described in subsection (a), the Secretary shall review relevant regulations and guidance and, through a public process, update such regulations and guidance as the Secretary determines appropriate.

"(c) DEFINITIONS.—For purposes of this section, the terms 'regenerative medicine therapy' and 'regenerative advanced therapy' have the meanings given such terms in section 506(g).".

SEC. 3037. 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 with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement";

(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 material differences between the health care economic information and the labeling approved for the drug under section 505 or under section 351 of the Public Health Service Act. The requirements set forth in

section 505(a) or in subsections (a) and (k) of 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)(A) For purposes of this paragraph, the term 'health care economic information' means any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences, which may be based on the separate or aggregated clinical consequences of the represented health outcomes, of the use of a drug. Such analysis may be comparative to the use of another drug, to another health care intervention, or to no intervention.

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

SEC. 3038. COMBINATION PRODUCT INNOVATION.

(a) IN GENERAL.—Section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) is amended—

(1) by striking paragraph (3);

(2) by redesignating paragraph (2) as paragraph (7);

(3) by redesignating paragraphs (4) and (5) as paragraphs (8) and (9), respectively;

(4) by striking "(g)(1)" and all that follows through the end of paragraph (1) and inserting the following:

"(g)(1)(A) The Secretary shall, in accordance with this subsection, assign a primary agency center to regulate products that constitute a combination of a drug, device, or biological product.

"(B) The Secretary shall conduct the premarket review of any combination product under a single application, whenever appropriate.

"(C) For purposes of this subsection, the term 'primary mode of action' means the single mode of action of a combination product expected to make the greatest contribution to the overall intended therapeutic effects of the combination product.

"(D) The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

"(i) a drug (other than a biological product), the agency center charged with premarket review of drugs shall have primary jurisdiction;

"(ii) a device, the agency center charged with premarket review of devices shall have primary jurisdiction; or

"(iii) a biological product, the agency center charged with premarket review of biological products shall have primary jurisdiction.

"(E) In determining the primary mode of action of a combination product, the Secretary shall not determine that the primary mode of action is that of a drug or biological product solely because

the combination product has any chemical action within or on the human body.

"(F) If a sponsor of a combination product disagrees with the determination under subparagraph (D)—

"(i) such sponsor may request, and the Secretary shall provide, a substantive rationale to such sponsor that references scientific evidence provided by the sponsor and any other scientific evidence relied upon by the Secretary to support such determination; and

"(ii)(I) the sponsor of the combination product may propose one or more studies (which may be nonclinical, clinical, or both) to establish the relevance, if any, of the chemical action in achieving the primary mode of action of such product;

"(II) if the sponsor proposes any such studies, the Secretary and the sponsor of such product shall collaborate and seek to reach agreement, within a reasonable time of such proposal, not to exceed 90 calendar days, on the design of such studies; and

"(III) if an agreement is reached under subclause (II) and the sponsor conducts one or more of such studies, the Secretary shall consider the data resulting from any such study when reevaluating the determination of the primary mode of action of such product, and unless and until such reevaluation has occurred and the Secretary issues a new determination, the determination of the Secretary under subparagraph (D) shall remain in effect.

"(2)(A)(i) To establish clarity and certainty for the sponsor, the sponsor of a combination product may request a meeting on such combination product. If the Secretary concludes that a determination of the primary mode of action pursuant to paragraph (1)(D) is necessary, the sponsor may request such meeting only after the Secretary makes such determination. If the sponsor submits a written meeting request, the Secretary shall, not later than 75 calendar days after receiving such request, meet with the sponsor of such combination product.

"(ii) A meeting under clause (i) may—

"(I) address the standards and requirements for market approval or clearance of the combination product;

"(II) address other issues relevant to such combination product, such as requirements related to postmarket modification of such combination product and good manufacturing practices applicable to such combination product; and

"(III) identify elements under subclauses (I) and (II) that may be more appropriate for discussion and agreement with the Secretary at a later date given that scientific or other information is not available, or agreement is otherwise not feasible regarding such elements, at the time a request for such meeting is made.

"(iii) Any agreement under this subparagraph shall be in writing and made part of the administrative record by the Secretary.

"(iv) Any such agreement shall remain in effect, except—

"(I) upon the written agreement of the Secretary and the sponsor or applicant; or

"(II) pursuant to a decision by the director of the reviewing division of the primary agency center, or a person more senior than such director, in consultation with consulting centers and the Office, as appropriate, that an issue essential to determining whether the standard for market clearance or other applicable standard under this Act or the Public Health Service Act applicable to the combination product has been identified since the agreement was reached, or that deviating from the agreement is otherwise justifiable based on scientific evidence, for public health reasons.

"(3) For purposes of conducting the premarket review of a combination product that contains an approved constituent part described in paragraph (4), the Secretary may require that the sponsor of such combination product submit to the Secretary only data or information that the Secretary determines is necessary to meet the standard for clearance or approval, as applicable, under this Act or the Public Health Service Act, including any incremental risks and benefits posed by such combination product, using a risk-based approach and taking into account any prior finding of safety and effectiveness or substantial equivalence for the approved constituent part relied upon by the applicant in accordance with paragraph (5).

"(4) For purposes of paragraph (3), an approved constituent part is—

"(A) a drug constituent part of a combination product being reviewed in a single application or request under section 515, 510(k), or 513(f)(2) (submitted in accordance with paragraph (5)), that is an approved drug, provided such application or request complies with paragraph (5);

"(B) a device constituent part approved under section 515 that is referenced by the sponsor and that is available for use by the Secretary under section 520(h)(4); or

"(C) any constituent part that was previously approved, cleared, or classified under section 505, 510(k), 513(f)(2), or 515 of this Act for which the sponsor has a right of reference or any constituent part that is a nonprescription drug, as defined in section 760(a)(2).

"(5)(A) If an application is submitted under section 515 or 510(k) or a request is submitted under section 513(f)(2), consistent with any determination made under paragraph (1)(D), for a combination product containing as a constituent part an approved drug—

"(i) the application or request shall include the certification or statement described in section 505(b)(2); and

"(ii) the applicant or requester shall provide notice as described in section 505(b)(3).

"(B) For purposes of this paragraph and paragraph (4), the term 'approved drug' means an active ingredient—

"(i) that was in an application previously approved under section 505(c);

"(ii) where such application is relied upon by the applicant submitting the application or request described in subparagraph (A);

"(iii) for which full reports of investigations that have been made to show whether such drug is safe for use and whether such drug is effective in use were not conducted by or for the applicant submitting the application or request described in subparagraph (A); and

"(iv) for which the applicant submitting the application or request described in subparagraph (A) has not obtained a right of reference or use from the person by or for whom the investigations described in clause (iii) were conducted.

"(C) The following provisions shall apply with respect to an application or request described in subparagraph (A) to the same extent and in the same manner as if such application or request were an application described in section 505(b)(2) that referenced the approved drug:

"(i) Subparagraphs (A), (B), (C), and (D) of section 505(c)(3).

"(ii) Clauses (ii), (iii), and (iv) of section 505(c)(3)(E).

"(iii) Subsections (b) and (c) of section 505A.

"(iv) Section 505E(a).

"(v) Section 527(a).

"(D) Notwithstanding any other provision of this subsection, an application or request for classification for a combination product described in subparagraph (A) shall be considered an application submitted under section 505(b)(2) for purposes of section 271(e)(2)(A) of title 35, United States Code.

"(6) Nothing in this subsection shall be construed as prohibiting a sponsor from submitting separate applications for the constituent parts of a combination product, unless the Secretary determines that a single application is necessary.";

(5) in paragraph (8) (as redesignated by paragraph (3))—

(A) in subparagraph (C)—

(i) by amending clause (i) to read as follows:

"(i) In carrying out this subsection, the Office shall help to ensure timely and effective premarket review that involves more than one agency center by coordinating such reviews, overseeing the timeliness of such reviews, and overseeing the alignment of feedback regarding such reviews.";

(ii) in clause (ii), by inserting "and alignment" after "the timeliness" each place it appears; and

(iii) by adding at the end the following new clauses:

"(iii) The Office shall ensure that, with respect to a combination product, a designated person or persons in the primary agency center is the primary point or points of contact for the sponsor of such combination product. The Office shall also coordinate commu-

nications to and from any consulting center involved in such premarket review, if requested by such primary agency center or any such consulting center. Agency communications and commitments, to the extent consistent with other provisions of law and the requirements of all affected agency centers, from the primary agency center shall be considered as communication from the Secretary on behalf of all agency centers involved in the review.

"(iv) The Office shall, with respect to the premarket review of a combination product—

"(I) ensure that any meeting between the Secretary and the sponsor of such product is attended by each agency center involved in the review, as appropriate;

"(II) ensure that each consulting agency center has completed its premarket review and provided the results of such review to the primary agency center in a timely manner; and

"(III) ensure that each consulting center follows the guidance described in clause (vi) and advises, as appropriate, on other relevant regulations, guidances, and policies.

"(v) In seeking agency action with respect to a combination product, the sponsor of such product—

"(I) shall identify the product as a combination product; and

"(II) may request in writing the participation of representatives of the Office in meetings related to such combination product, or to have the Office otherwise engage on such regulatory matters concerning the combination product.

"(vi) Not later than 4 years after the date of enactment of the 21st Century Cures Act, and after a public comment period of not less than 60 calendar days, the Secretary shall issue a final guidance that describes—

"(I) the structured process for managing pre-submission interactions with sponsors developing combination products;

"(II) the best practices for ensuring that the feedback in such pre-submission interactions represents the Agency's best advice based on the information provided during such pre-submission interactions;

"(III) the information that is required to be submitted with a meeting request under paragraph (2), how such meetings relate to other types of meetings in the Food and Drug Administration, and the form and content of any agreement reached through a meeting under such paragraph (2);"; and

(B) in subparagraph (G)—

(i) in the matter preceding clause (i), by inserting "(except with respect to clause (iv), beginning not later than one year after the date of the enactment of the 21st Century Cures Act)" after "enactment of this paragraph";

(ii) in clause (ii), by striking "and" at the end;

(iii) in clause (iii), by striking the period at the end and inserting "; and"; and

(iv) by adding at the end the following new clause:

"(iv) identifying the percentage of combination products for which a dispute resolution, with respect to premarket review, was requested by the combination product's sponsor."; and

(6) in paragraph (9) (as redesignated by paragraph (3))—

(A) in subparagraph (C)—

(i) in clause (i), by striking the comma at the end and inserting a semicolon;

(ii) in clause (ii), by striking ", and" at the end and inserting a semicolon;

(iii) in clause (iii), by striking the period at the end and inserting "; and"; and

(iv) by adding at the end the following:

"(iv) de novo classification under section 513(a)(1)."; and

(B) by adding at the end the following:

"(D) The terms 'premarket review' and 'reviews' include all activities of the Food and Drug Administration conducted prior to approval or clearance of an application, notification, or request for classification submitted under section 505, 510(k), 513(f)(2), 515, or 520 of this Act or under section 351 of the Public Health Service Act, including with respect to investigational use of the product.".

(b) INFORMATION FOR APPROVAL OF COMBINATION PRODUCTS.—Section 520(h)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(h)(4)) is amended—

(1) in subparagraph (A), by striking "Any information" and inserting "Subject to subparagraph (C), any information"; and

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

"(C) No information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) may be used to approve or clear any application submitted under section 515 or 510(k) or to classify a product under section 513(f)(2) for a combination product containing as a constituent part an approved drug (as defined in section 503(g)(5)(B)) unless—

"(i) the application includes the certification or statement referenced in section 503(g)(5)(A);

"(ii) the applicant provides notice as described in section 503(g)(5)(A); and

"(iii) the Secretary's approval of such application is subject to the provisions in section 503(g)(5)(C).".

(c) [21 U.S.C. 355 note]

[21 U.S.C. 355 note] VARIATIONS FROM CGMP STREAMLINED APPROACH.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the "Secretary") shall identify types of combination products and manufacturing processes with respect to which the Secretary proposes that good manufacturing processes may be adopted that vary from the requirements set forth in section 4.4 of title 21, Code of Federal Regulations (or any successor regulations) or that the Secretary proposes can satisfy the requirements in section 4.4 through alternative or streamlined mechanisms. The Secretary shall identify such types, variations from such requirements, and such mechanisms, in a proposed list published in the Federal Register. After a public comment period regarding the appropriate good manufacturing practices for such types, the Secretary shall publish a final list in the Federal Register, notwithstanding section 553 of title 5, United States Code. The Secretary shall evaluate such types, variations, and mechanisms using a risk-based approach. The Secretary shall periodically review such final list.

Subtitle E—Antimicrobial Innovation and Stewardship

SEC. 3041. ANTIMICROBIAL RESISTANCE MONITORING.

(a) IN GENERAL.—Section 319E of the Public Health Service Act (42 U.S.C. 247d-5) is amended—

(1) by redesignating subsections (f) and (g) as subsections (l) and (m), respectively; and

(2) by inserting after subsection (e), the following:

"(f) MONITORING AT FEDERAL HEALTH CARE FACILITIES.—The Secretary shall encourage reporting on aggregate antimicrobial drug use and antimicrobial resistance to antimicrobial drugs and the implementation of antimicrobial stewardship programs by health care facilities of the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service and shall provide technical assistance to the Secretary of Defense and the Secretary of Veterans Affairs, as appropriate and upon request.

"(g) REPORT ON ANTIMICROBIAL RESISTANCE IN HUMANS AND USE OF ANTIMICROBIAL DRUGS.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, and annually thereafter, the Secretary shall prepare and make publicly available data and information concerning—

"(1) aggregate national and regional trends of antimicrobial resistance in humans to antimicrobial drugs, including such drugs approved under section 506(h) of the Federal Food, Drug, and Cosmetic Act;

"(2) antimicrobial stewardship, which may include summaries of State efforts to address antimicrobial resistance in humans to antimicrobial drugs and antimicrobial stewardship; and

"(3) coordination between the Director of the Centers for Disease Control and Prevention and the Commissioner of Food and Drugs with respect to the monitoring of—

"(A) any applicable resistance under paragraph (1); and

"(B) drugs approved under section 506(h) of the Federal Food, Drug, and Cosmetic Act.

"(h) INFORMATION RELATED TO ANTIMICROBIAL STEWARDSHIP PROGRAMS.—The Secretary shall, as appropriate, disseminate guidance, educational materials, or other appropriate materials related to the development and implementation of evidence-based antimicrobial stewardship programs or practices at health care facilities, such as nursing homes and other long-term care facilities, ambulatory surgical centers, dialysis centers, outpatient clinics, and hospitals, including community and rural hospitals.

"(i) SUPPORTING STATE-BASED ACTIVITIES TO COMBAT ANTIMICROBIAL RESISTANCE.—The Secretary shall continue to work with State and local public health departments on statewide or regional programs related to antimicrobial resistance. Such efforts may include activities to related to—

"(1) identifying patterns of bacterial and fungal resistance in humans to antimicrobial drugs;

"(2) preventing the spread of bacterial and fungal infections that are resistant to antimicrobial drugs; and

"(3) promoting antimicrobial stewardship.

"(j) ANTIMICROBIAL RESISTANCE AND STEWARDSHIP ACTIVITIES.—

"(1) IN GENERAL.—For the purposes of supporting stewardship activities, examining changes in antimicrobial resistance, and evaluating the effectiveness of section 506(h) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall—

"(A) provide a mechanism for facilities to report data related to their antimicrobial stewardship activities (including analyzing the outcomes of such activities); and

"(B) evaluate—

"(i) antimicrobial resistance data using a standardized approach; and

"(ii) trends in the utilization of drugs approved under such section 506(h) with respect to patient populations.

"(2) USE OF SYSTEMS.—The Secretary shall use available systems, including the National Healthcare Safety Network or other systems identified by the Secretary, to fulfill the requirements or conduct activities under this section.

"(k) ANTIMICROBIAL.—For purposes of subsections (f) through (j), the term 'antimicrobial' includes any antibacterial or antifungal drugs, and may include drugs that eliminate or inhibit the growth of other microorganisms, as appropriate.".

(b) [42 U.S.C. 247d-5 note]

[42 U.S.C. 247d-5 note] AVAILABILITY OF DATA.—The Secretary shall make the data collected pursuant to this subsection public. Nothing in this subsection 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, or section 1905 of title 18, United States Code.

SEC. 3042. LIMITED POPULATION PATHWAY.

Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356), as amended by section 3033, is further amended by adding at the end the following:

"(h) LIMITED POPULATION PATHWAY FOR ANTIBACTERIAL AND ANTIFUNGAL DRUGS.—

"(1) IN GENERAL.—The Secretary may approve an antibacterial or antifungal drug, alone or in combination with one or more other drugs, as a limited population drug pursuant to this subsection only if—

"(A) the drug is intended to treat a serious or life-threatening infection in a limited population of patients with unmet needs;

"(B) the standards for approval under section 505(c) and (d), or the standards for licensure under section 351 of the Public Health Service Act, as applicable, are met; and

"(C) the Secretary receives a written request from the sponsor to approve the drug as a limited population drug pursuant to this subsection.

"(2) BENEFIT-RISK CONSIDERATION.—The Secretary's determination of safety and effectiveness of an antibacterial or

antifungal drug shall reflect the benefit-risk profile of such drug in the intended limited population, taking into account the severity, rarity, or prevalence of the infection the drug is intended to treat and the availability or lack of alternative treatment in such limited population. Such drug may be approved under this subsection notwithstanding a lack of evidence to fully establish a favorable benefit-risk profile in a population that is broader than the intended limited population.

"(3) ADDITIONAL REQUIREMENTS.—A drug approved under this subsection shall be subject to the following requirements, in addition to any other applicable requirements of this Act:

"(A) LABELING.—To indicate that the safety and effectiveness of a drug approved under this subsection has been demonstrated only with respect to a limited population—

"(i) all labeling and advertising of an antibacterial or antifungal drug approved under this subsection shall contain the statement 'Limited Population' in a prominent manner and adjacent to, and not more prominent than—

"(I) the proprietary name of such drug, if any; or

"(II) if there is no proprietary name, the established name of the drug, if any, as defined in section 503(e)(3), or, in the case of a drug that is a biological product, the proper name, as defined by regulation; and

"(ii) the prescribing information for the 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.'.

"(B) PROMOTIONAL MATERIAL.—The sponsor of an antibacterial or antifungal drug subject to this subsection shall submit to the Secretary copies of all promotional materials related to such drug at least 30 calendar days prior to dissemination of the materials.

"(4) OTHER PROGRAMS.—A sponsor of a drug that seeks approval of a drug under this subsection may also seek designation or approval, as applicable, of such drug under other applicable sections or subsections of this Act or the Public Health Service Act.

"(5) GUIDANCE.—Not later than 18 months after the date of enactment of the 21st Century Cures Act, the Secretary shall issue draft guidance describing criteria, processes, and other general considerations for demonstrating the safety and effectiveness of limited population antibacterial and antifungal drugs. The Secretary shall publish final guidance within 18 months of the close of the public comment period on such draft guidance. The Secretary may approve antibacterial and antifungal drugs under this subsection prior to issuing guidance under this paragraph.

"(6) ADVICE.—The Secretary shall provide prompt advice to the sponsor of a drug for which the sponsor seeks approval

under this subsection to enable the sponsor to plan a development program to obtain the necessary data for such approval, and to conduct any additional studies that would be required to gain approval of such drug for use in a broader population.

"(7) TERMINATION OF LIMITATIONS.—If, after approval of a drug under this subsection, the Secretary approves a broader indication for such drug under section 505(b) or section 351(a) of the Public Health Service Act, the Secretary may remove any postmarketing conditions, including requirements with respect to labeling and review of promotional materials under paragraph (3), applicable to the approval of the drug under this subsection.

"(8) RULES OF CONSTRUCTION.—Nothing in this subsection shall be construed to alter the authority of the Secretary to approve drugs pursuant to this Act or section 351 of the Public Health Service Act, including the standards of evidence and applicable conditions for approval under such Acts, the standards of approval of a drug under such Acts, or to alter the authority of the Secretary to monitor drugs pursuant to such Acts.

"(9) REPORTING AND ACCOUNTABILITY.—

"(A) BIENNIAL REPORTING.—The Secretary shall report to Congress not less often than once every 2 years on the number of requests for approval, and the number of approvals, of an antibacterial or antifungal drug under this subsection.

"(B) GAO REPORT.—Not later than December 2021, the Comptroller General of the United States 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 coordination of activities required under section 319E of the Public Health Service Act. Such report shall include a review of such activities, and the extent to which the use of the pathway established under this subsection has streamlined premarket approval for antibacterial or antifungal drugs for limited populations, if such pathway has functioned as intended, if such pathway has helped provide for safe and effective treatment for patients, if such premarket approval would be appropriate for other categories of drugs, and if the authorities under this subsection have affected antibacterial or antifungal resistance.".

SEC. 3043. [21 U.S.C. 356 note] PRESCRIBING AUTHORITY.

Nothing in this subtitle, or an amendment made by this subtitle, shall be construed to restrict the prescribing of antimicrobial drugs or other products, including drugs approved under subsection (h) of section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) (as added by section 3042), by health care professionals, or to limit the practice of health care.

SEC. 3044. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS; ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.

(a) IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 511 the following:

"SEC. 511A. [21 U.S.C. 360a-2]

[21 U.S.C. 360a-2] SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS

"(a) PURPOSE; IDENTIFICATION OF CRITERIA.—

"(1) PURPOSE.—The purpose of this section is to clarify the Secretary's authority to—

"(A) efficiently update susceptibility test interpretive criteria for antimicrobial drugs when necessary for public health, due to, among other things, the constant evolution of microorganisms that leads to the development of resistance to drugs that have been effective in decreasing morbidity and mortality for patients, which warrants unique management of antimicrobial drugs that is inappropriate for most other drugs in order to delay or prevent the development of further resistance to existing therapies;

"(B) provide for public notice of the availability of recognized interpretive criteria and interpretive criteria standards; and

"(C) clear under section 510(k), classify under section 513(f)(2), or approve under section 515, antimicrobial susceptibility testing devices utilizing updated, recognized susceptibility test interpretive criteria to characterize the in vitro susceptibility of particular bacteria, fungi, or other microorganisms, as applicable, to antimicrobial drugs.

"(2) IDENTIFICATION OF CRITERIA.—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) the relationship of susceptibility test interpretive criteria to morbidity and mortality associated with the disease or condition for which such drug is used; 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 and interpretive criteria in accordance with paragraph (2) (referred to in this section as the 'Interpretive Criteria Website').

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

"(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)(A) 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 by the Secretary to be appropriate for the drug.

"(C) REQUIRED STATEMENTS.—The Interpretive Criteria Website shall include statements conveying—

"(i) that the website provides information about the in vitro susceptibility of bacteria, fungi, or other microorganisms, as applicable to a certain drug (or drugs);

"(ii) that—

"(I) the safety and efficacy of such drugs in treating clinical infections due to such bacteria, fungi, or other microorganisms, as applicable, may or may not have been established in adequate and well-controlled clinical trials in order for the susceptibility information described in clause (i) to be included on the website; and

"(II) the clinical significance of such susceptibility information in such instances is unknown;

"(iii) that the approved product labeling for specific drugs provides the uses for which the Secretary has approved the product; and

"(iv) any other information that the Secretary determines appropriate to adequately convey the meaning of the data supporting the recognition or listing of susceptibility test interpretive criteria standards or susceptibility test interpretive criteria included 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.

"(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.—

"(1) EVALUATION AND PUBLICATION.—

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

"(i) 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

"(ii) 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).

"(B) UPON APPROVAL OF A DRUG.—Upon the approval of an initial or supplemental application for an antimicrobial drug under section 505 of this Act or section 351 of the Public Health Service Act, as applicable, where such approval is based on susceptibility test interpretive criteria which differ from those contained in a standard recognized, or from those otherwise listed, by the Secretary pursuant to this subsection, or for which there are no relevant interpretive criteria standards recognized, or interpretive criteria otherwise listed, by the Secretary pursuant to this subsection, the Secretary shall update the lists under subparagraphs (A) and (B) of subsection (b)(2) to include the susceptibility test interpretive criteria upon which such approval was based.

"(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)(A) and publish such compilation in the Federal Register and provide for public comment. If the Secretary receives comments, the Secretary shall review such comments and, if the Secretary determines appropriate, update pursuant to this subsection susceptibility test interpretive criteria standards or criteria—

"(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 which differ from those contained in a standard recognized, or from those otherwise listed, by the Secretary pursuant to subsection (b)(2).

"(d) ANTIMICROBIAL DRUG LABELING.—

"(1) DRUGS MARKETED PRIOR TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—

"(A) IN GENERAL.—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 of this Act or section 351 of the Public Health Service Act, as applicable, for each such drug, not later than 1 year after establishment of the Interpretive Criteria Website described in subsection (b)(1), shall remove susceptibility test interpretive criteria, if any, and related information from the approved drug labeling and replace it with a reference to the Interpretive Criteria Website.

"(B) LABELING CHANGES.—The labeling changes required by this section shall be considered a minor change under section 314.70 of title 21, Code of Federal Regulations (or any successor regulations) that may be implemented through documentation in the next applicable annual report.

"(2) DRUGS MARKETED SUBSEQUENT TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—With respect to antimicrobial drugs approved on or after the date of the establishment of the Interpretive Criteria Website described in subsection (b)(1), 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, 505, 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 includes statements conveying—

"(i) that the device provides information about the in vitro susceptibility of bacteria, fungi, or other microorganisms, as applicable to antimicrobial drugs;

"(ii) that—

"(I) the safety and efficacy of such drugs in treating clinical infections due to such bacteria, fungi, or other microorganisms, as applicable, may or may not have been established in adequate and well-controlled clinical trials in order for the device to report the susceptibility of such bacteria, fungi, or other microorganisms, as applicable, to such drugs; and

"(II) the clinical significance of such susceptibility information in those instances is unknown;

"(iii) that the approved labeling for drugs tested using such a device provides the uses for which the Secretary has approved such drugs; and

"(iv) any other information the Secretary determines appropriate to adequately convey the meaning of the data supporting the recognition or listing of susceptibility test interpretive criteria standards or susceptibility test interpretive criteria described in subparagraph (A).

"(C) The antimicrobial susceptibility testing device meets all other requirements to be cleared under section 510(k), classified under section 513(f)(2), or approved under section 515.

"(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.

"(5) The term 'interpretive criteria standard' means a compilation of susceptibility test interpretive criteria developed by a standard development organization that meets the criteria set forth in subsection (b)(2)(A)(i).

"(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

"(1) alter the standards of evidence under subsection (c) or (d) of section 505 (including the substantial evidence standard under section 505(d)) or under section 351 of the Public Health Service Act (as applicable); or

"(2) with respect to clearing devices under section 510(k), classifying devices under section 513(f)(2), or approving devices under section 515—

"(A) apply with respect to any drug, device, or biological product, in any context other than an antimicrobial drug and an antimicrobial susceptibility testing device that uses susceptibility test interpretive criteria to characterize and report the susceptibility of certain bacteria, fungi, or other microorganisms, as applicable, to such drug to reflect patient morbidity and mortality in accordance with this section; or

"(B) unless specifically stated, 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 PRIOR 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) ADDITION TO CATEGORIES OF MISBRANDED DRUGS.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

"(dd) If it is an antimicrobial drug, as defined in section 511A(f), and its labeling fails to conform with the requirements under section 511A(d).".

(3) RECOGNITION OF INTERPRETIVE CRITERIA STANDARD 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 a susceptibility test interpretive criteria standard under section 511A, by posting on the Interpretive Criteria Website in accordance with such section)".

(c) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy

and Commerce of the House of Representatives a report on the progress made in implementing section 511A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a), as added by subsection (a).

(d) [21 U.S.C. 360a-2 note]

[21 U.S.C. 360a-2 note] 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 updating the lists established under section 511A(b) of the Federal Food, Drug, and Cosmetic Act and posted on the Interpretive Criteria Website established under section 511A(c) of such Act.

Subtitle F—Medical Device Innovations

SEC. 3051. BREAKTHROUGH DEVICES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515A, as added by section 3034(b), the following:

"SEC. 515C. [21 U.S.C. 360e-3]

[21 U.S.C. 360e-3] BREAKTHROUGH DEVICES

"(a) PURPOSE.—The purpose of this section is to encourage the Secretary, and provide the Secretary with sufficient authority, to apply efficient and flexible approaches to expedite the development of, and prioritize the Food and Drug Administration's review of, devices that represent breakthrough technologies.

"(b) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish a program to expedite the development of, and provide for the priority review for, devices, as determined by the Secretary—

"(1) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and

"(2)(A) that represent breakthrough technologies;

"(B) for which no approved or cleared alternatives exist;

"(C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to 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

"(D) the availability of which is in the best interest of patients.

"(c) REQUEST FOR DESIGNATION.—A sponsor of a device may request that the Secretary designate such device for expedited development and 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 notification under section 510(k), or a petition for classification under section 513(f)(2).

"(d) DESIGNATION PROCESS.—

"(1) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under subsection (c), the Secretary shall determine whether the device that is the subject of the request meets the criteria described in subsection (b). If the Secretary determines that the device meets the criteria, the

Secretary shall designate the device for expedited development and priority review.

"(2) REVIEW.—Review of a request under subsection (c) shall be undertaken by a team that is composed of experienced staff and senior managers of the Food and Drug Administration.

"(3) WITHDRAWAL.—The Secretary may not withdraw a designation granted under this section on the basis of the criteria under subsection (b) no longer applying because of the subsequent clearance or approval of another device that—

"(A) was designated under this section; or

"(B) was given priority review under section 515(d)(5), as in effect prior to the date of enactment of the 21st Century Cures Act.

"(e) EXPEDITED DEVELOPMENT AND PRIORITY REVIEW.—

"(1) ACTIONS.—For purposes of expediting the development and review of devices designated under subsection (d) the Secretary shall—

"(A) assign a team of staff, including a team leader with appropriate subject matter expertise and experience, for each device for which a request is submitted under subsection (c);

"(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 (c) for the device;

"(C) adopt an efficient process for timely dispute resolution;

"(D) provide for interactive and timely communication with the sponsor of the device during the development program and review process;

"(E) expedite the Secretary's review of manufacturing and quality systems compliance, as applicable;

"(F) disclose to the sponsor, not less than 5 business days in advance, the topics of any consultation the Secretary intends to undertake with external experts or an advisory committee concerning the sponsor's device and provide the sponsor the opportunity to recommend such external experts;

"(G) provide for advisory committee input, as the Secretary determines appropriate (including in response to the request of the sponsor) for applications submitted under section 515(c); 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 (d), 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 and flexible as practicable, when scientifically appropriate;

"(C) facilitate, when scientifically appropriate, expedited and efficient development and review of the device through utilization of timely postmarket data collection with regard to application for approval under section 515(c); and

"(D) agree in writing to clinical protocols that the Secretary will consider binding on the Secretary and the sponsor, subject to—

"(i) changes to such protocols agreed to in writing by the sponsor and the Secretary; or

"(ii) a decision, made by the director of the office responsible for reviewing the device submission, that a substantial scientific issue essential to determining the safety or effectiveness of such device exists, provided that such decision is in writing, and is made only after the Secretary provides to the device sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the substantial scientific issue.

"(f) PRIORITY REVIEW GUIDANCE.—

"(1) CONTENT.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall issue guidance on the implementation of this section. Such guidance shall—

"(A) set forth the process by which a person may seek a designation under subsection (d);

"(B) provide a template for requests under subsection (c);

"(C) identify the criteria the Secretary will use in evaluating a request for designation under this section; and

"(D) identify the criteria and processes the Secretary will use to assign a team of staff, including team leaders, to review devices designated for expedited development and priority review, including any training required for such personnel to ensure effective and efficient review.

"(2) PROCESS.—Prior to finalizing the guidance under paragraph (1), the Secretary shall seek public comment on a proposed guidance.

"(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect—

"(1) 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 and application of the least burdensome means of evaluating device effectiveness or demonstrating substantial equivalence between devices with differing technological characteristics, as applicable;

"(2) the authority of the Secretary with respect to clinical holds under section 520(g)(8)(A);

"(3) the authority of the Secretary to act on an application pursuant to section 515(d) before completion of an establishment inspection, as the Secretary determines appropriate; or

"(4) the authority of the Secretary with respect to postmarket surveillance under sections 519(h) and 522.".

(b) DOCUMENTATION AND REVIEW OF SIGNIFICANT DECISIONS.—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 515C," after "application under section 515,".

(c) TERMINATION OF PREVIOUS PROGRAM.—

(1) IN GENERAL.—Section 515(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)) is amended—

(A) by striking paragraph (5); and

(B) by redesignating paragraph (6) as paragraph (5).

(2) CONFORMING AMENDMENT.—Section 737(5) of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 379i(5)) is amended by striking "515(d)(6)" and inserting "515(d)(5)".

(d) REPORT.—On January 1, 2019, the Secretary of Health and Human Services shall issue a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives—

(1) on the program under section 515C of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), in bringing safe and effective devices included in such program to patients as soon as possible; and

(2) that includes recommendations, if any, to strengthen the program to better meet patient device needs in a manner as timely as possible.

SEC. 3052. HUMANITARIAN DEVICE EXEMPTION.

(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) [21 U.S.C. 360j note]

[21 U.S.C. 360j note] 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 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. 3053. RECOGNITION OF STANDARDS.

(a) IN GENERAL.—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 estab-

lished by a nationally or internationally recognized standard organization.

"(ii) Not later than 60 calendar 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 response 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 shall make a response issued under clause (ii)(II) publicly available, in such a 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 clause (ii)(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 all, part, or none of a standard, including the scientific, technical, regulatory, or other basis for the decision regarding such recognition."; and

(2) by adding at the end the following:

"(4) 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.".

(b) ⟦21 U.S.C. 360d note⟧

⟦21 U.S.C. 360d note⟧ GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall review and update, if necessary, previously published guidance and standard operating procedures identifying the principles for recognizing standards, and for withdrawing the recognition of standards, under section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)), taking into account the experience with and reliance on a standard by foreign regulatory authorities and the device industry, and whether recognition of a standard will promote harmonization among regulatory authorities in the regulation of devices.

SEC. 3054. 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 calendar days after the date of enactment of the 21st Century Cures Act and at least once every 5 years thereafter, as the Secretary determines appropriate, 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 "(m)(1)" and all that follows through "by the Secretary." and inserting the following:

"(m)(1) The Secretary shall—

"(A) not later than 90 days after the date of enactment of the 21st Century Cures Act and at least once every 5 years thereafter, as the Secretary determines appropriate—

"(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 calendar days for public comment beginning on the date of the publication of such notice; and

"(B) not later than 210 calendar days after the date of enactment of the 21st Century Cures Act, publish in the Federal Register a list representing the Secretary's final determination with respect to the devices contained in the list published under subparagraph (A).''; and

(2) in paragraph (2)—

(A) by striking "1 day after the date of publication of a list under this subsection," and inserting "1 calendar day after the date of publication of the final list under paragraph (1)(B),"; and

(B) by striking "30-day period" and inserting "60-calendar-day period"; and

(C) 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. 3055. CLASSIFICATION PANELS.

(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) When a device is specifically the subject of review by a classification panel, the Secretary shall—

"(i) ensure that adequate expertise is represented on the classification panel to assess—

"(I) the disease or condition which the device is intended to cure, treat, mitigate, prevent, or diagnose; and

"(II) the technology of the device; and

"(ii) provide an opportunity for the person whose device is specifically the subject of panel review to provide recommendations on the expertise needed among the voting members of the panel.

"(C) For purposes of subparagraph (B)(i), the term 'adequate expertise' means that the membership of the classification panel 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.

"(D) The Secretary shall provide an annual opportunity for patients, representatives of patients, and sponsors of medical device submissions to provide recommendations for individuals with appropriate expertise to fill voting member positions on classification panels.".

(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, subject to the discretion of the panel chairperson, by designating a representative who will be provided a time during the panel meeting to address the panel for the purpose of correcting misstatements of fact or providing clarifying information, and permitting the person or representative to call on experts within the person's organization to address such specific issues in the time provided"; and

(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 device shall—

"(I) provide adequate time for initial presentations by the person whose device 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 device.".

SEC. 3056. INSTITUTIONAL REVIEW BOARD FLEXIBILITY.

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

(1) in subsection (g)(3)—

(A) in subparagraph (A)(i)—

(i) by striking "local"; and

(ii) by striking "which has been"; and

(B) in subparagraph (B), by striking "a local institutional" and inserting "an institutional"; and

(2) in subsection (m)(4)—

(A) by striking subparagraph (A) and inserting the following:

"(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) in subparagraph (B), by striking "a local institutional" and inserting "an institutional"; and

(C) in the matter following subparagraph (B), by striking "local".

SEC. 3057. [42 U.S.C. 263a note] CLIA WAIVER IMPROVEMENTS.

(a) DRAFT REVISED GUIDANCE.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, 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 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, acting through the Commissioner of Food and Drugs, shall finalize the draft guidance published under subsection (a) not later than 1 year after the comment period for such draft guidance closes.

SEC. 3058. LEAST BURDENSOME DEVICE REVIEW.

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

"(j) TRAINING AND OVERSIGHT OF LEAST BURDENSOME REQUIREMENTS.—

"(1) The Secretary shall—

"(A) ensure that each employee of the Food and Drug Administration who is involved in the review of premarket submissions, including supervisors, receives training regarding the meaning and implementation of the least burdensome requirements under subsections (a)(3)(D) and (i)(1)(D) of this section and section 515(c)(5); and

"(B) periodically assess the implementation of the least burdensome requirements, including the employee training under subparagraph (A), to ensure that the least burdensome requirements are fully and consistently applied.

"(2) Not later than 18 months after the date of enactment of the 21st Century Cures Act, the ombudsman for any organizational unit of the Food and Drug Administration responsible for the premarket review of devices shall—

"(A) conduct an audit of the training described in paragraph (1)(A), including the effectiveness of such training in implementing the least burdensome requirements;

"(B) include in such audit interviews of persons who are representatives of the device industry regarding their experiences in the device premarket review process, including with respect to the application of least burdensome concepts to premarket review and decisionmaking;

"(C) include in such audit a list of the measurement tools the Secretary uses to assess the implementation of the least burdensome requirements, including under paragraph (1)(B) and section 517A(a)(3), and may also provide feedback on the effectiveness of such tools in the implementation of the least burdensome requirements;

"(D) summarize the findings of such audit in a final audit report; and

"(E) within 30 calendar days of completion of such final audit report, make such final audit report available—

"(i) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives; and

"(ii) on the Internet website of the Food and Drug Administration.".

(b) PREMARKET APPLICATIONS.—Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is amended by adding at the end the following:

"(5)(A) In requesting additional information with respect to an application under this section, the Secretary shall consider the least burdensome appropriate means necessary to demonstrate a reasonable assurance of device safety and effectiveness.

"(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) For purposes of this paragraph, the Secretary shall consider the role of postmarket information in determining the least burdensome means of demonstrating a reasonable assurance of device safety and effectiveness.

"(D) Nothing in this paragraph alters the standards for premarket approval of a device.".

(c) RATIONALE FOR SIGNIFICANT DECISIONS REGARDING DEVICES.—Section 517A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g-1(a)) is amended by adding at the end the following:

"(3) APPLICATION OF LEAST BURDENSOME REQUIREMENTS.—The substantive summary required under this subsection shall include a brief statement regarding how the least burdensome requirements were considered and applied consistent with section 513(i)(1)(D), section 513(a)(3)(D), and section 515(c)(5), as applicable.".

SEC. 3059. CLEANING INSTRUCTIONS AND VALIDATION DATA REQUIREMENT.

(a) IN GENERAL.—Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended by adding at the end the following:

"(q) REUSABLE MEDICAL DEVICES.—

"(1) IN GENERAL.—Not later than 180 days after the date of enactment of the 21st Century Cures Act, the Secretary shall identify and publish a list of reusable device types for which reports under subsection (k) are required to include—

"(A) instructions for use, which have been validated in a manner specified by the Secretary; and

"(B) validation data, the types of which shall be specified by the Secretary;

regarding cleaning, disinfection, and sterilization, and for which a substantial equivalence determination may be based.

"(2) REVISION OF LIST.—The Secretary shall revise the list under paragraph (2), as the Secretary determines appropriate, with notice in the Federal Register.

"(3) CONTENT OF REPORTS.—Reports under subsection (k) that are submitted after the publication of the list described in paragraph (1), for devices or types of devices included on such list, shall include such instructions for use and validation data.".

(b) [21 U.S.C. 360 note] DEVICE MODIFICATIONS.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue final guidance regarding when a premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) is required to be submitted for a modification or change to a legally marketed device. Such final guidance shall be issued not later than 1 year after the date on which the comment period closes for the draft guidance on such subject.

SEC. 3060. CLARIFYING MEDICAL SOFTWARE REGULATION.

(a) IN GENERAL.—Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following:

"(o) REGULATION OF MEDICAL AND CERTAIN DECISIONS SUPPORT SOFTWARE.—

"(1) The term device, as defined in section 201(h), shall not include a software function that is intended—

"(A) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;

"(B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

"(C) to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or

display the equivalent of a paper medical chart, so long as—

"(i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;

"(ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and

"(iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

"(D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings; or

"(E) unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, for the purpose of—

"(i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);

"(ii) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and

"(iii) enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

"(2) In the case of a product with multiple functions that contains—

"(A) at least one software function that meets the criteria under paragraph (1) or that otherwise does not meet the definition of device under section 201(h); and

"(B) at least one function that does not meet the criteria under paragraph (1) and that otherwise meets the definition of a device under section 201(h),

the Secretary shall not regulate the software function of such product described in subparagraph (A) as a device. Notwithstanding the preceding sentence, when assessing the safety and effectiveness of the device function or functions of such product described in subparagraph (B), the Secretary may assess the impact that the software function or functions described in subparagraph (A) have on such device function or functions.

"(3)(A) Notwithstanding paragraph (1), a software function described in subparagraph (C), (D), or (E) of paragraph (1) shall not be excluded from the definition of device under section 201(h) if—

"(i) the Secretary makes a finding that use of such software function would be reasonably likely to have serious adverse health consequences; and

"(ii) the software function has been identified in a final order issued by the Secretary under subparagraph (B).

"(B) Subparagraph (A) shall apply only if the Secretary—

"(i) publishes a notification and proposed order in the Federal Register;

"(ii) includes in such notification the Secretary's finding, including the rationale and identification of the evidence on which such finding was based, as described in subparagraph (A)(i); and

"(iii) provides for a period of not less than 30 calendar days for public comment before issuing a final order or withdrawing such proposed order.

"(C) In making a finding under subparagraph (A)(i) with respect to a software function, the Secretary shall consider—

"(i) the likelihood and severity of patient harm if the software function were to not perform as intended;

"(ii) the extent to which the software function is intended to support the clinical judgment of a health care professional;

"(iii) whether there is a reasonable opportunity for a health care professional to review the basis of the information or treatment recommendation provided by the software function; and

"(iv) the intended user and user environment, such as whether a health care professional will use a software function of a type described in subparagraph (E) of paragraph (1).

"(4) Nothing in this subsection shall be construed as limiting the authority of the Secretary to—

"(A) exercise enforcement discretion as to any device subject to regulation under this Act;

"(B) regulate software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans; or

"(C) regulate software as a device under this Act if such software meets the criteria under section 513(a)(1)(C).".

(b) ⟦21 U.S.C. 360j note⟧

⟦21 U.S.C. 360j note⟧ REPORTS.—The Secretary of Health and Human Services (referred to in this subsection as the "Secretary"), after consultation with agencies and offices of the Department of Health and Human Services involved in health information technology, shall publish a report, not later than 2 years after the date of enactment of this Act and every 2 years thereafter, that—

(1) includes input from outside experts, such as representatives of patients, consumers, health care providers, startup companies, health plans or other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, em-

ployers, and other stakeholders with relevant expertise, as determined by the Secretary;

(2) examines information available to the Secretary on any risks and benefits to health associated with software functions described in section 520(o)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) (as amended by subsection (a)); and

(3) summarizes findings regarding the impact of such software functions on patient safety, including best practices to promote safety, education, and competency related to such functions.

(c) CLASSIFICATION OF ACCESSORIES.—Section 513(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)) is amended by adding at the end the following:

"(9) The Secretary shall classify an accessory under this section based on the intended use of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used.".

(d) CONFORMING AMENDMENT.—Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended by adding at the end the following: "The term 'device' does not include software functions excluded pursuant to section 520(o).".

Subtitle G—Improving Scientific Expertise and Outreach at FDA

SEC. 3071. SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH AND BIOMEDICAL PRODUCT ASSESSMENT 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)—

(A) in paragraph (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'), not to exceed 2,000 members, the purpose of which is to recruit and retain outstanding and qualified scientific and technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment";

(B) by amending paragraph (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."; and

(C) by adding at the end the following:

"(3) The Secretary shall assign experts under this section to agencies within the Department of Health and Human Services taking into account the need for the expertise of such expert.";

(3) 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"; and

(B) in paragraph (1), by inserting "or a doctoral or master's level degree in engineering, bioinformatics, or a related or emerging field," after the comma;

(4) in subsection (d)(2), 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 amount of annual compensation (excluding expenses) specified in section 102 of title 3, United States Code";

(5) by striking subsection (e); and

(6) by redesignating subsections (f) and (g) as subsections (e) and (f), respectively.

(b) GAO STUDY.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study of the effectiveness of the amendments to section 228 of the Public Health Service Act (42 U.S.C. 237) made by subsection (a) and the impact of such amendments, if any, on all agencies or departments of the Department of Health and Human Services, and, not later than 4 years after the date of enactment of this Act, shall submit a report based on such study to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(2) CONTENT OF STUDY AND REPORT.—The study and report under paragraph (1) shall include an examination of the extent to which recruitment and retention of outstanding and qualified scientific, medical, or technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment have improved or otherwise have been affected by the amendments to section 228 of the Public Health Service Act (42 U.S.C. 237) made by subsection (a), including by determining, during the period between the date of enactment of this Act and the completion of the study—

(A) the total number of members recruited and retained under the Senior Biomedical Research and Biomedical Product Assessment Service under such section 228, and the effect of increasing the number of members eligible for such Service;

(B) the number of members of such Senior Biomedical Research and Biomedical Product Assessment Service hired with a doctoral level degree in biomedicine or a related field, and the number of such members hired with a doctoral or master's level degree in engineering, bioinformatics, or a related or emerging field; and

(C) the number of Senior Biomedical Research and Biomedical Product Assessment Service members that have been hired by each agency or department of the Department of Health and Human Services, and how such Department assigns such members to each agency or department.

SEC. 3072. HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL, AND PROFESSIONAL PERSONNEL.

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

"SEC. 714A. [21 U.S.C. 379d-3a]

[21 U.S.C. 379d-3a] HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL, AND PROFESSIONAL PERSONNEL

"(a) IN GENERAL.—The Secretary may, notwithstanding title 5, United States Code, governing appointments in the competitive service, appoint outstanding and qualified candidates to scientific, technical, or professional positions that support the development, review, and regulation of medical products. Such positions shall be within the competitive service.

"(b) COMPENSATION.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, including any requirement with respect to General Schedule pay rates under subchapter III of chapter 53 of title 5, United States Code, and consistent with the requirements of paragraph (2), the Commissioner of Food and Drugs may determine and set—

"(A) the annual rate of pay of any individual appointed under subsection (a); and

"(B) for purposes of retaining qualified employees, the annual rate of pay for any qualified scientific, technical, or professional personnel appointed to a position described in subsection (a) before the date of enactment of the 21st Century Cures Act.

"(2) LIMITATION.—The annual rate of pay established pursuant to paragraph (1) may not exceed the amount of annual compensation (excluding expenses) specified in section 102 of title 3, United States Code.

"(3) PUBLIC AVAILABILITY.—The annual rate of pay provided to an individual in accordance with this section shall be publicly available information.

"(c) RULE OF CONSTRUCTION.—The authorities under this section shall not be construed to affect the authority provided under section 714.

"(d) REPORT ON WORKFORCE PLANNING.—

"(1) IN GENERAL.—Not later than 18 months after the date of enactment of the 21st Century Cures Act, the Secretary shall submit a report on workforce planning to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that examines the extent to which the Food and Drug Administration has a critical need for qualified individuals for scientific, technical, or professional positions, including—

"(A) an analysis of the workforce needs at the Food and Drug Administration and the Secretary's strategic plan for addressing such needs, including through use of the authority under this section; and

"(B) a recruitment and retention plan for hiring qualified scientific, technical, and professional candidates, which may include the use of—

"(i) recruitment through nongovernmental recruitment or placement agencies;

"(ii) recruitment through academic institutions;

"(iii) recruitment or hiring bonuses, if applicable;

"(iv) recruitment using targeted direct hiring authorities; and

"(v) retention of qualified scientific, technical, and professional employees using the authority under this section, or other applicable authorities of the Secretary.

"(2) RECOMMENDATIONS.—The report under paragraph (1) may include the recommendations of the Commissioner of Food and Drugs that would help the Food and Drug Administration to better recruit and retain qualified individuals for scientific, technical, or professional positions at the agency.".

(b) GAO STUDY AND REPORT.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study of the ability of the Food and Drug Administration to hire, train, and retain qualified scientific, technical, and professional staff, not including contractors, necessary to fulfill the mission of the Food and Drug Administration to protect and promote public health. Not later than January 1, 2022, the Comptroller General shall submit a report on such study to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(2) CONTENTS OF STUDY.—The Comptroller General shall include in the study and report under paragraph (1)—

(A) information about the progress of the Food and Drug Administration in recruiting and retaining qualified scientific, technical, and professional staff outstanding in the field of biomedical research, clinical research evaluation, and biomedical product assessment;

(B) the extent to which critical staffing needs exist at the Food and Drug Administration, and barriers to hiring, training, and retaining qualified staff, if any;

(C) an examination of the recruitment and retention strategies of the Food and Drug Administration, including examining any strategic workforce plan, focused on improving scientific, technical, and professional staff recruitment and retention; and

(D) recommendations for potential improvements that would address staffing needs of the Food and Drug Administration.

SEC. 3073. ESTABLISHMENT OF FOOD AND DRUG ADMINISTRATION INTERCENTER INSTITUTES.

(a) IN GENERAL.—Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

"SEC. 1014. [21 U.S.C. 399g]

[21 U.S.C. 399g] FOOD AND DRUG ADMINISTRATION INTERCENTER INSTITUTES

"(a) IN GENERAL.—The Secretary shall establish one or more Intercenter Institutes within the Food and Drug Administration (referred to in this section as an 'Institute') for a major disease area or areas. With respect to the major disease area of focus of an Institute, such Institute shall develop and implement processes for coordination of activities, as applicable to such major disease area or areas, among the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health (for the purposes of this section, referred to as the 'Centers'). Such activities may include—

"(1) coordination of staff from the Centers with diverse product expertise in the diagnosis, cure, mitigation, treatment, or prevention of the specific diseases relevant to the major disease area of focus of the Institute;

"(2) streamlining, where appropriate, the review of medical products to diagnose, cure, mitigate, treat, or prevent the specific diseases relevant to the major disease area of focus of the Institute, applying relevant standards under sections 505, 510(k), 513(f)(2), and 515 of this Act and section 351 of the Public Health Service Act, and other applicable authorities;

"(3) promotion of scientific programs within the Centers related to the major disease area of focus of the Institute;

"(4) development of programs and enhancement of strategies to recruit, train, and provide continuing education opportunities for the personnel of the Centers with expertise related to the major disease area of focus of the Institute;

"(5) enhancement of the interactions of the Centers with patients, sponsors, and the external biomedical community regarding the major disease area of focus of the Institute; and

"(6) facilitation of the collaborative relationships of the Centers with other agencies within the Department of Health and Human Services regarding the major disease area of focus of the Institute.

"(b) PUBLIC PROCESS.—The Secretary shall provide a period for public comment during the time that each Institute is being implemented.

"(c) TIMING.—The Secretary shall establish at least one Institute under subsection (a) before the date that is 1 year after the date of enactment of the 21st Century Cures Act.

"(d) TERMINATION OF INSTITUTES.—The Secretary may terminate any Institute established pursuant to this section if the Secretary determines such Institute is no longer benefitting the public health. Not less than 60 days prior to so terminating an Institute, the Secretary shall provide public notice, including the rationale for such termination.".

(b) TECHNICAL AMENDMENTS.—Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended—

(1) by redesignating section 1012 as section 1013; and

(2) by redesignating the second section 1011 (with respect to improving the training of State, local, territorial, and tribal food safety officials), as added by section 209(a) of the FDA

Food Safety Modernization Act (Public Law 111-353), as section 1012.

SEC. 3074. [42 U.S.C. 3506a] SCIENTIFIC ENGAGEMENT.

(a) IN GENERAL.—Scientific meetings that are attended by scientific or medical personnel, or other professionals, of the Department of Health and Human Services for whom attendance at such meeting is directly related to their professional duties and the mission of the Department—

(1) shall not be considered conferences for the purposes of complying with Federal reporting requirements contained in annual appropriations Acts or in this section; and

(2) shall not be considered conferences for purposes of a restriction contained in an annual appropriations Act, based on Office of Management and Budget Memorandum M-12-12 or any other regulation restricting travel to such meeting.

(b) LIMITATION.—Nothing in this section shall be construed to exempt travel for scientific meetings from Federal regulations relating to travel.

(c) REPORTS.—Not later than 90 days after the end of the fiscal year, each operating division of the Department of Health and Human Services shall prepare, and post on an Internet website of the operating division, an annual report on scientific meeting attendance and related travel spending for each fiscal year. Such report shall include—

(1) general information concerning the scientific meeting activities involved;

(2) information concerning the total amount expended for such meetings;

(3) a description of all such meetings that were attended by scientific or medical personnel, or other professionals, of each such operating division where the total amount expended by the operating division associated with each such meeting were in excess of $30,000, including—

(A) the total amount of meeting expenses incurred by the operating division for such meeting;

(B) the location of such meeting;

(C) the date of such meeting;

(D) a brief explanation on how such meeting advanced the mission of the operating division; and

(E) the total number of individuals whose travel expenses or other scientific meeting expenses were paid by the operating division; and

(4) with respect to any such meeting where the total expenses to the operating division exceeded $150,000, a description of the exceptional circumstances that necessitated the expenditure of such amounts.

SEC. 3075. DRUG SURVEILLANCE.

(a) NEW DRUGS.—Section 505(k)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(k)(5)), as amended by section 3102, is further amended—

(1) in subparagraph (A), by striking ", bi-weekly screening" and inserting "screenings";

(2) in subparagraph (B), as redesignated by section 3102(1)(C), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(C) make available on the Internet website of the Food and Drug Administration—

"(i) guidelines, developed with input from experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that detail best practices for drug safety surveillance using the Adverse Event Reporting System; and

"(ii) criteria for public posting of adverse event signals.".

(b) FAERS REVISION.—Section 505(r)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(r)(2)(D)) is amended by striking ", by 18 months" and all that follows through the semicolon at the end of the subparagraph and inserting "and making publicly available on the Internet website established under paragraph (1) best practices for drug safety surveillance activities for drugs approved under this section or section 351 of the Public Health Service Act;".

(c) RISK EVALUATION AND MITIGATION STRATEGIES.—Section 505-1(f)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355-1(f)(5)) is amended—

(1) in the matter preceding subparagraph (A), by inserting "or other advisory committee" after "(or successor committee)"; and

(2) in subparagraph (B), by striking "at least annually," and inserting "periodically".

SEC. 3076. 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 established 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".

Subtitle H—Medical Countermeasures Innovation

SEC. 3081. MEDICAL COUNTERMEASURE GUIDELINES.

Section 319F-2 of the Public Health Service Act (42 U.S.C. 247d-6b) is amended—

(1) in subsection (a), by adding at the end the following:

"(3) UTILIZATION GUIDELINES.—The Secretary shall ensure timely and accurate recommended utilization guidelines for qualified countermeasures (as defined in section 319F-1), qualified pandemic and epidemic products (as defined in section

319F-3), and security countermeasures (as defined in subsection (c)), including for such products in the stockpile."; and

(2) in subsection (g)—

(A) by amending paragraph (4) to read as follows:

"(4) REPORT ON SECURITY COUNTERMEASURE PROCUREMENT.—Not later than March 1 of each year in which the Secretary determines that the amount of funds available for procurement of security countermeasures is less than $1,500,000,000, the Secretary shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives a report detailing the amount of such funds available for procurement and the impact such amount of funding will have—

"(A) in meeting the security countermeasure needs identified under this section; and

"(B) on the annual Public Health Emergency Medical Countermeasures Enterprise and Strategy Implementation Plan (pursuant to section 2811(d)).".

SEC. 3082. CLARIFYING BARDA CONTRACTING AUTHORITY.

(a) IN GENERAL.—Section 319F-2(g) of the Public Health Service Act (42 U.S.C. 247d-6b(g)) is amended by adding at the end the following:

"(5) CLARIFICATION ON CONTRACTING AUTHORITY.—The Secretary, acting through the Director of the Biomedical Advanced Research and Development Authority, shall carry out the programs funded by the special reserve fund (for the procurement of security countermeasures under subsection (c) and for carrying out section 319L), including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section and section 319L.".

(b) BARDA CONTRACTING AUTHORITY.—Section 319L(c)(3) of the Public Health Service Act (42 U.S.C. 247d-7c) is amended by inserting ", including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section" before the period.

SEC. 3083. COUNTERMEASURE BUDGET PLAN.

Section 2811(b)(7) of the Public Health Service Act (42 U.S.C. 300hh-10(b)(7)) is amended—

(1) in the matter preceding subparagraph (A), by striking the first sentence and inserting "Develop, and update not later than March 1 of each year, a coordinated 5-year budget plan based on the medical countermeasure priorities described in subsection (d), including with respect to chemical, biological, radiological, and nuclear agent or agents that may present a threat to the Nation, including such agents that are novel or emerging infectious diseases, and the corresponding efforts to develop qualified countermeasures (as defined in section 319F-1), security countermeasures (as defined in section 319F-2), and qualified pandemic or epidemic products (as defined in section 319F-3) for each such threat.";

(2) in subparagraph (C), by striking "; and" and inserting a semicolon;

(3) in subparagraph (D), by striking "to the appropriate committees of Congress upon request." and inserting ", not later than March 15 of each year, to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives; and"; and

(4) by adding at the end the following:

"(E) not later than March 15 of each year, be made publicly available in a manner that does not compromise national security.".

SEC. 3084. MEDICAL COUNTERMEASURES INNOVATION.

Section 319L(c)(4) of the Public Health Service Act (42 U.S.C. 247d-7e(c)(4)) is amended by adding at the end the following:

"(E) MEDICAL COUNTERMEASURES INNOVATION PARTNER.—

"(i) IN GENERAL.—To support the purposes described in paragraph (2), the Secretary, acting through the Director of BARDA, may enter into an agreement (including through the use of grants, contracts, cooperative agreements, or other transactions as described in paragraph (5)) with an independent, nonprofit entity to—

"(I) foster and accelerate the development and innovation of medical countermeasures and technologies that may assist advanced research and the development of qualified countermeasures and qualified pandemic or epidemic products, including through the use of strategic venture capital practices and methods;

"(II) promote the development of new and promising technologies that address urgent medical countermeasure needs, as identified by the Secretary;

"(III) address unmet public health needs that are directly related to medical countermeasure requirements, such as novel antimicrobials for multidrug resistant organisms and multiuse platform technologies for diagnostics, prophylaxis, vaccines, and therapeutics; and

"(IV) provide expert consultation and advice to foster viable medical countermeasure innovators, including helping qualified countermeasure innovators navigate unique industry challenges with respect to developing chemical, biological, radiological, and nuclear countermeasure products.

"(ii) ELIGIBILITY.—

"(I) IN GENERAL.—To be eligible to enter into an agreement under clause (i) an entity shall—

"(aa) be an independent, nonprofit entity;

"(bb) have a demonstrated record of being able to create linkages between innovators and investors and leverage such partnerships and resources for the purpose of addressing identified strategic needs of the Federal Government;

"(cc) have experience in promoting novel technology innovation;

"(dd) be problem-driven and solution-focused based on the needs, requirements, and problems identified by the Secretary under clause (iv);

"(ee) demonstrate the ability, or the potential ability, to promote the development of medical countermeasure products;

"(ff) demonstrate expertise, or the capacity to develop or acquire expertise, related to technical and regulatory considerations with respect to medical countermeasures; and

"(gg) not be within the Department of Health and Human Services.

"(II) PARTNERING EXPERIENCE.—In selecting an entity with which to enter into an agreement under clause (i), the Secretary shall place a high value on the demonstrated experience of the entity in partnering with the Federal Government to meet identified strategic needs.

"(iii) NOT AGENCY.—An entity that enters into an agreement under clause (i) shall not be deemed to be a Federal agency for any purpose, including for any purpose under title 5, United States Code.

"(iv) DIRECTION.—Pursuant to an agreement entered into under this subparagraph, the Secretary, acting through the Director of BARDA, shall provide direction to the entity that enters into an agreement under clause (i). As part of this agreement the Director of BARDA shall—

"(I) communicate the medical countermeasure needs, requirements, and problems to be addressed by the entity under the agreement;

"(II) develop a description of work to be performed by the entity under the agreement;

"(III) provide technical feedback and appropriate oversight over work carried out by the entity under the agreement, including subsequent development and partnerships consistent with the needs and requirements set forth in this subparagraph;

"(IV) ensure fair consideration of products developed under the agreement in order to maintain competition to the maximum practical extent, as applicable and appropriate under applicable provisions of this section; and

"(V) ensure, as a condition of the agreement that the entity—

"(aa) has in place a comprehensive set of policies that demonstrate a commitment to transparency and accountability;

"(bb) protects against conflicts of interest through a comprehensive set of policies that address potential conflicts of interest, ethics, disclosure, and reporting requirements;

"(cc) provides monthly accounting on the use of funds provided under such agreement; and

"(dd) provides on a quarterly basis, reports regarding the progress made toward meeting the identified needs set forth in the agreement.

"(v) SUPPLEMENT NOT SUPPLANT.—Activities carried out under this subparagraph shall supplement, and not supplant, other activities carried out under this section.

"(vi) NO ESTABLISHMENT OF ENTITY.—To prevent unnecessary duplication and target resources effectively, nothing in this subparagraph shall be construed to authorize the Secretary to establish within the Department of Health and Human Services an entity for the purposes of carrying out this subparagraph.

"(vii) TRANSPARENCY AND OVERSIGHT.—Upon request, the Secretary shall provide to Congress the information provided to the Secretary under clause (iv)(V)(dd).

"(viii) INDEPENDENT EVALUATION.—Not later than 4 years after the date of enactment of the 21st Century Cures Act, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the Secretary and the appropriate committees of Congress a report, concerning the activities conducted under this subparagraph. Such report shall include recommendations with respect to any agreement or activities carried out pursuant to this subparagraph.

"(ix) SUNSET.—This subparagraph shall have no force or effect after September 30, 2022.".

SEC. 3085. STREAMLINING PROJECT BIOSHIELD PROCUREMENT.

Section 319F-2(c) of the Public Health Service Act (42 U.S.C. 247d-6b(c)) is amended—

(1) in paragraph (4)(A)(ii), by striking "make a recommendation under paragraph (6) that the special reserve fund as defined in subsection (h) be made available for the procurement of such countermeasure" and inserting "and subject to the availability of appropriations, make available the special reserve fund as defined in subsection (h) for procurement of such countermeasure, as applicable";

(2) in paragraph (6)—

(A) by striking subparagraphs (A), (B), and (E);

(B) by redesignating subparagraphs (C) and (D) as subparagraphs (A) and (B), respectively;

(C) by amending subparagraph (A), as so redesignated, to read as follows:

"(A) NOTICE TO APPROPRIATE CONGRESSIONAL COMMITTEES.—The Secretary shall notify the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives of each decision to make available the special reserve fund as defined in subsection (h) for procurement of a security countermeasure, including, where available, the number of, the nature of, and other information concerning potential suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons for each such rejection."; and

(D) in the heading, by striking "Recommendation for president's approval" and inserting "**Recommendations for procurement**"; and

(3) in paragraph (7)—

(A) by striking subparagraphs (A) and (B) and inserting the following:

"(A) PAYMENTS FROM SPECIAL RESERVE FUND.—The special reserve fund as defined in subsection (h) shall be available for payments made by the Secretary to a vendor for procurement of a security countermeasure in accordance with the provisions of this paragraph."; and

(B) by redesignating subparagraph (C) as subparagraph (B).

SEC. 3086. ENCOURAGING TREATMENTS FOR AGENTS THAT PRESENT A NATIONAL SECURITY THREAT.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by inserting after section 565 the following:

"SEC. 565A. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR AGENTS THAT PRESENT NATIONAL SECURITY THREATS

"(a) DEFINITIONS.—In this section:

"(1) HUMAN DRUG APPLICATION.—The term 'human drug application' has the meaning given such term in section 735(1).

"(2) PRIORITY REVIEW.—The term 'priority review', with respect to a human drug application, means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures in the Food and Drug Administration and goals identified in the letters described in section 101(b) of the Food and Drug Administration Safety and Innovation Act.

"(3) PRIORITY REVIEW VOUCHER.—The term 'priority review voucher' means a voucher issued by the Secretary to the sponsor of a material threat medical countermeasure applica-

tion that entitles the holder of such voucher to priority review of a single human drug application submitted under section 505(b)(1) or section 351(a) of the Public Health Service Act after the date of approval of the material threat medical countermeasure application.

"(4) MATERIAL THREAT MEDICAL COUNTERMEASURE APPLICATION.—The term 'material threat medical countermeasure application' means an application that—

"(A) is a human drug application for a drug intended for use—

"(i) to prevent, or treat harm from a biological, chemical, radiological, or nuclear agent identified as a material threat under section 319F-2(c)(2)(A)(ii) of the Public Health Service Act; or

"(ii) to mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, or biological product against such agent; and

"(B) the Secretary determines eligible for priority review;

"(C) is approved after the date of enactment of the 21st Century Cures Act; and

"(D) is for a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 505(b)(1) or section 351(a) of the Public Health Service Act.

"(b) PRIORITY REVIEW VOUCHER.—

"(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a material threat medical countermeasure application upon approval by the Secretary of such material threat medical countermeasure application.

"(2) TRANSFERABILITY.—The sponsor of a material threat medical countermeasure application that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a human drug for which an application under section 505(b)(1) or section 351(a) of the Public Health Service Act will be submitted after the date of the approval of the material threat medical countermeasure application. There is no limit on the number of times a priority review voucher may be transferred before such voucher is used.

"(3) NOTIFICATION.—

"(A) IN GENERAL.—The sponsor of a human drug application shall notify the Secretary not later than 90 calendar days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

"(B) TRANSFER AFTER NOTICE.—The sponsor of a human drug application that provides notification of the

intent of such sponsor to use the voucher for the human drug application under subparagraph (A) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application described in the notification.

"(c) PRIORITY REVIEW USER FEE.—

"(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

"(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year.

"(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2016, for that fiscal year, the amount of the priority review user fee.

"(4) PAYMENT.—

"(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 505(b)(1) or section 351(a) of the Public Health Service Act for which the priority review voucher is used.

"(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

"(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

"(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

"(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

"(6) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.

"(d) NOTICE OF ISSUANCE OF VOUCHER AND APPROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary shall publish a notice in the Federal Register and on the Internet website of the Food and Drug Administration not later than 30 calendar days after the occurrence of each of the following:

"(1) The Secretary issues a priority review voucher under this section.

"(2) The Secretary approves a drug pursuant to an application submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act for which the sponsor

of the application used a priority review voucher issued under this section.

"(e) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing in this section precludes a sponsor who seeks a priority review voucher under this section from participating in any other incentive program, including under this Act, except that no sponsor of a material threat medical countermeasure application may receive more than one priority review voucher issued under any section of this Act with respect to such drug.

"(f) RELATION TO OTHER PROVISIONS.—The provisions of this section shall supplement, not supplant, any other provisions of this Act or the Public Health Service Act that encourage the development of medical countermeasures.

"(g) SUNSET.—The Secretary may not award any priority review vouchers under subsection (b) after October 1, 2023.".

SEC. 3087. PAPERWORK REDUCTION ACT WAIVER DURING A PUBLIC HEALTH EMERGENCY.

Section 319 of the Public Health Service Act (42 U.S.C. 247d) is amended by adding at the end the following:

"(f) DETERMINATION WITH RESPECT TO PAPERWORK REDUCTION ACT WAIVER DURING A PUBLIC HEALTH EMERGENCY.—

"(1) DETERMINATION.—If the Secretary determines, after consultation with such public health officials as may be necessary, that—

"(A)(i) the criteria set forth for a public health emergency under paragraph (1) or (2) of subsection (a) has been met; or

"(ii) a disease or disorder, including a novel and emerging public health threat, is significantly likely to become a public health emergency; and

"(B) the circumstances of such public health emergency, or potential for such significantly likely public health emergency, including the specific preparation for and response to such public health emergency or threat, necessitate a waiver from the requirements of subchapter I of chapter 35 of title 44, United States Code (commonly referred to as the Paperwork Reduction Act),

then the requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate investigation of, and response to, such public health emergency during the period of such public health emergency or the period of time necessary to determine if a disease or disorder, including a novel and emerging public health threat, will become a public health emergency as provided for in this paragraph. The requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate postresponse review regarding such public health emergency if such immediate postresponse review does not exceed a reasonable length of time.

"(2) TRANSPARENCY.—If the Secretary determines that a waiver is necessary under paragraph (1), the Secretary shall promptly post on the Internet website of the Department of Health and Human Services a brief justification for such waiv-

er, the anticipated period of time such waiver will be in effect, and the agencies and offices within the Department of Health and Human Services to which such waiver shall apply, and update such information posted on the Internet website of the Department of Health and Human Services, as applicable.

"(3) EFFECTIVENESS OF WAIVER.—Any waiver under this subsection shall take effect on the date on which the Secretary posts information on the Internet website as provided for in this subsection.

"(4) TERMINATION OF WAIVER.—Upon determining that the circumstances necessitating a waiver under paragraph (1) no longer exist, the Secretary shall promptly update the Internet website of the Department of Health and Human Services to reflect the termination of such waiver.

"(5) LIMITATIONS.—

"(A) PERIOD OF WAIVER.—The period of a waiver under paragraph (1) shall not exceed the period of time for the related public health emergency, including a public health emergency declared pursuant to subsection (a), and any immediate postresponse review regarding the public health emergency consistent with the requirements of this subsection.

"(B) SUBSEQUENT COMPLIANCE.—An initiative subject to a waiver under paragraph (1) that is ongoing after the date on which the waiver expires, shall be subject to the requirements of subchapter I of chapter 35 of title 44, United States Code, and the Secretary shall ensure that compliance with such requirements occurs in as timely a manner as possible based on the applicable circumstances, but not to exceed 30 calendar days after the expiration of the applicable waiver.".

SEC. 3088. CLARIFYING FOOD AND DRUG ADMINISTRATION EMERGENCY USE AUTHORIZATION.

(a) AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE IN EMERGENCIES.—Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3) is amended—

(1) in subsection (a)(2)—

(A) in subparagraph (A)—

(i) by striking "or 515" and inserting "512, or 515"; and

(ii) by inserting "or conditionally approved under section 571 of this Act" after "Public Health Service Act"; and

(B) in subparagraph (B), by inserting "conditionally approved under section 571," after "approved," each place the term appears;

(2) in subsection (b)(4), by striking the second comma after "determination";

(3) in subsection (e)(3)(B), by striking "section 503(b)" and inserting "subsection (b) or (f) of section 503 or under section 504";

(4) in subsection (f)(2)—

(A) by inserting ", or an animal to which," after "to a patient to whom"; and

(B) by inserting "or by the veterinarian caring for such animal, as applicable" after "attending physician";

(5) in subsection (g)(1), by inserting "conditional approval under section 571," after "approval,";

(6) in subsection (h)(1), by striking "or section 520(g)"and inserting "512(j), or 520(g)"; and

(7) in subsection (k), by striking "section 520(g),"and inserting "512(j), or 520(g)".

(b) NEW ANIMAL DRUGS.—Section 512(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(a)(1)) is amended—

(1) in subparagraph (B), by striking "or" at the end;

(2) in subparagraph (C), by striking the period and inserting "; or"; and

(3) by inserting after subparagraph (C) the following:

"(D) there is in effect an authorization pursuant to section 564 with respect to such use or intended use of such drug, and such drug, its labeling, and such use conform to any conditions of such authorization.".

(c) EMERGENCY USE OF MEDICAL PRODUCTS.—Section 564A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3a) is amended—

(1) in subsection (a)(1)(A), by inserting ", conditionally approved under section 571," after "chapter"; and

(2) in subsection (d), by striking "sections 503(b) and 520(e)" and inserting "subsections (b) and (f) of section 503, section 504, and section 520(e)".

(d) PRODUCTS HELD FOR EMERGENCY USE.—Section 564B(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3b(2)) is amended—

(1) in subparagraph (A)—

(A) by inserting "or conditionally approved under section 571 of this Act" after "Public Health Service Act"; and

(B) by striking "or 515" and inserting "512, or 515"; and

(2) in subparagraph (B), by striking "or 520" and inserting "512, or 520".

Subtitle I—Vaccine Access, Certainty, and Innovation

SEC. 3091. PREDICTABLE REVIEW TIMELINES OF VACCINES BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.

(a) CONSIDERATION OF NEW VACCINES.—Upon the licensure of any vaccine or any new indication for a vaccine, the Advisory Committee on Immunization Practices (in this section referred to as the "Advisory Committee") shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting.

(b) ADDITIONAL INFORMATION.—If the Advisory Committee does not make a recommendation 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 shall provide an update on the status of such committee's review.

(c) CONSIDERATION FOR BREAKTHROUGH THERAPIES AND FOR POTENTIAL USE DURING PUBLIC HEALTH EMERGENCY.—The Advisory Committee shall make recommendations with respect to the use of certain vaccines in a timely manner, as appropriate, including vaccines that—

(1) are designated as a breakthrough therapy under section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) and licensed under section 351 of the Public Health Service Act (42 U.S.C. 262); or

(2) could be used in a public health emergency.

(d) DEFINITION.—In this section, 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 of the Public Health Service Act (42 U.S.C. 217a), acting through the Director of the Centers for Disease Control and Prevention.".

SEC. 3092. REVIEW OF PROCESSES AND CONSISTENCY OF ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES RECOMMENDATIONS.

(a) REVIEW.—The Director of the Centers for Disease Control and Prevention shall conduct a review of the processes used by the Advisory Committee on Immunization Practices in formulating and issuing recommendations pertaining to vaccines, including with respect to consistency.

(b) CONSIDERATIONS.—The review under subsection (a) shall include an assessment of—

(1) the criteria used to evaluate new and existing vaccines, including the identification of any areas for which flexibility in evaluating such criteria is necessary and the reason for such flexibility;

(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 work groups of the Advisory Committee on Immunization Practices are consistent among such groups, including the identification of reasons for any variation.

(c) STAKEHOLDERS.—In carrying out the review under subsection (a), the Director of the Centers for Disease 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 any recommendations on improving the consistency of the processes 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. 3093. [42 U.S.C. 300aa-2 note] ENCOURAGING VACCINE INNOVATION.

(a) VACCINE MEETINGS.—The Director of the Centers for Disease Control and Prevention shall ensure that appropriate staff within the relevant centers and divisions of the Office of Infectious Diseases, and others, as appropriate, coordinate with respect to the public health needs, epidemiology, and program planning and implementation considerations related to immunization, including with regard to meetings with stakeholders related to such topics.

(b) REPORT ON VACCINE INNOVATION.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary"), in collaboration with appropriate agencies or offices within the Department of Health and Human Services, including the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Biomedical Advanced Research and Development Authority, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and post publicly on the Internet website of the Department of Health and Human Services, a report on ways to promote innovation in the development of vaccines that minimize the burden of infectious disease.

(2) CONTENTS.—The report described in paragraph (1) shall review the current status of vaccine development and, as appropriate—

(A) consider the optimal process to determine which vaccines would be beneficial to public health and how information on such vaccines is disseminated to key stakeholders;

(B) examine and identify whether obstacles exist that inhibit the development of beneficial vaccines; and

(C) make recommendations about how best to remove any obstacles identified under subparagraph (B) in order to promote and incentivize vaccine innovation and development.

(3) CONSULTATION.—In preparing the report under this subsection, the Secretary may consult with—

(A) representatives of relevant Federal agencies and departments, including the Department of Defense and the Department of Veterans Affairs;

(B) academic researchers;

(C) developers and manufacturers of vaccines;

(D) medical and public health practitioners;

(E) representatives of patient, policy, and advocacy organizations; and

(F) representatives of other entities, as the Secretary determines appropriate.

(c) UPDATES RELATED TO MATERNAL IMMUNIZATION.—

(1) ADDITIONAL VACCINES.—Section 2114(e) of the Public Health Service Act (42 U.S.C. 300aa-14(e)) is amended by adding at the end the following:

"(3) VACCINES RECOMMENDED FOR USE IN PREGNANT WOMEN.—The Secretary shall revise the Vaccine Injury Table included in subsection (a), through the process described in subsection (c), to include vaccines recommended by the Centers for Disease Control and Prevention for routine administration in pregnant women and the information described in subparagraphs (B) and (C) of paragraph (2) with respect to such vaccines.".

(2) PETITION CONTENT.—Section 2111 of the Public Health Service Act (42 U.S.C. 300aa-11) is amended by adding at the end the following:

"(f) MATERNAL IMMUNIZATION.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, for purposes of this subtitle, both a woman who received a covered vaccine while pregnant and any child who was in utero at the time such woman received the vaccine shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine.

"(2) DEFINITION.—As used in this subsection, the term 'child' shall have the meaning given that term by subsections (a) and (b) of section 8 of title 1, United States Code, except that, for purposes of this subsection, such section 8 shall be applied as if the term 'include' in subsection (a) of such section were replaced with the term 'mean'.".

(3) PETITIONERS.—Section 2111(b)(2) of the Public Health Service Act (42 U.S.C. 300aa-11(b)(2)) is amended by adding "A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine." at the end.

Subtitle J—Technical Corrections

SEC. 3101. TECHNICAL CORRECTIONS.

(a) FFDCA.—

(1) REFERENCES.—Except as otherwise expressly provided, whenever in this subsection an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to that section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(2) AMENDMENTS.—

(A) PROHIBITED ACTS.—Section 301(r) (21 U.S.C. 331(r)) is amended by inserting ", drug," after "device" each place the term appears.

(B) NEW DRUGS.—Section 505 (21 U.S.C. 355) is amended—

(i) in subsection (d), in the last sentence, by striking "premarket approval" and inserting "marketing approval"; and

(ii) in subsection (q)(5)(A), by striking "subsection (b)(2) or (j) of the Act or 351(k)" and inserting "subsection (b)(2) or (j) of this section or section 351(k)".

(C) RISK EVALUATION AND MITIGATION STRATEGIES.—Section 505-1(h)(21 U.S.C. 355-1(h)) is amended—

(i) in paragraph (2)(A)(iii)—

(I) in the clause heading, by striking "label" and inserting "labeling";

(II) by striking "label" each place the term appears and inserting "labeling"; and

(III) by striking "sponsor" and inserting "responsible person"; and

(ii) in paragraph (8), by striking "and (7)." and inserting "and (7)".

(D) PEDIATRIC STUDY PLANS.—Section 505B (21 U.S.C. 355c) is amended—

(i) in subsection (e)—

(I) in paragraph (2)—

(aa) in subparagraph (A), by inserting "study" after "initial pediatric" each place the term appears; and

(bb) in subparagraph (B), in the subparagraph heading, by striking "**initial plan**" and inserting "**initial pediatric study plan**";

(II) in paragraph (5), in the paragraph heading, by inserting "**agreed initial pediatric study**" before "**plan**"; and

(III) in paragraph (6), by striking "agreed initial pediatric plan" and inserting "agreed initial pediatric study plan"; and

(ii) in subsection (f)(1), by inserting "and any significant amendments to such plans," after "agreed initial pediatric study plans,".

(E) DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF LIVE-SAVING DRUGS.—Section 506C (21 U.S.C. 356c) is amended—

(i) in subsection (c), by striking "discontinuation" and inserting "discontinuance"; and

(ii) in subsection (g)(1), by striking "section 505(j) that could help" and inserting "section 505(j), that could help".

(F) ANNUAL REPORTING ON DRUG SHORTAGES.—Section 506C-1(a) (21 U.S.C. 331(a)) is amended, in the matter before paragraph (1)—

(i) by striking "Not later than the end of calendar year 2013, and not later than the end of each calendar year thereafter," and inserting "Not later than March 31 of each calendar year,"; and

(ii) by inserting ", with respect to the preceding calendar year," after "a report".

(G) DRUG SHORTAGE LIST.—Section 506E(b)(3)(E) (21 U.S.C. 356e(b)(3)(E)) is amended by striking "discontinuation" and inserting "discontinuance".

(H) INSPECTIONS OF ESTABLISHMENTS.—Section 510(h) (21 U.S.C. 360(h)) is amended—

(i) in paragraph (4), in the matter preceding subparagraph (A), by striking "establishing the risk-based scheduled" and inserting "establishing a risk-based schedule"; and

(ii) in paragraph (6)—

(I) in subparagraph (A), by striking "fiscal" and inserting "calendar" each place the term appears; and

(II) in subparagraph (B), by striking "an active ingredient of a drug, a finished drug product, or an excipient of a drug" and inserting "an active ingredient of a drug or a finished drug product".

(I) CLASSIFICATION OF DEVICES INTENDED FOR HUMAN USE.—Section 513(f)(2)(A) (21 U.S.C. 360c(f)(2)(A)) is amended—

(i) in clause (i), by striking "within 30 days"; and

(ii) in clause (iv), by striking "low-moderate" and inserting "low to moderate".

(J) PREMARKET APPROVAL.—Section 515(a)(1) (21 U.S.C. 360e(a)(1)) is amended by striking "subject to a an order" and inserting "subject to an order".

(K) PROGRAM TO IMPROVE THE DEVICE RECALL SYSTEM.—Section 518A (21 U.S.C. 360h-1) is amended—

(i) by striking subsection (c); and

(ii) by redesignating subsection (d) as subsection (c).

(L) UNIQUE DEVICE IDENTIFIER.—Section 519(f) (21 U.S.C. 360i(f)) is amended by striking "and life sustaining" and inserting "or life sustaining".

(M) PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.—Section 524(c)(4)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n(c)(4)(A)) is amended by striking "Services Act" and inserting "Service Act".

(N) PRIORITY REVIEW FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS.—Section 524A (21 U.S.C. 360n-1) is amended—

(i) by striking "If the Secretary" and inserting the following:

"(a) IN GENERAL.—If the Secretary";

(ii) by striking "any" and inserting "the first"; and

(iii) by adding at the end the following:

"(b) CONSTRUCTION.—Nothing in this section shall prohibit the Secretary from giving priority review to a human drug application or efficacy supplement submitted for approval under section 505(b) that otherwise meets the criteria for the Secretary to grant priority review.".

(O) CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.—Section 569(a)(2)(A) (21 U.S.C. 360bbb-8(a)(2)(A)) is amended, in the first sentence, by striking "subsection (c)" and inserting "subsection (b)".

(P) OPTIMIZING GLOBAL CLINICAL TRIALS.—Section 569A(c) (21 U.S.C. 360bbb-8a(c)) is amended by inserting "or under the Public Health Service Act" after "this Act".

(Q) USE OF CLINICAL INVESTIGATION DATA FROM OUTSIDE THE UNITED STATES.—Section 569B (21 U.S.C. 360bbb-8b) is amended by striking "drug or device" and inserting "drug, biological product, or device" each place the term appears.

(R) MEDICAL GASES DEFINITIONS.—Section 575(1)(H) (21 U.S.C. 360ddd(1)(H)) is amended—

(i) by inserting "for a new drug" after "any period of exclusivity"; and

(ii) by inserting "or any period of exclusivity for a new animal drug under section 512(c)(2)(F)," after "section 505A,".

(S) REGULATION OF MEDICAL GASES.—Section 576(a) (21 U.S.C. 360ddd-1(a)) is amended—

(i) in the matter preceding subparagraph (A) of paragraph (1), by inserting "who seeks to initially introduce or deliver for introduction a designated medical gas into interstate commerce" after "any person"; and

(ii) in paragraph (3)—

(I) in subparagraph (A)—

(aa) in clause (i)(VIII), by inserting "for a new drug" after "any period of exclusivity"; and

(bb) in clause (ii), in the matter preceding subclause (I), by inserting "the" before "final use"; and

(II) in subparagraph (B)—

(aa) in clause (i), by inserting "for a new drug" after "any period of exclusivity"; and

(bb) in clause (ii), by inserting a comma after "drug product".

(T) INAPPLICABILITY OF DRUG FEES TO DESIGNATED MEDICAL GASES.—Section 577 (21 U.S.C. 360ddd-2) is amended by inserting "or 740(a)" after "section 736(a)".

(U) CONFLICTS OF INTEREST.—Section 712(e)(1)(B) (21 U.S.C. 379d-1(e)(1)(B)) is amended by striking "services" and inserting "service".

(V) AUTHORITY TO ASSESS AND USE BIOSIMILAR BIOLOGICAL PRODUCT FEES.—Section 744H(a) (21 U.S.C. 379j-52(a)) is amended—

(i) in paragraph (1)(A)(v), by striking "Biosimilars User Fee Act of 2012" and inserting "Biosimilar User Fee Act of 2012"; and

(ii) in paragraph (2)(B), by striking "Biosimilars User Fee Act of 2012" and inserting "Biosimilar User Fee Act of 2012".

(W) REGISTRATION OF COMMERCIAL IMPORTERS.—

(i) AMENDMENT.—Section 801(s)(2) (21 U.S.C. 381(s)(2)) is amended by adding at the end the following:

"(D) EFFECTIVE DATE.—In establishing the effective date of the regulations under subparagraph (A), the Secretary shall, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, as determined appropriate by the Secretary of Health and Human Services, provide a reasonable period of time for an importer of a drug to comply with good importer practices, taking into account differences among importers and types of imports, including based on the level of risk posed by the imported product.".

(ii) CONFORMING AMENDMENT.—Section 714 of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144; 126 Stat. 1074) is amended by striking subsection (d).

(X) RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.—Section 809(a)(2) (21 U.S.C. 384e(a)(2)) is amended by striking "conduction" and inserting "conducting".

(b) FDASIA.—

(1) FINDINGS RELATING TO DRUG APPROVAL.—Section 901(a)(1)(A) of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144; 21 U.S.C. 356 note) is amended by striking "serious and life-threatening diseases" and inserting "serious or life-threatening diseases".

(2) REPORTING OF INCLUSION OF DEMOGRAPHIC SUBGROUPS.—Section 907 of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144; 126 Stat. 1092, 1093) is amended—

(A) in the section heading, by striking "**biologics**" in the heading and inserting "**biological products**"; and

(B) in subsection (a)(2)(B), by striking "applications for new drug applications" and inserting "new drug applications".

(3) COMBATING PRESCRIPTION DRUG ABUSE.—Section 1122 of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144; 126 Stat. 1112, 1113) is amended—

(A) in subsection (a)(2), by striking "dependance" and inserting "dependence"; and

(B) in subsection (c), by striking "promulgate" and inserting "issue".

SEC. 3102. COMPLETED STUDIES.

The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 505(k)(5) (21 U.S.C. 355(k)(5))—

(A) in subparagraph (A), by inserting "and" after the semicolon;

(B) by striking subparagraph (B); and

(C) by redesignating subparagraph (C) as subparagraph (B);

(2) in section 505A (21 U.S.C. 355a), by striking subsection (p);

(3) in section 505B (21 U.S.C. 355c)—

(A) by striking subsection (l); and

(B) by redesignating subsection (m) as subsection (l); and

(4) in section 523 (21 U.S.C. 360m), by striking subsection (d).

TITLE IV—DELIVERY

SEC. 4001. ASSISTING DOCTORS AND HOSPITALS IN IMPROVING QUALITY OF CARE FOR PATIENTS.

(a) IN GENERAL.—The Health Information Technology for Economic and Clinical Health Act (title XIII of division A of Public Law 111-5) is amended—

(1) by adding at the end of part 1 of subtitle A the following:

"SEC. 13103. [42 U.S.C. 300jj-11 note]

[42 U.S.C. 300jj-11 note] ASSISTING DOCTORS AND HOSPITALS IN IMPROVING QUALITY OF CARE FOR PATIENTS

"(a) REDUCTION IN BURDENS GOAL.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary'), in consultation with providers of health services, health care suppliers of services, health care payers, health professional societies, health information technology developers, health care quality organizations, health care accreditation organizations, public health entities, States, and other appropriate entities, shall, in accordance with subsection (b)—

"(1) establish a goal with respect to the reduction of regulatory or administrative burdens (such as documentation requirements) relating to the use of electronic health records;

"(2) develop a strategy for meeting the goal established under paragraph (1); and

"(3) develop recommendations for meeting the goal established under paragraph (1).

"(b) STRATEGY AND RECOMMENDATIONS.—

"(1) IN GENERAL.—To achieve the goal established under subsection (a)(1), the Secretary, in consultation with the entities described in such subsection, shall, not later than 1 year after the date of enactment of the 21st Century Cures Act, develop a strategy and recommendations to meet the goal in accordance with this subsection.

"(2) STRATEGY.—The strategy developed under paragraph (1) shall address the regulatory and administrative burdens (such as documentation requirements) relating to the use of electronic health records. Such strategy shall include broad public comment and shall prioritize—

"(A)(i) incentives for meaningful use of certified EHR technology for eligible professionals and hospitals under sections 1848(a)(7) and 1886(b)(3)(B)(ix), respectively, of the Social Security Act (42 U.S.C. 1395w-4(a)(7), 1395ww(b)(3)(B)(ix));

"(ii) the program for making payments under section 1903(a)(3)(F) of the Social Security Act (42 U.S.C. 1396b(a)(3)(F)) to encourage the adoption and use of certified EHR technology by Medicaid providers;

"(iii) the Merit-based Incentive Payment System under section 1848(q) of the Social Security Act (42 U.S.C. 1395w-4(q));

"(iv) alternative payment models (as defined in section 1833(z)(3)(C) of the Social Security Act (42 U.S.C. 1395l(z)(3)(C));

"(v) the Hospital Value-Based Purchasing Program under section 1886(o) of the Social Security Act (42 U.S.C. 1395ww(o)); and

"(vi) other value-based payment programs, as the Secretary determines appropriate;

"(B) health information technology certification;

"(C) standards and implementation specifications, as appropriate;

"(D) activities that provide individuals access to their electronic health information;

"(E) activities related to protecting the privacy of electronic health information;

"(F) activities related to protecting the security of electronic health information;

"(G) activities related to facilitating health and clinical research;

"(H) activities related to public health;

"(I) activities related to aligning and simplifying quality measures across Federal programs and other payers;

"(J) activities related to reporting clinical data for administrative purposes; and

"(K) other areas, as the Secretary determines appropriate.

"(3) RECOMMENDATIONS.—The recommendations developed under paragraph (1) shall address—

"(A) actions that improve the clinical documentation experience;

"(B) actions that improve patient care;

"(C) actions to be taken by the Secretary and by other entities; and

"(D) other areas, as the Secretary determines appropriate, to reduce the reporting burden required of health care providers.

"(4) FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the development of the goal, strategies, or recommendations described in this section.

"(c) APPLICATION OF CERTAIN REGULATORY REQUIREMENTS.—A physician (as defined in section 1861(r)(1) of the Social Security Act), to the extent consistent with applicable State law, may delegate electronic medical record documentation requirements specified in regulations promulgated by the Centers for Medicare & Medicaid Services to a person performing a scribe function who is not such physician if such physician has signed and verified the documentation."; and

(2) in the table of contents in section 13001(b), by inserting after the item relating to section 13102 the following:

"13103. Assisting doctors and hospitals in improving the quality and care for patients.".

(b) CERTIFICATION OF HEALTH INFORMATION TECHNOLOGY FOR MEDICAL SPECIALTIES AND SITES OF SERVICE.—Section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj-11(c)(5)) is amended by adding at the end the following:

"(C) HEALTH INFORMATION TECHNOLOGY FOR MEDICAL SPECIALTIES AND SITES OF SERVICE.—

"(i) IN GENERAL.—The National Coordinator shall encourage, keep, or recognize, through existing authorities, the voluntary certification of health information technology under the program developed under subparagraph (A) for use in medical specialties and sites of service for which no such technology is available or where more technological advancement or integration is needed.

"(ii) SPECIFIC MEDICAL SPECIALTIES.—The Secretary shall accept public comment on specific medical specialties and sites of service, in addition to those described in clause (i), for the purpose of selecting additional specialties and sites of service as necessary.

"(iii) HEALTH INFORMATION TECHNOLOGY FOR PEDIATRICS.—Not later than 18 months after the date of enactment of the 21st Century Cures Act, the Secretary, in consultation with relevant stakeholders, shall make recommendations for the voluntary certification of health information technology for use by pediatric health providers to support the health care of children. Not later than 2 years after the date of enactment of the 21st Century Cures Act, the Secretary shall adopt certification criteria under section 3004 to support the voluntary certification of health information technology for use by pediatric health providers to support the health care of children.".

(c) MEANINGFUL USE STATISTICS.—

(1) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the HIT Advisory Committee of the Office of the National Coordinator for Health Information Technology, a report concerning attestation statistics for the Medicare and Medicaid EHR Meaningful Use Incentive programs to assist in informing standards adoption and related practices. Such statistics shall include attestation information delineated by State, including, to the extent practicable, the number of providers who did not meet the minimum criteria necessary to attest for the Medicare and Medicaid EHR Meaningful Use Incentive programs for a calendar year, and shall be made publicly available on the Internet website of the Secretary on at least a quarterly basis.

(2) AUTHORITY TO ALTER FORMAT.—The Secretary of Health and Human Services may alter the format of the reports on the attestation of eligible health care professionals following the first performance year of the Merit-based Incentive Payment System to account for changes arising from the implementation of such payment system.

SEC. 4002. TRANSPARENT REPORTING ON USABILITY, SECURITY, AND FUNCTIONALITY.

(a) ENHANCEMENTS TO CERTIFICATION.—Section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj-11), as amended by section 4001(b), is further amended by adding at the end the following:

"(D) CONDITIONS OF CERTIFICATION.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary, through notice and comment rulemaking, shall require, as a condition of certification and maintenance of certification for programs maintained or recognized under this paragraph, consistent with other conditions and requirements under this title, that the health information technology developer or entity—

"(i) does not take any action that constitutes information blocking as defined in section 3022(a);

"(ii) provides assurances satisfactory to the Secretary that such developer or entity, unless for legitimate purposes specified by the Secretary, will not take any action described in clause (i) or any other action that may inhibit the appropriate exchange, access, and use of electronic health information;

"(iii) does not prohibit or restrict communication regarding—

"(I) the usability of the health information technology;

"(II) the interoperability of the health information technology;

"(III) the security of the health information technology;

"(IV) relevant information regarding users' experiences when using the health information technology;

"(V) the business practices of developers of health information technology related to exchanging electronic health information; and

"(VI) the manner in which a user of the health information technology has used such technology;

"(iv) has published application programming interfaces and allows health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces or successor technology or standards, as provided for under applicable law, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws;

"(v) has successfully tested the real world use of the technology for interoperability (as defined in section 3000) in the type of setting in which such technology would be marketed;

"(vi) provides to the Secretary an attestation that the developer or entity—

"(I) has not engaged in any of the conduct described in clause (i);

"(II) has provided assurances satisfactory to the Secretary in accordance with clause (ii);

"(III) does not prohibit or restrict communication as described in clause (iii);

"(IV) has published information in accordance with clause (iv);

"(V) ensures that its technology allows for health information to be exchanged, accessed, and used, in the manner described in clause (iv); and

"(VI) has undertaken real world testing as described in clause (v); and

"(vii) submits reporting criteria in accordance with section 3009A(b).".

"(E) COMPLIANCE WITH CONDITIONS OF CERTIFICATION.—The Secretary may encourage compliance with the conditions of certification described in subparagraph (D) and take action to discourage noncompliance, as appropriate.".

(b) EHR SIGNIFICANT HARDSHIP EXCEPTION.—

(1) APPLICATION TO ELIGIBLE PROFESSIONALS.—

(A) IN CASE OF DECERTIFICATION.—Section 1848(a)(7)(B) of the Social Security Act (42 U.S.C. 1395w-4(a)(7)(B)) is amended by inserting after the first sentence the following new sentence: "The Secretary shall exempt an eligible professional from the application of the payment adjustment under subparagraph (A) with respect to a year, subject to annual renewal, if the Secretary determines that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by such professional has been decertified under a program kept or recognized pursuant to section 3001(c)(5) of the Public Health Service Act.".

(B) CONTINUED APPLICATION UNDER MIPS.—Section 1848(o)(2)(D) of the Social Security Act (42 U.S.C. 1395w-4(o)(2)(D)) is amended by adding at the end the following new sentence: "The provisions of subparagraphs (B) and (D) of subsection (a)(7), shall apply to assessments of MIPS eligible professionals under subsection (q) with respect to the performance category described in subsection (q)(2)(A)(iv) in an appropriate manner which may be similar to the manner in which such provisions apply with respect to payment adjustments made under subsection (a)(7)(A).".

(2) APPLICATION TO ELIGIBLE HOSPITALS.—Section 1886(b)(3)(B)(ix)(II) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(ix)(II)) is amended by inserting after the first sentence the following new sentence: "The Secretary shall exempt an eligible hospital from the application of the payment adjustment under subclause (I) with respect to a fiscal year, subject to annual renewal, if the Secretary determines that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used

by such hospital is decertified under a program kept or recognized pursuant to section 3001(c)(5) of the Public Health Service Act.".

(c) ELECTRONIC HEALTH RECORD REPORTING PROGRAM.—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:

"SEC. 3009A. ELECTRONIC HEALTH RECORD REPORTING PROGRAM

"(a) REPORTING CRITERIA.—

"(1) CONVENING OF STAKEHOLDERS.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall convene stakeholders, as described in paragraph (2), for the purpose of developing the reporting criteria in accordance with paragraph (3).

"(2) DEVELOPMENT OF REPORTING CRITERIA.—The reporting criteria under this subsection shall be developed through a public, transparent process that reflects input from relevant stakeholders, including—

"(A) health care providers, including primary care and specialty care health care professionals;

"(B) hospitals and hospital systems;

"(C) health information technology developers;

"(D) patients, consumers, and their advocates;

"(E) data sharing networks, such as health information exchanges;

"(F) authorized certification bodies and testing laboratories;

"(G) security experts;

"(H) relevant manufacturers of medical devices;

"(I) experts in health information technology market economics;

"(J) public and private entities engaged in the evaluation of health information technology performance;

"(K) quality organizations, including the consensus based entity described in section 1890 of the Social Security Act;

"(L) experts in human factors engineering and the measurement of user-centered design; and

"(M) other entities or individuals, as the Secretary determines appropriate.

"(3) CONSIDERATIONS FOR REPORTING CRITERIA.—The reporting criteria developed under this subsection—

"(A) shall include measures that reflect categories including—

"(i) security;

"(ii) usability and user-centered design;

"(iii) interoperability;

"(iv) conformance to certification testing; and

"(v) other categories, as appropriate to measure the performance of electronic health record technology;

"(B) may include categories such as—

"(i) enabling the user to order and view the results of laboratory tests, imaging tests, and other diagnostic tests;

"(ii) submitting, editing, and retrieving data from registries such as clinician-led clinical data registries;

"(iii) accessing and exchanging information and data from and through health information exchanges;

"(iv) accessing and exchanging information and data from medical devices;

"(v) accessing and exchanging information and data held by Federal, State, and local agencies and other applicable entities useful to a health care provider or other applicable user in the furtherance of patient care;

"(vi) accessing and exchanging information from other health care providers or applicable users;

"(vii) accessing and exchanging patient generated information;

"(viii) providing the patient or an authorized designee with a complete copy of their health information from an electronic record in a computable format;

"(ix) providing accurate patient information for the correct patient, including exchanging such information, and avoiding the duplication of patients records; and

"(x) other categories regarding performance, accessibility, as the Secretary determines appropriate; and

"(C) shall be designed to ensure that small and start-up health information technology developers are not unduly disadvantaged by the reporting criteria.

"(4) MODIFICATIONS.—After the reporting criteria have been developed under paragraph (3), the Secretary may convene stakeholders and conduct a public comment period for the purpose of modifying the reporting criteria developed under such paragraph.

"(b) PARTICIPATION.—As a condition of maintaining certification under section 3001(c)(5)(D), a developer of certified electronic health records shall submit to an appropriate recipient of a grant, contract, or agreement under subsection (c)(1) responses to the criteria developed under subsection (a), with respect to all certified technology offered by such developer.

"(c) REPORTING PROGRAM.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall award grants, contracts, or agreements to independent entities on a competitive basis to support the convening of stakeholders as described in subsection (a)(2), collect the information required to be reported in accordance with the criteria established as described subsection (a)(3), and develop and implement a process in accordance with paragraph (5) and report such information to the Secretary.

"(2) APPLICATIONS.—An independent entity that seeks a grant, contract, or agreement under this subsection shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including a description of—

"(A) the proposed method for reviewing and summarizing information gathered based on reporting criteria established under subsection (a);

"(B) if applicable, the intended focus on a specific subset of certified electronic health record technology users, such as health care providers, including primary care, specialty care, and care provided in rural settings; hospitals and hospital systems; and patients, consumers, and patients and consumer advocates;

"(C) the plan for widely distributing reports described in paragraph (6);

"(D) the period for which the grant, contract, or agreement is requested, which may be up to 2 years; and

"(E) the budget for reporting program participation, and whether the eligible independent entity intends to continue participation after the period of the grant, contract, or agreement.

"(3) CONSIDERATIONS FOR INDEPENDENT ENTITIES.—In awarding grants, contracts, and agreements under paragraph (1), the Secretary shall give priority to independent entities with appropriate expertise in health information technology usability, interoperability, and security (especially entities with such expertise in electronic health records) with respect to—

"(A) health care providers, including primary care, specialty care, and care provided in rural settings;

"(B) hospitals and hospital systems; and

"(C) patients, consumers, and patient and consumer advocates.

"(4) LIMITATIONS.—

"(A) ASSESSMENT AND REDETERMINATION.—Not later than 4 years after the date of enactment of the 21st Century Cures Act and every 2 years thereafter, the Secretary, in consultation with stakeholders, shall—

"(i) assess performance of the recipients of the grants, contracts, and agreements under paragraph (1) based on quality and usability of reports described in paragraph (6); and

"(ii) re-determine grants, contracts, and agreements as necessary.

"(B) PROHIBITIONS ON PARTICIPATION.—The Secretary may not award a grant, contract, or cooperative agreement under paragraph (1) to—

"(i) a proprietor of certified health information technology or a business affiliate of such a proprietor;

"(ii) a developer of certified health information technology; or

"(iii) a State or local government agency.

"(5) FEEDBACK.—Based on reporting criteria established under subsection (a), the recipients of grants, contracts, and agreements under paragraph (1) shall develop and implement a process to collect and verify confidential feedback on such criteria from—

"(A) health care providers, patients, and other users of certified electronic health record technology; and

"(B) developers of certified electronic health record technology.

"(6) REPORTS.—

"(A) DEVELOPMENT OF REPORTS.—Each recipient of a grant, contract, or agreement under paragraph (1) shall report on the information reported to such recipient pursuant to subsection (a) and the user feedback collected under paragraph (5) by preparing summary reports and detailed reports of such information.

"(B) DISTRIBUTION OF REPORTS.—Each recipient of a grant, contract, or agreement under paragraph (1) shall submit the reports prepared under subparagraph (A) to the Secretary for public distribution in accordance with subsection (d).

"(d) PUBLICATION.—The Secretary shall distribute widely, as appropriate, and publish, on the Internet website of the Office of the National Coordinator—

"(1) the reporting criteria developed under subsection (a); and

"(2) the summary and detailed reports under subsection (c)(6).

"(e) REVIEW.—Each recipient of a grant, contract, or agreement under paragraph (1) shall develop and implement a process through which participating electronic health record technology developers may review and recommend changes to the reports created under subsection (c)(6) for products developed by such developer prior to the publication of such report under subsection (d).

"(f) ADDITIONAL RESOURCES.—The Secretary may provide additional resources on the Internet website of the Office of the National Coordinator to better inform consumers of health information technology. Such reports may be carried out through partnerships with private organizations with appropriate expertise.".

(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $15,000,000 for purposes of carrying out subparagraph (D) of section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj-11) (as added by subsection (a)) and section 3009A of the Public Health Service Act (as added by subsection (b)), including for purposes of administering any contracts, grants, or agreements, to remain available until expended.

SEC. 4003. INTEROPERABILITY.

(a) DEFINITION.—Section 3000 of the Public Health Service Act (42 U.S.C. 300jj) is amended—

(1) by redesignating paragraphs (10) through (14), as paragraphs (11) through (15), respectively; and

(2) by inserting after paragraph (9) the following:

"(10) INTEROPERABILITY.—The term 'interoperability', with respect to health information technology, means such health information technology that—

"(A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;

"(B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and

"(C) does not constitute information blocking as defined in section 3022(a).".

(b) SUPPORT FOR INTEROPERABLE NETWORK EXCHANGE.—Section 3001(c) of the Public Health Service Act (42 U.S.C. 300jj-11(c)) is amended by adding at the end the following:

"(9) SUPPORT FOR INTEROPERABLE NETWORKS EXCHANGE.—

"(A) IN GENERAL.—The National Coordinator shall, in collaboration with the National Institute of Standards and Technology and other relevant agencies within the Department of Health and Human Services, for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally. Such convention may occur at a frequency determined appropriate by the Secretary.

"(B) ESTABLISHING A TRUSTED EXCHANGE FRAMEWORK.—

"(i) IN GENERAL.—Not later than 6 months after the date of enactment of the 21st Century Cures Act, the National Coordinator shall convene appropriate public and private stakeholders to develop or support a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks. The common agreement may include—

"(I) a common method for authenticating trusted health information network participants;

"(II) a common set of rules for trusted exchange;

"(III) organizational and operational policies to enable the exchange of health information among networks, including minimum conditions for such exchange to occur; and

"(IV) a process for filing and adjudicating noncompliance with the terms of the common agreement.

"(ii) TECHNICAL ASSISTANCE.—The National Coordinator, in collaboration with the National Institute of Standards and Technology, shall provide technical assistance on how to implement the trusted exchange framework and common agreement under this paragraph.

"(iii) PILOT TESTING.—The National Coordinator, in consultation with the National Institute of Standards and Technology, shall provide for the pilot testing of the trusted exchange framework and common agreement established or supported under this subsection (as authorized under section 13201 of the Health Information Technology for Economic and Clinical

Health Act). The National Coordinator, in consultation with the National Institute of Standards and Technology, may delegate pilot testing activities under this clause to independent entities with appropriate expertise.

"(C) PUBLICATION OF A TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT.—Not later than 1 year after convening stakeholders under subparagraph (A), the National Coordinator shall publish on its public Internet website, and in the Federal register, the trusted exchange framework and common agreement developed or supported under subparagraph (B). Such trusted exchange framework and common agreement shall be published in a manner that protects proprietary and security information, including trade secrets and any other protected intellectual property.

"(D) DIRECTORY OF PARTICIPATING HEALTH INFORMATION NETWORKS.—

"(i) IN GENERAL.—Not later than 2 years after convening stakeholders under subparagraph (A), and annually thereafter, the National Coordinator shall publish on its public Internet website a list of the health information networks that have adopted the common agreement and are capable of trusted exchange pursuant to the common agreement developed or supported under paragraph (B).

"(ii) PROCESS.—The Secretary shall, through notice and comment rulemaking, establish a process for health information networks that voluntarily elect to adopt the trusted exchange framework and common agreement to attest to such adoption of the framework and agreement.

"(E) APPLICATION OF THE TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT.—As appropriate, Federal agencies contracting or entering into agreements with health information exchange networks may require that as each such network upgrades health information technology or trust and operational practices, such network may adopt, where available, the trusted exchange framework and common agreement published under subparagraph (C).

"(F) RULE OF CONSTRUCTION.—

"(i) GENERAL ADOPTION.—Nothing in this paragraph shall be construed to require a health information network to adopt the trusted exchange framework or common agreement.

"(ii) ADOPTION WHEN EXCHANGE OF INFORMATION IS WITHIN NETWORK.—Nothing in this paragraph shall be construed to require a health information network to adopt the trusted exchange framework or common agreement for the exchange of electronic health information between participants of the same network.

"(iii) EXISTING FRAMEWORKS AND AGREEMENTS.—The trusted exchange framework and common agree-

ment published under subparagraph (C) shall take into account existing trusted exchange frameworks and agreements used by health information networks to avoid the disruption of existing exchanges between participants of health information networks.

"(iv) APPLICATION BY FEDERAL AGENCIES.—Notwithstanding clauses (i), (ii), and (iii), Federal agencies may require the adoption of the trusted exchange framework and common agreement published under subparagraph (C) for health information exchanges contracting with or entering into agreements pursuant to subparagraph (E).

"(v) CONSIDERATION OF ONGOING WORK.—In carrying out this paragraph, the Secretary shall ensure the consideration of activities carried out by public and private organizations related to exchange between health information exchanges to avoid duplication of efforts.".

(c) [42 U.S.C. 300jj-11 note] [42 U.S.C. 300jj-11 note] PROVIDER DIGITAL CONTACT INFORMATION INDEX.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the "Secretary") shall, directly or through a partnership with a private entity, establish a provider digital contact information index to provide digital contact information for health professionals and health facilities.

(2) USE OF EXISTING INDEX.—In establishing the initial index under paragraph (1), the Secretary may utilize an existing provider directory to make such digital contact information available.

(3) CONTACT INFORMATION.—An index established under this subsection shall ensure that contact information is available at the individual health care provider level and at the health facility or practice level.

(4) RULE OF CONSTRUCTION.—

(A) IN GENERAL.—The purpose of this subsection is to encourage the exchange of electronic health information by providing the most useful, reliable, and comprehensive index of providers possible. In furthering such purpose, the Secretary shall include all health professionals and health facilities applicable to provide a useful, reliable, and comprehensive index for use in the exchange of health information.

(B) LIMITATION.—In no case shall exclusion from the index of providers be used as a measure to achieve objectives other the objectives described in subparagraph (A).

(d) STANDARDS DEVELOPMENT ORGANIZATIONS.—Section 3004 of the Public Health Service Act (42 U.S.C. 300jj-14) is amended by adding at the end the following:

"(c) DEFERENCE TO STANDARDS DEVELOPMENT ORGANIZATIONS.—In adopting and implementing standards under this section, the Secretary shall give deference to standards published by

standards development organizations and voluntary consensus-based standards bodies.".

(e) HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE.—

(1) IN GENERAL.—Title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.) is amended by striking sections 3002 (42 U.S.C. 300jj-12) and 3003 (42 U.S.C. 300jj-13) and inserting the following:

"SEC. 3002. [42 U.S.C. 300jj-12]

[42 U.S.C. 300jj-12] HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE

"(a) ESTABLISHMENT.—There is established a Health Information Technology Advisory Committee (referred to in this section as the 'HIT Advisory Committee') to recommend to the National Coordinator, consistent with the implementation of the strategic plan described in section 3001(c)(3), policies, and, for purposes of adoption under section 3004, standards, implementation specifications, and certification criteria, relating to the implementation of a health information technology infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information. Such Committee shall serve to unify the roles of, and replace, the HIT Policy Committee and the HIT Standards Committee, as in existence before the date of the enactment of the 21st Century Cures Act.

"(b) DUTIES.—

"(1) RECOMMENDATIONS ON POLICY FRAMEWORK TO ADVANCE AN INTEROPERABLE HEALTH INFORMATION TECHNOLOGY INFRASTRUCTURE.—

"(A) IN GENERAL.—The HIT Advisory Committee shall recommend to the National Coordinator a policy framework for adoption by the Secretary consistent with the strategic plan under section 3001(c)(3) for advancing the target areas described in this subsection. Such policy framework shall seek to prioritize achieving advancements in the target areas specified in subparagraph (B) of paragraph (2) and may, to the extent consistent with this section, incorporate policy recommendations made by the HIT Policy Committee, as in existence before the date of the enactment of the 21st Century Cures Act.

"(B) UPDATES.—The HIT Advisory Committee shall propose updates to such recommendations to the policy framework and make new recommendations, as appropriate.

"(2) GENERAL DUTIES AND TARGET AREAS.—

"(A) IN GENERAL.—The HIT Advisory Committee shall recommend to the National Coordinator for purposes of adoption under section 3004, standards, implementation specifications, and certification criteria and an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria. Such recommendations shall include recommended standards, architectures, and software schemes for access to electronic individually identifiable health information

across disparate systems including user vetting, authentication, privilege management, and access control.

"(B) PRIORITY TARGET AREAS.—For purposes of this section, the HIT Advisory Committee shall make recommendations under subparagraph (A) with respect to at least each of the following target areas:

"(i) Achieving a health information technology infrastructure, nationally and locally, that allows for the electronic access, exchange, and use of health information, including through technology that provides accurate patient information for the correct patient, including exchanging such information, and avoids the duplication of patient records.

"(ii) The promotion and protection of privacy and security of health information in health information technology, including technologies that allow for an accounting of disclosures and protections against disclosures of individually identifiable health information made by a covered entity for purposes of treatment, payment, and health care operations (as such terms are defined for purposes of the regulation promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996), including for the segmentation and protection from disclosure of specific and sensitive individually identifiable health information with the goal of minimizing the reluctance of patients to seek care.

"(iii) The facilitation of secure access by an individual to such individual's protected health information and access to such information by a family member, caregiver, or guardian acting on behalf of a patient, including due to age-related and other disability, cognitive impairment, or dementia.

"(iv) Subject to subparagraph (D), any other target area that the HIT Advisory Committee identifies as an appropriate target area to be considered under this subparagraph.

"(C) ADDITIONAL TARGET AREAS.—For purposes of this section, the HIT Advisory Committee may make recommendations under subparagraph (A), in addition to areas described in subparagraph (B), with respect to any of the following areas:

"(i) The use of health information technology to improve the quality of health care, such as by promoting the coordination of health care and improving continuity of health care among health care providers, reducing medical errors, improving population health, reducing chronic disease, and advancing research and education.

"(ii) The use of technologies that address the needs of children and other vulnerable populations.

"(iii) The use of electronic systems to ensure the comprehensive collection of patient demographic data,

including at a minimum, race, ethnicity, primary language, and gender information.

"(iv) The use of self-service, telemedicine, home health care, and remote monitoring technologies.

"(v) The use of technologies that meet the needs of diverse populations.

"(vi) The use of technologies that support—

"(I) data for use in quality and public reporting programs;

"(II) public health; or

"(III) drug safety.

"(vii) The use of technologies that allow individually identifiable health information to be rendered unusable, unreadable, or indecipherable to unauthorized individuals when such information is transmitted in a health information network or transported outside of the secure facilities or systems where the disclosing covered entity is responsible for security conditions.

"(viii) The use of a certified health information technology for each individual in the United States.

"(D) AUTHORITY FOR TEMPORARY ADDITIONAL PRIORITY TARGET AREAS.—For purposes of subparagraph (B)(iv), the HIT Advisory Committee may identify an area to be considered for purposes of recommendations under this subsection as a target area described in subparagraph (B) if—

"(i) the area is so identified for purposes of responding to new circumstances that have arisen in the health information technology community that affect the interoperability, privacy, or security of health information, or affect patient safety; and

"(ii) at least 30 days prior to treating such area as if it were a target area described in subparagraph (B), the National Coordinator provides adequate notice to Congress of the intent to treat such area as so described.

"(E) FOCUS OF COMMITTEE WORK.—It is the sense of Congress that the HIT Advisory Committee shall focus its work on the priority areas described in subparagraph (B) before proceeding to other work under subparagraph (C).

"(3) RULES RELATING TO RECOMMENDATIONS FOR STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—

"(A) IN GENERAL.—The HIT Advisory Committee shall recommend to the National Coordinator standards, implementation specifications, and certification criteria described in subsection (a), which may include standards, implementation specifications, and certification criteria that have been developed, harmonized, or recognized by the HIT Advisory Committee or predecessor committee. The HIT Advisory Committee shall update such recommendations and make new recommendations as appropriate, including in response to a notification sent under section 3004(a)(2)(B). Such recommendations shall be consistent with the latest recommendations made by the Committee.

"(B) HARMONIZATION.—The HIT Advisory Committee may recognize harmonized or updated standards from an entity or entities for the purpose of harmonizing or updating standards and implementation specifications in order to achieve uniform and consistent implementation of the standards and implementation specification.

"(C) PILOT TESTING OF STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—In the development, harmonization, or recognition of standards and implementation specifications, the HIT Advisory Committee for purposes of recommendations under paragraph (2)(B), shall, as appropriate, provide for the testing of such standards and specifications by the National Institute for Standards and Technology under section 13201(a) of the Health Information Technology for Economic and Clinical Health Act.

"(D) CONSISTENCY.—The standards, implementation specifications, and certification criteria recommended under paragraph (2)(B) shall be consistent with the standards for information transactions and data elements adopted pursuant to section 1173 of the Social Security Act.

"(E) SPECIAL RULE RELATED TO INTEROPERABILITY.—Any recommendation made by the HIT Advisory Committee after the date of the enactment of this subparagraph with respect to interoperability of health information technology shall be consistent with interoperability as described in section 3000.

"(4) FORUM.—The HIT Advisory Committee shall serve as a forum for the participation of a broad range of stakeholders with specific expertise in policies, including technical expertise, relating to the matters described in paragraphs (1), (2), and (3) to provide input on the development, harmonization, and recognition of standards, implementation specifications, and certification criteria necessary for the development and adoption of health information technology infrastructure nationally and locally that allows for the electronic access, exchange, and use of health information.

"(5) SCHEDULE.—Not later than 30 days after the date on which the HIT Advisory Committee first meets, such HIT Advisory Committee shall develop a schedule for the assessment of policy recommendations developed under paragraph (1). The HIT Advisory Committee shall update such schedule annually. The Secretary shall publish such schedule in the Federal Register.

"(6) PUBLIC INPUT.—The HIT Advisory Committee shall conduct open public meetings and develop a process to allow for public comment on the schedule described in paragraph (5) and recommendations described in this subsection. Under such process comments shall be submitted in a timely manner after the date of publication of a recommendation under this subsection.

"(c) MEASURED PROGRESS IN ADVANCING PRIORITY AREAS.—

"(1) IN GENERAL.—For purposes of this section, the National Coordinator, in collaboration with the Secretary, shall establish, and update as appropriate, objectives and bench-

marks for advancing and measuring the advancement of the priority target areas described in subsection (b)(2)(B).

"(2) ANNUAL PROGRESS REPORTS ON ADVANCING INTEROPERABILITY.—

"(A) IN GENERAL.—The HIT Advisory Committee, in consultation with the National Coordinator, shall annually submit to the Secretary and Congress a report on the progress made during the preceding fiscal year in—

"(i) achieving a health information technology infrastructure, nationally and locally, that allows for the electronic access, exchange, and use of health information; and

"(ii) meeting the objectives and benchmarks described in paragraph (1).

"(B) CONTENT.—Each such report shall include, for a fiscal year—

"(i) a description of the work conducted by the HIT Advisory Committee during the preceding fiscal year with respect to the areas described in subsection (b)(2)(B);

"(ii) an assessment of the status of the infrastructure described in subparagraph (A), including the extent to which electronic health information is appropriately and readily available to enhance the access, exchange, and the use of electronic health information between users and across technology offered by different developers;

"(iii) the extent to which advancements have been achieved with respect to areas described in subsection (b)(2)(B);

"(iv) an analysis identifying existing gaps in policies and resources for—

"(I) achieving the objectives and benchmarks established under paragraph (1); and

"(II) furthering interoperability throughout the health information technology infrastructure;

"(v) recommendations for addressing the gaps identified in clause (iii); and

"(vi) a description of additional initiatives as the HIT Advisory Committee and National Coordinator determine appropriate.

"(3) SIGNIFICANT ADVANCEMENT DETERMINATION.—The Secretary shall periodically, based on the reports submitted under this subsection, review the target areas described in subsection (b)(2)(B), and, based on the objectives and benchmarks established under paragraph (1), the Secretary shall determine if significant advancement has been achieved with respect to such an area. Such determination shall be taken into consideration by the HIT Advisory Committee when determining to what extent the Committee makes recommendations for an area other than an area described in subsection (b)(2)(B).

"(d) MEMBERSHIP AND OPERATIONS.—

"(1) IN GENERAL.—The National Coordinator shall take a leading position in the establishment and operations of the HIT Advisory Committee.

"(2) MEMBERSHIP.—The membership of the HIT Advisory Committee shall—

"(A) include at least 25 members, of which—

"(i) no fewer than 2 members are advocates for patients or consumers of health information technology;

"(ii) 3 members are appointed by the Secretary, 1 of whom shall be appointed to represent the Department of Health and Human Services and 1 of whom shall be a public health official;

"(iii) 2 members are appointed by the majority leader of the Senate;

"(iv) 2 members are appointed by the minority leader of the Senate;

"(v) 2 members are appointed by the Speaker of the House of Representatives;

"(vi) 2 members are appointed by the minority leader of the House of Representatives; and

"(vii) such other members are appointed by the Comptroller General of the United States; and

"(B) at least reflect providers, ancillary health care workers, consumers, purchasers, health plans, health information technology developers, researchers, patients, relevant Federal agencies, and individuals with technical expertise on health care quality, system functions, privacy, security, and on the electronic exchange and use of health information, including the use standards for such activity.

"(3) PARTICIPATION.—The members of the HIT Advisory Committee shall represent a balance among various sectors of the health care system so that no single sector unduly influences the recommendations of the Committee.

"(4) TERMS.—

"(A) IN GENERAL.—The terms of the members of the HIT Advisory Committee shall be for 3 years, except that the Secretary shall designate staggered terms of the members first appointed.

"(B) VACANCIES.—Any member appointed to fill a vacancy in the membership of the HIT Advisory Committee that occurs prior to the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has been appointed. A vacancy in the HIT Advisory Committee shall be filled in the manner in which the original appointment was made.

"(C) LIMITS.—Members of the HIT Advisory Committee shall be limited to two 3-year terms, for a total of not to exceed 6 years of service on the Committee.

"(5) OUTSIDE INVOLVEMENT.—The HIT Advisory Committee shall ensure an opportunity for the participation in activities of the Committee of outside advisors, including individuals with expertise in the development of policies and stand-

ards for the electronic exchange and use of health information, including in the areas of health information privacy and security.

"(6) QUORUM.—A majority of the members of the HIT Advisory Committee shall constitute a quorum for purposes of voting, but a lesser number of members may meet and hold hearings.

"(7) CONSIDERATION.—The National Coordinator shall ensure that the relevant and available recommendations and comments from the National Committee on Vital and Health Statistics are considered in the development of policies.

"(8) ASSISTANCE.—For the purposes of carrying out this section, the Secretary may provide or ensure that financial assistance is provided by the HIT Advisory Committee to defray in whole or in part any membership fees or dues charged by such Committee to those consumer advocacy groups and not-for-profit entities that work in the public interest as a party of their mission.

"(e) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.), other than section 14 of such Act, shall apply to the HIT Advisory Committee.

"(f) PUBLICATION.—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 policy recommendations made by the HIT Advisory Committee under this section.".

(2) TECHNICAL AND CONFORMING AMENDMENTS.—Title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.) is amended—

(A) by striking—

(i) "HIT Policy Committee" and "HIT Standards Committee" each place that such terms appear (other than within the term "HIT Policy Committee and the HIT Standards Committee" or within the term "HIT Policy Committee or the HIT Standards Committee") and inserting "HIT Advisory Committee";

(ii) "HIT Policy Committee and the HIT Standards Committee" each place that such term appears and inserting "HIT Advisory Committee"; and

(iii) "HIT Policy Committee or the HIT Standards Committee" each place that such term appears and inserting "HIT Advisory Committee";

(B) in section 3000 (42 U.S.C. 300jj)—

(i) by striking paragraphs (7) and (8) and redesignating paragraphs (9) through (14) as paragraphs (8) through (13), respectively; and

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

"(7) HIT ADVISORY COMMITTEE.—The term 'HIT Advisory Committee' means such Committee established under section 3002(a).";

(C) in section 3001(c) (42 U.S.C. 300jj-11(c))—

(i) in paragraph (1)(A), by striking "under section 3003" and inserting "under section 3002";

(ii) in paragraph (2), by striking subparagraph (B) and inserting the following:

"(B) HIT ADVISORY COMMITTEE.—The National Coordinator shall be a leading member in the establishment and operations of the HIT Advisory Committee and shall serve as a liaison between that Committee and the Federal Government.";

(D) in section 3004(b)(3) (42 U.S.C. 300jj-14(b)(3)), by striking "3003(b)(2)" and inserting "3002(b)(4)";

(E) in section 3007(b) (42 U.S.C. 300jj-17(b)), by striking "3003(a)" and inserting "3002(a)(2)"; and

(F) in section 3008 (42 U.S.C. 300jj-18)—

(i) in subsection (b), by striking "or 3003"; and

(ii) in subsection (c), by striking "3003(b)(1)(A)" and inserting "3002(b)(2)".

(3) [42 U.S.C. 300jj-12 note]

[42 U.S.C. 300jj-12 note] TRANSITION TO THE HIT ADVISORY COMMITTEE.—The Secretary of Health and Human Services shall provide for an orderly and timely transition to the HIT Advisory Committee established under amendments made by this section.

(f) PRIORITIES FOR ADOPTION OF STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—Title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.), as amended by subsection (e), is further amended by inserting after section 3002 the following:

"SEC. 3003. [42 U.S.C. 300jj-13]

[42 U.S.C. 300jj-13] SETTING PRIORITIES FOR STANDARDS ADOPTION

"(a) IDENTIFYING PRIORITIES.—

"(1) IN GENERAL.—Not later than 6 months after the date on which the HIT Advisory Committee first meets, the National Coordinator shall periodically convene the HIT Advisory Committee to—

"(A) identify priority uses of health information technology, focusing on priorities—

"(i) arising from the implementation of the incentive programs for the meaningful use of certified EHR technology, the Merit-based Incentive Payment System, Alternative Payment Models, the Hospital Value-Based Purchasing Program, and any other value-based payment program determined appropriate by the Secretary;

"(ii) related to the quality of patient care;

"(iii) related to public health;

"(iv) related to clinical research;

"(v) related to the privacy and security of electronic health information;

"(vi) related to innovation in the field of health information technology;

"(vii) related to patient safety;

"(viii) related to the usability of health information technology;

"(ix) related to individuals' access to electronic health information; and

"(x) other priorities determined appropriate by the Secretary;

"(B) identify existing standards and implementation specifications that support the use and exchange of electronic health information needed to meet the priorities identified in subparagraph (A); and

"(C) publish a report summarizing the findings of the analysis conducted under subparagraphs (A) and (B) and make appropriate recommendations.

"(2) PRIORITIZATION.—In identifying such standards and implementation specifications under paragraph (1)(B), the HIT Advisory Committee shall prioritize standards and implementation specifications developed by consensus-based standards development organizations.

"(3) GUIDELINES FOR REVIEW OF EXISTING STANDARDS AND SPECIFICATIONS.—In consultation with the consensus-based entity described in section 1890 of the Social Security Act and other appropriate Federal agencies, the analysis of existing standards under paragraph (1)(B) shall include an evaluation of the need for a core set of common data elements and associated value sets to enhance the ability of certified health information technology to capture, use, and exchange structured electronic health information.

"(b) REVIEW OF ADOPTED STANDARDS.—

"(1) IN GENERAL.—Beginning 5 years after the date of enactment of the 21st Century Cures Act and every 3 years thereafter, the National Coordinator shall convene stakeholders to review the existing set of adopted standards and implementation specifications and make recommendations with respect to whether to—

"(A) maintain the use of such standards and implementation specifications; or

"(B) phase out such standards and implementation specifications.

"(2) PRIORITIES.—The HIT Advisory Committee, in collaboration with the National Institute for Standards and Technology, shall annually and through the use of public input, review and publish priorities for the use of health information technology, standards, and implementation specifications to support those priorities.

"(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prevent the use or adoption of novel standards that improve upon the existing health information technology infrastructure and facilitate the secure exchange of health information.".

SEC. 4004. INFORMATION BLOCKING.

Subtitle C of title XXX of the Public Health Service Act (42 U.S.C. 300jj-51 et seq.) is amended by adding at the end the following:

"SEC. 3022. [42 U.S.C. 300jj-52] INFORMATION BLOCKING

"(a) DEFINITION.—

"(1) IN GENERAL.—In this section, the term 'information blocking' means a practice that—

"(A) except as required by law or specified by the Secretary pursuant to rulemaking under paragraph (3), is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and

"(B)(i) if conducted by a health information technology developer, exchange, or network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or

"(ii) if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

"(2) PRACTICES DESCRIBED.—The information blocking practices described in paragraph (1) may include—

"(A) practices that restrict authorized access, exchange, or use under applicable State or Federal law of such information for treatment and other permitted purposes under such applicable law, including transitions between certified health information technologies;

"(B) implementing health information technology in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, exchanging, or using electronic health information; and

"(C) implementing health information technology in ways that are likely to—

"(i) restrict the access, exchange, or use of electronic health information with respect to exporting complete information sets or in transitioning between health information technology systems; or

"(ii) lead to fraud, waste, or abuse, or impede innovations and advancements in health information access, exchange, and use, including care delivery enabled by health information technology.

"(3) RULEMAKING.—The Secretary, through rulemaking, shall identify reasonable and necessary activities that do not constitute information blocking for purposes of paragraph (1).

"(4) NO ENFORCEMENT BEFORE EXCEPTION IDENTIFIED.—The term 'information blocking' does not include any practice or conduct occurring prior to the date that is 30 days after the date of enactment of the 21st Century Cures Act.

"(5) CONSULTATION.—The Secretary may consult with the Federal Trade Commission in promulgating regulations under this subsection, to the extent that such regulations define practices that are necessary to promote competition and consumer welfare.

"(6) APPLICATION.—The term 'information blocking', with respect to an individual or entity, shall not include an act or practice other than an act or practice committed by such individual or entity.

"(7) CLARIFICATION.—In carrying out this section, the Secretary shall ensure that health care providers are not penal-

ized for the failure of developers of health information technology or other entities offering health information technology to such providers to ensure that such technology meets the requirements to be certified under this title.

"(b) INSPECTOR GENERAL AUTHORITY.—

"(1) IN GENERAL.—The inspector general of the Department of Health and Human Services (referred to in this section as the 'Inspector General') may investigate any claim that—

"(A) a health information technology developer of certified health information technology or other entity offering certified health information technology—

"(i) submitted a false attestation under section 3001(c)(5)(D)(vii); or

"(ii) engaged in information blocking;

"(B) a health care provider engaged in information blocking; or

"(C) a health information exchange or network engaged in information blocking.

"(2) PENALTIES.—

"(A) DEVELOPERS, NETWORKS, AND EXCHANGES.—Any individual or entity described in subparagraph (A) or (C) of paragraph (1) that the Inspector General, following an investigation conducted under this subsection, determines to have committed information blocking shall be subject to a civil monetary penalty determined by the Secretary for all such violations identified through such investigation, which may not exceed $1,000,000 per violation. Such determination shall take into account factors such as the nature and extent of the information blocking and harm resulting from such information blocking, including, where applicable, the number of patients affected, the number of providers affected, and the number of days the information blocking persisted.

"(B) PROVIDERS.—Any individual or entity described in subparagraph (B) of paragraph (1) determined by the Inspector General to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking.

"(C) PROCEDURE.—The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b) of such section) shall apply to a civil money penalty applied under this paragraph in the same manner as such provisions apply to a civil money penalty or proceeding under such section 1128A(a).

"(D) RECOVERED PENALTY FUNDS.—The amounts recovered under this paragraph shall be allocated as follows:

"(i) ANNUAL OPERATING EXPENSES.—Each year following the establishment of the authority under this subsection, the Office of the Inspector General shall provide to the Secretary an estimate of the costs to carry out investigations under this section. Such estimate may include reasonable reserves to account for

variance in annual amounts recovered under this paragraph. There is authorized to be appropriated for purposes of carrying out this section an amount equal to the amount specified in such estimate for the fiscal year.

"(ii) APPLICATION TO OTHER PROGRAMS.—The amounts recovered under this paragraph and remaining after amounts are made available under clause (i) shall be transferred to the Federal Hospital Insurance Trust Fund under section 1817 of the Social Security Act and the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act, in such proportion as the Secretary determines appropriate.

"(E) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to the Office of the Inspector General to carry out this section $10,000,000, to remain available until expended.

"(3) RESOLUTION OF CLAIMS.—

"(A) IN GENERAL.—The Office of the Inspector General, if such Office determines that a consultation regarding the health privacy and security rules promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note) will resolve an information blocking claim, may refer such instances of information blocking to the Office for Civil Rights of the Department of Health and Human Services for resolution.

"(B) LIMITATION ON LIABILITY.—If a health care provider or health information technology developer makes information available based on a good faith reliance on consultations with the Office for Civil Rights of the Department of Health and Human Services pursuant to a referral under subparagraph (A), with respect to such information, the health care provider or developer shall not be liable for such disclosure or disclosures made pursuant to subparagraph (A).

"(c) IDENTIFYING BARRIERS TO EXCHANGE OF CERTIFIED HEALTH INFORMATION TECHNOLOGY.—

"(1) TRUSTED EXCHANGE DEFINED.—In this section, the term 'trusted exchange' with respect to certified electronic health records means that the certified electronic health record technology has the technical capability to enable secure health information exchange between users and multiple certified electronic health record technology systems.

"(2) GUIDANCE.—The National Coordinator, in consultation with the Office for Civil Rights of the Department of Health and Human Services, shall issue guidance on common legal, governance, and security barriers that prevent the trusted exchange of electronic health information.

"(3) REFERRAL.—The National Coordinator and the Office for Civil Rights of the Department of Health and Human Services may refer to the Inspector General instances or patterns of refusal to exchange health information with an individual or entity using certified electronic health record technology that is

technically capable of trusted exchange and under conditions when exchange is legally permissible.

"(d) ADDITIONAL PROVISIONS.—

"(1) INFORMATION SHARING PROVISIONS.—The National Coordinator may serve as a technical consultant to the Inspector General and the Federal Trade Commission for purposes of carrying out this section. The National Coordinator may, notwithstanding any other provision of law, share information related to claims or investigations under subsection (b) with the Federal Trade Commission for purposes of such investigations and shall share information with the Inspector General, as required by law.

"(2) PROTECTION FROM DISCLOSURE OF INFORMATION.—Any information that is received by the National Coordinator in connection with a claim or suggestion of possible information blocking and that could reasonably be expected to facilitate identification of the source of the information—

"(A) shall not be disclosed by the National Coordinator except as may be necessary to carry out the purpose of this section;

"(B) shall be exempt from mandatory disclosure under section 552 of title 5, United States Code, as provided by subsection (b)(3) of such section; and

"(C) may be used by the Inspector General or Federal Trade Commission for reporting purposes to the extent that such information could not reasonably be expected to facilitate identification of the source of such information.

"(3) STANDARDIZED PROCESS.—

"(A) IN GENERAL.—The National Coordinator shall implement a standardized process for the public to submit reports on claims of—

"(i) health information technology products or developers of such products (or other entities offering such products to health care providers) not being interoperable or resulting in information blocking;

"(ii) actions described in subsection (b)(1) that result in information blocking as described in subsection (a); and

"(iii) any other act described in subsection (a).

"(B) COLLECTION OF INFORMATION.—The standardized process implemented under subparagraph (A) shall provide for the collection of such information as the originating institution, location, type of transaction, system and version, timestamp, terminating institution, locations, system and version, failure notice, and other related information.

"(4) NONDUPLICATION OF PENALTY STRUCTURES.—In carrying out this subsection, the Secretary shall, to the extent possible, ensure that penalties do not duplicate penalty structures that would otherwise apply with respect to information blocking and the type of individual or entity involved as of the day before the date of the enactment of this section.".

SEC. 4005. [42 U.S.C. 300jj-14 note] LEVERAGING ELECTRONIC HEALTH RECORDS TO IMPROVE PATIENT CARE.

(a) REQUIREMENT RELATING TO REGISTRIES.—

(1) IN GENERAL.—To be certified in accordance with title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.), electronic health records shall be capable of transmitting to, and where applicable, receiving and accepting data from, registries in accordance with standards recognized by the Office of the National Coordinator for Health Information Technology, including clinician-led clinical data registries, that are also certified to be technically capable of receiving and accepting from, and where applicable, transmitting data to certified electronic health record technology in accordance with such standards.

(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require the certification of registries beyond the technical capability to exchange data in accordance with applicable recognized standards.

(b) DEFINITION.—For purposes of this Act, the term "clinician-led clinical data registry" means a clinical data repository—

(1) that is established and operated by a clinician-led or controlled, tax-exempt (pursuant to section 501(c) of the Internal Revenue Code of 1986), professional society or other similar clinician-led or -controlled organization, or such organization's controlled affiliate, devoted to the care of a population defined by a particular disease, condition, exposure or therapy;

(2) that is designed to collect detailed, standardized data on an ongoing basis for medical procedures, services, or therapies for particular diseases, conditions, or exposures;

(3) that provides feedback to participants who submit reports to the repository;

(4) that meets standards for data quality including—

(A) systematically collecting clinical and other health care data, using standardized data elements and having procedures in place to verify the completeness and validity of those data; and

(B) being subject to regular data checks or audits to verify completeness and validity; and

(5) that provides ongoing participant training and support.

(c) TREATMENT OF HEALTH INFORMATION TECHNOLOGY DEVELOPERS WITH RESPECT TO PATIENT SAFETY ORGANIZATIONS.—

(1) IN GENERAL.—In applying part C of title IX of the Public Health Service Act (42 U.S.C. 299b-21 et seq.), a health information technology developer shall be treated as a provider (as defined in section 921 of such Act) for purposes of reporting and conducting patient safety activities concerning improving clinical care through the use of health information technology that could result in improved patient safety, health care quality, or health care outcomes.

(2) REPORT.—Not later than 4 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning best practices and current trends voluntarily provided, without identifying individual providers or disclosing or using protected health information or individually identifiable information, by patient safety organizations to improve the in-

tegration of health information technology into clinical practice.

SEC. 4006. EMPOWERING PATIENTS AND IMPROVING PATIENT ACCESS TO THEIR ELECTRONIC HEALTH INFORMATION.

(a) USE OF HEALTH INFORMATION EXCHANGES FOR PATIENT ACCESS.—Section 3009 of the Public Health Service Act (42 U.S.C. 300jj-19) is amended by adding at the end the following:

"(c) PROMOTING PATIENT ACCESS TO ELECTRONIC HEALTH INFORMATION THROUGH HEALTH INFORMATION EXCHANGES.—

"(1) IN GENERAL.—The Secretary shall use existing authorities to encourage partnerships between health information exchange organizations and networks and health care providers, health plans, and other appropriate entities with the goal of offering patients access to their electronic health information in a single, longitudinal format that is easy to understand, secure, and may be updated automatically.

"(2) EDUCATION OF PROVIDERS.—The Secretary, in coordination with the Office for Civil Rights of the Department of Health and Human Services, shall—

"(A) educate health care providers on ways of leveraging the capabilities of health information exchanges (or other relevant platforms) to provide patients with access to their electronic health information;

"(B) clarify misunderstandings by health care providers about using health information exchanges (or other relevant platforms) for patient access to electronic health information; and

"(C) to the extent practicable, educate providers about health information exchanges (or other relevant platforms) that employ some or all of the capabilities described in paragraph (1).

"(3) REQUIREMENTS.—In carrying out paragraph (1), the Secretary, in coordination with the Office for Civil Rights, shall issue guidance to health information exchanges related to best practices to ensure that the electronic health information provided to patients is—

"(A) private and secure;

"(B) accurate;

"(C) verifiable; and

"(D) where a patient's authorization to exchange information is required by law, easily exchanged pursuant to such authorization.

"(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to preempt State laws applicable to patient consent for the access of information through a health information exchange (or other relevant platform) that provide protections to patients that are greater than the protections otherwise provided for under applicable Federal law.

"(d) EFFORTS TO PROMOTE ACCESS TO HEALTH INFORMATION.—The National Coordinator and the Office for Civil Rights of the Department of Health and Human Services shall jointly promote patient access to health information in a manner that would ensure that such information is available in a form convenient for the pa-

tient, in a reasonable manner, without burdening the health care provider involved.

"(e) ACCESSIBILITY OF PATIENT RECORDS.—

"(1) ACCESSIBILITY AND UPDATING OF INFORMATION.—

"(A) IN GENERAL.—The Secretary, in consultation with the National Coordinator, shall promote policies that ensure that a patient's electronic health information is accessible to that patient and the patient's designees, in a manner that facilitates communication with the patient's health care providers and other individuals, including researchers, consistent with such patient's consent.

"(B) UPDATING EDUCATION ON ACCESSING AND EXCHANGING PERSONAL HEALTH INFORMATION.—To promote awareness that an individual has a right of access to inspect, obtain a copy of, and transmit to a third party a copy of such individual's protected health information pursuant to the Health Information Portability and Accountability Act, Privacy Rule (subpart E of part 164 of title 45, Code of Federal Regulations), the Director of the Office for Civil Rights, in consultation with the National Coordinator, shall assist individuals and health care providers in understanding a patient's rights to access and protect personal health information under the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191), including providing best practices for requesting personal health information in a computable format, including using patient portals or third-party applications and common cases when a provider is permitted to exchange and provide access to health information.".

"(2) CERTIFYING USABILITY FOR PATIENTS.—In carrying out certification programs under section 3001(c)(5), the National Coordinator may require that—

"(A) the certification criteria support—

"(i) patient access to their electronic health information, including in a single longitudinal format that is easy to understand, secure, and may be updated automatically;

"(ii) the patient's ability to electronically communicate patient-reported information (such as family history and medical history); and

"(iii) patient access to their personal electronic health information for research at the option of the patient; and

"(B) the HIT Advisory Committee develop and prioritize standards, implementation specifications, and certification criteria required to help support patient access to electronic health information, patient usability, and support for technologies that offer patients access to their electronic health information in a single, longitudinal format that is easy to understand, secure, and may be updated automatically.".

(b) ACCESS TO INFORMATION IN AN ELECTRONIC FORMAT.—Section 13405(e) of the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. 17935) is amended—

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

(2) by redesignating paragraph (2) as paragraph (3); and

(3) by inserting after paragraph (1), the following:

"(2) if the individual makes a request to a business associate for access to, or a copy of, protected health information about the individual, or if an individual makes a request to a business associate to grant such access to, or transmit such copy directly to, a person or entity designated by the individual, a business associate may provide the individual with such access or copy, which may be in an electronic form, or grant or transmit such access or copy to such person or entity designated by the individual; and".

SEC. 4007. GAO STUDY ON PATIENT MATCHING.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study to—

(1) review the policies and activities of the Office of the National Coordinator for Health Information Technology and other relevant stakeholders, which may include standards development organizations, experts in the technical aspects of health information technology, health information technology developers, providers of health services, health care suppliers, health care payers, health care quality organizations, States, health information technology policy experts, and other appropriate entities, to ensure appropriate patient matching to protect patient privacy and security with respect to electronic health records and the exchange of electronic health information; and

(2) survey ongoing efforts related to the policies and activities described in paragraph (1) and the effectiveness of such efforts occurring in the private sector.

(b) AREAS OF CONCENTRATION.—In conducting the study under subsection (a), the Comptroller General shall—

(1) evaluate current methods used in certified electronic health records for patient matching based on performance related to factors such as—

(A) the privacy of patient information;

(B) the security of patient information;

(C) improving matching rates;

(D) reducing matching errors; and

(E) reducing duplicate records; and

(2) determine whether the Office of the National Coordinator for Health Information Technology could improve patient matching by taking steps including—

(A) defining additional data elements to assist in patient data matching;

(B) agreeing on a required minimum set of elements that need to be collected and exchanged;

(C) requiring electronic health records to have the ability to make certain fields required and use specific standards; and

(D) other options recommended by the relevant stakeholders consulted pursuant to subsection (a).

(c) REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General shall submit to the appropriate committees of Congress a report concerning the findings of the study conducted under subsection (a).

SEC. 4008. GAO STUDY ON PATIENT ACCESS TO HEALTH INFORMATION.

(a) STUDY.—

(1) IN GENERAL.—The Comptroller General of the United States (referred to in this section as the "Comptroller General") shall build on prior Government Accountability Office studies and other literature review and conduct a study to review patient access to their own protected health information, including barriers to such patient access and complications or difficulties providers experience in providing access to patients. In conducting such study, the Comptroller General shall consider the increase in adoption of health information technology and the increasing prevalence of protected health information that is maintained electronically.

(2) AREAS OF CONCENTRATION.—In conducting the review under paragraph (1), the Comptroller General shall consider—

(A) instances when covered entities charge individuals, including patients, third parties, and health care providers, for record requests, including records that are requested in an electronic format;

(B) examples of the amounts and types of fees charged to individuals for record requests, including instances when the record is requested to be transmitted to a third party;

(C) the extent to which covered entities are unable to provide the access requested by individuals in the form and format requested by the individual, including examples of such instances;

(D) instances in which third parties may request protected health information through patients' individual right of access, including instances where such requests may be used to circumvent appropriate fees that may be charged to third parties;

(E) opportunities that permit covered entities to charge appropriate fees to third parties for patient records while providing patients with access to their protected health information at low or no cost;

(F) the ability of providers to distinguish between requests originating from an individual that require limitation to a cost-based fee and requests originating from third parties that may not be limited to cost-based fees; and

(G) other circumstances that may inhibit the ability of providers to provide patients with access to their records, and the ability of patients to gain access to their records.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General shall submit a report to Congress on the findings of the study conducted under subsection (a).

SEC. 4009. IMPROVING MEDICARE LOCAL COVERAGE DETERMINATIONS.

(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 Internet website of such contractor and on the Medicare Internet 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) Hyperlinks 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) [42 U.S.C. 1395y note] [42 U.S.C. 1395y note] 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 enactment of this Act.

SEC. 4010. MEDICARE PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN.

Section 1808 of the Social Security Act (42 U.S.C. 1395b-9) is amended by adding at the end the following new subsection:

"(d) PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN.—

"(1) IN GENERAL.—Not later than 12 months after the date of 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) are with respect to coverage, coding, or payment under this title for such products.

"(2) APPLICATION.—The second sentence of subsection (c)(2) shall apply to the ombudsman under subparagraph (A) in the same manner as such sentence applies to the Medicare Beneficiary Ombudsman under subsection (c).".

SEC. 4011. 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:

"(t) 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 am-

bulatory surgical center under this title, the Secretary shall, for 2018 and each year thereafter, make available to the public via a searchable Internet website, with respect to an appropriate number of such items and services—

"(A) the estimated payment amount for the item or service 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 the 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 mechanisms in existence on the date of enactment of this subsection, such as the portion of the Internet website of the Centers for Medicare & Medicaid Services on which information comparing physician performance is posted (commonly referred to as the Physician Compare Internet 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 Federal Supplementary Medical Insurance Trust Fund under section 1841 to the Centers for Medicare & Medicaid Services Program Management Account, of $6,000,000 for fiscal year 2017, to remain available until expended.".

SEC. 4012. TELEHEALTH SERVICES IN MEDICARE.

(a) PROVISION OF INFORMATION BY CENTERS FOR MEDICARE & MEDICAID SERVICES.—Not later than 1 year after the date of 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 (42 U.S.C. 1395 et seq.) and the Medicaid program under title XIX of such Act (42 U.S.C. 1396 et seq.) 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 such title XVIII, 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 such Act (42 U.S.C. 1315a).

(3) The types of high-volume services (and related diagnoses) under such title XVIII which might be suitable to be furnished using 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 enactment of this Act.

(b) PROVISION OF INFORMATION BY MEDPAC.—Not later than March 15, 2018, the Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b-6) shall, using quantitative and qualitative research methods, provide information to the committees of jurisdiction of the House of Representatives and the Senate that identifies—

(1) the telehealth services for which payment can be made, as of the date of enactment of this Act, under the fee-for-service program under parts A and B of title XVIII of such Act;

(2) the telehealth services for which payment can be made, as of such date, under private health insurance plans; and

(3) with respect to services identified under paragraph (2) but not under paragraph (1), ways in which payment for such services might be incorporated into such fee-for-service program (including any recommendations for ways to accomplish this incorporation).

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

(1) 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

(2) any expansion of telehealth services under the Medicare program under title XVIII of such Act 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 if the service was furnished in person, including standards of care, unless specifically addressed in subsequent legislation; and

(C) involve clinically appropriate means to furnish such services.

TITLE V—SAVINGS

SEC. 5001. SAVINGS IN THE MEDICARE IMPROVEMENT FUND.

Section 1898(b)(1) of the Social Security Act (42 U.S.C. 1395iii(b)(1)), as amended by section 704(h) of the Comprehensive Addiction and Recovery Act of 2016, is amended by striking "$140,000,000" and inserting "$270,000,000".

SEC. 5002. MEDICAID REIMBURSEMENT TO STATES FOR DURABLE MEDICAL EQUIPMENT.

Section 1903(i)(27) of the Social Security Act (42 U.S.C. 1396b(i)(27)) is amended by striking "January 1, 2019" and inserting "January 1, 2018".

SEC. 5003. PENALTIES FOR VIOLATIONS OF GRANTS, CONTRACTS, AND OTHER AGREEMENTS.

(a) IN GENERAL.—Section 1128A of the Social Security Act (42 U.S.C. 1320a-7a) is amended by adding at the end the following new subsections:

"(o) Any person (including an organization, agency, or other entity, but excluding a program beneficiary, as defined in subsection (q)(4)) that, with respect to a grant, contract, or other agreement for which the Secretary provides funding—

"(1) knowingly presents or causes to be presented a specified claim (as defined in subsection (r)) under such grant, contract, or other agreement that the person knows or should know is false or fraudulent;

"(2) knowingly makes, uses, or causes to be made or used any false statement, omission, or misrepresentation of a material fact in any application, proposal, bid, progress report, or other document that is required to be submitted in order to directly or indirectly receive or retain funds provided in whole or in part by such Secretary pursuant to such grant, contract, or other agreement;

"(3) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent specified claim under such grant, contract, or other agreement;

"(4) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation (as defined in subsection (s)) to pay or transmit funds or property to such Secretary with respect to such grant, contract, or other agreement, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit funds or property to such Secretary with respect to such grant, contract, or other agreement; or

"(5) fails to grant timely access, upon reasonable request (as defined by such Secretary in regulations), to the Inspector General of the Department, for the purpose of audits, investigations, evaluations, or other statutory functions of such Inspector General in matters involving such grants, contracts, or other agreements;

"shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty in cases under paragraph (1), of not more than $10,000 for each specified claim; in cases under paragraph (2), not more than $50,000 for each false statement, omission, or misrepresentation of a material fact; in cases under paragraph (3), not more than $50,000 for each false record or statement; in cases under paragraph (4), not more than $50,000 for each false record or statement or $10,000 for each day that the person knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay; or in cases under paragraph (5), not more than $15,000 for each day of the failure described in such paragraph. In addition, in cases under paragraphs

(1) and (3), such a person shall be subject to an assessment of not more than 3 times the amount claimed in the specified claim described in such paragraph in lieu of damages sustained by the United States or a specified State agency because of such specified claim, and in cases under paragraphs (2) and (4), such a person shall be subject to an assessment of not more than 3 times the total amount of the funds described in paragraph (2) or (4), respectively (or, in the case of an obligation to transmit property to the Secretary described in paragraph (4), of the value of the property described in such paragraph) in lieu of damages sustained by the United States or a specified State agency because of such case. In addition, the Secretary may make a determination in the same proceeding to exclude the person from participation in the Federal health care programs (as defined in section 1128B(f)(1)) and to direct the appropriate State agency to exclude the person from participation in any State health care program.

"(p) The provisions of subsections (c), (d), (g), and (h) shall apply to a civil money penalty or assessment under subsection (o) in the same manner as such provisions apply to a penalty, assessment, or proceeding under subsection (a). In applying subsection (d), each reference to a claim under such subsection shall be treated as including a reference to a specified claim (as defined in subsection (r)).

"(q) For purposes of this subsection and subsections (o) and (p):

"(1) The term 'Department' means the Department of Health and Human Services.

"(2) The term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

"(3) The term 'other agreement' includes a cooperative agreement, scholarship, fellowship, loan, subsidy, payment for a specified use, donation agreement, award, or subaward (regardless of whether one or more of the persons entering into the agreement is a contractor or subcontractor).

"(4) The term 'program beneficiary' means, in the case of a grant, contract, or other agreement designed to accomplish the objective of awarding or otherwise furnishing benefits or assistance to individuals and for which the Secretary provides funding, an individual who applies for, or who receives, such benefits or assistance from such grant, contract, or other agreement. Such term does not include, with respect to such grant, contract, or other agreement, an officer, employee, or agent of a person or entity that receives such grant or that enters into such contract or other agreement.

"(5) The term 'recipient' includes a subrecipient or subcontractor.

"(6) The term 'specified State agency' means an agency of a State government established or designated to administer or supervise the administration of a grant, contract, or other agreement funded in whole or in part by the Secretary.

"(r) For purposes of this section, the term 'specified claim' means any application, request, or demand under a grant, contract, or other agreement for money or property, whether or not the United States or a specified State agency has title to the money or

property, that is not a claim (as defined in subsection (i)(2)) and that—

"(1) is presented or caused to be presented to an officer, employee, or agent of the Department or agency thereof, or of any specified State agency; or

"(2) is made to a contractor, grantee, or any other recipient if the money or property is to be spent or used on the Department's behalf or to advance a Department program or interest, and if the Department—

"(A) provides or has provided any portion of the money or property requested or demanded; or

"(B) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

"(s) For purposes of subsection (o), the term 'obligation' means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, for a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.".

(b) CONFORMING AMENDMENTS.—Section 1128A of the Social Security Act (42 U.S.C. 1320a-7a) is amended—

(1) in subsection (e), by inserting "or specified claim" after "claim" in the first sentence; and

(2) in subsection (f)—

(A) in the matter preceding paragraph (1)—

(i) by inserting "or specified claim (as defined in subsection (r))" after "district where the claim"; and

(ii) by inserting "(or, with respect to a person described in subsection (o), the person)" after "claimant"; and

(B) in the matter following paragraph (4), by inserting "(or, in the case of a penalty or assessment under subsection (o), by a specified State agency (as defined in subsection (q)(6))," after "or a State agency".

SEC. 5004. REDUCING OVERPAYMENTS OF INFUSION DRUGS.

(a) TREATMENT OF INFUSION DRUGS FURNISHED THROUGH DURABLE MEDICAL EQUIPMENT.—Section 1842(o)(1) of the Social Security Act (42 U.S.C. 1395u(o)(1)) is amended—

(1) in subparagraph (C), by inserting "(and including a drug or biological described in subparagraph (D)(i) furnished on or after January 1, 2017)" after "2005"; and

(2) in subparagraph (D)—

(A) by striking "infusion drugs" and inserting "infusion drugs or biologicals" each place it appears; and

(B) in clause (i)—

(i) by striking "2004" and inserting "2004, and before January 1, 2017"; and

(ii) by striking "for such drug".

(b) NONINCLUSION OF DME INFUSION DRUGS UNDER DME COMPETITIVE ACQUISITION PROGRAMS.—

(1) IN GENERAL.—Section 1847(a)(2)(A) of the Social Security Act (42 U.S.C. 1395w-3(a)(2)(A)) is amended—

(A) by striking "and excluding" and inserting ", excluding"; and

(B) by inserting before the period at the end the following: ", and excluding drugs and biologicals described in section 1842(o)(1)(D)".

(2) CONFORMING AMENDMENT.—Section 1842(o)(1)(D)(ii) of the Social Security Act (42 U.S.C. 1395u(o)(1)(D)(ii)) is amended by striking "2007" and inserting "2007, and before the date of the enactment of the 21st Century Cures Act.".

SEC. 5005. INCREASING OVERSIGHT OF TERMINATION OF MEDICAID PROVIDERS.

(a) INCREASED OVERSIGHT AND REPORTING.—

(1) STATE REPORTING REQUIREMENTS.—Section 1902(kk) of the Social Security Act (42 U.S.C. 1396a(kk)) is amended—

(A) by redesignating paragraph (8) as paragraph (9); and

(B) by inserting after paragraph (7) the following new paragraph:

"(8) PROVIDER TERMINATIONS.—

"(A) IN GENERAL.—Beginning on July 1, 2018, in the case of a notification under subsection (a)(41) with respect to a termination for a reason specified in section 455.101 of title 42, Code of Federal Regulations (as in effect on November 1, 2015) or for any other reason specified by the Secretary, of the participation of a provider of services or any other person under the State plan (or under a waiver of the plan), the State, not later than 30 days after the effective date of such termination, submits to the Secretary with respect to any such provider or person, as appropriate—

"(i) the name of such provider or person;

"(ii) the provider type of such provider or person;

"(iii) the specialty of such provider's or person's practice;

"(iv) the date of birth, Social Security number, national provider identifier (if applicable), Federal taxpayer identification number, and the State license or certification number of such provider or person (if applicable);

"(v) the reason for the termination;

"(vi) a copy of the notice of termination sent to the provider or person;

"(vii) the date on which such termination is effective, as specified in the notice; and

"(viii) any other information required by the Secretary.

"(B) EFFECTIVE DATE DEFINED.—For purposes of this paragraph, the term 'effective date' means, with respect to a termination described in subparagraph (A), the later of—

"(i) the date on which such termination is effective, as specified in the notice of such termination; or

"(ii) the date on which all appeal rights applicable to such termination have been exhausted or the timeline for any such appeal has expired.".

(2) CONTRACT REQUIREMENT FOR MANAGED CARE ENTITIES.—Section 1932(d) of the Social Security Act (42 U.S.C. 1396u-2(d)) is amended by adding at the end the following new paragraph:

"(5) CONTRACT REQUIREMENT FOR MANAGED CARE ENTITIES.—With respect to any contract with a managed care entity under section 1903(m) or 1905(t)(3) (as applicable), no later than July 1, 2018, such contract shall include a provision that providers of services or persons terminated (as described in section 1902(kk)(8)) from participation under this title, title XVIII, or title XXI shall be terminated from participating under this title as a provider in any network of such entity that serves individuals eligible to receive medical assistance under this title.".

(3) TERMINATION NOTIFICATION DATABASE.—Section 1902 of the Social Security Act (42 U.S.C. 1396a) is amended by adding at the end the following new subsection:

"(ll) TERMINATION NOTIFICATION DATABASE.—In the case of a provider of services or any other person whose participation under this title or title XXI is terminated (as described in subsection (kk)(8)), the Secretary shall, not later than 30 days after the date on which the Secretary is notified of such termination under subsection (a)(41) (as applicable), review such termination and, if the Secretary determines appropriate, include such termination in any database or similar system developed pursuant to section 6401(b)(2) of the Patient Protection and Affordable Care Act (42 U.S.C. 1395cc note; Public Law 111-148).".

(4) NO FEDERAL FUNDS FOR ITEMS AND SERVICES FURNISHED BY TERMINATED PROVIDERS.—Section 1903 of the Social Security Act (42 U.S.C. 1396b) is amended—

(A) in subsection (i)(2)—

(i) in subparagraph (A), by striking the comma at the end and inserting a semicolon;

(ii) in subparagraph (B), by striking "or" at the end; and

(iii) by adding at the end the following new subparagraph:

"(D) beginning on July 1, 2018, under the plan by any provider of services or person whose participation in the State plan is terminated (as described in section 1902(kk)(8)) after the date that is 60 days after the date on which such termination is included in the database or other system under section 1902(ll); or"; and

(B) in subsection (m), by inserting after paragraph (2) the following new paragraph:

"(3) No payment shall be made under this title to a State with respect to expenditures incurred by the State for payment for services provided by a managed care entity (as defined under section 1932(a)(1)) under the State plan under this title (or under a waiver of the plan) unless the State—

"(A) beginning on July 1, 2018, has a contract with such entity that complies with the requirement specified in section 1932(d)(5); and

"(B) beginning on January 1, 2018, complies with the requirement specified in section 1932(d)(6)(A).".

(5) [42 U.S.C. 1396a note]

[42 U.S.C. 1396a note] DEVELOPMENT OF UNIFORM TERMINOLOGY FOR REASONS FOR PROVIDER TERMINATION.—Not later than July 1, 2017, the Secretary of Health and Human Services shall, in consultation with the heads of State agencies administering State Medicaid plans (or waivers of such plans), issue regulations establishing uniform terminology to be used with respect to specifying reasons under subparagraph (A)(v) of paragraph (8) of section 1902(kk) of the Social Security Act (42 U.S.C. 1396a(kk)), as added by paragraph (1), for the termination (as described in such paragraph (8)) of the participation of certain providers in the Medicaid program under title XIX of such Act or the Children's Health Insurance Program under title XXI of such Act.

(6) CONFORMING AMENDMENT.—Section 1902(a)(41) of the Social Security Act (42 U.S.C. 1396a(a)(41)) is amended by striking "provide that whenever" and inserting "provide, in accordance with subsection (kk)(8) (as applicable), that whenever".

(b) INCREASING AVAILABILITY OF MEDICAID PROVIDER INFORMATION.—

(1) FFS PROVIDER ENROLLMENT.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) is amended by inserting after paragraph (77) the following new paragraph:

"(78) provide that, not later than January 1, 2017, in the case of a State that pursuant to its State plan or waiver of the plan for medical assistance pays for medical assistance on a fee-for-service basis, the State shall require each provider furnishing items and services to, or ordering, prescribing, referring, or certifying eligibility for, services for individuals eligible to receive medical assistance under such plan to enroll with the State agency and provide to the State agency the provider's identifying information, including the name, specialty, date of birth, Social Security number, national provider identifier (if applicable), Federal taxpayer identification number, and the State license or certification number of the provider (if applicable);".

(2) MANAGED CARE PROVIDER ENROLLMENT.—Section 1932(d) of the Social Security Act (42 U.S.C. 1396u-2(d)), as amended by subsection (a)(2), is amended by adding at the end the following new paragraph:

"(6) ENROLLMENT OF PARTICIPATING PROVIDERS.—

"(A) IN GENERAL.—Beginning not later than January 1, 2018, a State shall require that, in order to participate as a provider in the network of a managed care entity that provides services to, or orders, prescribes, refers, or certifies eligibility for services for, individuals who are eligible for medical assistance under the State plan under this title (or under a waiver of the plan) and who are enrolled with the entity, the provider is enrolled consistent with section 1902(kk) with the State agency administering the State plan under this title. Such enrollment shall include providing to the State agency the provider's identifying information, including the name, specialty, date of birth, Social Security number, national provider identifier, Federal taxpayer identification number, and the State license or certification number of the provider.

"(B) RULE OF CONSTRUCTION.—Nothing in subparagraph (A) shall be construed as requiring a provider described in such subparagraph to provide services to individuals who are not enrolled with a managed care entity under this title.".

(c) COORDINATION WITH CHIP.—

(1) IN GENERAL.—Section 2107(e)(1) of the Social Security Act (42 U.S.C. 1397gg(e)(1)) is amended—

(A) by redesignating subparagraphs (B), (C), (D), (E), (F), (G), (H), (I), (J), (K), (L), (M), (N), and (O) as subparagraphs (D), (E), (F), (G), (H), (I), (J), (K), (M), (N), (O), (P), (Q), and (R), respectively;

(B) by inserting after subparagraph (A) the following new subparagraphs:

"(B) Section 1902(a)(39) (relating to termination of participation of certain providers).

"(C) Section 1902(a)(78) (relating to enrollment of providers participating in State plans providing medical assistance on a fee-for-service basis).";

(C) by inserting after subparagraph (K) (as redesignated by subparagraph (A)) the following new subparagraph:

"(L) Section 1903(m)(3) (relating to limitation on payment with respect to managed care)."; and

(D) in subparagraph (P) (as redesignated by subparagraph (A)), by striking "(a)(2)(C) and (h)" and inserting "(a)(2)(C) (relating to Indian enrollment), (d)(5) (relating to contract requirement for managed care entities), (d)(6) (relating to enrollment of providers participating with a managed care entity), and (h) (relating to special rules with respect to Indian enrollees, Indian health care providers, and Indian managed care entities)".

(2) EXCLUDING FROM MEDICAID PROVIDERS EXCLUDED FROM CHIP.—Section 1902(a)(39) of the Social Security Act (42 U.S.C. 1396a(a)(39)) is amended by striking "title XVIII or any other State plan under this title" and inserting "title XVIII, any other State plan under this title (or waiver of the plan), or any State child health plan under title XXI (or waiver of the plan) and such termination is included by the Secretary in any database or similar system developed pursuant to section 6401(b)(2) of the Patient Protection and Affordable Care Act".

(d) [42 U.S.C. 1396a note] [42 U.S.C. 1396a note] RULE OF CONSTRUCTION.—Nothing in this section shall be construed as changing or limiting the appeal rights of providers or the process for appeals of States under the Social Security Act.

(e) OIG REPORT.—Not later than March 31, 2020, the Inspector General of the Department of Health and Human Services shall submit to Congress a report on the implementation of the amendments made by this section. Such report shall include the following:

(1) An assessment of the extent to which providers who are included under subsection (ll) of section 1902 of the Social Security Act (42 U.S.C. 1396a) (as added by subsection (a)(3)) in the database or similar system referred to in such subsection are terminated (as described in paragraph (8) of subsection

(kk) of such section, as added by subsection (a)(1)) from participation in all State plans under title XIX of such Act (or waivers of such plans).

(2) Information on the amount of Federal financial participation paid to States under section 1903 of such Act in violation of the limitation on such payment specified in subparagraph (D) of subsection (i)(2) of such section and paragraph (3) of subsection (m) of such section, as added by subsection (a)(4).

(3) An assessment of the extent to which contracts with managed care entities under title XIX of such Act comply with the requirement specified in paragraph (5) of section 1932(d) of such Act, as added by subsection (a)(2).

(4) An assessment of the extent to which providers have been enrolled under section 1902(a)(78) or 1932(d)(6)(A) of such Act (42 U.S.C. 1396a(a)(78), 1396u-2(d)(6)(A)) with State agencies administering State plans under title XIX of such Act (or waivers of such plans).

SEC. 5006. REQUIRING PUBLICATION OF FEE-FOR-SERVICE PROVIDER DIRECTORY.

(a) IN GENERAL.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) is amended—

(1) in paragraph (81), by striking "and" at the end;

(2) in paragraph (82), by striking the period at the end and inserting "; and"; and

(3) by inserting after paragraph (82) the following new paragraph:

"(83) provide that, not later than January 1, 2017, in the case of a State plan (or waiver of the plan) that provides medical assistance on a fee-for-service basis or through a primary care case-management system described in section 1915(b)(1) (other than a primary care case management entity (as defined by the Secretary)), the State shall publish (and update on at least an annual basis) on the public website of the State agency administering the State plan, a directory of the physicians described in subsection (mm) and, at State option, other providers described in such subsection that—

"(A) includes—

"(i) with respect to each such physician or provider—

"(I) the name of the physician or provider;

"(II) the specialty of the physician or provider;

"(III) the address at which the physician or provider provides services; and

"(IV) the telephone number of the physician or provider; and

"(ii) with respect to any such physician or provider participating in such a primary care case-management system, information regarding—

"(I) whether the physician or provider is accepting as new patients individuals who receive medical assistance under this title; and

"(II) the physician's or provider's cultural and linguistic capabilities, including the languages spoken by the physician or provider or by the

skilled medical interpreter providing interpretation services at the physician's or provider's office; and

"(B) may include, at State option, with respect to each such physician or provider—

"(i) the Internet website of such physician or provider; or

"(ii) whether the physician or provider is accepting as new patients individuals who receive medical assistance under this title.".

(b) DIRECTORY PHYSICIAN OR PROVIDER DESCRIBED.—Section 1902 of the Social Security Act (42 U.S.C. 1396a), as amended by section 5005(a)(3), is further amended by adding at the end the following new subsection:

"(mm) DIRECTORY PHYSICIAN OR PROVIDER DESCRIBED.—A physician or provider described in this subsection is—

"(1) in the case of a physician or provider of a provider type for which the State agency, as a condition on receiving payment for items and services furnished by the physician or provider to individuals eligible to receive medical assistance under the State plan, requires the enrollment of the physician or provider with the State agency, a physician or a provider that—

"(A) is enrolled with the agency as of the date on which the directory is published or updated (as applicable) under subsection (a)(83); and

"(B) received payment under the State plan in the 12-month period preceding such date; and

"(2) in the case of a physician or provider of a provider type for which the State agency does not require such enrollment, a physician or provider that received payment under the State plan (or a waiver of the plan) in the 12-month period preceding the date on which the directory is published or updated (as applicable) under subsection (a)(83).".

(c) [42 U.S.C. 1396a note]

[42 U.S.C. 1396a note] RULE OF CONSTRUCTION.—

(1) IN GENERAL.—The amendment made by subsection (a) shall not be construed to apply in the case of a State (as defined for purposes of title XIX of the Social Security Act) in which all the individuals enrolled in the State plan under such title (or under a waiver of such plan), other than individuals described in paragraph (2), are enrolled with a medicaid managed care organization (as defined in section 1903(m)(1)(A) of such Act (42 U.S.C. 1396b(m)(1)(A))), including prepaid inpatient health plans and prepaid ambulatory health plans (as defined by the Secretary of Health and Human Services).

(2) INDIVIDUALS DESCRIBED.—An individual described in this paragraph is an individual who is an Indian (as defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603)) or an Alaska Native.

(d) [42 U.S.C. 1396a note]

[42 U.S.C. 1396a note] EXCEPTION FOR STATE LEGISLATION.—In the case of a State plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), which the Secretary of Health and Human Services determines requires State legislation in order for the respective plan to meet one or more additional requirements im-

posed by amendments made by this section, the respective plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet such an additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session shall be considered to be a separate regular session of the State legislature.

SEC. 5007. FAIRNESS IN MEDICAID SUPPLEMENTAL NEEDS TRUSTS.

(a) IN GENERAL.—Section 1917(d)(4)(A) of the Social Security Act (42 U.S.C. 1396p(d)(4)(A)) is amended by inserting "the individual," after "for the benefit of such individual by".

(b) [42 U.S.C. 1396p note]

[42 U.S.C. 1396p note] EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to trusts established on or after the date of the enactment of this Act.

SEC. 5008. ELIMINATING FEDERAL FINANCIAL PARTICIPATION WITH RESPECT TO EXPENDITURES UNDER MEDICAID FOR AGENTS USED FOR COSMETIC PURPOSES OR HAIR GROWTH.

(a) IN GENERAL.—Section 1903(i)(21) of the Social Security Act (42 U.S.C. 1396b(i)(21)) is amended by inserting "section 1927(d)(2)(C) (relating to drugs when used for cosmetic purposes or hair growth), except where medically necessary, and" after "drugs described in".

(b) [42 U.S.C. 1396b note]

[42 U.S.C. 1396b note] EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to calendar quarters beginning on or after the date of the enactment of this Act.

SEC. 5009. AMENDMENT TO THE PREVENTION AND PUBLIC HEALTH FUND.

Section 4002(b) of the Patient Protection and Affordable Care Act (42 U.S.C. 300u-11(b)) is amended—

(1) in paragraph (3), by striking "$1,250,000,000" and inserting "$900,000,000";

(2) in paragraph (4), by striking "$1,500,000,000" and inserting "$1,000,000,000"; and

(3) by striking paragraph (5) and inserting the following:

"(5) for fiscal year 2022, $1,500,000,000;

"(6) for fiscal year 2023, $1,000,000,000;

"(7) for fiscal year 2024, $1,700,000,000; and

"(8) for fiscal year 2025 and each fiscal year thereafter, $2,000,000,000.".

SEC. 5010. STRATEGIC PETROLEUM RESERVE DRAWDOWN.

(a) [42 U.S.C. 6241 note]

[42 U.S.C. 6241 note] DRAWDOWN AND SALE.—

(1) IN GENERAL.—Notwithstanding section 161 of the Energy Policy and Conservation Act (42 U.S.C. 6241), except as provided in subsections (b) and (c), the Secretary of Energy shall drawdown and sell from the Strategic Petroleum Reserve—

(A) 10,000,000 barrels of crude oil during fiscal year 2017;

(B) 9,000,000 barrels of crude oil during fiscal year 2018; and

(C) 6,000,000 barrels of crude oil during fiscal year 2019.

(2) DEPOSIT OF AMOUNTS RECEIVED FROM SALE.—Amounts received from a sale under paragraph (1) shall be deposited in the general fund of the Treasury during the fiscal year in which the sale occurs.

(b) [42 U.S.C. 6241 note]

[42 U.S.C. 6241 note] EMERGENCY PROTECTION.—The Secretary shall not draw down and sell crude oil under this section in quantities that would limit the authority to sell petroleum products under section 161(h) of the Energy Policy and Conservation Act (42 U.S.C. 6241(h)) in the full quantity authorized by that subsection.

(c) STRATEGIC PETROLEUM DRAWDOWN LIMITATIONS.—Subparagraphs (C) and (D) of section 161(h)(2) of the Energy Policy and Conservation Act (42 U.S.C. 6241(h)(2)(C) and (D)) are both amended by striking "500,000,000" and inserting "450,000,000".

SEC. 5011. RESCISSION OF PORTION OF ACA TERRITORY FUNDING.

Of the unobligated amounts available under section 1323(c)(1) of the Patient Protection and Affordable Care Act (42 U.S.C. 18043(c)(1)), $464,000,000 is rescinded immediately upon the date of the enactment of this Act.

SEC. 5012. MEDICARE COVERAGE OF HOME INFUSION THERAPY.

(a) IN GENERAL.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended—

(1) in subsection (s)(2)—

(A) by striking "and" at the end of subparagraph (EE);

(B) by inserting "and" at the end of subparagraph (FF); and

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

"(GG) home infusion therapy (as defined in subsection (iii)(1));"; and

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

"(iii) HOME INFUSION THERAPY.—(1) The term 'home infusion therapy' means the items and services described in paragraph (2) furnished by a qualified home infusion therapy supplier (as defined in paragraph (3)(D)) which are furnished in the individual's home (as defined in paragraph (3)(B)) to an individual—

"(A) who is under the care of an applicable provider (as defined in paragraph (3)(A)); and

"(B) with respect to whom a plan prescribing the type, amount, and duration of infusion therapy services that are to be furnished such individual has been established by a physician (as defined in subsection (r)(1)) and is periodically reviewed by a physician (as so defined) in coordination with the furnishing of home infusion drugs (as defined in paragraph (3)(C)) under part B.

"(2) The items and services described in this paragraph are the following:

"(A) Professional services, including nursing services, furnished in accordance with the plan.

"(B) Training and education (not otherwise paid for as durable medical equipment (as defined in subsection (n)), remote monitoring, and monitoring services for the provi-

sion of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier.

"(3) For purposes of this subsection:

"(A) The term 'applicable provider' means—

"(i) a physician;

"(ii) a nurse practitioner; and

"(iii) a physician assistant.

"(B) The term 'home' means a place of residence used as the home of an individual (as defined for purposes of subsection (n)).

"(C) The term 'home infusion drug' means a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment (as defined in subsection (n)). Such term does not include the following:

"(i) Insulin pump systems.

"(ii) A self-administered drug or biological on a self-administered drug exclusion list.

"(D)(i) The term 'qualified home infusion therapy supplier' means a pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider or services or supplier furnishes items or services and that—

"(I) furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs;

"(II) ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis;

"(III) is accredited by an organization designated by the Secretary pursuant to section 1834(u)(5); and

"(IV) meets such other requirements as the Secretary determines appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage plans under part C and in the private sector.

"(ii) A qualified home infusion therapy supplier may subcontract with a pharmacy, physician, provider of services, or supplier to meet the requirements of this subparagraph.".

(b) PAYMENT AND RELATED REQUIREMENTS FOR HOME INFUSION THERAPY.—Section 1834 of the Social Security Act (42 U.S.C. 1395m), as amended by section 4011, is further amended by adding at the end the following new subsection:

"(u) PAYMENT AND RELATED REQUIREMENTS FOR HOME INFUSION THERAPY.—

"(1) PAYMENT.—

"(A) SINGLE PAYMENT.—

"(i) IN GENERAL.—Subject to clause (iii) and subparagraphs (B) and (C), the Secretary shall implement a payment system under which a single payment is made under this title to a qualified home infusion therapy supplier for items and services described in

subparagraphs (A) and (B) of section 1861(iii)(2)) furnished by a qualified home infusion therapy supplier (as defined in section 1861(iii)(3)(D)) in coordination with the furnishing of home infusion drugs (as defined in section 1861(iii)(3)(C)) under this part.

"(ii) UNIT OF SINGLE PAYMENT.—A unit of single payment under the payment system implemented under this subparagraph is for each infusion drug administration calendar day in the individual's home. The Secretary shall, as appropriate, establish single payment amounts for types of infusion therapy, including to take into account variation in utilization of nursing services by therapy type.

"(iii) LIMITATION.—The single payment amount determined under this subparagraph after application of subparagraph (B) and paragraph (3) shall not exceed the amount determined under the fee schedule under section 1848 for infusion therapy services furnished in a calendar day if furnished in a physician office setting, except such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day.

"(B) REQUIRED ADJUSTMENTS.—The Secretary shall adjust the single payment amount determined under subparagraph (A) for home infusion therapy services under section 1861(iii)(1) to reflect other factors such as—

"(i) a geographic wage index and other costs that may vary by region; and

"(ii) patient acuity and complexity of drug administration.

"(C) DISCRETIONARY ADJUSTMENTS.—

"(i) IN GENERAL.—Subject to clause (ii), the Secretary may adjust the single payment amount determined under subparagraph (A) (after application of subparagraph (B)) to reflect outlier situations and other factors as the Secretary determines appropriate.

"(ii) REQUIREMENT OF BUDGET NEUTRALITY.—Any adjustment under this subparagraph shall be made in a budget neutral manner.

"(2) CONSIDERATIONS.—In developing the payment system under this subsection, the Secretary may consider the costs of furnishing infusion therapy in the home, consult with home infusion therapy suppliers, consider payment amounts for similar items and services under this part and part A, and consider payment amounts established by Medicare Advantage plans under part C and in the private insurance market for home infusion therapy (including average per treatment day payment amounts by type of home infusion therapy).

"(3) ANNUAL UPDATES.—

"(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall update the single payment amount under this subsection from year to year beginning in 2022 by increasing the single payment amount from the prior year by the percentage increase in the Consumer Price Index for

all urban consumers (United States city average) for the 12-month period ending with June of the preceding year.

"(B) ADJUSTMENT.—For each year, the Secretary shall reduce the percentage increase described in subparagraph (A) by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II). The application of the preceding sentence may result in a percentage being less than 0.0 for a year, and may result in payment being less than such payment rates for the preceding year.

"(4) AUTHORITY TO APPLY PRIOR AUTHORIZATION.—The Secretary may, as determined appropriate by the Secretary, apply prior authorization for home infusion therapy services under section 1861(iii)(1).

"(5) ACCREDITATION OF QUALIFIED HOME INFUSION THERAPY SUPPLIERS.—

"(A) FACTORS FOR DESIGNATION OF ACCREDITATION ORGANIZATIONS.—The Secretary shall consider the following factors in designating accreditation organizations under subparagraph (B) and in reviewing and modifying the list of accreditation organizations designated pursuant to subparagraph (C):

"(i) The ability of the organization to conduct timely reviews of accreditation applications.

"(ii) The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D)).

"(iii) Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

"(iv) Such other factors as the Secretary determines appropriate.

"(B) DESIGNATION.—Not later than January 1, 2021, the Secretary shall designate organizations to accredit suppliers furnishing home infusion therapy. The list of accreditation organizations so designated may be modified pursuant to subparagraph (C).

"(C) REVIEW AND MODIFICATION OF LIST OF ACCREDITATION ORGANIZATIONS.—

"(i) IN GENERAL.—The Secretary shall review the list of accreditation organizations designated under subparagraph (B) taking into account the factors under subparagraph (A). Taking into account the results of such review, the Secretary may, by regulation, modify the list of accreditation organizations designated under subparagraph (B).

"(ii) SPECIAL RULE FOR ACCREDITATIONS DONE PRIOR TO REMOVAL FROM LIST OF DESIGNATED ACCREDITATION ORGANIZATIONS.—In the case where the Secretary removes an organization from the list of accreditation organizations designated under subparagraph (B), any supplier that is accredited by the organization during the period beginning on the date on which the organization is designated as an accreditation organization under subparagraph (B) and ending on the date

on which the organization is removed from such list shall be considered to have been accredited by an organization designated by the Secretary under subparagraph (B) for the remaining period such accreditation is in effect.

"(D) RULE FOR ACCREDITATIONS MADE PRIOR TO DESIGNATION.—In the case of a supplier that is accredited before January 1, 2021, by an accreditation organization designated by the Secretary under subparagraph (B) as of January 1, 2019, such supplier shall be considered to have been accredited by an organization designated by the Secretary under such paragraph as of January 1, 2023, for the remaining period such accreditation is in effect.

"(6) NOTIFICATION OF INFUSION THERAPY OPTIONS AVAILABLE PRIOR TO FURNISHING HOME INFUSION THERAPY.—Prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan described in section 1861(iii)(1) for the individual shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy under this part.".

(c) CONFORMING AMENDMENTS.—

(1) PAYMENT REFERENCE.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)) is amended—

(A) by striking "and" before "(AA)"; and

(B) by inserting before the semicolon at the end the following: ", and (BB) with respect to home infusion therapy, the amount paid shall be an amount equal to 80 percent of the lesser of the actual charge for the services or the amount determined under section 1834(u)".

(2) DIRECT PAYMENT.—The first sentence of section 1842(b)(6) of the Social Security Act (42 U.S.C. 1395u(b)(6)) is amended—

(A) by striking "and" before "(H)"; and

(B) by inserting before the period at the end the following: ", and (I) in the case of home infusion therapy, payment shall be made to the qualified home infusion therapy supplier".

(3) EXCLUSION FROM HOME HEALTH SERVICES.—Section 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)) is amended, in the first sentence, by inserting the following before the period at the end: "and home infusion therapy (as defined in subsection (iii)(i))".

(d) [42 U.S.C. 13951 note] EFFECTIVE DATE.—The amendments made by this section shall apply to items and services furnished on or after January 1, 2021, except that the amendments made by paragraphs (1) and (2) of subsection (c) shall apply to items and services furnished on or after January 1, 2019.

DIVISION B—HELPING FAMILIES IN MENTAL HEALTH CRISIS

SEC. 6000. [42 U.S.C. 201 note] SHORT TITLE.

This division may be cited as the "Helping Families in Mental Health Crisis Reform Act of 2016".

TITLE VI—STRENGTHENING LEADERSHIP AND ACCOUNTABILITY

Subtitle A—Leadership

SEC. 6001. ASSISTANT SECRETARY FOR MENTAL HEALTH AND SUBSTANCE USE.

(a) ASSISTANT SECRETARY.—Section 501(c) of the Public Health Service Act (42 U.S.C. 290aa(c)) is amended to read as follows:

"(c) ASSISTANT SECRETARY AND DEPUTY ASSISTANT SECRETARY.—

"(1) ASSISTANT SECRETARY.—The Administration shall be headed by an official to be known as the Assistant Secretary for Mental Health and Substance Use (hereinafter in this title referred to as the 'Assistant Secretary') who shall be appointed by the President, by and with the advice and consent of the Senate.

"(2) DEPUTY ASSISTANT SECRETARY.—The Assistant Secretary, with the approval of the Secretary, may appoint a Deputy Assistant Secretary and may employ and prescribe the functions of such officers and employees, including attorneys, as are necessary to administer the activities to be carried out through the Administration.".

(b) [42 U.S.C. 290aa note]

[42 U.S.C. 290aa note] TRANSFER OF AUTHORITIES.—The Secretary of Health and Human Services shall delegate to the Assistant Secretary for Mental Health and Substance Use all duties and authorities that—

(1) as of the day before the date of enactment of this Act, were vested in the Administrator of the Substance Abuse and Mental Health Services Administration; and

(2) are not terminated by this Act.

(c) CONFORMING AMENDMENTS.—Title V of the Public Health Service Act (42 U.S.C. 290aa et seq.), as amended by the previous provisions of this section, is further amended—

(1) by striking "Administrator of the Substance Abuse and Mental Health Services Administration" each place it appears and inserting "Assistant Secretary for Mental Health and Substance Use"; and

(2) by striking "Administrator" or "Administrator" each place it appears (including in any headings) and inserting "Assistant Secretary" or "Assistant Secretary", respectively, except where the term "Administrator" appears—

(A) in each of subsections (e) and (f) of section 501 of such Act (42 U.S.C. 290aa), including the headings of such subsections, within the term "Associate Administrator";

(B) in section 507(b)(6) of such Act (42 U.S.C. 290bb(b)(6)), within the term "Administrator of the Health Resources and Services Administration";

(C) in section 507(b)(6) of such Act (42 U.S.C. 290bb(b)(6)), within the term "Administrator of the Centers for Medicare & Medicaid Services";

(D) in section 519B(c)(1)(B) of such Act (42 U.S.C. 290bb-25b(c)(1)(B)), within the term "Administrator of the National Highway Traffic Safety Administration"; or

(E) in each of sections 519B(c)(1)(B), 520C(a), and 520D(a) of such Act (42 U.S.C. 290bb-25b(c)(1)(B), 290bb-34(a), 290bb-35(a)), within the term "Administrator of the Office of Juvenile Justice and Delinquency Prevention".

(d) 【42 U.S.C. 290aa note】

【42 U.S.C. 290aa note】 REFERENCES.—After executing subsections (a), (b), and (c), any reference in statute, regulation, or guidance to the Administrator of the Substance Abuse and Mental Health Services Administration shall be construed to be a reference to the Assistant Secretary for Mental Health and Substance Use.

SEC. 6002. STRENGTHENING THE LEADERSHIP OF THE SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION.

Section 501 of the Public Health Service Act (42 U.S.C. 290aa), as amended by section 6001, is further amended—

(1) in subsection (b)—

(A) in the subsection heading, by striking "**Agencies**" and inserting "Centers"; and

(B) in the matter preceding paragraph (1), by striking "entities" and inserting "Centers";

(2) in subsection (d)—

(A) in paragraph (1)—

(i) by striking "agencies" each place the term appears and inserting "Centers"; and

(ii) by striking "such agency" and inserting "such Center";

(B) in paragraph (2)—

(i) by striking "agencies" and inserting "Centers";

(ii) by striking "with respect to substance abuse" and inserting "with respect to substance use disorders"; and

(iii) by striking "and individuals who are substance abusers" and inserting "and individuals with substance use disorders";

(C) in paragraph (5), by striking "substance abuse" and inserting "substance use disorder";

(D) in paragraph (6)—

(i) by striking "the Centers for Disease Control" and inserting "the Centers for Disease Control and Prevention,";

(ii) by striking "Administration develop" and inserting "Administration, develop";

(iii) by striking "HIV or tuberculosis among substance abusers and individuals with mental illness" and inserting "HIV, hepatitis, tuberculosis, and other communicable diseases among individuals with mental or substance use disorders,"; and

(iv) by striking "illnesses" at the end and inserting "diseases or disorders";

(E) in paragraph (7), by striking "abuse utilizing anti-addiction medications, including methadone" and inserting "use disorders, including services that utilize drugs or devices approved or cleared by the Food and Drug Administration for the treatment of substance use disorders";

(F) in paragraph (8)—

(i) by striking "Agency for Health Care Policy Research" and inserting "Agency for Healthcare Research and Quality"; and

(ii) by striking "treatment and prevention" and inserting "prevention and treatment";

(G) in paragraph (9)—

(i) by inserting "and maintenance" after "development";

(ii) by striking "Agency for Health Care Policy Research" and inserting "Agency for Healthcare Research and Quality"; and

(iii) by striking "treatment and prevention services" and inserting "prevention, treatment, and recovery support services and are appropriately incorporated into programs carried out by the Administration";

(H) in paragraph (10), by striking "abuse" and inserting "use disorder";

(I) by striking paragraph (11) and inserting the following:

"(11) work with relevant agencies of the Department of Health and Human Services on integrating mental health promotion and substance use disorder prevention with general health promotion and disease prevention and integrating mental and substance use disorders treatment services with physical health treatment services;";

(J) in paragraph (13)—

(i) in the matter preceding subparagraph (A), by striking "this title, assure that" and inserting "this title or part B of title XIX, or grant programs otherwise funded by the Administration";

(ii) in subparagraph (A)—

(I) by inserting "require that" before "all grants"; and

(II) by striking "and" at the end;

(iii) by redesignating subparagraph (B) as subparagraph (C);

(iv) by inserting after subparagraph (A) the following:

"(B) ensure that the director of each Center of the Administration consistently documents the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded;";

(v) in subparagraph (C), as so redesignated—

(I) by inserting "require that" before "all grants"; and

(II) in clause (ii), by inserting "and" after the semicolon at the end; and

(vi) by adding at the end the following:

"(D) inform a State when any funds are awarded through such a grant to any entity within such State;";

(K) in paragraph (16), by striking "abuse and mental health information" and inserting "use disorder information, including evidence-based and promising best practices for prevention, treatment, and recovery support services for individuals with mental and substance use disorders,";

(L) in paragraph (17)—

(i) by striking "substance abuse" and inserting "substance use disorder"; and

(ii) by striking "and" at the end;

(M) in paragraph (18), by striking the period and inserting a semicolon; and

(N) by adding at the end the following:

"(19) consult with State, local, and tribal governments, nongovernmental entities, and individuals with mental illness, particularly adults with a serious mental illness, children with a serious emotional disturbance, and the family members of such adults and children, with respect to improving community-based and other mental health services;

"(20) collaborate with the Secretary of Defense and the Secretary of Veterans Affairs to improve the provision of mental and substance use disorder services provided by the Department of Defense and the Department of Veterans Affairs to members of the Armed Forces, veterans, and the family members of such members and veterans, including through the provision of services using the telehealth capabilities of the Department of Defense and the Department of Veterans Affairs;

"(21) collaborate with the heads of relevant Federal agencies and departments, States, communities, and nongovernmental experts to improve mental and substance use disorders services for chronically homeless individuals, including by designing strategies to provide such services in supportive housing;

"(22) work with States and other stakeholders to develop and support activities to recruit and retain a workforce addressing mental and substance use disorders;

"(23) collaborate with the Attorney General and representatives of the criminal justice system to improve mental and substance use disorders services for individuals who have been arrested or incarcerated;

"(24) after providing an opportunity for public input, set standards for grant programs under this title for mental and substance use disorders services and prevention programs, which standards may address—

"(A) the capacity of the grantee to implement the award;

"(B) requirements for the description of the program implementation approach;

"(C) the extent to which the grant plan submitted by the grantee as part of its application must explain how the

grantee will reach the population of focus and provide a statement of need, which may include information on how the grantee will increase access to services and a description of measurable objectives for improving outcomes;

"(D) the extent to which the grantee must collect and report on required performance measures; and

"(E) the extent to which the grantee is proposing to use evidence-based practices; and

"(25) advance, through existing programs, the use of performance metrics, including those based on the recommendations on performance metrics from the Assistant Secretary for Planning and Evaluation under section 6021(d) of the Helping Families in Mental Health Crisis Reform Act of 2016."; and

(3) in subsection (m), by adding at the end the following:

"(4) EMERGENCY RESPONSE.—Amounts made available for carrying out this subsection shall remain available through the end of the fiscal year following the fiscal year for which such amounts are appropriated.".

SEC. 6003. CHIEF MEDICAL OFFICER.

Section 501 of the Public Health Service Act (42 U.S.C. 290aa), as amended by sections 6001 and 6002, is further amended—

(1) by redesignating subsections (g) through (j) and subsections (k) through (o) as subsections (h) through (k) and subsections (m) through (q), respectively;

(2) in subsection (e)(3)(C), by striking "subsection (k)" and inserting "subsection (m)";

(3) in subsection (f)(2)(C)(iii), by striking "subsection (k)" and inserting "subsection (m)"; and

(4) by inserting after subsection (f) the following:

"(g) CHIEF MEDICAL OFFICER.—

"(1) IN GENERAL.—The Assistant Secretary, with the approval of the Secretary, shall appoint a Chief Medical Officer to serve within the Administration.

"(2) ELIGIBLE CANDIDATES.—The Assistant Secretary shall select the Chief Medical Officer from among individuals who—

"(A) have a doctoral degree in medicine or osteopathic medicine;

"(B) have experience in the provision of mental or substance use disorder services;

"(C) have experience working with mental or substance use disorder programs;

"(D) have an understanding of biological, psychosocial, and pharmaceutical treatments of mental or substance use disorders; and

"(E) are licensed to practice medicine in one or more States.

"(3) DUTIES.—The Chief Medical Officer shall—

"(A) serve as a liaison between the Administration and providers of mental and substance use disorders prevention, treatment, and recovery services;

"(B) assist the Assistant Secretary in the evaluation, organization, integration, and coordination of programs operated by the Administration;

"(C) promote evidence-based and promising best practices, including culturally and linguistically appropriate practices, as appropriate, for the prevention and treatment of, and recovery from, mental and substance use disorders, including serious mental illness and serious emotional disturbances;

"(D) participate in regular strategic planning with the Administration;

"(E) coordinate with the Assistant Secretary for Planning and Evaluation to assess the use of performance metrics to evaluate activities within the Administration related to mental and substance use disorders; and

"(F) coordinate with the Assistant Secretary to ensure mental and substance use disorders grant programs within the Administration consistently utilize appropriate performance metrics and evaluation designs.".

SEC. 6004. IMPROVING THE QUALITY OF BEHAVIORAL HEALTH PROGRAMS.

Section 505 of the Public Health Service Act (42 U.S.C. 290aa-4), as amended by section 6001(c), is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 505. CENTER FOR BEHAVIORAL HEALTH STATISTICS AND QUALITY";

(2) by redesignating subsections (a) through (d) as subsections (b) through (e), respectively;

(3) before subsection (b), as redesignated by paragraph (2), by inserting the following:

"(a) IN GENERAL.—The Assistant Secretary shall maintain within the Administration a Center for Behavioral Health Statistics and Quality (in this section referred to as the 'Center'). The Center shall be headed by a Director (in this section referred to as the 'Director') appointed by the Secretary from among individuals with extensive experience and academic qualifications in research and analysis in behavioral health care or related fields.";

(4) in subsection (b), as redesignated by paragraph (2)—

(A) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively;

(B) by striking "The Secretary, acting" and all that follows through "year on—" and inserting" The Director shall—

"(1) coordinate the Administration's integrated data strategy, including by collecting data each year on—";

(C) in the subparagraph (B), as redesignated by subparagraph (A), by striking "Assistant Secretary" and inserting "Director"; and

(D) by adding at the end the following new paragraphs:

"(2) provide statistical and analytical support for activities of the Administration;

"(3) recommend a core set of performance metrics to evaluate activities supported by the Administration; and

"(4) coordinate with the Assistant Secretary, the Assistant Secretary for Planning and Evaluation, and the Chief Medical Officer appointed under section 501(g), as appropriate, to improve the quality of services provided by programs of the Administration and the evaluation of activities carried out by the Administration.".

(5) in subsection (c), as so redesignated—

(A) by striking "With respect to the activities" and inserting "Mental Health.—With respect to the activities";

(B) by striking "Assistant Secretary" each place it appears and inserting "Director"; and

(C) by striking "subsection (a)" and inserting "subsection (b)(1)";

(6) in subsection (d), as so redesignated—

(A) by striking the subsection designation and all that follows through "With respect to the activities" and inserting the following:

"(d) SUBSTANCE ABUSE.—

"(1) IN GENERAL.—With respect to the activities";

(B) in paragraph (1)—

(i) in the matter before subparagraph (A)—

(I) by striking "subsection (a)" and inserting "subsection (b)(1)"; and

(II) by striking "Assistant Secretary" each place it appears and inserting "Director"; and

(ii) in subparagraph (B), by inserting "in coordination with the Centers for Disease Control and Prevention" before the semicolon at the end; and

(C) in paragraph (2), by striking "**Annual surveys**" and inserting "Annual surveys; public availability of data.—Annual surveys"; and

(7) in subsection (e), as so redesignated—

(A) by striking "After consultation" and inserting "Consultation.—After consultation"; and

(B) by striking "Assistant Secretary shall develop" and inserting "Assistant Secretary shall use existing standards and best practices to develop".

SEC. 6005. STRATEGIC PLAN.

Section 501 of the Public Health Service Act (42 U.S.C. 290aa), as amended by sections 6001 through 6003, is further amended by inserting after subsection (k), as redesignated by section 6003, the following:

"(l) STRATEGIC PLAN.—

"(1) IN GENERAL.—Not later than September 30, 2018, and every 4 years thereafter, the Assistant Secretary shall develop and carry out a strategic plan in accordance with this subsection for the planning and operation of activities carried out by the Administration, including evidence-based programs.

"(2) COORDINATION.—In developing and carrying out the strategic plan under this subsection, the Assistant Secretary shall take into consideration the findings and recommendations of the Assistant Secretary for Planning and Evaluation under section 6021(d) of the Helping Families in Mental

Health Crisis Reform Act of 2016 and the report of the Interdepartmental Serious Mental Illness Coordinating Committee under section 6031 of such Act.

"(3) PUBLICATION OF PLAN.—Not later than September 30, 2018, and every 4 years thereafter, the Assistant Secretary shall—

"(A) submit the strategic plan developed under paragraph (1) to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate; and

"(B) post such plan on the Internet website of the Administration.

"(4) CONTENTS.—The strategic plan developed under paragraph (1) shall—

"(A) identify strategic priorities, goals, and measurable objectives for mental and substance use disorders activities and programs operated and supported by the Administration, including priorities to prevent or eliminate the burden of mental and substance use disorders;

"(B) identify ways to improve the quality of services for individuals with mental and substance use disorders, and to reduce homelessness, arrest, incarceration, violence, including self-directed violence, and unnecessary hospitalization of individuals with a mental or substance use disorder, including adults with a serious mental illness or children with a serious emotional disturbance;

"(C) ensure that programs provide, as appropriate, access to effective and evidence-based prevention, diagnosis, intervention, treatment, and recovery services, including culturally and linguistically appropriate services, as appropriate, for individuals with a mental or substance use disorder;

"(D) identify opportunities to collaborate with the Health Resources and Services Administration to develop or improve—

"(i) initiatives to encourage individuals to pursue careers (especially in rural and underserved areas and with rural and underserved populations) as psychiatrists, including child and adolescent psychiatrists, psychologists, psychiatric nurse practitioners, physician assistants, clinical social workers, certified peer support specialists, licensed professional counselors, or other licensed or certified mental health or substance use disorder professionals, including such professionals specializing in the diagnosis, evaluation, or treatment of adults with a serious mental illness or children with a serious emotional disturbance; and

"(ii) a strategy to improve the recruitment, training, and retention of a workforce for the treatment of individuals with mental or substance use disorders, or co-occurring disorders;

"(E) identify opportunities to improve collaboration with States, local governments, communities, and Indian tribes and tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act); and

"(F) specify a strategy to disseminate evidence-based and promising best practices related to prevention, diagnosis, early intervention, treatment, and recovery services related to mental illness, particularly for adults with a serious mental illness and children with a serious emotional disturbance, and for individuals with a substance use disorder.".

SEC. 6006. BIENNIAL REPORT CONCERNING ACTIVITIES AND PROGRESS.

(a) IN GENERAL.—Section 501 of the Public Health Service Act (42 U.S.C. 290aa), as so amended, is further amended by amending subsection (m), as redesignated by section 6003, to read as follows:

"(m) BIENNIAL REPORT CONCERNING ACTIVITIES AND PROGRESS.—Not later than September 30, 2020, and every 2 years thereafter, the Assistant Secretary shall prepare and submit to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, and post on the Internet website of the Administration, a report containing at a minimum—

"(1) a review of activities conducted or supported by the Administration, including progress toward strategic priorities, goals, and objectives identified in the strategic plan developed under subsection (l);

"(2) an assessment of programs and activities carried out by the Assistant Secretary, including the extent to which programs and activities under this title and part B of title XIX meet identified goals and performance measures developed for the respective programs and activities;

"(3) a description of the progress made in addressing gaps in mental and substance use disorders prevention, treatment, and recovery services and improving outcomes by the Administration, including with respect to serious mental illnesses, serious emotional disturbances, and co-occurring disorders;

"(4) a description of the manner in which the Administration coordinates and partners with other Federal agencies and departments related to mental and substance use disorders, including activities related to—

"(A) the implementation and dissemination of research findings into improved programs, including with respect to how advances in serious mental illness and serious emotional disturbance research have been incorporated into programs;

"(B) the recruitment, training, and retention of a mental and substance use disorders workforce;

"(C) the integration of mental disorder services, substance use disorder services, and physical health services;

"(D) homelessness; and

"(E) veterans;

"(5) a description of the manner in which the Administration promotes coordination by grantees under this title, and part B of title XIX, with State or local agencies; and

"(6) a description of the activities carried out under section 501A(e), with respect to mental and substance use disorders, including—

"(A) the number and a description of grants awarded;

"(B) the total amount of funding for grants awarded;

"(C) a description of the activities supported through such grants, including outcomes of programs supported; and

"(D) information on how the National Mental Health and Substance Use Policy Laboratory is consulting with the Assistant Secretary for Planning and Evaluation and collaborating with the Center for Substance Abuse Treatment, the Center for Substance Abuse Prevention, the Center for Behavioral Health Statistics and Quality, and the Center for Mental Health Services to carry out such activities; and

"(7) recommendations made by the Assistant Secretary for Planning and Evaluation under section 6021 of the Helping Families in Mental Health Crisis Reform Act of 2016 to improve programs within the Administration, and actions taken in response to such recommendations to improve programs within the Administration.

The Assistant Secretary may meet reporting requirements established under this title by providing the contents of such reports as an addendum to the biennial report established under this subsection, notwithstanding the timeline of other reporting requirements in this title. Nothing in this subsection shall be construed to alter the content requirements of such reports or authorize the Assistant Secretary to alter the timeline of any such reports to be less frequent than biennially, unless as specified in this title.".

(b) CONFORMING AMENDMENT.—Section 508(p) of the Public Health Service Act (42 U.S.C. 290bb-1(p)) is amended by striking "section 501(k)" and inserting "section 501(m)".

SEC. 6007. AUTHORITIES OF CENTERS FOR MENTAL HEALTH SERVICES, SUBSTANCE ABUSE PREVENTION, AND SUBSTANCE ABUSE TREATMENT.

(a) CENTER FOR MENTAL HEALTH SERVICES.—Section 520(b) of the Public Health Service Act (42 U.S.C. 290bb-31(b)) is amended—

(1) by redesignating paragraphs (3) through (15) as paragraphs (4) through (16), respectively;

(2) by inserting after paragraph (2) the following:

"(3) collaborate with the Director of the National Institute of Mental Health and the Chief Medical Officer, appointed under section 501(g), to ensure that, as appropriate, programs related to the prevention and treatment of mental illness and the promotion of mental health and recovery support are carried out in a manner that reflects the best available science and evidence-based practices, including culturally and linguistically appropriate services, as appropriate;";

(3) in paragraph (5), as so redesignated, by inserting ", including through programs that reduce risk and promote resiliency" before the semicolon;

(4) in paragraph (6), as so redesignated, by inserting "in collaboration with the Director of the National Institute of Mental Health," before "develop";

(5) in paragraph (8), as so redesignated, by inserting ", increase meaningful participation of individuals with mental illness in programs and activities of the Administration," before "and protect the legal";

(6) in paragraph (10), as so redesignated, by striking "professional and paraprofessional personnel pursuant to section 303" and inserting "health paraprofessional personnel and health professionals";

(7) in paragraph (11), as so redesignated, by inserting "and tele-mental health" after "rural mental health";

(8) in paragraph (12), as so redesignated, by striking "establish a clearinghouse for mental health information to assure the widespread dissemination of such information" and inserting "disseminate mental health information, including evidence-based practices,";

(9) in paragraph (15), as so redesignated, by striking "and" at the end;

(10) in paragraph (16), as so redesignated, by striking the period and inserting "; and"; and

(11) by adding at the end the following:

"(17) ensure the consistent documentation of the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded.".

(b) DIRECTOR OF THE CENTER FOR SUBSTANCE ABUSE PREVENTION.—Section 515 of the Public Health Service Act (42 U.S.C. 290bb-21) is amended—

(1) in the section heading, by striking "**office**" and inserting "**center**";

(2) in subsection (a)—

(A) by striking "an Office" and inserting "a Center"; and

(B) by striking "The Office" and inserting "The Prevention Center"; and

(3) in subsection (b)—

(A) in paragraph (1), by inserting "through the reduction of risk and the promotion of resiliency" before the semicolon;

(B) by redesignating paragraphs (3) through (11) as paragraphs (4) through (12), respectively;

(C) by inserting after paragraph (2) the following:

"(3) collaborate with the Director of the National Institute on Drug Abuse, the Director of the National Institute on Alcohol Abuse and Alcoholism, and States to promote the study of substance abuse prevention and the dissemination and implementation of research findings that will improve the delivery and effectiveness of substance abuse prevention activities;";

(D) in paragraph (4), as so redesignated, by striking "literature on the adverse effects of cocaine free base

(known as crack)" and inserting "educational information on the effects of drugs abused by individuals, including drugs that are emerging as abused drugs";

(E) in paragraph (6), as so redesignated—

(i) by striking "substance abuse counselors" and inserting "health professionals who provide substance use and misuse prevention and treatment services"; and

(ii) by striking "drug abuse education, prevention," and inserting "illicit drug use education and prevention";

(F) by amending paragraph (7), as so redesignated, to read as follows:

"(7) in cooperation with the Director of the Centers for Disease Control and Prevention, develop and disseminate educational materials to increase awareness for individuals at greatest risk for substance use disorders to prevent the transmission of communicable diseases, such as HIV, hepatitis, tuberculosis, and other communicable diseases;";

(G) in paragraph (9), as so redesignated—

(i) by striking "to discourage" and inserting "that reduce the risk of"; and

(ii) by inserting before the semicolon "and promote resiliency";

(H) in paragraph (11), as so redesignated, by striking "and" after the semicolon;

(I) in paragraph (12), as so redesignated, by striking the period and inserting a semicolon; and

(J) by adding at the end the following:

"(13) ensure the consistent documentation of the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded; and

"(14) assist and support States in preventing illicit drug use, including emerging illicit drug use issues.".

(c) DIRECTOR OF THE CENTER FOR SUBSTANCE ABUSE TREATMENT.—Section 507 of the Public Health Service Act (42 U.S.C. 290bb) is amended—

(1) in subsection (a)—

(A) by striking "treatment of substance abuse" and inserting "treatment of substance use disorders"; and

(B) by striking "abuse treatment systems" and inserting "use disorder treatment systems"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "abuse" and inserting "use disorder";

(B) in paragraph (3), by striking "abuse" and inserting "use disorder";

(C) in paragraph (4), by striking "individuals who abuse drugs" and inserting "individuals who illicitly use drugs";

(D) in paragraph (9), by striking "carried out by the Director";

(E) by striking paragraph (10);

(F) by redesignating paragraphs (11) through (14) as paragraphs (10) through (13), respectively;

(G) in paragraph (12), as so redesignated, by striking "; and" and inserting a semicolon; and

(H) by striking paragraph (13), as so redesignated, and inserting the following:

"(13) ensure the consistent documentation of the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded; and

"(14) work with States, providers, and individuals in recovery, and their families, to promote the expansion of recovery support services and systems of care oriented toward recovery.".

SEC. 6008. ADVISORY COUNCILS.

Section 502(b) of the Public Health Service Act (42 U.S.C. 290aa-1(b)) is amended—

(1) in paragraph (2)—

(A) in subparagraph (E), by striking "and" after the semicolon;

(B) by redesignating subparagraph (F) as subparagraph (J); and

(C) by inserting after subparagraph (E), the following:

"(F) the Chief Medical Officer, appointed under section 501(g);

"(G) the Director of the National Institute of Mental Health for the advisory councils appointed under subsections (a)(1)(A) and (a)(1)(D);

"(H) the Director of the National Institute on Drug Abuse for the advisory councils appointed under subsections (a)(1)(A), (a)(1)(B), and (a)(1)(C);

"(I) the Director of the National Institute on Alcohol Abuse and Alcoholism for the advisory councils appointed under subsections (a)(1)(A), (a)(1)(B), and (a)(1)(C); and"; and

(2) in paragraph (3), by adding at the end the following:

"(C) Not less than half of the members of the advisory council appointed under subsection (a)(1)(D)—

"(i) shall—

"(I) have a medical degree;

"(II) have a doctoral degree in psychology; or

"(III) have an advanced degree in nursing or social work from an accredited graduate school or be a certified physician assistant; and

"(ii) shall specialize in the mental health field.

"(D) Not less than half of the members of the advisory councils appointed under subsections (a)(1)(B) and (a)(1)(C)—

"(i) shall—

"(I) have a medical degree;

"(II) have a doctoral degree; or

"(III) have an advanced degree in nursing, public health, behavioral or social sciences, or so-

cial work from an accredited graduate school or be a certified physician assistant; and

"(ii) shall have experience in the provision of substance use disorder services or the development and implementation of programs to prevent substance misuse.".

SEC. 6009. PEER REVIEW.

Section 504(b) of the Public Health Service Act (42 U.S.C. 290aa-3(b)) is amended by adding at the end the following: "In the case of any such peer review group that is reviewing a grant, cooperative agreement, or contract related to mental illness treatment, not less than half of the members of such peer review group shall be licensed and experienced professionals in the prevention, diagnosis, or treatment of, or recovery from, mental illness or co-occurring mental illness and substance use disorders and have a medical degree, a doctoral degree in psychology, or an advanced degree in nursing or social work from an accredited program, and the Secretary, in consultation with the Assistant Secretary, shall, to the extent possible, ensure such peer review groups include broad geographic representation, including both urban and rural representatives.".

Subtitle B—Oversight and Accountability

SEC. 6021. [42 U.S.C. 290aa note] IMPROVING OVERSIGHT OF MENTAL AND SUBSTANCE USE DISORDERS PROGRAMS THROUGH THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Assistant Secretary for Planning and Evaluation, shall ensure efficient and effective planning and evaluation of mental and substance use disorders prevention and treatment programs and related activities.

(b) EVALUATION STRATEGY.—In carrying out subsection (a), the Assistant Secretary for Planning and Evaluation shall, not later than 180 days after the date of enactment of this Act, develop a strategy for conducting ongoing evaluations that identifies priority programs to be evaluated by the Assistant Secretary for Planning and Evaluation and priority programs to be evaluated by other relevant offices and agencies within the Department of Health and Human Services. The strategy shall—

(1) include a plan for evaluating programs related to mental and substance use disorders, including co-occurring disorders, across agencies, as appropriate, including programs related to—

(A) prevention, intervention, treatment, and recovery support services, including such services for adults with a serious mental illness or children with a serious emotional disturbance;

(B) the reduction of homelessness and incarceration among individuals with a mental or substance use disorder; and

(C) public health and health services; and

(2) include a plan for assessing the use of performance metrics to evaluate activities carried out by entities receiving grants, contracts, or cooperative agreements related to mental and substance use disorders prevention and treatment services under title V or title XIX of the Public Health Service Act (42 U.S.C. 290aa et seq.; 42 U.S.C. 300w et seq.).

(c) CONSULTATION.—In carrying out this section, the Assistant Secretary for Planning and Evaluation shall consult, as appropriate, with the Assistant Secretary for Mental Health and Substance Use, the Chief Medical Officer of the Substance Abuse and Mental Health Services Administration appointed under section 501(g) of the Public Health Service Act (42 U.S.C. 290aa(g)), as amended by section 6003, the Behavioral Health Coordinating Council of the Department of Health and Human Services, other agencies within the Department of Health and Human Services, and other relevant Federal departments and agencies.

(d) RECOMMENDATIONS.—In carrying out this section, the Assistant Secretary for Planning and Evaluation shall provide recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Mental Health and Substance Use, and the Congress on improving the quality of prevention and treatment programs and activities related to mental and substance use disorders, including recommendations for the use of performance metrics. The Assistant Secretary for Mental Health and Substance Use shall include such recommendations in the biennial report required by subsection 501(m) of the Public Health Service Act, as redesignated by section 6003 of this Act.

SEC. 6022. REPORTING FOR PROTECTION AND ADVOCACY ORGANIZATIONS.

(a) PUBLIC AVAILABILITY OF REPORTS.—Section 105(a)(7) of the Protection and Advocacy for Individuals with Mental Illness Act (42 U.S.C. 10805(a)(7)) is amended by striking "is located a report" and inserting "is located, and make publicly available, a report".

(b) DETAILED ACCOUNTING.—Section 114(a) of the Protection and Advocacy for Individuals with Mental Illness Act (42 U.S.C. 10824(a)) is amended—

(1) in paragraph (3), by striking "and" at the end;

(2) in paragraph (4), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(5) using data from the existing required annual program progress reports submitted by each system funded under this title, a detailed accounting for each such system of how funds are spent, disaggregated according to whether the funds were received from the Federal Government, the State government, a local government, or a private entity.".

SEC. 6023. GAO STUDY.

(a) IN GENERAL.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services and the Assistant Secretary for Mental Health and Substance Use, shall conduct an independent evaluation, and submit a report, to the Committee on Health, Education, Labor, and Pen-

sions of the Senate and the Committee on Energy and Commerce of the House of Representatives, on programs funded by allotments made under title I of the Protection and Advocacy for Individuals with Mental Illness Act (42 U.S.C. 10801 et seq.).

(b) CONTENTS.—The report and evaluation required under subsection (a) shall include—

(1) a review of the programs described in such subsection that are carried out by State agencies and such programs that are carried out by private, nonprofit organizations; and

(2) a review of the compliance of the programs described in subsection (a) with statutory and regulatory responsibilities, such as—

(A) responsibilities relating to family engagement;

(B) responsibilities relating to the grievance procedure for clients or prospective clients of the system to assure that individuals with mental illness have full access to the services of the system, for individuals who have received or are receiving mental health services, and for family members of such individuals with mental illness, or representatives of such individuals or family members, to assure that the eligible system is operating in compliance with the provisions of the Protection and Advocacy for Individuals with Mental Illness Act, as required to be established by section 105(a)(9) of such Act (42 U.S.C. 10805(a)(9));

(C) investigation of alleged abuse and neglect of persons with mental illness;

(D) availability of adequate medical and behavioral health treatment;

(E) denial of rights for persons with mental illness; and

(F) compliance with the Federal prohibition on lobbying.

Subtitle C—Interdepartmental Serious Mental Illness Coordinating Committee

[Section 6031 was repealed by section 1121(c)(2)(B)(i) of division FF of Public Law 117–328.]

TITLE VII—ENSURING MENTAL AND SUBSTANCE USE DISORDERS PREVENTION, TREATMENT, AND RECOVERY PROGRAMS KEEP PACE WITH SCIENCE AND TECHNOLOGY

SEC. 7001. ENCOURAGING INNOVATION AND EVIDENCE-BASED PROGRAMS.

Title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) is amended by inserting after section 501 (42 U.S.C. 290aa) the following:

"SEC. 501A. [42 U.S.C. 290aa-0] NATIONAL MENTAL HEALTH AND SUBSTANCE USE POLICY LABORATORY

"(a) IN GENERAL.—There shall be established within the Administration a National Mental Health and Substance Use Policy Laboratory (referred to in this section as the 'Laboratory').

"(b) RESPONSIBILITIES.—The Laboratory shall—

"(1) continue to carry out the authorities and activities that were in effect for the Office of Policy, Planning, and Innovation as such Office existed prior to the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016;

"(2) identify, coordinate, and facilitate the implementation of policy changes likely to have a significant effect on mental health, mental illness, recovery supports, and the prevention and treatment of substance use disorder services;

"(3) work with the Center for Behavioral Health Statistics and Quality to collect, as appropriate, information from grantees under programs operated by the Administration in order to evaluate and disseminate information on evidence-based practices, including culturally and linguistically appropriate services, as appropriate, and service delivery models;

"(4) provide leadership in identifying and coordinating policies and programs, including evidence-based programs, related to mental and substance use disorders;

"(5) periodically review programs and activities operated by the Administration relating to the diagnosis or prevention of, treatment for, and recovery from, mental and substance use disorders to—

"(A) identify any such programs or activities that are duplicative;

"(B) identify any such programs or activities that are not evidence-based, effective, or efficient; and

"(C) formulate recommendations for coordinating, eliminating, or improving programs or activities identified under subparagraph (A) or (B) and merging such programs or activities into other successful programs or activities; and

"(6) carry out other activities as deemed necessary to continue to encourage innovation and disseminate evidence-based programs and practices.

"(c) EVIDENCE-BASED PRACTICES AND SERVICE DELIVERY MODELS.—

"(1) IN GENERAL.—In carrying out subsection (b)(3), the Laboratory—

"(A) may give preference to models that improve—

"(i) the coordination between mental health and physical health providers;

"(ii) the coordination among such providers and the justice and corrections system; and

"(iii) the cost effectiveness, quality, effectiveness, and efficiency of health care services furnished to adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis; and

"(B) may include clinical protocols and practices that address the needs of individuals with early serious mental illness.

"(2) CONSULTATION.—In carrying out this section, the Laboratory shall consult with—

"(A) the Chief Medical Officer appointed under section 501(g);

"(B) representatives of the National Institute of Mental Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism, on an ongoing basis;

"(C) other appropriate Federal agencies;

"(D) clinical and analytical experts with expertise in psychiatric medical care and clinical psychological care, health care management, education, corrections health care, and mental health court systems, as appropriate; and

"(E) other individuals and agencies as determined appropriate by the Assistant Secretary.

"(d) DEADLINE FOR BEGINNING IMPLEMENTATION.—The Laboratory shall begin implementation of this section not later than January 1, 2018.

"(e) PROMOTING INNOVATION.—

"(1) IN GENERAL.—The Assistant Secretary, in coordination with the Laboratory, may award grants to States, local governments, Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), educational institutions, and nonprofit organizations to develop evidence-based interventions, including culturally and linguistically appropriate services, as appropriate, for—

"(A) evaluating a model that has been scientifically demonstrated to show promise, but would benefit from further applied development, for—

"(i) enhancing the prevention, diagnosis, intervention, and treatment of, and recovery from, mental illness, serious emotional disturbances, substance use disorders, and co-occurring illness or disorders; or

"(ii) integrating or coordinating physical health services and mental and substance use disorders services; and

"(B) expanding, replicating, or scaling evidence-based programs across a wider area to enhance effective screening, early diagnosis, intervention, and treatment with respect to mental illness, serious mental illness, serious emotional disturbances, and substance use disorders, primarily by—

"(i) applying such evidence-based programs to the delivery of care, including by training staff in effective evidence-based treatments; or

"(ii) integrating such evidence-based programs into models of care across specialties and jurisdictions.

"(2) CONSULTATION.—In awarding grants under this subsection, the Assistant Secretary shall, as appropriate, consult with the Chief Medical Officer, appointed under section 501(g), the advisory councils described in section 502, the National Institute of Mental Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism, as appropriate.

"(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated—

"(A) to carry out paragraph (1)(A), $7,000,000 for the period of fiscal years 2018 through 2020; and

"(B) to carry out paragraph (1)(B), $7,000,000 for the period of fiscal years 2018 through 2020.".

SEC. 7002. PROMOTING ACCESS TO INFORMATION ON EVIDENCE-BASED PROGRAMS AND PRACTICES.

Part D of title V of the Public Health Service Act (42 U.S.C. 290dd et seq.) is amended by inserting after section 543 of such Act (42 U.S.C. 290dd-2) the following:

"SEC. 543A. PROMOTING ACCESS TO INFORMATION ON EVIDENCE-BASED PROGRAMS AND PRACTICES

"(a) IN GENERAL.—The Assistant Secretary shall, as appropriate, improve access to reliable and valid information on evidence-based programs and practices, including information on the strength of evidence associated with such programs and practices, related to mental and substance use disorders for States, local communities, nonprofit entities, and other stakeholders, by posting on the Internet website of the Administration information on evidence-based programs and practices that have been reviewed by the Assistant Secretary in accordance with the requirements of this section.

"(b) APPLICATIONS.—

"(1) APPLICATION PERIOD.—In carrying out subsection (a), the Assistant Secretary may establish a period for the submission of applications for evidence-based programs and practices to be posted publicly in accordance with subsection (a).

"(2) NOTICE.—In establishing the application period under paragraph (1), the Assistant Secretary shall provide for the public notice of such application period in the Federal Register. Such notice may solicit applications for evidence-based programs and practices to address gaps in information identified by the Assistant Secretary, the National Mental Health and Substance Use Policy Laboratory established under section

501A, or the Assistant Secretary for Planning and Evaluation, including pursuant to the evaluation and recommendations under section 6021 of the Helping Families in Mental Health Crisis Reform Act of 2016 or priorities identified in the strategic plan under section 501(l).

"(c) REQUIREMENTS.—The Assistant Secretary may establish minimum requirements for the applications submitted under subsection (b), including applications related to the submission of research and evaluation.

"(d) REVIEW AND RATING.—

"(1) IN GENERAL.—The Assistant Secretary shall review applications prior to public posting in accordance with subsection (a), and may prioritize the review of applications for evidence-based programs and practices that are related to topics included in the notice provided under subsection (b)(2).

"(2) SYSTEM.—In carrying out paragraph (1), the Assistant Secretary may utilize a rating and review system, which may include information on the strength of evidence associated with the evidence-based programs and practices and a rating of the methodological rigor of the research supporting the applications.

"(3) PUBLIC ACCESS TO METRICS AND RATING.—The Assistant Secretary shall make the metrics used to evaluate applications under this section, and any resulting ratings of such applications, publicly available.".

SEC. 7003. PRIORITY MENTAL HEALTH NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

Section 520A of the Public Health Service Act (42 U.S.C. 290bb-32) is amended—

(1) in subsection (a)—

(A) in paragraph (4), by inserting before the period ", which may include technical assistance centers"; and

(B) in the flush sentence following paragraph (4)—

(i) by inserting ", contracts," before "or cooperative agreements"; and

(ii) by striking "Indian tribes and tribal organizations" and inserting "Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service, or"; and

(2) by amending subsection (f) to read as follows:

"(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $394,550,000 for each of fiscal years 2018 through 2022.".

SEC. 7004. PRIORITY SUBSTANCE USE DISORDER TREATMENT NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

Section 509 of the Public Health Service Act (42 U.S.C. 290bb-2) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "abuse" and inserting "use disorder";

(B) in paragraph (3), by inserting before the period "that permit States, local governments, communities, and Indian tribes and tribal organizations (as the terms 'Indian tribes' and 'tribal organizations' are defined in section 4 of the Indian Self-Determination and Education Assistance Act) to focus on emerging trends in substance abuse and co-occurrence of substance use disorders with mental illness or other conditions"; and

(C) in the flush sentence following paragraph (3)—

(i) by inserting ", contracts," before "or cooperative agreements"; and

(ii) by striking "Indian tribes and tribal organizations," and inserting "Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service, or";

(2) in subsection (b)—

(A) in paragraph (1), by striking "abuse" and inserting "use disorder"; and

(B) in paragraph (2), by striking "abuse" and inserting "use disorder";

(3) in subsection (e), by striking "abuse" and inserting "use disorder"; and

(4) in subsection (f), by striking "$300,000,000" and all that follows through the period and inserting "$333,806,000 for each of fiscal years 2018 through 2022.".

SEC. 7005. PRIORITY SUBSTANCE USE DISORDER PREVENTION NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

Section 516 of the Public Health Service Act (42 U.S.C. 290bb-22) is amended—

(1) in the section heading, by striking "**abuse**" and inserting "**use disorder**";

(2) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "abuse" and inserting "use disorder";

(B) in paragraph (3), by inserting before the period ", including such programs that focus on emerging drug abuse issues"; and

(C) in the flush sentence following paragraph (3)—

(i) by inserting ", contracts," before "or cooperative agreements"; and

(ii) by striking "Indian tribes and tribal organizations," and inserting "Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service,";

(3) in subsection (b)—

(A) in paragraph (1), by striking "abuse" and inserting "use disorder"; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "; and" at the end and inserting ";";

(ii) in subparagraph (B)—

(I) by striking "abuse" and inserting "use disorder"; and

(II) by striking the period and inserting "; and"; and

(iii) by adding at the end the following:

"(C) substance use disorder prevention among high-risk groups.";

(4) in subsection (e), by striking "abuse" and inserting "use disorder"; and

(5) in subsection (f), by striking "$300,000,000" and all that follows through the period and inserting "$211,148,000 for each of fiscal years 2018 through 2022.".

TITLE VIII—SUPPORTING STATE PREVENTION ACTIVITIES AND RESPONSES TO MENTAL HEALTH AND SUBSTANCE USE DISORDER NEEDS

SEC. 8001. COMMUNITY MENTAL HEALTH SERVICES BLOCK GRANT.

(a) FORMULA GRANTS.—Section 1911(b) of the Public Health Service Act (42 U.S.C. 300x(b)) is amended—

(1) by redesignating paragraphs (1) through (3) as paragraphs (2) through (4), respectively; and

(2) by inserting before paragraph (2) (as so redesignated) the following:

"(1) providing community mental health services for adults with a serious mental illness and children with a serious emotional disturbance as defined in accordance with section 1912(c);".

(b) STATE PLAN.—Section 1912(b) of the Public Health Service Act (42 U.S.C. 300x-1(b)) is amended—

(1) in paragraph (3), by redesignating subparagraphs (A) through (C) as clauses (i) through (iii), respectively, and realigning the margins accordingly;

(2) by redesignating paragraphs (1) through (5) as subparagraphs (A) through (E), respectively, and realigning the margins accordingly;

(3) in the matter preceding subparagraph (A) (as so redesignated), by striking "With respect to" and all that follows through "are as follows:" and inserting "In accordance with subsection (a), a State shall submit to the Secretary a plan every two years that, at a minimum, includes each of the following:";

(4) by inserting before subparagraph (A) (as so redesignated) the following:

"(1) SYSTEM OF CARE.—A description of the State's system of care that contains the following:";

(5) by striking subparagraph (A) (as so redesignated) and inserting the following:

"(A) COMPREHENSIVE COMMUNITY-BASED HEALTH SYSTEMS.—The plan shall—

"(i) identify the single State agency to be responsible for the administration of the program under the grant, including any third party who administers mental health services and is responsible for complying with the requirements of this part with respect to the grant;

"(ii) provide for an organized community-based system of care for individuals with mental illness, and describe available services and resources in a comprehensive system of care, including services for individuals with co-occurring disorders;

"(iii) include a description of the manner in which the State and local entities will coordinate services to maximize the efficiency, effectiveness, quality, and cost-effectiveness of services and programs to produce the best possible outcomes (including health services, rehabilitation services, employment services, housing services, educational services, substance use disorder services, legal services, law enforcement services, social services, child welfare services, medical and dental care services, and other support services to be provided with Federal, State, and local public and private resources) with other agencies to enable individuals receiving services to function outside of inpatient or residential institutions, to the maximum extent of their capabilities, including services to be provided by local school systems under the Individuals with Disabilities Education Act;

"(iv) include a description of how the State promotes evidence-based practices, including those evidence-based programs that address the needs of individuals with early serious mental illness regardless of the age of the individual at onset, provide comprehensive individualized treatment, or integrate mental and physical health services;

"(v) include a description of case management services;

"(vi) include a description of activities that seek to engage adults with a serious mental illness or children with a serious emotional disturbance and their caregivers where appropriate in making health care decisions, including activities that enhance communication among individuals, families, caregivers, and treatment providers; and

"(vii) as appropriate to, and reflective of, the uses the State proposes for the block grant funds, include—

"(I) a description of the activities intended to reduce hospitalizations and hospital stays using the block grant funds;

"(II) a description of the activities intended to reduce incidents of suicide using the block grant funds;

"(III) a description of how the State integrates mental health and primary care using the block grant funds, which may include providing, in the case of individuals with co-occurring mental and substance use disorders, both mental and substance use disorders services in primary care settings or arrangements to provide primary and specialty care services in community-based mental and substance use disorders settings; and

"(IV) a description of recovery and recovery support services for adults with a serious mental illness and children with a serious emotional disturbance.";

(6) in subparagraph (B) (as so redesignated)—

(A) by striking "The plan contains" and inserting "The plan shall contain"; and

(B) by striking "presents quantitative targets to be achieved in the implementation of the system described in paragraph (1)" and inserting "present quantitative targets and outcome measures for programs and services provided under this subpart";

(7) in subparagraph (C) (as so redesignated)—

(A) by striking "serious emotional disturbance" in the matter preceding clause (i) (as so redesignated) and all that follows through "substance abuse services" in clause (i) (as so redesignated) and inserting the following: "a serious emotional disturbance (as defined pursuant to subsection (c)), the plan shall provide for a system of integrated social services, educational services, child welfare services, juvenile justice services, law enforcement services, and substance use disorder services";

(B) by striking "Education Act);" and inserting "Education Act)."; and

(C) by striking clauses (ii) and (iii) (as so redesignated);

(8) in subparagraph (D) (as so redesignated), by striking "plan describes" and inserting "plan shall describe";

(9) in subparagraph (E) (as so redesignated)—

(A) in the subparagraph heading by striking "**systems**" and inserting "services";

(B) in the first sentence, by striking "plan describes" and all that follows through "and provides for" and inserting "plan shall describe the financial resources available, the existing mental health workforce, and the workforce trained in treating individuals with co-occurring mental and substance use disorders, and shall provide for"; and

(C) in the second sentence—

(i) by striking "further describes" and inserting "shall further describe"; and

(ii) by striking "involved." and inserting "involved, and the manner in which the State intends to comply with each of the funding agreements in this subpart and subpart III.";

(10) by striking the flush matter at the end; and

(11) by adding at the end the following:

"(2) GOALS AND OBJECTIVES.—The establishment of goals and objectives for the period of the plan, including targets and milestones that are intended to be met, and the activities that will be undertaken to achieve those targets.".

(c) EARLY SERIOUS MENTAL ILLNESS.—Section 1920 of the Public Health Service Act (42 U.S.C. 300x-9) is amended by adding at the end the following:

"(c) EARLY SERIOUS MENTAL ILLNESS.—

"(1) IN GENERAL.—Except as provided in paragraph (2), a State shall expend not less than 10 percent of the amount the State receives for carrying out this section for each fiscal year to support evidence-based programs that address the needs of individuals with early serious mental illness, including psychotic disorders, regardless of the age of the individual at onset.

"(2) STATE FLEXIBILITY.—In lieu of expending 10 percent of the amount the State receives under this section for a fiscal year as required under paragraph (1), a State may elect to expend not less than 20 percent of such amount by the end of such succeeding fiscal year.".

(d) ADDITIONAL PROVISIONS.—Section 1915(b) of the Public Health Service Act (42 U.S.C. 300x-4(b)) is amended—

(1) in paragraph (3)—

(A) by striking "The Secretary" and inserting the following:

"(A) IN GENERAL.—The Secretary";

(B) by striking "paragraph (1) if" and inserting "paragraph (1) in whole or in part if";

(C) by striking "State justify the waiver." and inserting "State in the fiscal year involved or in the previous fiscal year justify the waiver"; and

(D) by adding at the end the following:

"(B) DATE CERTAIN FOR ACTION UPON REQUEST.—The Secretary shall approve or deny a request for a waiver under this paragraph not later than 120 days after the date on which the request is made.

"(C) APPLICABILITY OF WAIVER.—A waiver provided by the Secretary under this paragraph shall be applicable only to the fiscal year involved."; and

(2) in paragraph (4)—

(A) in subparagraph (A)—

(i) by inserting after the subparagraph designation the following: "In general.—";

(ii) by striking "In making a grant" and inserting the following:

"(i) DETERMINATION.—In making a grant"; and

(iii) by inserting at the end the following:

"(ii) ALTERNATIVE.—A State that has failed to comply with paragraph (1) and would otherwise be subject to a reduction in the State's allotment under section 1911 may, upon request by the State, in lieu of having the amount of the allotment under section 1911 for the State reduced for the fiscal year of the

grant, agree to comply with a negotiated agreement that is approved by the Secretary and carried out in accordance with guidelines issued by the Secretary. If a State fails to enter into or comply with a negotiated agreement, the Secretary may take action under this paragraph or the terms of the negotiated agreement."; and

(B) in subparagraph (B)—

(i) by inserting after the subparagraph designation the following: "Submission of information to the secretary.—"; and

(ii) by striking "subparagraph (A)" and inserting "subparagraph (A)(i)".

(e) APPLICATION FOR GRANT.—Section 1917(a) of the Public Health Service Act (42 U.S.C. 300x-6(a)) is amended—

(1) in paragraph (1), by striking "1941" and inserting "1942(a)"; and

(2) in paragraph (5), by striking "1915(b)(3)(B)" and inserting "1915(b)".

(f) FUNDING.—Section 1920 of the Public Health Service Act (42 U.S.C. 300x-9) is amended—

(1) in subsection (a)—

(A) by striking "section 505" and inserting "section 505(c)"; and

(B) by striking "$450,000,000" and all that follows through the period and inserting "$532,571,000 for each of fiscal years 2018 through 2022."; and

(2) in subsection (b)(2) by striking "sections 505 and" and inserting "sections 505(c) and".

SEC. 8002. SUBSTANCE ABUSE PREVENTION AND TREATMENT BLOCK GRANT.

(a) FORMULA GRANTS.—Section 1921(b) of the Public Health Service Act (42 U.S.C. 300x-21(b)) is amended—

(1) by inserting "carrying out the plan developed in accordance with section 1932(b) and for" after "for the purpose of"; and

(2) by striking "abuse" and inserting "use disorders".

(b) OUTREACH TO PERSONS WHO INJECT DRUGS.—Section 1923(b) of the Public Health Service Act (42 U.S.C. 300x-23(b)) is amended—

(1) in the subsection heading, by striking "**Regarding Intravenous Substance Abuse**" and inserting "**to Persons Who Inject Drugs**"; and

(2) by striking "for intravenous drug abuse" and inserting "for persons who inject drugs".

(c) REQUIREMENTS REGARDING TUBERCULOSIS AND HUMAN IMMUNODEFICIENCY VIRUS.—Section 1924 of the Public Health Service Act (42 U.S.C. 300x-24) is amended—

(1) in subsection (a)(1)—

(A) in the matter preceding subparagraph (A), by striking "substance abuse" and inserting "substance use disorders"; and

(B) in subparagraph (A), by striking "such abuse" and inserting "such disorders";

(2) in subsection (b)—

(A) in paragraph (1)(A), by striking "substance abuse" and inserting "substance use disorders";

(B) in paragraph (2), by inserting "and Prevention" after "Disease Control";

(C) in paragraph (3)—

(i) in the paragraph heading, by striking "abuse" and inserting "use disorders"; and

(ii) by striking "substance abuse" and inserting "substance use disorders"; and

(D) in paragraph (6)(B), by striking "substance abuse" and inserting "substance use disorders";

(3) by striking subsection (d); and

(4) by redesignating subsection (e) as subsection (d).

(d) GROUP HOMES.—Section 1925 of the Public Health Service Act (42 U.S.C. 300x-25) is amended—

(1) in the section heading, by striking "**recovering substance abusers**" and inserting "**persons in recovery from substance use disorders**"; and

(2) in subsection (a), in the matter preceding paragraph (1), by striking "recovering substance abusers" and inserting "persons in recovery from substance use disorders".

(e) ADDITIONAL AGREEMENTS.—Section 1928 of the Public Health Service Act (42 U.S.C. 300x-28) is amended—

(1) in subsection (a), by striking "(relative to fiscal year 1992)";

(2) by striking subsection (b) and inserting the following:

"(b) PROFESSIONAL DEVELOPMENT.—A funding agreement for a grant under section 1921 is that the State involved will ensure that prevention, treatment, and recovery personnel operating in the State's substance use disorder prevention, treatment, and recovery systems have an opportunity to receive training, on an ongoing basis, concerning—

"(1) recent trends in substance use disorders in the State;

"(2) improved methods and evidence-based practices for providing substance use disorder prevention and treatment services;

"(3) performance-based accountability;

"(4) data collection and reporting requirements; and

"(5) any other matters that would serve to further improve the delivery of substance use disorder prevention and treatment services within the State."; and

(3) in subsection (d)(1), by striking "substance abuse" and inserting "substance use disorders".

(f) REPEAL.—Section 1929 of the Public Health Service Act (42 U.S.C. 300x-29) is repealed.

(g) MAINTENANCE OF EFFORT.—Section 1930 of the Public Health Service Act (42 U.S.C. 300x-30) is amended—

(1) in subsection (c)(1), by striking "in the State justify the waiver" and inserting "exist in the State, or any part of the State, to justify the waiver"; and

(2) in subsection (d), by inserting at the end the following:

"(3) ALTERNATIVE.—A State that has failed to comply with this section and would otherwise be subject to a reduction in

the State's allotment under section 1921, may, upon request by the State, in lieu of having the State's allotment under section 1921 reduced, agree to comply with a negotiated agreement that is approved by the Secretary and carried out in accordance with guidelines issued by the Secretary. If a State fails to enter into or comply with a negotiated agreement, the Secretary may take action under this paragraph or the terms of the negotiated agreement.".

(h) RESTRICTIONS ON EXPENDITURES.—Section 1931(b)(1) of the Public Health Service Act (42 U.S.C. 300x-31(b)(1)) is amended by striking "substance abuse" and inserting "substance use disorders".

(i) APPLICATION.—Section 1932 of the Public Health Service Act (42 U.S.C. 300x-32) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "subsections (c) and (d)(2)" and inserting "subsection (c)"; and

(B) in paragraph (5), by striking "the information required in section 1929, the information required in section 1930(c)(2), and";

(2) in subsection (b)—

(A) by striking paragraph (1) and inserting the following:

"(1) IN GENERAL.—In order for a State to be in compliance with subsection (a)(6), the State shall submit to the Secretary a plan that, at a minimum, includes the following:

"(A) A description of the State's system of care that—

"(i) identifies the single State agency responsible for the administration of the program, including any third party who administers substance use disorder services and is responsible for complying with the requirements of the grant;

"(ii) provides information on the need for substance use disorder prevention and treatment services in the State, including estimates on the number of individuals who need treatment, who are pregnant women, women with dependent children, individuals with a co-occurring mental health and substance use disorder, persons who inject drugs, and persons who are experiencing homelessness;

"(iii) provides aggregate information on the number of individuals in treatment within the State, including the number of such individuals who are pregnant women, women with dependent children, individuals with a co-occurring mental health and substance use disorder, persons who inject drugs, and persons who are experiencing homelessness;

"(iv) provides a description of the system that is available to provide services by modality, including the provision of recovery support services;

"(v) provides a description of the State's comprehensive statewide prevention efforts, including the number of individuals being served in the system, target populations, and priority needs, and provides a de-

scription of the amount of funds from the prevention set-aside expended on primary prevention;

"(vi) provides a description of the financial resources available;

"(vii) describes the existing substance use disorders workforce and workforce trained in treating co-occurring substance use and mental disorders;

"(viii) includes a description of how the State promotes evidence-based practices; and

"(ix) describes how the State integrates substance use disorder services and primary health care, which in the case of those individuals with co-occurring mental health and substance use disorders may include providing both mental health and substance use disorder services in primary care settings or providing primary and specialty care services in community-based mental health and substance use disorder service settings.

"(B) The establishment of goals and objectives for the period of the plan, including targets and milestones that are intended to be met, and the activities that will be undertaken to achieve those targets.

"(C) A description of how the State will comply with each funding agreement for a grant under section 1921 that is applicable to the State, including a description of the manner in which the State intends to expend grant funds."; and

(B) in paragraph (2)—

(i) in the paragraph heading, by striking "**authority of secretary regarding modifications**" and inserting "**modifications**";

(ii) by striking "As a condition" and inserting the following:

"(A) AUTHORITY OF SECRETARY.—As a condition;"; and

(iii) by adding at the end the following:

"(B) STATE REQUEST FOR MODIFICATION.—If the State determines that a modification to such plan is necessary, the State may request the Secretary to approve the modification. Any such modification shall be in accordance with paragraph (1) and section 1941."; and

(C) in paragraph (3), by inserting, ", including any modification under paragraph (2)" after "subsection (a)(6)"; and

(3) in subsection (e)(2), by striking "section 1922(c)" and inserting "section 1922(b)".

(j) DEFINITIONS.—Section 1934 of the Public Health Service Act (42 U.S.C. 300x-34) is amended—

(1) in paragraph (3), by striking "substance abuse" and inserting "substance use disorders"; and

(2) in paragraph (7), by striking "substance abuse" and inserting "substance use disorders".

(k) FUNDING.—Section 1935 of the Public Health Service Act (42 U.S.C. 300x-35) is amended—

(1) in subsection (a)—

(A) by striking "section 505" and inserting "section 505(d)"; and

(B) by striking "$2,000,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003" and inserting "$1,858,079,000 for each of fiscal years 2018 through 2022."; and

(2) in subsection (b)(1)(B) by striking "sections 505 and" and inserting "sections 505(d) and".

SEC. 8003. ADDITIONAL PROVISIONS RELATED TO THE BLOCK GRANTS.

Subpart III of part B of title XIX of the Public Health Service Act (42 U.S.C. 300x-51 et seq.) is amended—

(1) in section 1943(a)(3) (42 U.S.C. 300x-53(a)(3)), by striking "section 505" and inserting "subsections (c) and (d) of section 505";

(2) in section 1953(b) (42 U.S.C. 300x-63(b)), by striking "substance abuse" and inserting "substance use disorder"; and

(3) by adding at the end the following:

"SEC. 1957. [42 U.S.C. 300x-67]

[42 U.S.C. 300x-67] PUBLIC HEALTH EMERGENCIES

"In the case of a public health emergency (as determined under section 319), the Secretary, on a State by State basis, may, as the circumstances of the emergency reasonably require and for the period of the emergency, grant an extension, or waive application deadlines or compliance with any other requirement, of a grant authorized under section 521, 1911, or 1921 or an allotment authorized under Public Law 99-319 (42 U.S.C. 10801 et seq.).

"SEC. 1958. [42 U.S.C. 300x-68]

[42 U.S.C. 300x-68] JOINT APPLICATIONS

"The Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, shall permit a joint application to be submitted for grants under subpart I and subpart II upon the request of a State. Such application may be jointly reviewed and approved by the Secretary with respect to such subparts, consistent with the purposes and authorized activities of each such grant program. A State submitting such a joint application shall otherwise meet the requirements with respect to each such subpart.".

SEC. 8004. STUDY OF DISTRIBUTION OF FUNDS UNDER THE SUBSTANCE ABUSE PREVENTION AND TREATMENT BLOCK GRANT AND THE COMMUNITY MENTAL HEALTH SERVICES BLOCK GRANT.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Assistant Secretary for Mental Health and Substance Use, shall through a grant or contract, or through an agreement with a third party, conduct a study on the formulas for distribution of funds under the substance abuse prevention and treatment block grant, and the community mental health services block grant, under part B of title XIX of the Public Health Service Act (42 U.S.C. 300x et seq.) and recommend changes if necessary. Such study shall include—

(1) an analysis of whether the distributions under such block grants accurately reflect the need for the services under the grants in the States;

(2) an examination of whether the indices used under the formulas for distribution of funds under such block grants are appropriate, and if not, alternatives recommended by the Secretary;

(3) where recommendations are included under paragraph (2) for the use of different indices, a description of the variables and data sources that should be used to determine the indices;

(4) an evaluation of the variables and data sources that are being used for each of the indices involved, and whether such variables and data sources accurately represent the need for services, the cost of providing services, and the ability of the States to pay for such services;

(5) the effect that the minimum allotment requirements for each such block grant have on each State's final allotment and the effect of such requirements, if any, on each State's formula-based allotment;

(6) recommendations for modifications to the minimum allotment provisions to ensure an appropriate distribution of funds; and

(7) any other information that the Secretary determines appropriate.

(b) REPORT.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report containing the findings and recommendations of the study conducted under subsection (a) and the study conducted under section 9004(g).

TITLE IX—PROMOTING ACCESS TO MENTAL HEALTH AND SUBSTANCE USE DISORDER CARE

Subtitle A—Helping Individuals and Families

SEC. 9001. GRANTS FOR TREATMENT AND RECOVERY FOR HOMELESS INDIVIDUALS.

Section 506 of the Public Health Service Act (42 U.S.C. 290aa-5) is amended—

(1) in subsection (a), by striking "substance abuse" and inserting "substance use disorder";

(2) in subsection (b)—

(A) in paragraphs (1) and (3), by striking "substance abuse" each place the term appears and inserting "substance use disorder"; and

(B) in paragraph (4), by striking "substance abuse" and inserting "a substance use disorder";

(3) in subsection (c)—

(A) in paragraph (1), by striking "substance abuse disorder" and inserting "substance use disorder"; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "substance abuse" and inserting "a substance use disorder"; and

(ii) in subparagraph (B), by striking "substance abuse" and inserting "substance use disorder"; and

(4) in subsection (e), by striking ", $50,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003" and inserting "$41,304,000 for each of fiscal years 2018 through 2022".

SEC. 9002. GRANTS FOR JAIL DIVERSION PROGRAMS.

Section 520G of the Public Health Service Act (42 U.S.C. 290bb-38) is amended—

(1) by striking "substance abuse" each place such term appears and inserting "substance use disorder";

(2) in subsection (a)—

(A) by striking "Indian tribes, and tribal organizations" and inserting "and Indian tribes and tribal organizations (as the terms 'Indian tribes' and 'tribal organizations' are defined in section 4 of the Indian Self-Determination and Education Assistance Act)"; and

(B) by inserting "or a health facility or program operated by or in accordance with a contract or grant with the Indian Health Service," after "entities,";

(3) in subsection (c)(2)(A)(i), by striking "the best known" and inserting "evidence-based";

(4) by redesignating subsections (d) through (i) as subsections (e) through (j), respectively;

(5) by inserting after subsection (c) the following:

"(d) SPECIAL CONSIDERATION REGARDING VETERANS.—In awarding grants under subsection (a), the Secretary shall, as appropriate, give special consideration to entities proposing to use grant funding to support jail diversion services for veterans.";

(6) in subsection (e), as so redesignated—

(A) in paragraph (3), by striking "; and" and inserting a semicolon;

(B) in paragraph (4), by striking the period and inserting "; and"; and

(C) by adding at the end the following:

"(5) develop programs to divert individuals prior to booking or arrest."; and

(7) in subsection (j), as so redesignated, by striking "$10,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 through 2003" and inserting "$4,269,000 for each of fiscal years 2018 through 2022".

SEC. 9003. PROMOTING INTEGRATION OF PRIMARY AND BEHAVIORAL HEALTH CARE.

Section 520K of the Public Health Service Act (42 U.S.C. 290bb-42) is amended to read as follows:

"SEC. 520K. INTEGRATION INCENTIVE GRANTS AND COOPERATIVE AGREEMENTS

"(a) DEFINITIONS.—In this section:

"(1) ELIGIBLE ENTITY.—The term 'eligible entity' means a State, or other appropriate State agency, in collaboration with 1 or more qualified community programs as described in sec-

tion 1913(b)(1) or 1 or more community health centers as described in section 330.

"(2) INTEGRATED CARE.—The term 'integrated care' means collaborative models or practices offering mental and physical health services, which may include practices that share the same space in the same facility.

"(3) SPECIAL POPULATION.—The term 'special population' means—

"(A) adults with a mental illness who have co-occurring physical health conditions or chronic diseases;

"(B) adults with a serious mental illness who have co-occurring physical health conditions or chronic diseases;

"(C) children and adolescents with a serious emotional disturbance with co-occurring physical health conditions or chronic diseases; or

"(D) individuals with a substance use disorder.

"(b) GRANTS AND COOPERATIVE AGREEMENTS.—

"(1) IN GENERAL.—The Secretary may award grants and cooperative agreements to eligible entities to support the improvement of integrated care for primary care and behavioral health care in accordance with paragraph (2).

"(2) PURPOSES.—A grant or cooperative agreement awarded under this section shall be designed to—

"(A) promote full integration and collaboration in clinical practices between primary and behavioral health care;

"(B) support the improvement of integrated care models for primary care and behavioral health care to improve the overall wellness and physical health status of adults with a serious mental illness or children with a serious emotional disturbance; and

"(C) promote integrated care services related to screening, diagnosis, prevention, and treatment of mental and substance use disorders, and co-occurring physical health conditions and chronic diseases.

"(c) APPLICATIONS.—

"(1) IN GENERAL.—An eligible entity seeking a grant or cooperative agreement under this section shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require, including the contents described in paragraph (2).

"(2) CONTENTS.—The contents described in this paragraph are—

"(A) a description of a plan to achieve fully collaborative agreements to provide services to special populations;

"(B) a document that summarizes the policies, if any, that serve as barriers to the provision of integrated care, and the specific steps, if applicable, that will be taken to address such barriers;

"(C) a description of partnerships or other arrangements with local health care providers to provide services to special populations;

"(D) an agreement and plan to report to the Secretary performance measures necessary to evaluate patient out-

comes and facilitate evaluations across participating projects; and

"(E) a plan for sustainability beyond the grant or cooperative agreement period under subsection (e).

"(d) GRANT AND COOPERATIVE AGREEMENT AMOUNTS.—

"(1) TARGET AMOUNT.—The target amount that an eligible entity may receive for a year through a grant or cooperative agreement under this section shall be $2,000,000.

"(2) ADJUSTMENT PERMITTED.—The Secretary, taking into consideration the quality of the application and the number of eligible entities that received grants under this section prior to the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, may adjust the target amount that an eligible entity may receive for a year through a grant or cooperative agreement under this section.

"(3) LIMITATION.—An eligible entity receiving funding under this section may not allocate more than 10 percent of funds awarded under this section to administrative functions, and the remaining amounts shall be allocated to health facilities that provide integrated care.

"(e) DURATION.—A grant or cooperative agreement under this section shall be for a period not to exceed 5 years.

"(f) REPORT ON PROGRAM OUTCOMES.—An eligible entity receiving a grant or cooperative agreement under this section shall submit an annual report to the Secretary that includes—

"(1) the progress made to reduce barriers to integrated care as described in the entity's application under subsection (c); and

"(2) a description of functional outcomes of special populations, including—

"(A) with respect to adults with a serious mental illness, participation in supportive housing or independent living programs, attendance in social and rehabilitative programs, participation in job training opportunities, satisfactory performance in work settings, attendance at scheduled medical and mental health appointments, and compliance with prescribed medication regimes;

"(B) with respect to individuals with co-occurring mental illness and physical health conditions and chronic diseases, attendance at scheduled medical and mental health appointments, compliance with prescribed medication regimes, and participation in learning opportunities related to improved health and lifestyle practices; and

"(C) with respect to children and adolescents with a serious emotional disturbance who have co-occurring physical health conditions and chronic diseases, attendance at scheduled medical and mental health appointments, compliance with prescribed medication regimes, and participation in learning opportunities at school and extracurricular activities.

"(g) TECHNICAL ASSISTANCE FOR PRIMARY-BEHAVIORAL HEALTH CARE INTEGRATION.—

"(1) IN GENERAL.—The Secretary may provide appropriate information, training, and technical assistance to eligible enti-

ties that receive a grant or cooperative agreement under this section, in order to help such entities meet the requirements of this section, including assistance with—

"(A) development and selection of integrated care models;

"(B) dissemination of evidence-based interventions in integrated care;

"(C) establishment of organizational practices to support operational and administrative success; and

"(D) other activities, as the Secretary determines appropriate.

"(2) ADDITIONAL DISSEMINATION OF TECHNICAL INFORMATION.—The information and resources provided by the Secretary under paragraph (1) shall, as appropriate, be made available to States, political subdivisions of States, Indian tribes or tribal organizations (as defined in section 4 of the Indian Self-Determination and Education Assistance Act), outpatient mental health and addiction treatment centers, community mental health centers that meet the criteria under section 1913(c), certified community behavioral health clinics described in section 223 of the Protecting Access to Medicare Act of 2014, primary care organizations such as Federally qualified health centers or rural health clinics as defined in section 1861(aa) of the Social Security Act, other community-based organizations, or other entities engaging in integrated care activities, as the Secretary determines appropriate.

"(h) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $51,878,000 for each of fiscal years 2018 through 2022.".

SEC. 9004. PROJECTS FOR ASSISTANCE IN TRANSITION FROM HOMELESSNESS.

(a) FORMULA GRANTS TO STATES.—Section 521 of the Public Health Service Act (42 U.S.C. 290cc-21) is amended by striking "1991 through 1994" and inserting "2018 through 2022".

(b) PURPOSE OF GRANTS.—Section 522 of the Public Health Service Act (42 U.S.C. 290cc-22) is amended—

(1) in subsection (a)(1)(B), by striking "substance abuse" and inserting "a substance use disorder";

(2) in subsection (b)(6), by striking "substance abuse" and inserting "substance use disorder";

(3) in subsection (c), by striking "substance abuse" and inserting "a substance use disorder";

(4) in subsection (e)—

(A) in paragraph (1), by striking "substance abuse" and inserting "a substance use disorder"; and

(B) in paragraph (2), by striking "substance abuse" and inserting "substance use disorder";

(5) by striking subsection (g) and redesignating subsections (h) and (i) as (g) and (h), accordingly; and

(6) in subsection (g), as redesignated by paragraph (5), by striking "substance abuse" each place such term appears and inserting "substance use disorder".

(c) DESCRIPTION OF INTENDED EXPENDITURES OF GRANT.—Section 527 of the Public Health Service Act (42 U.S.C. 290cc-27) is

amended by striking "substance abuse" each place such term appears and inserting "substance use disorder".

(d) TECHNICAL ASSISTANCE.—Section 530 of the Public Health Service Act (42 U.S.C. 290cc-30) is amended by striking "through the National Institute of Mental Health, the National Institute of Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse" and inserting "acting through the Assistant Secretary".

(e) DEFINITIONS.—Section 534(4) of the Public Health Service Act (42 U.S.C. 290cc-34(4)) is amended to read as follows:

"(4) SUBSTANCE USE DISORDER SERVICES.—The term 'substance use disorder services' has the meaning given the term 'substance abuse services' in section 330(h)(5)(C).".

(f) FUNDING.—Section 535(a) of the Public Health Service Act (42 U.S.C. 290cc-35(a)) is amended by striking "$75,000,000 for each of the fiscal years 2001 through 2003" and inserting "$64,635,000 for each of fiscal years 2018 through 2022".

(g) STUDY CONCERNING FORMULA.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Assistant Secretary for Mental Health and Substance Use (referred to in this section as the "Assistant Secretary") shall conduct a study concerning the formula used under section 524 of the Public Health Service Act (42 U.S.C. 290cc-24) for making allotments to States under section 521 of such Act (42 U.S.C. 290cc-21). Such study shall include an evaluation of quality indicators of need for purposes of revising the formula for determining the amount of each allotment for the fiscal years following the submission of the study.

(2) REPORT.—In accordance with section 8004(b), the Assistant Secretary shall submit to the committees of Congress described in such section a report concerning the results of the study conducted under paragraph (1).

SEC. 9005. NATIONAL SUICIDE PREVENTION LIFELINE PROGRAM.

Subpart 3 of part B of title V of the Public Health Service Act (42 U.S.C. 290bb-31 et seq.) is amended by inserting after section 520E-2 (42 U.S.C. 290bb-36b) the following:

"SEC. 520E-3. NATIONAL SUICIDE PREVENTION LIFELINE PROGRAM

"(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary, shall maintain the National Suicide Prevention Lifeline program (referred to in this section as the 'program'), authorized under section 520A and in effect prior to the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016.

"(b) ACTIVITIES.—In maintaining the program, the activities of the Secretary shall include—

"(1) coordinating a network of crisis centers across the United States for providing suicide prevention and crisis intervention services to individuals seeking help at any time, day or night;

"(2) maintaining a suicide prevention hotline to link callers to local emergency, mental health, and social services resources; and

"(3) consulting with the Secretary of Veterans Affairs to ensure that veterans calling the suicide prevention hotline

have access to a specialized veterans' suicide prevention hotline.

"(c) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $7,198,000 for each of fiscal years 2018 through 2022.".

SEC. 9006. CONNECTING INDIVIDUALS AND FAMILIES WITH CARE.

Subpart 3 of part B of title V of the Public Health Service Act (42 U.S.C. 290bb-31 et seq.), as amended by section 9005, is further amended by inserting after section 520E-3 the following:

"SEC. 520E-4. TREATMENT REFERRAL ROUTING SERVICE

"(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary, shall maintain the National Treatment Referral Routing Service (referred to in this section as the 'Routing Service') to assist individuals and families in locating mental and substance use disorders treatment providers.

"(b) ACTIVITIES OF THE SECRETARY.—To maintain the Routing Service, the activities of the Assistant Secretary shall include administering—

"(1) a nationwide, telephone number providing year-round access to information that is updated on a regular basis regarding local behavioral health providers and community-based organizations in a manner that is confidential, without requiring individuals to identify themselves, is in languages that include at least English and Spanish, and is at no cost to the individual using the Routing Service; and

"(2) an Internet website to provide a searchable, online treatment services locator of behavioral health treatment providers and community-based organizations, which shall include information on the name, location, contact information, and basic services provided by such providers and organizations.

"(c) REMOVING PRACTITIONER CONTACT INFORMATION.—In the event that the Internet website described in subsection (b)(2) contains information on any qualified practitioner that is certified to prescribe medication for opioid dependency under section 303(g)(2)(B) of the Controlled Substances Act, the Assistant Secretary—

"(1) shall provide an opportunity to such practitioner to have the contact information of the practitioner removed from the website at the request of the practitioner; and

"(2) may evaluate other methods to periodically update the information displayed on such website.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prevent the Assistant Secretary from using any unobligated amounts otherwise made available to the Administration to maintain the Routing Service.".

SEC. 9007. STRENGTHENING COMMUNITY CRISIS RESPONSE SYSTEMS.

Section 520F of the Public Health Service Act (42 U.S.C. 290bb-37) is amended to read as follows:

"SEC. 520F. STRENGTHENING COMMUNITY CRISIS RESPONSE SYSTEMS

"(a) IN GENERAL.—The Secretary shall award competitive grants to—

"(1) State and local governments and Indian tribes and tribal organizations, to enhance community-based crisis response systems; or

"(2) States to develop, maintain, or enhance a database of beds at inpatient psychiatric facilities, crisis stabilization units, and residential community mental health and residential substance use disorder treatment facilities, for adults with a serious mental illness, children with a serious emotional disturbance, or individuals with a substance use disorder.

"(b) APPLICATIONS.—

"(1) IN GENERAL.—To receive a grant under subsection (a), an entity shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

"(2) COMMUNITY-BASED CRISIS RESPONSE PLAN.—An application for a grant under subsection (a)(1) shall include a plan for—

"(A) promoting integration and coordination between local public and private entities engaged in crisis response, including first responders, emergency health care providers, primary care providers, law enforcement, court systems, health care payers, social service providers, and behavioral health providers;

"(B) developing memoranda of understanding with public and private entities to implement crisis response services;

"(C) addressing gaps in community resources for crisis intervention and prevention; and

"(D) developing models for minimizing hospital readmissions, including through appropriate discharge planning.

"(3) BEDS DATABASE PLAN.—An application for a grant under subsection (a)(2) shall include a plan for developing, maintaining, or enhancing a real-time, Internet-based bed database to collect, aggregate, and display information about beds in inpatient psychiatric facilities and crisis stabilization units, and residential community mental health and residential substance use disorder treatment facilities to facilitate the identification and designation of facilities for the temporary treatment of individuals in mental or substance use disorder crisis.

"(c) DATABASE REQUIREMENTS.—A bed database described in this section is a database that—

"(1) includes information on inpatient psychiatric facilities, crisis stabilization units, and residential community mental health and residential substance use disorder facilities in the State involved, including contact information for the facility or unit;

"(2) provides real-time information about the number of beds available at each facility or unit and, for each available bed, the type of patient that may be admitted, the level of security provided, and any other information that may be necessary to allow for the proper identification of appropriate fa-

cilities for treatment of individuals in mental or substance use disorder crisis; and

"(3) enables searches of the database to identify available beds that are appropriate for the treatment of individuals in mental or substance use disorder crisis.

"(d) EVALUATION.—An entity receiving a grant under subsection (a)(1) shall submit to the Secretary, at such time, in such manner, and containing such information as the Secretary may reasonably require, a report, including an evaluation of the effect of such grant on—

"(1) local crisis response services and measures for individuals receiving crisis planning and early intervention supports;

"(2) individuals reporting improved functional outcomes; and

"(3) individuals receiving regular followup care following a crisis.

"(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $12,500,000 for the period of fiscal years 2018 through 2022.".

SEC. 9008. GARRETT LEE SMITH MEMORIAL ACT REAUTHORIZATION.

(a) SUICIDE PREVENTION TECHNICAL ASSISTANCE CENTER.—Section 520C of the Public Health Service Act (42 U.S.C. 290bb-34), as amended by section 6001, is further amended—

(1) in the section heading, by striking "**youth interagency research, training, and technical assistance centers**" and inserting "**suicide prevention technical assistance center**";

(2) in subsection (a), by striking "acting through the Assistant Secretary for Mental Health and Substance Use" and all that follows through the period at the end of paragraph (2) and inserting "acting through the Assistant Secretary, shall establish a research, training, and technical assistance resource center to provide appropriate information, training, and technical assistance to States, political subdivisions of States, federally recognized Indian tribes, tribal organizations, institutions of higher education, public organizations, or private nonprofit organizations regarding the prevention of suicide among all ages, particularly among groups that are at a high risk for suicide.";

(3) by striking subsections (b) and (c);

(4) by redesignating subsection (d) as subsection (b);

(5) in subsection (b), as so redesignated—

(A) in the subsection heading, by striking "**Additional Center**" and inserting "**Responsibilities of the Center**";

(B) in the matter preceding paragraph (1), by striking "The additional research" and all that follows through "nonprofit organizations for" and inserting "The center established under subsection (a) shall conduct activities for the purpose of";

(C) by striking "youth suicide" each place such term appears and inserting "suicide";

(D) in paragraph (1)—

(i) by striking "the development or continuation of" and inserting "developing and continuing"; and

(ii) by inserting "for all ages, particularly among groups that are at a high risk for suicide" before the semicolon at the end;

(E) in paragraph (2), by inserting "for all ages, particularly among groups that are at a high risk for suicide" before the semicolon at the end;

(F) in paragraph (3), by inserting "and tribal" after "statewide";

(G) in paragraph (5), by inserting "and prevention" after "intervention";

(H) in paragraph (8), by striking "in youth";

(I) in paragraph (9), by striking "and behavioral health" and inserting "health and substance use disorder"; and

(J) in paragraph (10), by inserting "conducting" before "other"; and

(6) by striking subsection (e) and inserting the following:

"(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $5,988,000 for each of fiscal years 2018 through 2022.

"(d) ANNUAL REPORT.—Not later than 2 years after the date of enactment of this subsection, the Secretary shall submit to Congress a report on the activities carried out by the center established under subsection (a) during the year involved, including the potential effects of such activities, and the States, organizations, and institutions that have worked with the center.".

(b) YOUTH SUICIDE EARLY INTERVENTION AND PREVENTION STRATEGIES.—Section 520E of the Public Health Service Act (42 U.S.C. 290bb-36) is amended—

(1) in paragraph (1) of subsection (a) and in subsection (c), by striking "substance abuse" each place such term appears and inserting "substance use disorder";

(2) in subsection (b)—

(A) in paragraph (2)—

(i) by striking "ensure that each State is awarded only 1 grant or cooperative agreement under this section" and inserting "ensure that a State does not receive more than 1 grant or cooperative agreement under this section at any 1 time"; and

(ii) by striking "been awarded" and inserting "received"; and

(B) by adding after paragraph (2) the following:

"(3) CONSIDERATION.—In awarding grants under this section, the Secretary shall take into consideration the extent of the need of the applicant, including the incidence and prevalence of suicide in the State and among the populations of focus, including rates of suicide determined by the Centers for Disease Control and Prevention for the State or population of focus.";

(3) in subsection (g)(2), by striking "2 years after the date of enactment of this section," and insert "2 years after the date

of enactment of Helping Families in Mental Health Crisis Reform Act of 2016,"; and

(4) by striking subsection (m) and inserting the following:

"(m) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $30,000,000 for each of fiscal years 2018 through 2022.".

SEC. 9009. ADULT SUICIDE PREVENTION.

Subpart 3 of part B of title V of the Public Health Service Act (42 U.S.C. 290bb-31 et seq.) is amended by adding at the end the following:

"SEC. 520L. ADULT SUICIDE PREVENTION

"(a) GRANTS.—

"(1) IN GENERAL.—The Assistant Secretary shall award grants to eligible entities described in paragraph (2) to implement suicide prevention and intervention programs, for individuals who are 25 years of age or older, that are designed to raise awareness of suicide, establish referral processes, and improve care and outcomes for such individuals who are at risk of suicide.

"(2) ELIGIBLE ENTITIES.—To be eligible to receive a grant under this section, an entity shall be a community-based primary care or behavioral health care setting, an emergency department, a State mental health agency (or State health agency with mental or behavioral health functions), public health agency, a territory of the United States, or an Indian tribe or tribal organization (as the terms 'Indian tribe' and 'tribal organization' are defined in section 4 of the Indian Self-Determination and Education Assistance Act).

"(3) USE OF FUNDS.—The grants awarded under paragraph (1) shall be used to implement programs, in accordance with such paragraph, that include one or more of the following components:

"(A) Screening for suicide risk, suicide intervention services, and services for referral for treatment for individuals at risk for suicide.

"(B) Implementing evidence-based practices to provide treatment for individuals at risk for suicide, including appropriate followup services.

"(C) Raising awareness and reducing stigma of suicide.

"(b) EVALUATIONS AND TECHNICAL ASSISTANCE.—The Assistant Secretary shall—

"(1) evaluate the activities supported by grants awarded under subsection (a), and disseminate, as appropriate, the findings from the evaluation; and

"(2) provide appropriate information, training, and technical assistance, as appropriate, to eligible entities that receive a grant under this section, in order to help such entities to meet the requirements of this section, including assistance with selection and implementation of evidence-based interventions and frameworks to prevent suicide.

"(c) DURATION.—A grant under this section shall be for a period of not more than 5 years.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $30,000,000 for the period of fiscal years 2018 through 2022.".

SEC. 9010. MENTAL HEALTH AWARENESS TRAINING GRANTS.

Section 520J of the Public Health Service Act (42 U.S.C. 290bb-41) is amended—

(1) in the section heading, by inserting "**mental health awareness**" before "**training**"; and

(2) in subsection (b)—

(A) in the subsection heading, by striking "**Illness**" and inserting "**Health**";

(B) in paragraph (1), by inserting "veterans, law enforcement, and other categories of individuals, as determined by the Secretary," after "emergency services personnel";

(C) in paragraph (5)—

(i) in the matter preceding subparagraph (A), by striking "to" and inserting "for evidence-based programs that provide training and education in accordance with paragraph (1) on matters including"; and

(ii) by striking subparagraphs (A) through (C) and inserting the following:

"(A) recognizing the signs and symptoms of mental illness; and

"(B)(i) resources available in the community for individuals with a mental illness and other relevant resources; or

"(ii) safely de-escalating crisis situations involving individuals with a mental illness."; and

(D) in paragraph (7), by striking ", $25,000,000" and all that follows through the period at the end and inserting "$14,693,000 for each of fiscal years 2018 through 2022.".

SEC. 9011. SENSE OF CONGRESS ON PRIORITIZING AMERICAN INDIANS AND ALASKA NATIVE YOUTH WITHIN SUICIDE PREVENTION PROGRAMS.

(a) FINDINGS.—The Congress finds as follows:

(1) Suicide is the eighth leading cause of death among American Indians and Alaska Natives across all ages.

(2) Among American Indians and Alaska Natives who are 10 to 34 years of age, suicide is the second leading cause of death.

(3) The suicide rate among American Indian and Alaska Native adolescents and young adults ages 15 to 34 (17.9 per 100,000) is approximately 1.3 times higher than the national average for that age group (13.3 per 100,000).

(b) SENSE OF CONGRESS.—It is the sense of Congress that the Secretary of Health and Human Services, in carrying out suicide prevention and intervention programs, should prioritize programs and activities for populations with disproportionately high rates of suicide, such as American Indians and Alaska Natives.

SEC. 9012. EVIDENCE-BASED PRACTICES FOR OLDER ADULTS.

Section 520A(e) of the Public Health Service Act (42 U.S.C. 290bb-32(e)) is amended by adding at the end the following:

"(3) GERIATRIC MENTAL DISORDERS.—The Secretary shall, as appropriate, provide technical assistance to grantees regarding evidence-based practices for the prevention and treatment of geriatric mental disorders and co-occurring mental health and substance use disorders among geriatric populations, as well as disseminate information about such evidence-based practices to States and nongrantees throughout the United States.".

SEC. 9013. NATIONAL VIOLENT DEATH REPORTING SYSTEM.

The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, is encouraged to improve, particularly through the inclusion of additional States, the National Violent Death Reporting System as authorized by title III of the Public Health Service Act (42 U.S.C. 241 et seq.). Participation in the system by the States shall be voluntary.

SEC. 9014. ASSISTED OUTPATIENT TREATMENT.

Section 224 of the Protecting Access to Medicare Act of 2014 (42 U.S.C. 290aa note) is amended—

(1) in subsection (e), by striking "and 2018," and inserting "2018, 2019, 2020, 2021, and 2022,"; and

(2) in subsection (g)—

(A) in paragraph (1), by striking "2018" and inserting "2022"; and

(B) in paragraph (2), by striking "is authorized to be appropriated to carry out this section $15,000,000 for each of fiscal years 2015 through 2018" and inserting "are authorized to be appropriated to carry out this section $15,000,000 for each of fiscal years 2015 through 2017, $20,000,000 for fiscal year 2018, $19,000,000 for each of fiscal years 2019 and 2020, and $18,000,000 for each of fiscal years 2021 and 2022".

SEC. 9015. ASSERTIVE COMMUNITY TREATMENT GRANT PROGRAM.

Part B of title V of the Public Health Service Act (42 U.S.C. 290bb et seq.), as amended by section 9009, is further amended by adding at the end the following:

"SEC. 520M. ASSERTIVE COMMUNITY TREATMENT GRANT PROGRAM

"(a) IN GENERAL.—The Assistant Secretary shall award grants to eligible entities—

"(1) to establish assertive community treatment programs for adults with a serious mental illness; or

"(2) to maintain or expand such programs.

"(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant under this section, an entity shall be a State, political subdivision of a State, Indian tribe or tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), mental health system, health care facility, or any other entity the Assistant Secretary deems appropriate.

"(c) SPECIAL CONSIDERATION.—In selecting among applicants for a grant under this section, the Assistant Secretary may give special consideration to the potential of the applicant's program to reduce hospitalization, homelessness, and involvement with the

criminal justice system while improving the health and social outcomes of the patient.

"(d) ADDITIONAL ACTIVITIES.—The Assistant Secretary shall—

"(1) not later than the end of fiscal year 2021, submit a report to the appropriate congressional committees on the grant program under this section, including an evaluation of—

"(A) any cost savings and public health outcomes such as mortality, suicide, substance use disorders, hospitalization, and use of services;

"(B) rates of involvement with the criminal justice system of patients;

"(C) rates of homelessness among patients; and

"(D) patient and family satisfaction with program participation; and

"(2) provide appropriate information, training, and technical assistance to grant recipients under this section to help such recipients to establish, maintain, or expand their assertive community treatment programs.

"(e) AUTHORIZATION OF APPROPRIATIONS.—

"(1) IN GENERAL.—To carry out this section, there is authorized to be appropriated $5,000,000 for the period of fiscal years 2018 through 2022.

"(2) USE OF CERTAIN FUNDS.—Of the funds appropriated to carry out this section in any fiscal year, not more than 5 percent shall be available to the Assistant Secretary for carrying out subsection (d).".

SEC. 9016. SOBER TRUTH ON PREVENTING UNDERAGE DRINKING REAUTHORIZATION.

Section 519B of the Public Health Service Act (42 U.S.C. 290bb-25b) is amended—

(1) in subsection (c)(3), by striking "fiscal year 2007" and all that follows through the period at the end and inserting "each of the fiscal years 2018 through 2022.";

(2) in subsection (d)(4), by striking "fiscal year 2007" and all that follows through the period at the end and inserting "each of the fiscal years 2018 through 2022.";

(3) in subsection (e)(1)(I), by striking "fiscal year 2007" and all that follows through the period at the end and inserting "each of the fiscal years 2018 through 2022.";

(4) in subsection (f)(2), by striking "$6,000,000 for fiscal year 2007" and all that follows through the period at the end and inserting "$3,000,000 for each of the fiscal years 2018 through 2022"; and

(5) by adding at the end the following new subsection:

"(g) REDUCING UNDERAGE DRINKING THROUGH SCREENING AND BRIEF INTERVENTION.—

"(1) GRANTS TO PEDIATRIC HEALTH CARE PROVIDERS TO REDUCE UNDERAGE DRINKING.—The Assistant Secretary may make grants to eligible entities to increase implementation of practices for reducing the prevalence of alcohol use among individuals under the age of 21, including college students.

"(2) PURPOSES.—Grants under this subsection shall be made to improve—

"(A) screening children and adolescents for alcohol use;

"(B) offering brief interventions to children and adolescents to discourage such use;

"(C) educating parents about the dangers of, and methods of discouraging, such use;

"(D) diagnosing and treating alcohol use disorders; and

"(E) referring patients, when necessary, to other appropriate care.

"(3) USE OF FUNDS.—An entity receiving a grant under this subsection may use such funding for the purposes identified in paragraph (2) by—

"(A) providing training to health care providers;

"(B) disseminating best practices, including culturally and linguistically appropriate best practices, as appropriate, and developing and distributing materials; and

"(C) supporting other activities, as determined appropriate by the Assistant Secretary.

"(4) APPLICATION.—To be eligible to receive a grant under this subsection, an entity shall submit an application to the Assistant Secretary at such time, and in such manner, and accompanied by such information as the Assistant Secretary may require. Each application shall include—

"(A) a description of the entity;

"(B) a description of activities to be completed;

"(C) a description of how the services specified in paragraphs (2) and (3) will be carried out and the qualifications for providing such services; and

"(D) a timeline for the completion of such activities.

"(5) DEFINITIONS.—For the purpose of this subsection:

"(A) BRIEF INTERVENTION.—The term 'brief intervention' means, after screening a patient, providing the patient with brief advice and other brief motivational enhancement techniques designed to increase the insight of the patient regarding the patient's alcohol use, and any realized or potential consequences of such use, to effect the desired related behavioral change.

"(B) CHILDREN AND ADOLESCENTS.—The term 'children and adolescents' means any person under 21 years of age.

"(C) ELIGIBLE ENTITY.—The term 'eligible entity' means an entity consisting of pediatric health care providers and that is qualified to support or provide the activities identified in paragraph (2).

"(D) PEDIATRIC HEALTH CARE PROVIDER.—The term 'pediatric health care provider' means a provider of primary health care to individuals under the age of 21 years.

"(E) SCREENING.—The term 'screening' means using validated patient interview techniques to identify and assess the existence and extent of alcohol use in a patient.".

SEC. 9017. CENTER AND PROGRAM REPEALS.

Part B of title V of the Public Health Service Act (42 U.S.C. 290bb et seq.) is amended by striking section 506B (42 U.S.C. 290aa-5b), the second section 514 (42 U.S.C. 290bb-9) relating to methamphetamine and amphetamine treatment initiatives, and each of sections 514A, 517, 519A, 519C, 519E, 520B, 520D, and

520H (42 U.S.C. 290bb-8, 290bb-23, 290bb-25a, 290bb-25c, 290bb-25e, 290bb-33, 290bb-35, and 290bb-39).

Subtitle B—Strengthening the Health Care Workforce

SEC. 9021. MENTAL AND BEHAVIORAL HEALTH EDUCATION AND TRAINING GRANTS.

Section 756 of the Public Health Service Act (42 U.S.C. 294e-1) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "of higher education"; and

(B) by striking paragraphs (1) through (4) and inserting the following:

"(1) accredited institutions of higher education or accredited professional training programs that are establishing or expanding internships or other field placement programs in mental health in psychiatry, psychology, school psychology, behavioral pediatrics, psychiatric nursing (which may include master's and doctoral level programs), social work, school social work, substance use disorder prevention and treatment, marriage and family therapy, occupational therapy, school counseling, or professional counseling, including such programs with a focus on child and adolescent mental health and transitional-age youth;

"(2) accredited doctoral, internship, and post-doctoral residency programs of health service psychology (including clinical psychology, counseling, and school psychology) for the development and implementation of interdisciplinary training of psychology graduate students for providing behavioral health services, including substance use disorder prevention and treatment services, as well as the development of faculty in health service psychology;

"(3) accredited master's and doctoral degree programs of social work for the development and implementation of interdisciplinary training of social work graduate students for providing behavioral health services, including substance use disorder prevention and treatment services, and the development of faculty in social work; and

"(4) State-licensed mental health nonprofit and for-profit organizations to enable such organizations to pay for programs for preservice or in-service training in a behavioral health-related paraprofessional field with preference for preservice or in-service training of paraprofessional child and adolescent mental health workers.";

(2) in subsection (b)—

(A) by striking paragraph (5);

(B) by redesignating paragraphs (1) through (4) as paragraphs (2) through (5), respectively;

(C) by inserting before paragraph (2), as so redesignated, the following:

"(1) an ability to recruit and place the students described in subsection (a) in areas with a high need and high demand population;";

(D) in paragraph (3), as so redesignated, by striking "subsection (a)" and inserting "paragraph (2), especially individuals with mental disorder symptoms or diagnoses, particularly children and adolescents, and transitional-age youth";

(E) in paragraph (4), as so redesignated, by striking ";" and inserting "; and"; and

(F) in paragraph (5), as so redesignated, by striking "; and" and inserting a period;

(3) in subsection (c), by striking "authorized under subsection (a)(1)" and inserting "awarded under paragraphs (2) and (3) of subsection (a)";

(4) by amending subsection (d) to read as follows:

"(d) PRIORITY.—In selecting grant recipients under this section, the Secretary shall give priority to—

"(1) programs that have demonstrated the ability to train psychology, psychiatry, and social work professionals to work in integrated care settings for purposes of recipients under paragraphs (1), (2), and (3) of subsection (a); and

"(2) programs for paraprofessionals that emphasize the role of the family and the lived experience of the consumer and family-paraprofessional partnerships for purposes of recipients under subsection (a)(4).''; and

(5) by striking subsection (e) and inserting the following:

"(e) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary shall include in the biennial report submitted to Congress under section 501(m) an assessment on the effectiveness of the grants under this section in—

"(1) providing graduate students support for experiential training (internship or field placement);

"(2) recruiting students interested in behavioral health practice;

"(3) recruiting students in accordance with subsection (b)(1);

"(4) developing and implementing interprofessional training and integration within primary care;

"(5) developing and implementing accredited field placements and internships; and

"(6) collecting data on the number of students trained in behavioral health care and the number of available accredited internships and field placements.

"(f) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2018 through 2022, there are authorized to be appropriated to carry out this section $50,000,000, to be allocated as follows:

"(1) For grants described in subsection (a)(1), $15,000,000.

"(2) For grants described in subsection (a)(2), $15,000,000.

"(3) For grants described in subsection (a)(3), $10,000,000.

"(4) For grants described in subsection (a)(4), $10,000,000.''.

SEC. 9022. [42 U.S.C. 294k] STRENGTHENING THE MENTAL AND SUBSTANCE USE DISORDERS WORKFORCE.

Part D of title VII of the Public Health Service Act (42 U.S.C. 294 et seq.) is amended by adding at the end the following:

"SEC. 760. TRAINING DEMONSTRATION PROGRAM

"(a) IN GENERAL.—The Secretary shall establish a training demonstration program to award grants to eligible entities to support—

"(1) training for medical residents and fellows to practice psychiatry and addiction medicine in underserved, community-based settings that integrate primary care with mental and substance use disorders prevention and treatment services;

"(2) training for nurse practitioners, physician assistants, health service psychologists, and social workers to provide mental and substance use disorders services in underserved community-based settings that integrate primary care and mental and substance use disorders services; and

"(3) establishing, maintaining, or improving academic units or programs that—

"(A) provide training for students or faculty, including through clinical experiences and research, to improve the ability to be able to recognize, diagnose, and treat mental and substance use disorders, with a special focus on addiction; or

"(B) develop evidence-based practices or recommendations for the design of the units or programs described in subparagraph (A), including curriculum content standards.

"(b) ACTIVITIES.—

"(1) TRAINING FOR RESIDENTS AND FELLOWS.—A recipient of a grant under subsection (a)(1)—

"(A) shall use the grant funds—

"(i)(I) to plan, develop, and operate a training program for medical psychiatry residents and fellows in addiction medicine practicing in eligible entities described in subsection (c)(1); or

"(II) to train new psychiatric residents and fellows in addiction medicine to provide and expand access to integrated mental and substance use disorders services; and

"(ii) to provide at least 1 training track that is—

"(I) a virtual training track that includes an in-person rotation at a teaching health center or in a community-based setting, followed by a virtual rotation in which the resident or fellow continues to support the care of patients at the teaching health center or in the community-based setting through the use of health information technology and, as appropriate, telehealth services;

"(II) an in-person training track that includes a rotation, during which the resident or fellow practices at a teaching health center or in a community-based setting; or

"(III) an in-person training track that includes a rotation during which the resident practices in

a community-based setting that specializes in the treatment of infants, children, adolescents, or pregnant or postpartum women; and

"(B) may use the grant funds to provide additional support for the administration of the program or to meet the costs of projects to establish, maintain, or improve faculty development, or departments, divisions, or other units necessary to implement such training.

"(2) TRAINING FOR OTHER PROVIDERS.—A recipient of a grant under subsection (a)(2)—

"(A) shall use the grant funds to plan, develop, or operate a training program to provide mental and substance use disorders services in underserved, community-based settings, as appropriate, that integrate primary care and mental and substance use disorders prevention and treatment services; and

"(B) may use the grant funds to provide additional support for the administration of the program or to meet the costs of projects to establish, maintain, or improve faculty development, or departments, divisions, or other units necessary to implement such program.

"(3) ACADEMIC UNITS OR PROGRAMS.—A recipient of a grant under subsection (a)(3) shall enter into a partnership with organizations such as an education accrediting organization (such as the Liaison Committee on Medical Education, the Accreditation Council for Graduate Medical Education, the Commission on Osteopathic College Accreditation, the Accreditation Commission for Education in Nursing, the Commission on Collegiate Nursing Education, the Accreditation Council for Pharmacy Education, the Council on Social Work Education, American Psychological Association Commission on Accreditation, or the Accreditation Review Commission on Education for the Physician Assistant) to carry out activities under subsection (a)(3).

"(c) ELIGIBLE ENTITIES.—

"(1) TRAINING FOR RESIDENTS AND FELLOWS.—To be eligible to receive a grant under subsection (a)(1), an entity shall—

"(A) be a consortium consisting of—

"(i) at least one teaching health center; and

"(ii) the sponsoring institution (or parent institution of the sponsoring institution) of—

"(I) a psychiatry residency program that is accredited by the Accreditation Council of Graduate Medical Education (or the parent institution of such a program); or

"(II) a fellowship in addiction medicine, as determined appropriate by the Secretary; or

"(B) be an entity described in subparagraph (A)(ii) that provides opportunities for residents or fellows to train in community-based settings that integrate primary care with mental and substance use disorders prevention and treatment services.

"(2) TRAINING FOR OTHER PROVIDERS.—To be eligible to receive a grant under subsection (a)(2), an entity shall be—

"(A) a teaching health center (as defined in section 749A(f));

"(B) a Federally qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act);

"(C) a community mental health center (as defined in section 1861(ff)(3)(B) of the Social Security Act);

"(D) a rural health clinic (as defined in section 1861(aa) of the Social Security Act);

"(E) a health center operated by the Indian Health Service, an Indian tribe, a tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act); or

"(F) an entity with a demonstrated record of success in providing training for nurse practitioners, physician assistants, health service psychologists, and social workers.

"(3) ACADEMIC UNITS OR PROGRAMS.—To be eligible to receive a grant under subsection (a)(3), an entity shall be a school of medicine or osteopathic medicine, a nursing school, a physician assistant training program, a school of pharmacy, a school of social work, an accredited public or nonprofit private hospital, an accredited medical residency program, or a public or private nonprofit entity which the Secretary has determined is capable of carrying out such grant.

"(d) PRIORITY.—

"(1) IN GENERAL.—In awarding grants under subsection (a)(1) or (a)(2), the Secretary shall give priority to eligible entities that—

"(A) demonstrate sufficient size, scope, and capacity to undertake the requisite training of an appropriate number of psychiatric residents, fellows, nurse practitioners, physician assistants, or social workers in addiction medicine per year to meet the needs of the area served;

"(B) demonstrate experience in training providers to practice team-based care that integrates mental and substance use disorder prevention and treatment services with primary care in community-based settings;

"(C) demonstrate experience in using health information technology and, as appropriate, telehealth to support—

"(i) the delivery of mental and substance use disorders services at the eligible entities described in subsections (c)(1) and (c)(2); and

"(ii) community health centers in integrating primary care and mental and substance use disorders treatment; or

"(D) have the capacity to expand access to mental and substance use disorders services in areas with demonstrated need, as determined by the Secretary, such as tribal, rural, or other underserved communities.

"(2) ACADEMIC UNITS OR PROGRAMS.—In awarding grants under subsection (a)(3), the Secretary shall give priority to eligible entities that—

"(A) have a record of training the greatest percentage of mental and substance use disorders providers who enter

and remain in these fields or who enter and remain in settings with integrated primary care and mental and substance use disorder prevention and treatment services;

"(B) have a record of training individuals who are from underrepresented minority groups, including native populations, or from a rural or disadvantaged background;

"(C) provide training in the care of vulnerable populations such as infants, children, adolescents, pregnant and postpartum women, older adults, homeless individuals, victims of abuse or trauma, individuals with disabilities, and other groups as defined by the Secretary;

"(D) teach trainees the skills to provide interprofessional, integrated care through collaboration among health professionals; or

"(E) provide training in cultural competency and health literacy.

"(e) DURATION.—Grants awarded under this section shall be for a minimum of 5 years.

"(f) STUDY AND REPORT.—

"(1) STUDY.—

"(A) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall conduct a study on the results of the demonstration program under this section.

"(B) DATA SUBMISSION.—Not later than 90 days after the completion of the first year of the training program and each subsequent year that the program is in effect, each recipient of a grant under subsection (a) shall submit to the Secretary such data as the Secretary may require for analysis for the report described in paragraph (2).

"(2) REPORT TO CONGRESS.—Not later than 1 year after receipt of the data described in paragraph (1)(B), the Secretary shall submit to Congress a report that includes—

"(A) an analysis of the effect of the demonstration program under this section on the quality, quantity, and distribution of mental and substance use disorders services;

"(B) an analysis of the effect of the demonstration program on the prevalence of untreated mental and substance use disorders in the surrounding communities of health centers participating in the demonstration; and

"(C) recommendations on whether the demonstration program should be expanded.

"(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $10,000,000 for each of fiscal years 2018 through 2022.".

SEC. 9023. [42 U.S.C. 294l-1 note] CLARIFICATION ON CURRENT ELIGIBILITY FOR LOAN REPAYMENT PROGRAMS.

The Administrator of the Health Resources and Services Administration shall clarify the eligibility pursuant to section 338B(b)(1)(B) of the Public Health Service Act (42 U.S.C. 254l-1(b)(1)(B)) of child and adolescent psychiatrists for the National Health Service Corps Loan Repayment Program under subpart III of part D of title III of such Act (42 U.S.C. 254l et seq.).

SEC. 9024. MINORITY FELLOWSHIP PROGRAM.

Title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) is amended by adding at the end the following:

"PART K—MINORITY FELLOWSHIP PROGRAM

"SEC. 597. [42 U.S.C. 290ll] FELLOWSHIPS

"(a) IN GENERAL.—The Secretary shall maintain a program, to be known as the Minority Fellowship Program, under which the Secretary shall award fellowships, which may include stipends, for the purposes of—

"(1) increasing the knowledge of mental and substance use disorders practitioners on issues related to prevention, treatment, and recovery support for individuals who are from racial and ethnic minority populations and who have a mental or substance use disorder;

"(2) improving the quality of mental and substance use disorder prevention and treatment services delivered to racial and ethnic minority populations; and

"(3) increasing the number of culturally competent mental and substance use disorders professionals who teach, administer services, conduct research, and provide direct mental or substance use disorder services to racial and ethnic minority populations.

"(b) TRAINING COVERED.—The fellowships awarded under subsection (a) shall be for postbaccalaureate training (including for master's and doctoral degrees) for mental and substance use disorder treatment professionals, including in the fields of psychiatry, nursing, social work, psychology, marriage and family therapy, mental health counseling, and substance use disorder and addiction counseling.

"(c) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $12,669,000 for each of fiscal years 2018 through 2022.".

SEC. 9025. LIABILITY PROTECTIONS FOR HEALTH PROFESSIONAL VOLUNTEERS AT COMMUNITY HEALTH CENTERS.

Section 224 of the Public Health Service Act (42 U.S.C. 233) is amended by adding at the end the following:

"(q)(1) For purposes of this section, a health professional volunteer at a deemed entity described in subsection (g)(4) shall, in providing a health professional service eligible for funding under section 330 to an individual, be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under paragraph (4)(C). The preceding sentence is subject to the provisions of this subsection.

"(2) In providing a health service to an individual, a health care practitioner shall for purposes of this subsection be considered to be a health professional volunteer at an entity described in subsection (g)(4) if the following conditions are met:

"(A) The service is provided to the individual at the facilities of an entity described in subsection (g)(4), or through offsite programs or events carried out by the entity.

"(B) The entity is sponsoring the health care practitioner pursuant to paragraph (3)(B).

"(C) The health care practitioner does not receive any compensation for the service from the individual, the entity described in subsection (g)(4), or any third-party payer (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program), except that the health care practitioner may receive repayment from the entity described in subsection (g)(4) for reasonable expenses incurred by the health care practitioner in the provision of the service to the individual, which may include travel expenses to or from the site of services.

"(D) Before the service is provided, the health care practitioner or the entity described in subsection (g)(4) posts a clear and conspicuous notice at the site where the service is provided of the extent to which the legal liability of the health care practitioner is limited pursuant to this subsection.

"(E) At the time the service is provided, the health care practitioner is licensed or certified in accordance with applicable Federal and State laws regarding the provision of the service.

"(F) At the time the service is provided, the entity described in subsection (g)(4) maintains relevant documentation certifying that the health care practitioner meets the requirements of this subsection.

"(3) Subsection (g) (other than paragraphs (3) and (5)) and subsections (h), (i), and (l) apply to a health care practitioner for purposes of this subsection to the same extent and in the same manner as such subsections apply to an officer, governing board member, employee, or contractor of an entity described in subsection (g)(4), subject to paragraph (4), and subject to the following:

"(A) The first sentence of paragraph (1) applies in lieu of the first sentence of subsection (g)(1)(A).

"(B) With respect to an entity described in subsection (g)(4), a health care practitioner is not a health professional volunteer at such entity unless the entity sponsors the health care practitioner. For purposes of this subsection, the entity shall be considered to be sponsoring the health care practitioner if—

"(i) with respect to the health care practitioner, the entity submits to the Secretary an application meeting the requirements of subsection (g)(1)(D); and

"(ii) the Secretary, pursuant to subsection (g)(1)(E), determines that the health care practitioner is deemed to be an employee of the Public Health Service.

"(C) In the case of a health care practitioner who is determined by the Secretary pursuant to subsection (g)(1)(E) to be a health professional volunteer at such entity, this subsection applies to the health care practitioner (with respect to services performed on behalf of the entity sponsoring the health care practitioner pursuant to subpara-

graph (B)) for any cause of action arising from an act or omission of the health care practitioner occurring on or after the date on which the Secretary makes such determination.

"(D) Subsection (g)(1)(F) applies to a health care practitioner for purposes of this subsection only to the extent that, in providing health services to an individual, each of the conditions specified in paragraph (2) is met.

"(4)(A) Amounts in the fund established under subsection (k)(2) shall be available for transfer under subparagraph (C) for purposes of carrying out this subsection.

"(B)(i) Not later than May 1 of each fiscal year, the Attorney General, in consultation with the Secretary, shall submit to the Congress a report providing an estimate of the amount of claims (together with related fees and expenses of witnesses) that, by reason of the acts or omissions of health professional volunteers, will be paid pursuant to this section during the calendar year that begins in the following fiscal year.

"(ii) Subsection (k)(1)(B) applies to the estimate under clause (i) regarding health professional volunteers to the same extent and in the same manner as such subsection applies to the estimate under such subsection regarding officers, governing board members, employees, and contractors of entities described in subsection (g)(4).

"(iii) The report shall include a summary of the data relied upon for the estimate in clause (i), including the number of claims filed and paid from the previous calendar year.

"(C) Not later than December 31 of each fiscal year, the Secretary shall transfer from the fund under subsection (k)(2) to the appropriate accounts in the Treasury an amount equal to the estimate made under subparagraph (B) for the calendar year beginning in such fiscal year, subject to the extent of amounts in the fund.

"(5)(A) This subsection shall take effect on October 1, 2017, except as provided in subparagraph (B) and paragraph (6).

"(B) Effective on the date of the enactment of this subsection—

"(i) the Secretary may issue regulations for carrying out this subsection, and the Secretary may accept and consider applications submitted pursuant to paragraph (3)(B); and

"(ii) reports under paragraph (4)(B) may be submitted to Congress.

"(6) Beginning on October 1, 2022, this subsection shall cease to have any force or effect.".

SEC. 9026. REPORTS.

(a) WORKFORCE DEVELOPMENT REPORT.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Administrator of the Health Resources and Services Administration, in consultation with the Assistant Secretary for Mental Health and Substance Use, shall conduct a study and publicly post on the appropriate

Internet website of the Department of Health and Human Services a report on the adult and pediatric mental health and substance use disorder workforce in order to inform Federal, State, and local efforts related to workforce enhancement.

(2) CONTENTS.—The report under this subsection shall contain—

(A) national and State-level projections of the supply and demand of the mental health and substance use disorder health workforce, disaggregated by profession;

(B) an assessment of the mental health and substance use disorder workforce capacity, strengths, and weaknesses as of the date of the report, including the extent to which primary care providers are preventing, screening, or referring for mental and substance use disorder services;

(C) information on trends within the mental health and substance use disorder provider workforce, including the number of individuals expected to enter the mental health workforce over the next 5 years; and

(D) any additional information determined by the Administrator of the Health Resources and Services Administration, in consultation with the Assistant Secretary for Mental Health and Substance Use, to be relevant to the mental health and substance use disorder provider workforce.

(b) PEER-SUPPORT SPECIALIST PROGRAMS.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study on peer-support specialist programs in up to 10 States that receive funding from the Substance Abuse and Mental Health Services Administration.

(2) CONTENTS OF STUDY.—In conducting the study under paragraph (1), the Comptroller General of the United States shall examine and identify best practices, in the States selected pursuant to such paragraph, related to training and credential requirements for peer-support specialist programs, such as—

(A) hours of formal work or volunteer experience related to mental and substance use disorders conducted through such programs;

(B) types of peer-support specialist exams required for such programs in the selected States;

(C) codes of ethics used by such programs in the selected States;

(D) required or recommended skill sets for such programs in the selected States; and

(E) requirements for continuing education.

(3) REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the study conducted under paragraph (1).

Subtitle C—Mental Health on Campus Improvement

SEC. 9031. MENTAL HEALTH AND SUBSTANCE USE DISORDER SERVICES ON CAMPUS.

Section 520E-2 of the Public Health Service Act (42 U.S.C. 290bb-36b) is amended—

(1) in the section heading, by striking "**and behavioral health**" and inserting "**health and substance use disorder**";

(2) in subsection (a)—

(A) by striking "Services," and inserting "Services and";

(B) by striking "and behavioral health problems" and inserting "health or substance use disorders";

(C) by striking "substance abuse" and inserting "substance use disorders"; and

(D) by adding after, "suicide attempts," the following: "prevent mental and substance use disorders, reduce stigma, and improve the identification and treatment for students at risk,";

(3) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking "for—" and inserting "for one or more of the following:"; and

(B) by striking paragraphs (1) through (6) and inserting the following:

"(1) Educating students, families, faculty, and staff to increase awareness of mental and substance use disorders.

"(2) The operation of hotlines.

"(3) Preparing informational material.

"(4) Providing outreach services to notify students about available mental and substance use disorder services.

"(5) Administering voluntary mental and substance use disorder screenings and assessments.

"(6) Supporting the training of students, faculty, and staff to respond effectively to students with mental and substance use disorders.

"(7) Creating a network infrastructure to link institutions of higher education with health care providers who treat mental and substance use disorders.

"(8) Providing mental and substance use disorders prevention and treatment services to students, which may include recovery support services and programming and early intervention, treatment, and management, including through the use of telehealth services.

"(9) Conducting research through a counseling or health center at the institution of higher education involved regarding improving the behavioral health of students through clinical services, outreach, prevention, or academic success, in a manner that is in compliance with all applicable personal privacy laws.

"(10) Supporting student groups on campus, including athletic teams, that engage in activities to educate students, in-

cluding activities to reduce stigma surrounding mental and behavioral disorders, and promote mental health.

"(11) Employing appropriately trained staff.

"(12) Developing and supporting evidence-based and emerging best practices, including a focus on culturally and linguistically appropriate best practices.";

(4) in subsection (c)(5), by striking "substance abuse" and inserting "substance use disorder";

(5) in subsection (d)—

(A) in the matter preceding paragraph (1), by striking "An institution of higher education desiring a grant under this section" and inserting "To be eligible to receive a grant under this section, an institution of higher education";

(B) by striking paragraph (1) and inserting—

"(1) A description of the population to be targeted by the program carried out under the grant, including veterans whenever possible and appropriate, and of identified mental and substance use disorder needs of students at the institution of higher education.";

(C) in paragraph (2), by inserting ", which may include, as appropriate and in accordance with subsection (b)(7), a plan to seek input from relevant stakeholders in the community, including appropriate public and private entities, in order to carry out the program under the grant" before the period at the end; and

(D) by adding after paragraph (5) the following new paragraphs:

"(6) An outline of the objectives of the program carried out under the grant.

"(7) For an institution of higher education proposing to use the grant for an activity described in paragraph (8) or (9) of subsection (b), a description of the policies and procedures of the institution of higher education that are related to applicable laws regarding access to, and sharing of, treatment records of students at any campus-based mental health center or partner organization, including the policies and State laws governing when such records can be accessed and shared for non-treatment purposes and a description of the process used by the institution of higher education to notify students of these policies and procedures, including the extent to which written consent is required.

"(8) An assurance that grant funds will be used to supplement and not supplant any other Federal, State, or local funds available to carry out activities of the type carried out under the grant.";

(6) in subsection (e)(1), by striking "and behavioral health problems" and inserting "health and substance use disorders";

(7) in subsection (f)(2)—

(A) by striking "and behavioral health" and inserting "health and substance use disorder"; and

(B) by striking "suicide and substance abuse" and inserting "suicide and substance use disorders";

(8) by redesignating subsection (h) as subsection (i);

(9) by inserting after subsection (g) the following new subsection:

"(h) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to grantees in carrying out this section."; and

(10) in subsection (i), as redesignated by paragraph (8), by striking "$5,000,000 for fiscal year 2005" and all that follows through the period at the end and inserting "$7,000,000 for each of fiscal years 2018 through 2022.".

SEC. 9032. INTERAGENCY WORKING GROUP ON COLLEGE MENTAL HEALTH.

(a) PURPOSE.—It is the purpose of this section to provide for the establishment of a College Campus Task Force to discuss mental and behavioral health concerns on campuses of institutions of higher education.

(b) ESTABLISHMENT.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall establish a College Campus Task Force (referred to in this section as the "Task Force") to discuss mental and behavioral health concerns on campuses of institutions of higher education.

(c) MEMBERSHIP.—The Task Force shall be composed of a representative from each Federal agency (as appointed by the head of the agency) that has jurisdiction over, or is affected by, mental health and education policies and projects, including—

(1) the Department of Education;

(2) the Department of Health and Human Services;

(3) the Department of Veterans Affairs; and

(4) such other Federal agencies as the Assistant Secretary for Mental Health and Substance Use, in consultation with the Secretary, determines to be appropriate.

(d) DUTIES.—The Task Force shall—

(1) serve as a centralized mechanism to coordinate a national effort to—

(A) discuss and evaluate evidence and knowledge on mental and behavioral health services available to, and the prevalence of mental illness among, the age population of students attending institutions of higher education in the United States;

(B) determine the range of effective, feasible, and comprehensive actions to improve mental and behavioral health on campuses of institutions of higher education;

(C) examine and better address the needs of the age population of students attending institutions of higher education dealing with mental illness;

(D) survey Federal agencies to determine which policies are effective in encouraging, and how best to facilitate outreach without duplicating, efforts relating to mental and behavioral health promotion;

(E) establish specific goals within and across Federal agencies for mental health promotion, including determinations of accountability for reaching those goals;

(F) develop a strategy for allocating responsibilities and ensuring participation in mental and behavioral health promotion, particularly in the case of competing agency priorities;

(G) coordinate plans to communicate research results relating to mental and behavioral health amongst the age population of students attending institutions of higher education to enable reporting and outreach activities to produce more useful and timely information;

(H) provide a description of evidence-based practices, model programs, effective guidelines, and other strategies for promoting mental and behavioral health on campuses of institutions of higher education;

(I) make recommendations to improve Federal efforts relating to mental and behavioral health promotion on campuses of institutions of higher education and to ensure Federal efforts are consistent with available standards, evidence, and other programs in existence as of the date of enactment of this Act;

(J) monitor Federal progress in meeting specific mental and behavioral health promotion goals as they relate to settings of institutions of higher education; and

(K) examine and disseminate best practices related to intracampus sharing of treatment records;

(2) consult with national organizations with expertise in mental and behavioral health, especially those organizations working with the age population of students attending institutions of higher education; and

(3) consult with and seek input from mental health professionals working on campuses of institutions of higher education as appropriate.

(e) MEETINGS.—

(1) IN GENERAL.—The Task Force shall meet not fewer than three times each year.

(2) ANNUAL CONFERENCE.—The Secretary shall sponsor an annual conference on mental and behavioral health in settings of institutions of higher education to enhance coordination, build partnerships, and share best practices in mental and behavioral health promotion, data collection, analysis, and services.

(f) DEFINITION.—In this section, the term "institution of higher education" has the meaning given such term in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001).

(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $1,000,000 for the period of fiscal years 2018 through 2022.

SEC. 9033. [42 U.S.C. 290ee-4] IMPROVING MENTAL HEALTH ON COLLEGE CAMPUSES.

Part D of title V of the Public Health Service Act (42 U.S.C. 290dd et seq.) is amended by adding at the end the following:

"SEC. 549. MENTAL AND BEHAVIORAL HEALTH OUTREACH AND EDUCATION ON COLLEGE CAMPUSES

"(a) PURPOSE.—It is the purpose of this section to increase access to, and reduce the stigma associated with, mental health services to ensure that students at institutions of higher education have the support necessary to successfully complete their studies.

"(b) NATIONAL PUBLIC EDUCATION CAMPAIGN.—The Secretary, acting through the Assistant Secretary and in collaboration with the Director of the Centers for Disease Control and Prevention, shall convene an interagency, public-private sector working group to plan, establish, and begin coordinating and evaluating a targeted public education campaign that is designed to focus on mental and behavioral health on the campuses of institutions of higher education. Such campaign shall be designed to—

"(1) improve the general understanding of mental health and mental disorders;

"(2) encourage help-seeking behaviors relating to the promotion of mental health, prevention of mental disorders, and treatment of such disorders;

"(3) make the connection between mental and behavioral health and academic success; and

"(4) assist the general public in identifying the early warning signs and reducing the stigma of mental illness.

"(c) COMPOSITION.—The working group convened under subsection (b) shall include—

"(1) mental health consumers, including students and family members;

"(2) representatives of institutions of higher education;

"(3) representatives of national mental and behavioral health associations and associations of institutions of higher education;

"(4) representatives of health promotion and prevention organizations at institutions of higher education;

"(5) representatives of mental health providers, including community mental health centers; and

"(6) representatives of private-sector and public-sector groups with experience in the development of effective public health education campaigns.

"(d) PLAN.—The working group under subsection (b) shall develop a plan that—

"(1) targets promotional and educational efforts to the age population of students at institutions of higher education and individuals who are employed in settings of institutions of higher education, including through the use of roundtables;

"(2) develops and proposes the implementation of research-based public health messages and activities;

"(3) provides support for local efforts to reduce stigma by using the National Health Information Center as a primary point of contact for information, publications, and service program referrals; and

"(4) develops and proposes the implementation of a social marketing campaign that is targeted at the population of students attending institutions of higher education and individuals who are employed in settings of institutions of higher education.

"(e) DEFINITION.—In this section, the term 'institution of higher education' has the meaning given such term in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001).

"(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $1,000,000 for the period of fiscal years 2018 through 2022.".

TITLE X—STRENGTHENING MENTAL AND SUBSTANCE USE DISORDER CARE FOR CHILDREN AND ADOLESCENTS

SEC. 10001. PROGRAMS FOR CHILDREN WITH A SERIOUS EMOTIONAL DISTURBANCE.

(a) COMPREHENSIVE COMMUNITY MENTAL HEALTH SERVICES FOR CHILDREN WITH A SERIOUS EMOTIONAL DISTURBANCE.—Section 561(a)(1) of the Public Health Service Act (42 U.S.C. 290ff(a)(1)) is amended by inserting ", which may include efforts to identify and serve children at risk" before the period.

(b) REQUIREMENTS WITH RESPECT TO CARRYING OUT PURPOSE OF GRANTS.—Section 562(b) of the Public Health Service Act (42 U.S.C. 290ff-1(b)) is amended by striking "will not provide an individual with access to the system if the individual is more than 21 years of age" and inserting "will provide an individual with access to the system through the age of 21 years".

(c) ADDITIONAL PROVISIONS.—Section 564(f) of the Public Health Service Act (42 U.S.C. 290ff-3(f)) is amended by inserting "(and provide a copy to the State involved)" after "to the Secretary".

(d) GENERAL PROVISIONS.—Section 565 of the Public Health Service Act (42 U.S.C. 290ff-4) is amended—

(1) in subsection (b)(1)—

(A) in the matter preceding subparagraph (A), by striking "receiving a grant under section 561(a)" and inserting ", regardless of whether such public entity is receiving a grant under section 561(a)"; and

(B) in subparagraph (B), by striking "pursuant to" and inserting "described in";

(2) in subsection (d)(1), by striking "not more than 21 years of age" and inserting "through the age of 21 years"; and

(3) in subsection (f)(1), by striking "$100,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003" and inserting "$119,026,000 for each of fiscal years 2018 through 2022".

SEC. 10002. INCREASING ACCESS TO PEDIATRIC MENTAL HEALTH CARE.

Title III of the Public Health Service Act is amended by inserting after section 330L of such Act (42 U.S.C. 254c-18) the following new section:

"SEC. 330M [42 U.S.C. 254c-19] PEDIATRIC MENTAL HEALTH CARE ACCESS GRANTS

"(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration and in coordination with other relevant Federal agencies, shall award grants to States, political subdivisions of States, and Indian tribes and tribal organizations (for purposes of this section, as such terms

are defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b)) to promote behavioral health integration in pediatric primary care by—

"(1) supporting the development of statewide or regional pediatric mental health care telehealth access programs; and

"(2) supporting the improvement of existing statewide or regional pediatric mental health care telehealth access programs.

"(b) PROGRAM REQUIREMENTS.—

"(1) IN GENERAL.—A pediatric mental health care telehealth access program referred to in subsection (a), with respect to which a grant under such subsection may be used, shall—

"(A) be a statewide or regional network of pediatric mental health teams that provide support to pediatric primary care sites as an integrated team;

"(B) support and further develop organized State or regional networks of pediatric mental health teams to provide consultative support to pediatric primary care sites;

"(C) conduct an assessment of critical behavioral consultation needs among pediatric providers and such providers' preferred mechanisms for receiving consultation, training, and technical assistance;

"(D) develop an online database and communication mechanisms, including telehealth, to facilitate consultation support to pediatric practices;

"(E) provide rapid statewide or regional clinical telephone or telehealth consultations when requested between the pediatric mental health teams and pediatric primary care providers;

"(F) conduct training and provide technical assistance to pediatric primary care providers to support the early identification, diagnosis, treatment, and referral of children with behavioral health conditions;

"(G) provide information to pediatric providers about, and assist pediatric providers in accessing, pediatric mental health care providers, including child and adolescent psychiatrists, and licensed mental health professionals, such as psychologists, social workers, or mental health counselors and in scheduling and conducting technical assistance;

"(H) assist with referrals to specialty care and community or behavioral health resources; and

"(I) establish mechanisms for measuring and monitoring increased access to pediatric mental health care services by pediatric primary care providers and expanded capacity of pediatric primary care providers to identify, treat, and refer children with mental health problems.

"(2) PEDIATRIC MENTAL HEALTH TEAMS.—In this subsection, the term 'pediatric mental health team' means a team consisting of at least one case coordinator, at least one child and adolescent psychiatrist, and at least one licensed clinical mental health professional, such as a psychologist, social worker,

or mental health counselor. Such a team may be regionally based.

"(c) APPLICATION.—A State, political subdivision of a State, Indian tribe, or tribal organization seeking a grant under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including a plan for the comprehensive evaluation of activities that are carried out with funds received under such grant.

"(d) EVALUATION.—A State, political subdivision of a State, Indian tribe, or tribal organization that receives a grant under this section shall prepare and submit an evaluation of activities that are carried out with funds received under such grant to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including a process and outcome evaluation.

"(e) ACCESS TO BROADBAND.—In administering grants under this section, the Secretary may coordinate with other agencies to ensure that funding opportunities are available to support access to reliable, high-speed Internet for providers.

"(f) MATCHING REQUIREMENT.—The Secretary may not award a grant under this section unless the State, political subdivision of a State, Indian tribe, or tribal organization involved agrees, with respect to the costs to be incurred by the State, political subdivision of a State, Indian tribe, or tribal organization in carrying out the purpose described in this section, to make available non-Federal contributions (in cash or in kind) toward such costs in an amount that is not less than 20 percent of Federal funds provided in the grant.

"(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated, $9,000,000 for the period of fiscal years 2018 through 2022.".

SEC. 10003. SUBSTANCE USE DISORDER TREATMENT AND EARLY INTERVENTION SERVICES FOR CHILDREN AND ADOLESCENTS.

The first section 514 of the Public Health Service Act (42 U.S.C. 290bb-7), relating to substance abuse treatment services for children and adolescents, is amended—

(1) in the section heading, by striking "**abuse treatment**" and inserting "**use disorder treatment and early intervention**";

(2) by striking subsection (a) and inserting the following:

"(a) IN GENERAL.—The Secretary shall award grants, contracts, or cooperative agreements to public and private nonprofit entities, including Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), or health facilities or programs operated by or in accordance with a contract or grant with the Indian Health Service, for the purpose of—

"(1) providing early identification and services to meet the needs of children and adolescents who are at risk of substance use disorders;

"(2) providing substance use disorder treatment services for children, including children and adolescents with co-occurring mental illness and substance use disorders; and

"(3) providing assistance to pregnant women, and parenting women, with substance use disorders, in obtaining treatment services, linking mothers to community resources to support independent family lives, and staying in recovery so that children are in safe, stable home environments and receive appropriate health care services.";

(3) in subsection (b)—

(A) by striking paragraph (1) and inserting the following:

"(1) apply evidence-based and cost-effective methods;";

(B) in paragraph (2)—

(i) by striking "treatment"; and

(ii) by inserting "substance abuse," after "child welfare,";

(C) in paragraph (3), by striking "substance abuse disorders" and inserting "substance use disorders, including children and adolescents with co-occurring mental illness and substance use disorders,";

(D) in paragraph (5), by striking "treatment;" and inserting "services; and";

(E) in paragraph (6), by striking "substance abuse treatment; and" and inserting "treatment."; and

(F) by striking paragraph (7); and

(4) in subsection (f), by striking "$40,000,000" and all that follows through the period and inserting "$29,605,000 for each of fiscal years 2018 through 2022.".

SEC. 10004. CHILDREN'S RECOVERY FROM TRAUMA.

The first section 582 of the Public Health Service Act (42 U.S.C. 290hh-1; relating to grants to address the problems of persons who experience violence related stress) is amended—

(1) in subsection (a), by striking "developing programs" and all that follows through the period at the end and inserting the following:" developing and maintaining programs that provide for—

"(1) the continued operation of the National Child Traumatic Stress Initiative (referred to in this section as the 'NCTSI'), which includes a cooperative agreement with a coordinating center, that focuses on the mental, behavioral, and biological aspects of psychological trauma response, prevention of the long-term consequences of child trauma, and early intervention services and treatment to address the long-term consequences of child trauma; and

"(2) the development of knowledge with regard to evidence-based practices for identifying and treating mental, behavioral, and biological disorders of children and youth resulting from witnessing or experiencing a traumatic event.";

(2) in subsection (b)—

(A) by striking "subsection (a) related" and inserting "subsection (a)(2) (related";

(B) by striking "treating disorders associated with psychological trauma" and inserting "treating mental, behavioral, and biological disorders associated with psychological trauma)"; and

(C) by striking "mental health agencies and programs that have established clinical and basic research" and inserting "universities, hospitals, mental health agencies, and other programs that have established clinical expertise and research";

(3) by redesignating subsections (c) through (g) as subsections (g) through (k), respectively;

(4) by inserting after subsection (b), the following:

"(c) CHILD OUTCOME DATA.—The NCTSI coordinating center described in subsection (a)(1) shall collect, analyze, report, and make publicly available, as appropriate, NCTSI-wide child treatment process and outcome data regarding the early identification and delivery of evidence-based treatment and services for children and families served by the NCTSI grantees.

"(d) TRAINING.—The NCTSI coordinating center shall facilitate the coordination of training initiatives in evidence-based and trauma-informed treatments, interventions, and practices offered to NCTSI grantees, providers, and partners.

"(e) DISSEMINATION AND COLLABORATION.—The NCTSI coordinating center shall, as appropriate, collaborate with—

"(1) the Secretary, in the dissemination of evidence-based and trauma-informed interventions, treatments, products, and other resources to appropriate stakeholders; and

"(2) appropriate agencies that conduct or fund research within the Department of Health and Human Services, for purposes of sharing NCTSI expertise, evaluation data, and other activities, as appropriate.

"(f) REVIEW.—The Secretary shall, consistent with the peer-review process, ensure that NCTSI applications are reviewed by appropriate experts in the field as part of a consensus-review process. The Secretary shall include review criteria related to expertise and experience in child trauma and evidence-based practices.";

(5) in subsection (g) (as so redesignated), by striking "with respect to centers of excellence are distributed equitably among the regions of the country" and inserting "are distributed equitably among the regions of the United States";

(6) in subsection (i) (as so redesignated), by striking "recipient may not exceed 5 years" and inserting "recipient shall not be less than 4 years, but shall not exceed 5 years"; and

(7) in subsection (j) (as so redesignated), by striking "$50,000,000" and all that follows through "2006" and inserting "$46,887,000 for each of fiscal years 2018 through 2022".

SEC. 10005. SCREENING AND TREATMENT FOR MATERNAL DEPRESSION.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 317L (42 U.S.C. 247b-13) the following:

"SEC. 317L-1. SCREENING AND TREATMENT FOR MATERNAL DEPRESSION

"(a) GRANTS.—The Secretary shall make grants to States to establish, improve, or maintain programs for screening, assessment, and treatment services, including culturally and linguistically appropriate services, as appropriate, for women who are pregnant, or

who have given birth within the preceding 12 months, for maternal depression.

"(b) APPLICATION.—To seek a grant under this section, a State shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require. At a minimum, any such application shall include explanations of—

"(1) how a program, or programs, will increase the percentage of women screened and treated, as appropriate, for maternal depression in 1 or more communities; and

"(2) how a program, or programs, if expanded, would increase access to screening and treatment services for maternal depression.

"(c) PRIORITY.—In awarding grants under this section, the Secretary may give priority to States proposing to improve or enhance access to screening services for maternal depression in primary care settings.

"(d) USE OF FUNDS.—The activities eligible for funding through a grant under subsection (a)—

"(1) shall include—

"(A) providing appropriate training to health care providers; and

"(B) providing information to health care providers, including information on maternal depression screening, treatment, and followup support services, and linkages to community-based resources; and

"(2) may include—

"(A) enabling health care providers (including obstetrician-gynecologists, pediatricians, psychiatrists, mental health care providers, and adult primary care clinicians) to provide or receive real-time psychiatric consultation (in-person or remotely) to aid in the treatment of pregnant and parenting women;

"(B) establishing linkages with and among community-based resources, including mental health resources, primary care resources, and support groups; and

"(C) utilizing telehealth services for rural areas and medically underserved areas (as defined in section 330I(a)).

"(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $5,000,000 for each of fiscal years 2018 through 2022.".

SEC. 10006. INFANT AND EARLY CHILDHOOD MENTAL HEALTH PROMOTION, INTERVENTION, AND TREATMENT.

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

"SEC. 399Z-2. [42 U.S.C. 280h-6] INFANT AND EARLY CHILDHOOD MENTAL HEALTH PROMOTION, INTERVENTION, AND TREATMENT

"(a) GRANTS.—The Secretary shall—

"(1) award grants to eligible entities to develop, maintain, or enhance infant and early childhood mental health promotion, intervention, and treatment programs, including—

"(A) programs for infants and children at significant risk of developing, showing early signs of, or having been diagnosed with mental illness, including a serious emotional disturbance; and

"(B) multigenerational therapy and other services that support the caregiving relationship; and

"(2) ensure that programs funded through grants under this section are evidence-informed or evidence-based models, practices, and methods that are, as appropriate, culturally and linguistically appropriate, and can be replicated in other appropriate settings.

"(b) ELIGIBLE CHILDREN AND ENTITIES.—In this section:

"(1) ELIGIBLE CHILD.—The term 'eligible child' means a child from birth to not more than 12 years of age who—

"(A) is at risk for, shows early signs of, or has been diagnosed with a mental illness, including a serious emotional disturbance; and

"(B) may benefit from infant and early childhood intervention or treatment programs or specialized preschool or elementary school programs that are evidence-based or that have been scientifically demonstrated to show promise but would benefit from further applied development.

"(2) ELIGIBLE ENTITY.—The term 'eligible entity' means a human services agency or nonprofit institution that—

"(A) employs licensed mental health professionals who have specialized training and experience in infant and early childhood mental health assessment, diagnosis, and treatment, or is accredited or approved by the appropriate State agency, as applicable, to provide for children from infancy to 12 years of age mental health promotion, intervention, or treatment services; and

"(B) provides services or programs described in subsection (a) that are evidence-based or that have been scientifically demonstrated to show promise but would benefit from further applied development.

"(c) APPLICATION.—An eligible entity seeking a grant under subsection (a) shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

"(d) USE OF FUNDS FOR EARLY INTERVENTION AND TREATMENT PROGRAMS.—An eligible entity may use amounts awarded under a grant under subsection (a)(1) to carry out the following:

"(1) Provide age-appropriate mental health promotion and early intervention services or mental illness treatment services, which may include specialized programs, for eligible children at significant risk of developing, showing early signs of, or having been diagnosed with a mental illness, including a serious emotional disturbance. Such services may include social and behavioral services as well as multigenerational therapy and other services that support the caregiving relationship.

"(2) Provide training for health care professionals with expertise in infant and early childhood mental health care with respect to appropriate and relevant integration with other disciplines such as primary care clinicians, early intervention spe-

cialists, child welfare staff, home visitors, early care and education providers, and others who work with young children and families.

"(3) Provide mental health consultation to personnel of early care and education programs (including licensed or regulated center-based and home-based child care, home visiting, preschool special education, and early intervention programs) who work with children and families.

"(4) Provide training for mental health clinicians in infant and early childhood in promising and evidence-based practices and models for infant and early childhood mental health treatment and early intervention, including with regard to practices for identifying and treating mental illness and behavioral disorders of infants and children resulting from exposure or repeated exposure to adverse childhood experiences or childhood trauma.

"(5) Provide age-appropriate assessment, diagnostic, and intervention services for eligible children, including early mental health promotion, intervention, and treatment services.

"(e) MATCHING FUNDS.—The Secretary may not award a grant under this section to an eligible entity unless the eligible entity agrees, with respect to the costs to be incurred by the eligible entity in carrying out the activities described in subsection (d), to make available non-Federal contributions (in cash or in kind) toward such costs in an amount that is not less than 10 percent of the total amount of Federal funds provided in the grant.

"(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $20,000,000 for the period of fiscal years 2018 through 2022.".

TITLE XI—COMPASSIONATE COMMUNICATION ON HIPAA

SEC. 11001. SENSE OF CONGRESS.

(a) FINDINGS.—Congress finds the following:

(1) According to the National Survey on Drug Use and Health, in 2015, there were approximately 9,800,000 adults in the United States with serious mental illness.

(2) The Substance Abuse and Mental Health Services Administration defines the term "serious mental illness" as an illness affecting individuals 18 years of age or older as having, at any time in the past year, a diagnosable mental, behavioral, or emotional disorder that results in serious functional impairment and substantially interferes with or limits one or more major life activities.

(3) In reporting on the incidence of serious mental illness, the Substance Abuse and Mental Health Services Administration includes major depression, schizophrenia, bipolar disorder, and other mental disorders that cause serious impairment.

(4) Adults with a serious mental illness are at a higher risk for chronic physical illnesses and premature death.

(5) According to the World Health Organization, adults with a serious mental illness have lifespans that are 10 to 25

years shorter than those without serious mental illness. The vast majority of these deaths are due to chronic physical medical conditions, such as cardiovascular, respiratory, and infectious diseases, as well as diabetes and hypertension.

(6) According to the World Health Organization, the majority of deaths of adults with a serious mental illness that are due to physical medical conditions are preventable.

(7) Supported decision making can facilitate care decisions in areas where serious mental illness may impact the capacity of an individual to determine a course of treatment while still allowing the individual to make decisions independently.

(8) Help should be provided to adults with a serious mental illness to address their acute or chronic physical illnesses, make informed choices about treatment, and understand and follow through with appropriate treatment.

(9) There is confusion in the health care community regarding permissible practices under the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (commonly known as "HIPAA"). This confusion may hinder appropriate communication of health care information or treatment preferences with appropriate caregivers.

(b) SENSE OF CONGRESS.—It is the sense of Congress that clarification is needed regarding the privacy rule promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note) regarding existing permitted uses and disclosures of health information by health care professionals to communicate with caregivers of adults with a serious mental illness to facilitate treatment.

SEC. 11002. CONFIDENTIALITY OF RECORDS.

Not later than 1 year after the date on which the Secretary of Health and Human Services (in this title referred to as the "Secretary") first finalizes regulations updating part 2 of title 42, Code of Federal Regulations, relating to confidentiality of alcohol and drug abuse patient records, after the date of enactment of this Act, the Secretary shall convene relevant stakeholders to determine the effect of such regulations on patient care, health outcomes, and patient privacy.

SEC. 11003. [42 U.S.C. 1320d-2 note] CLARIFICATION ON PERMITTED USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION.

(a) IN GENERAL.—The Secretary, acting through the Director of the Office for Civil Rights, shall ensure that health care providers, professionals, patients and their families, and others involved in mental or substance use disorder treatment have adequate, accessible, and easily comprehensible resources relating to appropriate uses and disclosures of protected health information under the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note).

(b) GUIDANCE.—

(1) ISSUANCE.—In carrying out subsection (a), not later than 1 year after the date of enactment of this section, the Secretary shall issue guidance clarifying the circumstances under

which, consistent with regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, a health care provider or covered entity may use or disclose protected health information.

(2) CIRCUMSTANCES ADDRESSED.—The guidance issued under this section shall address circumstances including those that—

(A) require the consent of the patient;

(B) require providing the patient with an opportunity to object;

(C) are based on the exercise of professional judgment regarding whether the patient would object when the opportunity to object cannot practicably be provided because of the incapacity of the patient or an emergency treatment circumstance; and

(D) are determined, based on the exercise of professional judgment, to be in the best interest of the patient when the patient is not present or otherwise incapacitated.

(3) COMMUNICATION WITH FAMILY MEMBERS AND CAREGIVERS.—In addressing the circumstances described in paragraph (2), the guidance issued under this section shall clarify permitted uses or disclosures of protected health information for purposes of—

(A) communicating with a family member of the patient, caregiver of the patient, or other individual, to the extent that such family member, caregiver, or individual is involved in the care of the patient;

(B) in the case that the patient is an adult, communicating with a family member of the patient, caregiver of the patient, or other individual involved in the care of the patient;

(C) in the case that the patient is a minor, communicating with the parent or caregiver of the patient;

(D) involving the family members or caregivers of the patient, or others involved in the patient's care or care plan, including facilitating treatment and medication adherence;

(E) listening to the patient, or receiving information with respect to the patient from the family or caregiver of the patient;

(F) communicating with family members of the patient, caregivers of the patient, law enforcement, or others when the patient presents a serious and imminent threat of harm to self or others; and

(G) communicating to law enforcement and family members or caregivers of the patient about the admission of the patient to receive care at, or the release of a patient from, a facility for an emergency psychiatric hold or involuntary treatment.

SEC. 11004. [42 U.S.C. 1320d-2 note] DEVELOPMENT AND DISSEMINATION OF MODEL TRAINING PROGRAMS.

(a) INITIAL PROGRAMS AND MATERIALS.—Not later than 1 year after the date of the enactment of this Act, the Secretary, in consultation with appropriate experts, shall identify the following

model programs and materials, or (in the case that no such programs or materials exist) recognize private or public entities to develop and disseminate each of the following:

(1) Model programs and materials for training health care providers (including physicians, emergency medical personnel, psychiatrists, including child and adolescent psychiatrists, psychologists, counselors, therapists, nurse practitioners, physician assistants, behavioral health facilities and clinics, care managers, and hospitals, including individuals such as general counsels or regulatory compliance staff who are responsible for establishing provider privacy policies) regarding the permitted uses and disclosures, consistent with the standards governing the privacy and security of individually identifiable health information promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note) and such part C, of the protected health information of patients seeking or undergoing mental or substance use disorder treatment.

(2) A model program and materials for training patients and their families regarding their rights to protect and obtain information under the standards and regulations specified in paragraph (1).

(b) PERIODIC UPDATES.—The Secretary shall—

(1) periodically review and update the model programs and materials identified or developed under subsection (a); and

(2) disseminate the updated model programs and materials to the individuals described in subsection (a).

(c) COORDINATION.—The Secretary shall carry out this section in coordination with the Director of the Office for Civil Rights within the Department of Health and Human Services, the Assistant Secretary for Mental Health and Substance Use, the Administrator of the Health Resources and Services Administration, and the heads of other relevant agencies within the Department of Health and Human Services.

(d) INPUT OF CERTAIN ENTITIES.—In identifying, reviewing, or updating the model programs and materials under subsections (a) and (b), the Secretary shall solicit the input of relevant national, State, and local associations; medical societies; licensing boards; providers of mental and substance use disorder treatment; organizations with expertise on domestic violence, sexual assault, elder abuse, and child abuse; and organizations representing patients and consumers and the families of patients and consumers.

(e) FUNDING.—There are authorized to be appropriated to carry out this section—

(1) $4,000,000 for fiscal year 2018;

(2) $2,000,000 for each of fiscal years 2019 and 2020; and

(3) $1,000,000 for each of fiscal years 2021 and 2022.

TITLE XII—MEDICAID MENTAL HEALTH COVERAGE

SEC. 12001. [42 U.S.C. 1396 note] RULE OF CONSTRUCTION RELATED TO MEDICAID COVERAGE OF MENTAL HEALTH SERVICES AND PRIMARY CARE SERVICES FURNISHED ON THE SAME DAY.

Nothing in title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) shall be construed as prohibiting separate payment under the State plan under such title (or under a waiver of the plan) for the provision of a mental health service or primary care service under such plan, with respect to an individual, because such service is—

(1) a primary care service furnished to the individual by a provider at a facility on the same day a mental health service is furnished to such individual by such provider (or another provider) at the facility; or

(2) a mental health service furnished to the individual by a provider at a facility on the same day a primary care service is furnished to such individual by such provider (or another provider) at the facility.

SEC. 12002. STUDY AND REPORT RELATED TO MEDICAID MANAGED CARE REGULATION.

(a) STUDY.—The Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services, shall conduct a study on coverage under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) of services provided through a medicaid managed care organization (as defined in section 1903(m) of such Act (42 U.S.C. 1396b(m)) or a prepaid inpatient health plan (as defined in section 438.2 of title 42, Code of Federal Regulations (or any successor regulation)) with respect to individuals over the age of 21 and under the age of 65 for the treatment of a mental health disorder in institutions for mental diseases (as defined in section 1905(i) of such Act (42 U.S.C. 1396d(i))). Such study shall include information on the following:

(1) The extent to which States, including the District of Columbia and each territory or possession of the United States, are providing capitated payments to such organizations or plans for enrollees who are receiving services in institutions for mental diseases.

(2) The number of individuals receiving medical assistance under a State plan under such title XIX, or a waiver of such plan, who receive services in institutions for mental diseases through such organizations and plans.

(3) The range of and average number of months, and the length of stay during such months, that such individuals are receiving such services in such institutions.

(4) How such organizations or plans determine when to provide for the furnishing of such services through an institution for mental diseases in lieu of other benefits (including the full range of community-based services) under their contract with the State agency administering the State plan under such

title XIX, or a waiver of such plan, to address psychiatric or substance use disorder treatment.

(5) The extent to which the provision of services within such institutions has affected the capitated payments for such organizations or plans.

(b) REPORT.—Not later than 3 years after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under subsection (a).

SEC. 12003. [42 U.S.C. 1315 note] GUIDANCE ON OPPORTUNITIES FOR INNOVATION.

Not later than 1 year after the date of the enactment of this Act, the Administrator of the Centers for Medicare & Medicaid Services shall issue a State Medicaid Director letter regarding opportunities to design innovative service delivery systems, including systems for providing community-based services, for adults with a serious mental illness or children with a serious emotional disturbance who are receiving medical assistance under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.). The letter shall include opportunities for demonstration projects under section 1115 of such Act (42 U.S.C. 1315) to improve care for such adults and children.

SEC. 12004. STUDY AND REPORT ON MEDICAID EMERGENCY PSYCHIATRIC DEMONSTRATION PROJECT.

(a) COLLECTION OF INFORMATION.—The Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services, shall, to the extent practical and data is available, with respect to each State that has participated in the demonstration project established under section 2707 of the Patient Protection and Affordable Care Act (42 U.S.C. 1396a note), collect from each such State information on the following:

(1) The number of institutions for mental diseases (as defined in section 1905(i) of the Social Security Act (42 U.S.C. 1396d(i))) and beds in such institutions that received payment for the provision of services to individuals who receive medical assistance under a State plan under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) (or under a waiver of such plan) through the demonstration project in each such State as compared to the total number of institutions for mental diseases and beds in the State.

(2) The extent to which there is a reduction in expenditures under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) or other spending on the full continuum of physical or mental health care for individuals who receive treatment in an institution for mental diseases under the demonstration project, including outpatient, inpatient, emergency, and ambulatory care, that is attributable to such individuals receiving treatment in institutions for mental diseases under the demonstration project.

(3) The number of forensic psychiatric hospitals, the number of beds in such hospitals, and the number of forensic psychiatric beds in other hospitals in such State, based on the most recent data available, to the extent practical, as determined by such Administrator.

(4) The amount of any disproportionate share hospital payments under section 1923 of the Social Security Act (42 U.S.C. 1396r-4) that institutions for mental diseases in the State received during the period beginning on July 1, 2012, and ending on June 30, 2015, and the extent to which the demonstration project reduced the amount of such payments.

(5) The most recent data regarding all facilities or sites in the State in which any adults with a serious mental illness who are receiving medical assistance under a State plan under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) (or under a waiver of such plan) are treated during the period referred to in paragraph (4), to the extent practical, as determined by the Administrator, including—

(A) the types of such facilities or sites (such as an institution for mental diseases, a hospital emergency department, or other inpatient hospital);

(B) the average length of stay in such a facility or site by such an individual, disaggregated by facility type; and

(C) the payment rate under the State plan (or a waivers of such plan) for services furnished to such an individual for that treatment, disaggregated by facility type, during the period in which the demonstration project is in operation.

(6) The extent to which the utilization of hospital emergency departments during the period in which the demonstration project was is in operation differed, with respect to individuals who are receiving medical assistance under a State plan under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) (or under a waiver of such plan), between—

(A) those individuals who received treatment in an institution for mental diseases under the demonstration project;

(B) those individuals who met the eligibility requirements for the demonstration project but who did not receive treatment in an institution for mental diseases under the demonstration project; and

(C) those adults with a serious mental illness who did not meet such eligibility requirements and did not receive treatment for such illness in an institution for mental diseases.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report that summarizes and analyzes the information collected under subsection (a). Such report may be submitted as part of the report required under section 2707(f) of the Patient Protection and Affordable Care Act (42 U.S.C. 1396a note) or separately.

SEC. 12005. [42 U.S.C. 1396d note] PROVIDING EPSDT SERVICES TO CHILDREN IN IMDS.

(a) IN GENERAL.—Section 1905(a)(16) of the Social Security Act (42 U.S.C. 1396d(a)(16)) is amended—

(1) by striking "effective January 1, 1973" and inserting "(A) effective January 1, 1973"; and

(2) by inserting before the semicolon at the end the following: ", and, (B) for individuals receiving services described in subparagraph (A), early and periodic screening, diagnostic, and treatment services (as defined in subsection (r)), whether or not such screening, diagnostic, and treatment services are furnished by the provider of the services described in such subparagraph".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply with respect to items and services furnished in calendar quarters beginning on or after January 1, 2019.

SEC. 12006. ELECTRONIC VISIT VERIFICATION SYSTEM REQUIRED FOR PERSONAL CARE SERVICES AND HOME HEALTH CARE SERVICES UNDER MEDICAID.

(a) IN GENERAL.—Section 1903 of the Social Security Act (42 U.S.C. 1396b) is amended by inserting after subsection (k) the following new subsection:

"(l)(1) Subject to paragraphs (3) and (4), with respect to any amount expended for personal care services or home health care services requiring an in-home visit by a provider that are provided under a State plan under this title (or under a waiver of the plan) and furnished in a calendar quarter beginning on or after January 1, 2019 (or, in the case of home health care services, on or after January 1, 2023), unless a State requires the use of an electronic visit verification system for such services furnished in such quarter under the plan or such waiver, the Federal medical assistance percentage shall be reduced—

"(A) in the case of personal care services—

"(i) for calendar quarters in 2019 and 2020, by .25 percentage points;

"(ii) for calendar quarters in 2021, by .5 percentage points;

"(iii) for calendar quarters in 2022, by .75 percentage points; and

"(iv) for calendar quarters in 2023 and each year thereafter, by 1 percentage point; and

"(B) in the case of home health care services—

"(i) for calendar quarters in 2023 and 2024, by .25 percentage points;

"(ii) for calendar quarters in 2025, by .5 percentage points;

"(iii) for calendar quarters in 2026, by .75 percentage points; and

"(iv) for calendar quarters in 2027 and each year thereafter, by 1 percentage point.

"(2) Subject to paragraphs (3) and (4), in implementing the requirement for the use of an electronic visit verification system under paragraph (1), a State shall—

"(A) consult with agencies and entities that provide personal care services, home health care services, or both under the State plan (or under a waiver of the plan) to ensure that such system—

"(i) is minimally burdensome;

"(ii) takes into account existing best practices and electronic visit verification systems in use in the State; and

"(iii) is conducted in accordance with the requirements of HIPAA privacy and security law (as defined in section 3009 of the Public Health Service Act);

"(B) take into account a stakeholder process that includes input from beneficiaries, family caregivers, individuals who furnish personal care services or home health care services, and other stakeholders, as determined by the State in accordance with guidance from the Secretary; and

"(C) ensure that individuals who furnish personal care services, home health care services, or both under the State plan (or under a waiver of the plan) are provided the opportunity for training on the use of such system.

"(3) Paragraphs (1) and (2) shall not apply in the case of a State that, as of the date of the enactment of this subsection, requires the use of any system for the electronic verification of visits conducted as part of both personal care services and home health care services, so long as the State continues to require the use of such system with respect to the electronic verification of such visits.

"(4)(A) In the case of a State described in subparagraph (B), the reduction under paragraph (1) shall not apply—

"(i) in the case of personal care services, for calendar quarters in 2019; and

"(ii) in the case of home health care services, for calendar quarters in 2023.

"(B) For purposes of subparagraph (A), a State described in this subparagraph is a State that demonstrates to the Secretary that the State—

"(i) has made a good faith effort to comply with the requirements of paragraphs (1) and (2) (including by taking steps to adopt the technology used for an electronic visit verification system); and

"(ii) in implementing such a system, has encountered unavoidable system delays.

"(5) In this subsection:

"(A) The term 'electronic visit verification system' means, with respect to personal care services or home health care services, a system under which visits conducted as part of such services are electronically verified with respect to—

"(i) the type of service performed;

"(ii) the individual receiving the service;

"(iii) the date of the service;

"(iv) the location of service delivery;

"(v) the individual providing the service; and

"(vi) the time the service begins and ends.

"(B) The term 'home health care services' means services described in section 1905(a)(7) provided under a State plan under this title (or under a waiver of the plan).

"(C) The term 'personal care services' means personal care services provided under a State plan under this title (or under a waiver of the plan), including services provided under section 1905(a)(24), 1915(c), 1915(i), 1915(j), or 1915(k) or under a wavier under section 1115.

"(6)(A) In the case in which a State requires personal care service and home health care service providers to utilize an electronic visit verification system operated by the State or a contractor on behalf of the State, the Secretary shall pay to the State, for each quarter, an amount equal to 90 per centum of so much of the sums expended during such quarter as are attributable to the design, development, or installation of such system, and 75 per centum of so much of the sums for the operation and maintenance of such system.

"(B) Subparagraph (A) shall not apply in the case in which a State requires personal care service and home health care service providers to utilize an electronic visit verification system that is not operated by the State or a contractor on behalf of the State.".

(b) [42 U.S.C. 1396b note]

[42 U.S.C. 1396b note] COLLECTION AND DISSEMINATION OF BEST PRACTICES.—Not later than January 1, 2018, the Secretary of Health and Human Services shall, with respect to electronic visit verification systems (as defined in subsection (l)(5) of section 1903 of the Social Security Act (42 U.S.C. 1396b), as inserted by subsection (a)), collect and disseminate best practices to State Medicaid Directors with respect to—

(1) training individuals who furnish personal care services, home health care services, or both under the State plan under title XIX of such Act (or under a waiver of the plan) on such systems and the operation of such systems and the prevention of fraud with respect to the provision of personal care services or home health care services (as defined in such subsection (l)(5)); and

(2) the provision of notice and educational materials to family caregivers and beneficiaries with respect to the use of such electronic visit verification systems and other means to prevent such fraud.

(c) [42 U.S.C. 1396b note]

[42 U.S.C. 1396b note] RULES OF CONSTRUCTION.—

(1) NO EMPLOYER-EMPLOYEE RELATIONSHIP ESTABLISHED.—Nothing in the amendment made by this section may be construed as establishing an employer-employee relationship between the agency or entity that provides for personal care services or home health care services and the individuals who, under a contract with such an agency or entity, furnish such services for purposes of part 552 of title 29, Code of Federal Regulations (or any successor regulations).

(2) NO PARTICULAR OR UNIFORM ELECTRONIC VISIT VERIFICATION SYSTEM REQUIRED.—Nothing in the amendment made by this section shall be construed to require the use of a particular or uniform electronic visit verification system (as defined in subsection (l)(5) of section 1903 of the Social Security Act (42 U.S.C. 1396b), as inserted by subsection (a)) by all agencies or entities that provide personal care services or home health care under a State plan under title XIX of the Social Se-

curity Act (or under a waiver of the plan) (42 U.S.C. 1396 et seq.).

(3) NO LIMITS ON PROVISION OF CARE.—Nothing in the amendment made by this section may be construed to limit, with respect to personal care services or home health care services provided under a State plan under title XIX of the Social Security Act (or under a waiver of the plan) (42 U.S.C. 1396 et seq.), provider selection, constrain beneficiaries' selection of a caregiver, or impede the manner in which care is delivered.

(4) NO PROHIBITION ON STATE QUALITY MEASURES REQUIREMENTS.—Nothing in the amendment made by this section shall be construed as prohibiting a State, in implementing an electronic visit verification system (as defined in subsection (l)(5) of section 1903 of the Social Security Act (42 U.S.C. 1396b), as inserted by subsection (a)), from establishing requirements related to quality measures for such system.

TITLE XIII—MENTAL HEALTH PARITY

SEC. 13001. ENHANCED COMPLIANCE WITH MENTAL HEALTH AND SUBSTANCE USE DISORDER COVERAGE REQUIREMENTS.

(a) COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—Section 2726(a) of the Public Health Service Act (42 U.S.C. 300gg-26(a)) is amended by adding at the end the following:

"(6) COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—

"(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Labor, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall issue a compliance program guidance document to help improve compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, and section 9812 of the Internal Revenue Code of 1986, as applicable. In carrying out this paragraph, the Secretaries may take into consideration the 2016 publication of the Department of Health and Human Services and the Department of Labor, entitled 'Warning Signs - Plan or Policy Non-Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance'.

"(B) EXAMPLES ILLUSTRATING COMPLIANCE AND NONCOMPLIANCE.—

"(i) IN GENERAL.—The compliance program guidance document required under this paragraph shall provide illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Secu-

rity Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, based on investigations of violations of such sections, including—

"(I) examples illustrating requirements for information disclosures and nonquantitative treatment limitations; and

"(II) descriptions of the violations uncovered during the course of such investigations.

"(ii) NONQUANTITATIVE TREATMENT LIMITATIONS.—To the extent that any example described in clause (i) involves a finding of compliance or noncompliance with regard to any requirement for nonquantitative treatment limitations, the example shall provide sufficient detail to fully explain such finding, including a full description of the criteria involved for approving medical and surgical benefits and the criteria involved for approving mental health and substance use disorder benefits.

"(iii) ACCESS TO ADDITIONAL INFORMATION REGARDING COMPLIANCE.—In developing and issuing the compliance program guidance document required under this paragraph, the Secretaries specified in subparagraph (A)—

"(I) shall enter into interagency agreements with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury to share findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable; and

"(II) shall seek to enter into an agreement with a State to share information on findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

"(C) RECOMMENDATIONS.—The compliance program guidance document shall include recommendations to advance compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, and encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. Such internal controls may include illustrative examples of nonquantitative treatment limitations on mental health and substance use disorder benefits, which may fail to comply with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, in relation to nonquantitative treatment limitations on medical and surgical benefits.

"(D) UPDATING THE COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—The Secretary, the Secretary of Labor, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall update the compliance program guidance document every 2 years to include illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.".

(b) ADDITIONAL GUIDANCE.—Section 2726(a) of the Public Health Service Act (42 U.S.C. 300gg-26(a)), as amended by subsection (a), is further amended by adding at the end the following:

"(7) ADDITIONAL GUIDANCE.—

"(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Labor, and the Secretary of the Treasury shall issue guidance to group health plans and health insurance issuers offering group or individual health insurance coverage to assist such plans and issuers in satisfying the requirements of this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

"(B) DISCLOSURE.—

"(i) GUIDANCE FOR PLANS AND ISSUERS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use for disclosing information to ensure compliance with the requirements under this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, (and any regulations promulgated pursuant to such sections, as applicable).

"(ii) DOCUMENTS FOR PARTICIPANTS, BENEFICIARIES, CONTRACTING PROVIDERS, OR AUTHORIZED REPRESENTATIVES.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use to provide any participant, beneficiary, contracting provider, or authorized representative, as applicable, with documents containing information that the health plans or issuers are required to disclose to participants, beneficiaries, contracting providers, or authorized representatives to ensure compliance with this section, section 712 of the Employee Retirement Income Secu-

rity Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, compliance with any regulation issued pursuant to such respective section, or compliance with any other applicable law or regulation. Such guidance shall include information that is comparative in nature with respect to—

"(I) nonquantitative treatment limitations for both medical and surgical benefits and mental health and substance use disorder benefits;

"(II) the processes, strategies, evidentiary standards, and other factors used to apply the limitations described in subclause (I); and

"(III) the application of the limitations described in subclause (I) to ensure that such limitations are applied in parity with respect to both medical and surgical benefits and mental health and substance use disorder benefits.

"(C) NONQUANTITATIVE TREATMENT LIMITATIONS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods, processes, strategies, evidentiary standards, and other factors that group health plans and health insurance issuers offering group or individual health insurance coverage may use regarding the development and application of nonquantitative treatment limitations to ensure compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, (and any regulations promulgated pursuant to such respective section), including—

"(i) examples of methods of determining appropriate types of nonquantitative treatment limitations with respect to both medical and surgical benefits and mental health and substance use disorder benefits, including nonquantitative treatment limitations pertaining to—

"(I) medical management standards based on medical necessity or appropriateness, or whether a treatment is experimental or investigative;

"(II) limitations with respect to prescription drug formulary design; and

"(III) use of fail-first or step therapy protocols;

"(ii) examples of methods of determining—

"(I) network admission standards (such as credentialing); and

"(II) factors used in provider reimbursement methodologies (such as service type, geographic market, demand for services, and provider supply, practice size, training, experience, and licensure) as such factors apply to network adequacy;

"(iii) examples of sources of information that may serve as evidentiary standards for the purposes of making determinations regarding the development

and application of nonquantitative treatment limitations;

"(iv) examples of specific factors, and the evidentiary standards used to evaluate such factors, used by such plans or issuers in performing a nonquantitative treatment limitation analysis;

"(v) examples of how specific evidentiary standards may be used to determine whether treatments are considered experimental or investigative;

"(vi) examples of how specific evidentiary standards may be applied to each service category or classification of benefits;

"(vii) examples of methods of reaching appropriate coverage determinations for new mental health or substance use disorder treatments, such as evidence-based early intervention programs for individuals with a serious mental illness and types of medical management techniques;

"(viii) examples of methods of reaching appropriate coverage determinations for which there is an indirect relationship between the covered mental health or substance use disorder benefit and a traditional covered medical and surgical benefit, such as residential treatment or hospitalizations involving voluntary or involuntary commitment; and

"(ix) additional illustrative examples of methods, processes, strategies, evidentiary standards, and other factors for which the Secretary determines that additional guidance is necessary to improve compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

"(D) PUBLIC COMMENT.—Prior to issuing any final guidance under this paragraph, the Secretary shall provide a public comment period of not less than 60 days during which any member of the public may provide comments on a draft of the guidance.".

(c) AVAILABILITY OF PLAN INFORMATION.—

(1) SOLICITATION OF PUBLIC FEEDBACK.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall solicit feedback from the public on how the disclosure request process for documents containing information that health plans or health insurance issuers are required under Federal or State law to disclose to participants, beneficiaries, contracting providers, or authorized representatives to ensure compliance with existing mental health parity and addiction equity requirements can be improved while continuing to ensure consumers' rights to access all information required by Federal or State law to be disclosed.

(2) PUBLIC AVAILABILITY.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall make such feedback publicly available.

(3) NAIC.—The Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall share feedback obtained pursuant to paragraph (1) directly with the National Association of Insurance Commissioners to the extent such feedback includes recommendations for the development of simplified information disclosure tools to provide consistent information for consumers. Such feedback may be taken into consideration by the National Association of Insurance Commissioners and other appropriate entities for the voluntary development and voluntary use of common templates and other sample standardized forms to improve consumer access to plan information.

(d) IMPROVING COMPLIANCE.—

(1) IN GENERAL.—In the case that the Secretary of Health and Human Services, the Secretary of Labor, or the Secretary of the Treasury determines that a group health plan or health insurance issuer offering group or individual health insurance coverage has violated, at least 5 times, section 2726 of the Public Health Service Act (42 U.S.C. 300gg-26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), or section 9812 of the Internal Revenue Code of 1986, respectively, the appropriate Secretary shall audit plan documents for such health plan or issuer in the plan year following the Secretary's determination in order to help improve compliance with such section.

(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the authority, as in effect on the day before the date of enactment of this Act, of the Secretary of Health and Human Services, the Secretary of Labor, or the Secretary of the Treasury to audit documents of health plans or health insurance issuers.

SEC. 13002. ACTION PLAN FOR ENHANCED ENFORCEMENT OF MENTAL HEALTH AND SUBSTANCE USE DISORDER COVERAGE.

(a) PUBLIC MEETING.—

(1) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall convene a public meeting of stakeholders described in paragraph (2) to produce an action plan for improved Federal and State coordination related to the enforcement of section 2726 of the Public Health Service Act (42 U.S.C. 300gg-26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), and section 9812 of the Internal Revenue Code of 1986, and any comparable provisions of State law (in this section such sections and provisions are collectively referred to as "mental health parity and addiction equity requirements").

(2) STAKEHOLDERS.—The stakeholders described in this paragraph shall include each of the following:

(A) The Federal Government, including representatives from—

(i) the Department of Health and Human Services;

(ii) the Department of the Treasury;

(iii) the Department of Labor; and

(iv) the Department of Justice.

(B) State governments, including—

(i) State health insurance commissioners;

(ii) appropriate State agencies, including agencies on public health or mental health; and

(iii) State attorneys general or other representatives of State entities involved in the enforcement of mental health parity and addiction equity requirements.

(C) Representatives from key stakeholder groups, including—

(i) the National Association of Insurance Commissioners;

(ii) health insurance issuers;

(iii) providers of mental health and substance use disorder treatment;

(iv) employers; and

(v) patients or their advocates.

(b) ACTION PLAN.—Not later than 6 months after the conclusion of the public meeting under subsection (a), the Secretary of Health and Human Services shall finalize the action plan described in such subsection and make it plainly available on the Internet website of the Department of Health and Human Services.

(c) CONTENT.—The action plan under this section shall—

(1) take into consideration the recommendations of the Mental Health and Substance Use Disorder Parity Task Force in its final report issued in October of 2016, and any subsequent Federal and State actions in relation to such recommendations;

(2) reflect the input of the stakeholders participating in the public meeting under subsection (a);

(3) identify specific strategic objectives regarding how the various Federal and State agencies charged with enforcement of mental health parity and addiction equity requirements will collaborate to improve enforcement of such requirements;

(4) provide a timeline for implementing the action plan; and

(5) provide specific examples of how such objectives may be met, which may include—

(A) providing common educational information and documents, such as the Consumer Guide to Disclosure Rights, to patients about their rights under mental health parity and addiction equity requirements;

(B) facilitating the centralized collection of, monitoring of, and response to patient complaints or inquiries relating to mental health parity and addiction equity requirements, which may be through the development and administration of—

(i) a single, toll-free telephone number; and

(ii) a new parity website—

(I) to help consumers find the appropriate Federal or State agency to assist with their parity complaints, appeals, and other actions; and

(II) that takes into consideration, but is not duplicative of, the parity beta site being tested, and released for public comment, by the Department of Health and Human Services as of the date of the enactment of this Act;

(C) Federal and State law enforcement agencies entering into memoranda of understanding to better coordinate enforcement responsibilities and information sharing—

(i) including whether such agencies should make the results of enforcement actions related to mental health parity and addiction equity requirements publicly available; and

(ii) which may include State Policy Academies on Parity Implementation for State Officials and other forums to bring together national experts to provide technical assistance to teams of State officials on strategies to advance compliance with mental health parity and addiction equity requirements in both the commercial market, and in the Medicaid program under title XIX of the Social Security Act and the State Children's Health Insurance Program under title XXI of such Act; and

(D) recommendations to the Congress regarding the need for additional legal authority to improve enforcement of mental health parity and addiction equity requirements, including the need for additional legal authority to ensure that nonquantitative treatment limitations are applied, and the extent and frequency of the applications of such limitations, both to medical and surgical benefits and to mental health and substance use disorder benefits in a comparable manner.

SEC. 13003. REPORT ON INVESTIGATIONS REGARDING PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, and annually thereafter for the subsequent 5 years, the Assistant Secretary of Labor of the Employee Benefits Security Administration, in collaboration with the Administrator of the Centers for Medicare & Medicaid Services and the Secretary of the Treasury, shall submit to the Committee on Energy and Commerce and the Committee on Education and the Workforce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report summarizing the results of all closed Federal investigations completed during the preceding 12-month period concerning compliance with mental health and substance use disorder coverage requirements under section 2726 of the Public Health Service Act (42 U.S.C. 300gg-26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), and section 9812 of the Internal Revenue Code of 1986.

(b) CONTENTS.—Subject to subsection (c), a report under subsection (a) shall, with respect to investigations described in such subsection, include each of the following:

(1) The number of complaints received and number of closed Federal investigations conducted during the covered re-

porting period, and, for each such investigation closed, which agency conducted the investigation, whether the health plan that is the subject of the investigation is fully insured or not fully insured and a summary of any coordination between the applicable State regulators and the Department of Labor, the Department of Health and Human Services, or the Department of the Treasury, and references to any guidance provided by the agencies addressing the category of violation committed.

(2) Each benefit classification examined by any such investigation conducted during the covered reporting period.

(3) Each subject matter, including compliance with requirements for quantitative and nonquantitative treatment limitations, of any such investigation conducted during the covered reporting period.

(4) A summary of the basis of the final decision rendered for each closed investigation conducted during the covered reporting period that resulted in a finding of a serious violation.

(c) LIMITATION.—Any individually identifiable information shall be excluded from reports under subsection (a) consistent with protections under the health privacy and security rules promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note).

SEC. 13004. GAO STUDY ON PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS.

Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury, 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 detailing the extent to which group health plans or health insurance issuers offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits, medicaid managed care organizations with a contract under section 1903(m) of the Social Security Act (42 U.S.C. 1396b(m)), and health plans provided under the State Children's Health Insurance Program under title XXI of the Social Security Act (42 U.S.C. 1397aa et seq.) comply with section 2726 of the Public Health Service Act (42 U.S.C. 300gg-26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), and section 9812 of the Internal Revenue Code of 1986, including—

(1) how nonquantitative treatment limitations, including medical necessity criteria, of such plans or issuers comply with such sections;

(2) how the responsible Federal departments and agencies ensure that such plans or issuers comply with such sections, including an assessment of how the Secretary of Health and Human Services has used its authority to conduct audits of such plans to ensure compliance;

(3) a review of how the various Federal and State agencies responsible for enforcing mental health parity requirements have improved enforcement of such requirements in accordance

with the objectives and timeline described in the action plan under section 13002; and

(4) recommendations for how additional enforcement, education, and coordination activities by responsible Federal and State departments and agencies could better ensure compliance with such sections, including recommendations regarding the need for additional legal authority.

SEC. 13005. [42 U.S.C. 237a note] INFORMATION AND AWARENESS ON EATING DISORDERS.

(a) INFORMATION.—The Secretary of Health and Human Services, acting through the Director of the Office on Women's Health, may—

(1) update information, related fact sheets, and resource lists related to eating disorders that are available on the public Internet website of the National Women's Health Information Center sponsored by the Office on Women's Health, to include—

(A) updated findings and current research related to eating disorders, as appropriate; and

(B) information about eating disorders, including information related to males and females;

(2) incorporate, as appropriate, and in coordination with the Secretary of Education, information from publicly available resources into appropriate obesity prevention programs developed by the Office on Women's Health; and

(3) make publicly available (through a public Internet website or other method) information, related fact sheets, and resource lists, as updated under paragraph (1), and the information incorporated into appropriate obesity prevention programs under paragraph (2).

(b) AWARENESS.—The Secretary of Health and Human Services may advance public awareness on—

(1) the types of eating disorders;

(2) the seriousness of eating disorders, including prevalence, comorbidities, and physical and mental health consequences;

(3) methods to identify, intervene, refer for treatment, and prevent behaviors that may lead to the development of eating disorders;

(4) discrimination and bullying based on body size;

(5) the effects of media on self-esteem and body image; and

(6) the signs and symptoms of eating disorders.

SEC. 13006. [42 U.S.C. 237a note] EDUCATION AND TRAINING ON EATING DISORDERS.

The Secretary of Health and Human Services may facilitate the identification of model programs and materials for educating and training health professionals in effective strategies to—

(1) identify individuals with eating disorders;

(2) provide early intervention services for individuals with eating disorders;

(3) refer patients with eating disorders for appropriate treatment;

(4) prevent the development of eating disorders; and

(5) provide appropriate treatment services for individuals with eating disorders.

SEC. 13007. CLARIFICATION OF EXISTING PARITY RULES.

If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage for eating disorder benefits, including residential treatment, such group health plan or health insurance issuer shall provide such benefits consistent with the requirements of section 2726 of the Public Health Service Act (42 U.S.C. 300gg-26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), and section 9812 of the Internal Revenue Code of 1986.

TITLE XIV—MENTAL HEALTH AND SAFE COMMUNITIES

Subtitle A—Mental Health and Safe Communities

SEC. 14001. LAW ENFORCEMENT GRANTS FOR CRISIS INTERVENTION TEAMS, MENTAL HEALTH PURPOSES.

(a) EDWARD BYRNE MEMORIAL JUSTICE ASSISTANCE GRANT PROGRAM.—Section 501(a)(1) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3751(a)(1)) is amended by adding at the end the following:

"(H) Mental health programs and related law enforcement and corrections programs, including behavioral programs and crisis intervention teams.".

(b) COMMUNITY ORIENTED POLICING SERVICES PROGRAM.—Section 1701(b) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796dd(b)) is amended—

(1) in paragraph (17), by striking "and" at the end;

(2) by redesignating paragraph (18) as paragraph (22);

(3) by inserting after paragraph (17) the following:

"(18) to provide specialized training to law enforcement officers to—

"(A) recognize individuals who have a mental illness; and

"(B) properly interact with individuals who have a mental illness, including strategies for verbal de-escalation of crises;

"(19) to establish collaborative programs that enhance the ability of law enforcement agencies to address the mental health, behavioral, and substance abuse problems of individuals encountered by law enforcement officers in the line of duty;

"(20) to provide specialized training to corrections officers to recognize individuals who have a mental illness;

"(21) to enhance the ability of corrections officers to address the mental health of individuals under the care and custody of jails and prisons, including specialized training and strategies for verbal de-escalation of crises; and"; and

(4) in paragraph (22), as redesignated, by striking "through (17)" and inserting "through (21)".

(c) MODIFICATIONS TO THE STAFFING FOR ADEQUATE FIRE AND EMERGENCY RESPONSE GRANTS.—Section 34(a)(1)(B) of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2229a(a)(1)(B)) is amended by inserting before the period at the end the following: "and to provide specialized training to paramedics, emergency medical services workers, and other first responders to recognize individuals who have mental illness and how to properly intervene with individuals with mental illness, including strategies for verbal de-escalation of crises".

SEC. 14002. ASSISTED OUTPATIENT TREATMENT PROGRAMS.

(a) IN GENERAL.—Section 2201 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796ii) is amended in paragraph (2)(B), by inserting before the semicolon the following: ", or court-ordered assisted outpatient treatment when the court has determined such treatment to be necessary".

(b) DEFINITIONS.—Section 2202 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796ii—1) is amended—

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

(2) in paragraph (2), by striking the period at the end and inserting a semicolon; and

(3) by adding at the end the following:

"(3) the term 'court-ordered assisted outpatient treatment' means a program through which a court may order a treatment plan for an eligible patient that—

"(A) requires such patient to obtain outpatient mental health treatment while the patient is not currently residing in a correctional facility or inpatient treatment facility; and

"(B) is designed to improve access and adherence by such patient to intensive behavioral health services in order to—

"(i) avert relapse, repeated hospitalizations, arrest, incarceration, suicide, property destruction, and violent behavior; and

"(ii) provide such patient with the opportunity to live in a less restrictive alternative to incarceration or involuntary hospitalization; and

"(4) the term 'eligible patient' means an adult, mentally ill person who, as determined by a court—

"(A) has a history of violence, incarceration, or medically unnecessary hospitalizations;

"(B) without supervision and treatment, may be a danger to self or others in the community;

"(C) is substantially unlikely to voluntarily participate in treatment;

"(D) may be unable, for reasons other than indigence, to provide for any of his or her basic needs, such as food, clothing, shelter, health, or safety;

"(E) has a history of mental illness or a condition that is likely to substantially deteriorate if the person is not provided with timely treatment; or

"(F) due to mental illness, lacks capacity to fully understand or lacks judgment to make informed decisions regarding his or her need for treatment, care, or supervision.".

SEC. 14003. [34 U.S.C. 10471 note] FEDERAL DRUG AND MENTAL HEALTH COURTS.

(a) DEFINITIONS.—In this section—

(1) the term "eligible offender" means a person who—

(A)(i) previously or currently has been diagnosed by a qualified mental health professional as having a mental illness, mental retardation, or co-occurring mental illness and substance abuse disorders; or

(ii) manifests obvious signs of mental illness, mental retardation, or co-occurring mental illness and substance abuse disorders during arrest or confinement or before any court;

(B) comes into contact with the criminal justice system or is arrested or charged with an offense that is not—

(i) a crime of violence, as defined under applicable State law or in section 3156 of title 18, United States Code; or

(ii) a serious drug offense, as defined in section 924(e)(2)(A) of title 18, United States Code; and

(C) is determined by a judge to be eligible; and

(2) the term "mental illness" means a diagnosable mental, behavioral, or emotional disorder—

(A) of sufficient duration to meet diagnostic criteria within the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association; and

(B) that has resulted in functional impairment that substantially interferes with or limits 1 or more major life activities.

(b) ESTABLISHMENT OF PROGRAM.—Not later than 1 year after the date of enactment of this Act, the Attorney General shall establish a pilot program to determine the effectiveness of diverting eligible offenders from Federal prosecution, Federal probation, or a Bureau of Prisons facility, and placing such eligible offenders in drug or mental health courts.

(c) PROGRAM SPECIFICATIONS.—The pilot program established under subsection (b) shall involve—

(1) continuing judicial supervision, including periodic review, of program participants who have a substance abuse problem or mental illness; and

(2) the integrated administration of services and sanctions, which shall include—

(A) mandatory periodic testing, as appropriate, for the use of controlled substances or other addictive substances during any period of supervised release or probation for each program participant;

(B) substance abuse treatment for each program participant who requires such services;

(C) diversion, probation, or other supervised release with the possibility of prosecution, confinement, or incarceration based on noncompliance with program requirements or failure to show satisfactory progress toward completing program requirements;

(D) programmatic offender management, including case management, and aftercare services, such as relapse prevention, health care, education, vocational training, job placement, housing placement, and child care or other family support services for each program participant who requires such services;

(E) outpatient or inpatient mental health treatment, as ordered by the court, that carries with it the possibility of dismissal of charges or reduced sentencing upon successful completion of such treatment;

(F) centralized case management, including—

(i) the consolidation of all cases, including violations of probations, of the program participant; and

(ii) coordination of all mental health treatment plans and social services, including life skills and vocational training, housing and job placement, education, health care, and relapse prevention for each program participant who requires such services; and

(G) continuing supervision of treatment plan compliance by the program participant for a term not to exceed the maximum allowable sentence or probation period for the charged or relevant offense and, to the extent practicable, continuity of psychiatric care at the end of the supervised period.

(d) IMPLEMENTATION; DURATION.—The pilot program established under subsection (b) shall be conducted—

(1) in not less than 1 United States judicial district, designated by the Attorney General in consultation with the Director of the Administrative Office of the United States Courts, as appropriate for the pilot program; and

(2) during fiscal year 2017 through fiscal year 2021.

(e) CRITERIA FOR DESIGNATION.—Before making a designation under subsection (d)(1), the Attorney General shall—

(1) obtain the approval, in writing, of the United States Attorney for the United States judicial district being designated;

(2) obtain the approval, in writing, of the chief judge for the United States judicial district being designated; and

(3) determine that the United States judicial district being designated has adequate behavioral health systems for treatment, including substance abuse and mental health treatment.

(f) ASSISTANCE FROM OTHER FEDERAL ENTITIES.—The Administrative Office of the United States Courts and the United States Probation Offices shall provide such assistance and carry out such functions as the Attorney General may request in monitoring, supervising, providing services to, and evaluating eligible offenders placed in a drug or mental health court under this section.

(g) REPORTS.—The Attorney General, in consultation with the Director of the Administrative Office of the United States Courts, shall monitor the drug and mental health courts under this section, and shall submit a report to Congress on the outcomes of the program at the end of the period described in subsection (d)(2).

SEC. 14004. MENTAL HEALTH IN THE JUDICIAL SYSTEM.

Part V of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796ii et seq.) is amended by inserting at the end the following:

"SEC. 2209. MENTAL HEALTH RESPONSES IN THE JUDICIAL SYSTEM

"(a) PRETRIAL SCREENING AND SUPERVISION.—

"(1) IN GENERAL.—The Attorney General may award grants to States, units of local government, territories, Indian Tribes, nonprofit agencies, or any combination thereof, to develop, implement, or expand pretrial services programs to improve the identification and outcomes of individuals with mental illness.

"(2) ALLOWABLE USES.—Grants awarded under this subsection may be may be used for—

"(A) behavioral health needs and risk screening of defendants, including verification of interview information, mental health evaluation, and criminal history screening;

"(B) assessment of risk of pretrial misconduct through objective, statistically validated means, and presentation to the court of recommendations based on such assessment, including services that will reduce the risk of pretrial misconduct;

"(C) followup review of defendants unable to meet the conditions of pretrial release;

"(D) evaluation of process and results of pre-trial service programs;

"(E) supervision of defendants who are on pretrial release, including reminders to defendants of scheduled court dates;

"(F) reporting on process and results of pretrial services programs to relevant public and private mental health stakeholders; and

"(G) data collection and analysis necessary to make available information required for assessment of risk.

"(b) BEHAVIORAL HEALTH ASSESSMENTS AND INTERVENTION.—

"(1) IN GENERAL.—The Attorney General may award grants to States, units of local government, territories, Indian Tribes, nonprofit agencies, or any combination thereof, to develop, implement, or expand a behavioral health screening and assessment program framework for State or local criminal justice systems.

"(2) ALLOWABLE USES.—Grants awarded under this subsection may be used for—

"(A) promotion of the use of validated assessment tools to gauge the criminogenic risk, substance abuse needs, and mental health needs of individuals;

"(B) initiatives to match the risk factors and needs of individuals to programs and practices associated with research-based, positive outcomes;

"(C) implementing methods for identifying and treating individuals who are most likely to benefit from coordinated supervision and treatment strategies, and identifying individuals who can do well with fewer interventions; and

"(D) collaborative decision-making among the heads of criminal justice agencies, mental health systems, judicial systems, substance abuse systems, and other relevant systems or agencies for determining how treatment and intensive supervision services should be allocated in order to maximize benefits, and developing and utilizing capacity accordingly.

"(c) USE OF GRANT FUNDS.—A State, unit of local government, territory, Indian Tribe, or nonprofit agency that receives a grant under this section shall, in accordance with subsection (b)(2), use grant funds for the expenses of a treatment program, including—

"(1) salaries, personnel costs, equipment costs, and other costs directly related to the operation of the program, including costs relating to enforcement;

"(2) payments for treatment providers that are approved by the State or Indian Tribe and licensed, if necessary, to provide needed treatment to program participants, including aftercare supervision, vocational training, education, and job placement; and

"(3) payments to public and nonprofit private entities that are approved by the State or Indian Tribe and licensed, if necessary, to provide alcohol and drug addiction treatment to offenders participating in the program.

"(d) SUPPLEMENT OF NON-FEDERAL FUNDS.—

"(1) IN GENERAL.—Grants awarded under this section shall be used to supplement, and not supplant, non-Federal funds that would otherwise be available for programs described in this section.

"(2) FEDERAL SHARE.—The Federal share of a grant made under this section may not exceed 50 percent of the total costs of the program described in an application under subsection (e).

"(e) APPLICATIONS.—To request a grant under this section, a State, unit of local government, territory, Indian Tribe, or nonprofit agency shall submit an application to the Attorney General in such form and containing such information as the Attorney General may reasonably require.

"(f) GEOGRAPHIC DISTRIBUTION.—The Attorney General shall ensure that, to the extent practicable, the distribution of grants under this section is equitable and includes—

"(1) each State; and

"(2) a unit of local government, territory, Indian Tribe, or nonprofit agency—

"(A) in each State; and

"(B) in rural, suburban, Tribal, and urban jurisdictions.

"(g) REPORTS AND EVALUATIONS.—For each fiscal year, each grantee under this section during that fiscal year shall submit to the Attorney General a report on the effectiveness of activities carried out using such grant. Each report shall include an evaluation in such form and containing such information as the Attorney General may reasonably require. The Attorney General shall specify the dates on which such reports shall be submitted.

"(h) ACCOUNTABILITY.—Grants awarded under this section shall be subject to the following accountability provisions:

"(1) AUDIT REQUIREMENT.—

"(A) DEFINITION.—In this paragraph, the term 'unresolved audit finding' means a finding in the final audit report of the Inspector General of the Department of Justice under subparagraph (C) that the audited grantee has used grant funds for an unauthorized expenditure or otherwise unallowable cost that is not closed or resolved within 1 year after the date on which final audit report is issued.

"(B) AUDITS.—Beginning in the first fiscal year beginning after the date of enactment of this section, and in each fiscal year thereafter, the Inspector General of the Department of Justice shall conduct audits of grantees under this section to prevent waste, fraud, and abuse of funds by grantees. The Inspector General shall determine the appropriate number of grantees to be audited each year.

"(C) FINAL AUDIT REPORT.—The Inspector General of the Department of Justice shall submit to the Attorney General a final report on each audit conducted under subparagraph (B).

"(D) MANDATORY EXCLUSION.—Grantees under this section about which there is an unresolved audit finding shall not be eligible to receive a grant under this section during the 2 fiscal years beginning after the end of the 1-year period described in subparagraph (A).

"(E) PRIORITY.—In making grants under this section, the Attorney General shall give priority to applicants that did not have an unresolved audit finding during the 3 fiscal years before submitting an application for a grant under this section.

"(F) REIMBURSEMENT.—If an entity receives a grant under this section during the 2-fiscal-year period during which the entity is prohibited from receiving grants under subparagraph (D), the Attorney General shall—

"(i) deposit an amount equal to the amount of the grant that was improperly awarded to the grantee into the General Fund of the Treasury; and

"(ii) seek to recoup the costs of the repayment under clause (i) from the grantee that was erroneously awarded grant funds.

"(2) NONPROFIT AGENCY REQUIREMENTS.—

"(A) DEFINITION.—For purposes of this paragraph and the grant program under this section, the term 'nonprofit agency' means an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C.

501(c)(3)) and is exempt from taxation under section 501(a) of the Internal Revenue Code of 1986 (26 U.S.C. 501(a)).

"(B) PROHIBITION.—The Attorney General may not award a grant under this section to a nonprofit agency that holds money in an offshore account for the purpose of avoiding paying the tax described in section 511(a) of the Internal Revenue Code of 1986 (26 U.S.C. 511(a)).

"(C) DISCLOSURE.—Each nonprofit agency that is awarded a grant under this section and uses the procedures prescribed in regulations to create a rebuttable presumption of reasonableness for the compensation of its officers, directors, trustees, and key employees, shall disclose to the Attorney General, in the application for the grant, the process for determining such compensation, including the independent persons involved in reviewing and approving such compensation, the comparability data used, and contemporaneous substantiation of the deliberation and decision. Upon request, the Attorney General shall make the information disclosed under this subparagraph available for public inspection.

"(3) CONFERENCE EXPENDITURES.—

"(A) LIMITATION.—Not more than $20,000 of the amounts made available to the Department of Justice to carry out this section may be used by the Attorney General, or by any individual or entity awarded a grant under this section to host, or make any expenditures relating to, a conference unless the Deputy Attorney General provides prior written authorization that the funds may be expended to host the conference or make such expenditure.

"(B) WRITTEN APPROVAL.—Written approval under subparagraph (A) shall include a written estimate of all costs associated with the conference, including the cost of all food, beverages, audio-visual equipment, honoraria for speakers, and entertainment.

"(C) REPORT.—The Deputy Attorney General shall submit an annual report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives on all conference expenditures approved under this paragraph.

"(4) ANNUAL CERTIFICATION.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, the Attorney General shall submit to the Committee on the Judiciary and the Committee on Appropriations of the Senate and the Committee on the Judiciary and the Committee on Appropriations of the House of Representatives an annual certification—

"(A) indicating whether—

"(i) all final audit reports issued by the Office of the Inspector General under paragraph (1) have been completed and reviewed by the appropriate Assistant Attorney General or Director;

"(ii) all mandatory exclusions required under paragraph (1)(D) have been issued; and

"(iii) any reimbursements required under paragraph (1)(F) have been made; and

"(B) that includes a list of any grantees excluded under paragraph (1)(D) from the previous year.

"(i) PREVENTING DUPLICATIVE GRANTS.—

"(1) IN GENERAL.—Before the Attorney General awards a grant to an applicant under this section, the Attorney General shall compare the possible grant with any other grants awarded to the applicant under this Act to determine whether the grants are for the same purpose.

"(2) REPORT.—If the Attorney General awards multiple grants to the same applicant for the same purpose, the Attorney General shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that includes—

"(A) a list of all duplicate grants awarded, including the total dollar amount of any such grants awarded; and

"(B) the reason the Attorney General awarded the duplicate grants.".

SEC. 14005. FORENSIC ASSERTIVE COMMUNITY TREATMENT INITIATIVES.

Section 2991 of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is amended by—

(1) redesignating subsection (j) as subsection (o); and

(2) inserting after subsection (i) the following:

"(j) FORENSIC ASSERTIVE COMMUNITY TREATMENT (FACT) INITIATIVE PROGRAM.—

"(1) IN GENERAL.—The Attorney General may make grants to States, units of local government, territories, Indian Tribes, nonprofit agencies, or any combination thereof, to develop, implement, or expand Assertive Community Treatment initiatives to develop forensic assertive community treatment (referred to in this subsection as 'FACT') programs that provide high intensity services in the community for individuals with mental illness with involvement in the criminal justice system to prevent future incarcerations.

"(2) ALLOWABLE USES.—Grant funds awarded under this subsection may be used for—

"(A) multidisciplinary team initiatives for individuals with mental illnesses with criminal justice involvement that address criminal justice involvement as part of treatment protocols;

"(B) FACT programs that involve mental health professionals, criminal justice agencies, chemical dependency specialists, nurses, psychiatrists, vocational specialists, forensic peer specialists, forensic specialists, and dedicated administrative support staff who work together to provide recovery oriented, 24/7 wraparound services;

"(C) services such as integrated evidence-based practices for the treatment of co-occurring mental health and substance-related disorders, assertive outreach and engagement, community-based service provision at participants' residence or in the community, psychiatric rehabili-

tation, recovery oriented services, services to address criminogenic risk factors, and community tenure;

"(D) payments for treatment providers that are approved by the State or Indian Tribe and licensed, if necessary, to provide needed treatment to eligible offenders participating in the program, including behavioral health services and aftercare supervision; and

"(E) training for all FACT teams to promote high-fidelity practice principles and technical assistance to support effective and continuing integration with criminal justice agency partners.

"(3) SUPPLEMENT AND NOT SUPPLANT.—Grants made under this subsection shall be used to supplement, and not supplant, non-Federal funds that would otherwise be available for programs described in this subsection.

"(4) APPLICATIONS.—To request a grant under this subsection, a State, unit of local government, territory, Indian Tribe, or nonprofit agency shall submit an application to the Attorney General in such form and containing such information as the Attorney General may reasonably require.".

SEC. 14006. ASSISTANCE FOR INDIVIDUALS TRANSITIONING OUT OF SYSTEMS.

Section 2976(f) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797w(f)) is amended—

(1) in paragraph (5), by striking "and" at the end;

(2) in paragraph (6), by striking the period at the end and inserting a semicolon; and

(3) by adding at the end the following:

"(7) provide mental health treatment and transitional services for those with mental illnesses or with co-occurring disorders, including housing placement or assistance; and".

SEC. 14007. CO-OCCURRING SUBSTANCE ABUSE AND MENTAL HEALTH CHALLENGES IN DRUG COURTS.

Part EE of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797u et seq.) is amended—

(1) in section 2951(a)(1) (42 U.S.C. 3797u(a)(1)), by inserting ", including co-occurring substance abuse and mental health problems," after "problems"; and

(2) in section 2959(a) (42 U.S.C. 3797u-8(a)), by inserting ", including training for drug court personnel and officials on identifying and addressing co-occurring substance abuse and mental health problems" after "part".

SEC. 14008. [34 U.S.C. 10652 note] MENTAL HEALTH TRAINING FOR FEDERAL UNIFORMED SERVICES.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Defense, the Secretary of Homeland Security, the Secretary of Health and Human Services, and the Secretary of Commerce shall provide the following to each of the uniformed services (as that term is defined in section 101 of title 10, United States Code) under their direction:

(1) TRAINING PROGRAMS.—Programs that offer specialized and comprehensive training in procedures to identify and re-

spond appropriately to incidents in which the unique needs of individuals with mental illnesses are involved.

(2) IMPROVED TECHNOLOGY.—Computerized information systems or technological improvements to provide timely information to Federal law enforcement personnel, other branches of the uniformed services, and criminal justice system personnel to improve the Federal response to mentally ill individuals.

(3) COOPERATIVE PROGRAMS.—The establishment and expansion of cooperative efforts to promote public safety through the use of effective intervention with respect to mentally ill individuals encountered by members of the uniformed services.

SEC. 14009. ADVANCING MENTAL HEALTH AS PART OF OFFENDER REENTRY.

(a) REENTRY DEMONSTRATION PROJECTS.—Section 2976(f) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797w(f)), as amended by section 14006, is amended—

(1) in paragraph (3)(C), by inserting "mental health services," before "drug treatment"; and

(2) by adding at the end the following:

"(8) target offenders with histories of homelessness, substance abuse, or mental illness, including a prerelease assessment of the housing status of the offender and behavioral health needs of the offender with clear coordination with mental health, substance abuse, and homelessness services systems to achieve stable and permanent housing outcomes with appropriate support service.".

(b) MENTORING GRANTS.—Section 211(b)(2) of the Second Chance Act of 2007 (42 U.S.C. 17531(b)(2)) is amended by inserting ", including mental health care" after "community".

SEC. 14010. SCHOOL MENTAL HEALTH CRISIS INTERVENTION TEAMS.

Section 2701(b) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797a(b)) is amended—

(1) by redesignating paragraphs (4) and (5) as paragraphs (5) and (6), respectively; and

(2) by inserting after paragraph (3) the following:

"(4) The development and operation of crisis intervention teams that may include coordination with law enforcement agencies and specialized training for school officials in responding to mental health crises.".

SEC. 14011. [34 U.S.C. 10153 note] ACTIVE-SHOOTER TRAINING FOR LAW ENFORCEMENT.

The Attorney General, as part of the Preventing Violence Against Law Enforcement and Ensuring Officer Resilience and Survivability Initiative (VALOR) of the Department of Justice, may provide safety training and technical assistance to local law enforcement agencies, including active-shooter response training.

SEC. 14012. CO-OCCURRING SUBSTANCE ABUSE AND MENTAL HEALTH CHALLENGES IN RESIDENTIAL SUBSTANCE ABUSE TREATMENT PROGRAMS.

Section 1901(a) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796ff(a)) is amended—

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

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

(3) by adding at the end the following:

"(3) developing and implementing specialized residential substance abuse treatment programs that identify and provide appropriate treatment to inmates with co-occurring mental health and substance abuse disorders or challenges.".

SEC. 14013. MENTAL HEALTH AND DRUG TREATMENT ALTERNATIVES TO INCARCERATION PROGRAMS.

Title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3711 et seq.) is amended by striking part CC and inserting the following:

"PART CC—MENTAL HEALTH AND DRUG TREATMENT ALTERNATIVES TO INCARCERATION PROGRAMS

"SEC. 2901. MENTAL HEALTH AND DRUG TREATMENT ALTERNATIVES TO INCARCERATION PROGRAMS

"(a) DEFINITIONS.—In this section—

"(1) the term 'eligible entity' means a State, unit of local government, Indian tribe, or nonprofit organization; and

"(2) the term 'eligible participant' means an individual who—

"(A) comes into contact with the criminal justice system or is arrested or charged with an offense that is not—

"(i) a crime of violence, as defined under applicable State law or in section 3156 of title 18, United States Code; or

"(ii) a serious drug offense, as defined in section 924(e)(2)(A) of title 18, United States Code;

"(B) has a history of, or a current—

"(i) substance use disorder;

"(ii) mental illness; or

"(iii) co-occurring mental illness and substance use disorder; and

"(C) has been approved for participation in a program funded under this section by the relevant law enforcement agency, prosecuting attorney, defense attorney, probation official, corrections official, judge, representative of a mental health agency, or representative of a substance abuse agency, as required by law.

"(b) PROGRAM AUTHORIZED.—The Attorney General may make grants to eligible entities to develop, implement, or expand a treatment alternative to incarceration program for eligible participants, including—

"(1) pre-booking treatment alternative to incarceration programs, including—

"(A) law enforcement training on substance use disorders, mental illness, and co-occurring mental illness and substance use disorders;

"(B) receiving centers as alternatives to incarceration of eligible participants;

"(C) specialized response units for calls related to substance use disorders, mental illness, or co-occurring mental illness and substance use disorders; and

"(D) other arrest and pre-booking treatment alternatives to incarceration models; or

"(2) post-booking treatment alternative to incarceration programs, including—

"(A) specialized clinical case management;

"(B) pre-trial services related to substances use disorders, mental illness, and co-occurring mental illness and substance use disorders;

"(C) prosecutor and defender based programs;

"(D) specialized probation;

"(E) treatment and rehabilitation programs; and

"(F) problem-solving courts, including mental health courts, drug courts, co-occurring mental health and substance abuse courts, DWI courts, and veterans treatment courts.

"(c) APPLICATION.—

"(1) IN GENERAL.—An eligible entity desiring a grant under this section shall submit an application to the Attorney General—

"(A) that meets the criteria under paragraph (2); and

"(B) at such time, in such manner, and accompanied by such information as the Attorney General may require.

"(2) CRITERIA.—An eligible entity, in submitting an application under paragraph (1), shall—

"(A) provide extensive evidence of collaboration with State and local government agencies overseeing health, community corrections, courts, prosecution, substance abuse, mental health, victims services, and employment services, and with local law enforcement agencies;

"(B) demonstrate consultation with the Single State Authority for Substance Abuse of the State (as that term is defined in section 201(e) of the Second Chance Act of 2007);

"(C) demonstrate that evidence-based treatment practices will be utilized; and

"(D) demonstrate that evidence-based screening and assessment tools will be used to place participants in the treatment alternative to incarceration program.

"(d) REQUIREMENTS.—Each eligible entity awarded a grant for a treatment alternative to incarceration program under this section shall—

"(1) determine the terms and conditions of participation in the program by eligible participants, taking into consideration the collateral consequences of an arrest, prosecution or criminal conviction;

"(2) ensure that each substance abuse and mental health treatment component is licensed and qualified by the relevant jurisdiction;

"(3) for programs described in subsection (b)(2), organize an enforcement unit comprised of appropriately trained law enforcement professionals under the supervision of the State,

Tribal, or local criminal justice agency involved, the duties of which shall include—

"(A) the verification of addresses and other contact information of each eligible participant who participates or desires to participate in the program; and

"(B) if necessary, the location, apprehension, arrest, and return to custody of an eligible participant in the program who has absconded from the facility of a treatment provider or has otherwise significantly violated the terms and conditions of the program, consistent with Federal and State confidentiality requirements;

"(4) notify the relevant criminal justice entity if any eligible participant in the program absconds from the facility of the treatment provider or otherwise violates the terms and conditions of the program, consistent with Federal and State confidentiality requirements;

"(5) submit periodic reports on the progress of treatment or other measured outcomes from participation in the program of each eligible participant in the program to the relevant State, Tribal, or local criminal justice agency, including mental health courts, drug courts, co-occurring mental health and substance abuse courts, DWI courts, and veterans treatment courts;

"(6) describe the evidence-based methodology and outcome measurements that will be used to evaluate the program, and specifically explain how such measurements will provide valid measures of the impact of the program; and

"(7) describe how the program could be broadly replicated if demonstrated to be effective.

"(e) USE OF FUNDS.—An eligible entity shall use a grant received under this section for expenses of a treatment alternative to incarceration program, including—

"(1) salaries, personnel costs, equipment costs, and other costs directly related to the operation of the program, including the enforcement unit;

"(2) payments for treatment providers that are approved by the relevant State or Tribal jurisdiction and licensed, if necessary, to provide needed treatment to eligible offenders participating in the program, including aftercare supervision, vocational training, education, and job placement; and

"(3) payments to public and nonprofit private entities that are approved by the State or Tribal jurisdiction and licensed, if necessary, to provide alcohol and drug addiction treatment to eligible offenders participating in the program.

"(f) SUPPLEMENT NOT SUPPLANT.—An eligible entity shall use Federal funds received under this section only to supplement the funds that would, in the absence of those Federal funds, be made available from other Federal and non-Federal sources for the activities described in this section, and not to supplant those funds. The Federal share of a grant made under this section may not exceed 50 percent of the total costs of the program described in an application under subsection (d).

"(g) GEOGRAPHIC DISTRIBUTION.—The Attorney General shall ensure that, to the extent practicable, the geographical distribution

of grants under this section is equitable and includes a grant to an eligible entity in—

"(1) each State;

"(2) rural, suburban, and urban areas; and

"(3) Tribal jurisdictions.

"(h) REPORTS AND EVALUATIONS.—Each fiscal year, each recipient of a grant under this section during that fiscal year shall submit to the Attorney General a report on the outcomes of activities carried out using that grant in such form, containing such information, and on such dates as the Attorney General shall specify.

"(i) ACCOUNTABILITY.—All grants awarded by the Attorney General under this section shall be subject to the following accountability provisions:

"(1) AUDIT REQUIREMENT.—

"(A) DEFINITION.—In this paragraph, the term 'unresolved audit finding' means a finding in the final audit report of the Inspector General of the Department of Justice that the audited grantee has utilized grant funds for an unauthorized expenditure or otherwise unallowable cost that is not closed or resolved within 12 months from the date on which the final audit report is issued.

"(B) AUDITS.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, and in each fiscal year thereafter, the Inspector General of the Department of Justice shall conduct audits of recipients of grants under this section to prevent waste, fraud, and abuse of funds by grantees. The Inspector General shall determine the appropriate number of grantees to be audited each year.

"(C) MANDATORY EXCLUSION.—A recipient of grant funds under this section that is found to have an unresolved audit finding shall not be eligible to receive grant funds under this section during the first 2 fiscal years beginning after the end of the 12-month period described in subparagraph (A).

"(D) PRIORITY.—In awarding grants under this section, the Attorney General shall give priority to eligible applicants that did not have an unresolved audit finding during the 3 fiscal years before submitting an application for a grant under this section.

"(E) REIMBURSEMENT.—If an entity is awarded grant funds under this section during the 2-fiscal-year period during which the entity is barred from receiving grants under subparagraph (C), the Attorney General shall—

"(i) deposit an amount equal to the amount of the grant funds that were improperly awarded to the grantee into the General Fund of the Treasury; and

"(ii) seek to recoup the costs of the repayment to the fund from the grant recipient that was erroneously awarded grant funds.

"(2) NONPROFIT ORGANIZATION REQUIREMENTS.—

"(A) DEFINITION.—For purposes of this paragraph and the grant programs under this part, the term 'nonprofit organization' means an organization that is described in sec-

tion 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of such Code.

"(B) PROHIBITION.—The Attorney General may not award a grant under this part to a nonprofit organization that holds money in offshore accounts for the purpose of avoiding paying the tax described in section 511(a) of the Internal Revenue Code of 1986.

"(C) DISCLOSURE.—Each nonprofit organization that is awarded a grant under this section and uses the procedures prescribed in regulations to create a rebuttable presumption of reasonableness for the compensation of its officers, directors, trustees, and key employees, shall disclose to the Attorney General, in the application for the grant, the process for determining such compensation, including the independent persons involved in reviewing and approving such compensation, the comparability data used, and contemporaneous substantiation of the deliberation and decision. Upon request, the Attorney General shall make the information disclosed under this subparagraph available for public inspection.

"(3) CONFERENCE EXPENDITURES.—

"(A) LIMITATION.—No amounts made available to the Department of Justice under this section may be used by the Attorney General, or by any individual or entity awarded discretionary funds through a cooperative agreement under this section, to host or support any expenditure for conferences that uses more than $20,000 in funds made available by the Department of Justice, unless the head of the relevant agency or department, provides prior written authorization that the funds may be expended to host the conference.

"(B) WRITTEN APPROVAL.—Written approval under subparagraph (A) shall include a written estimate of all costs associated with the conference, including the cost of all food, beverages, audio-visual equipment, honoraria for speakers, and entertainment.

"(C) REPORT.—The Deputy Attorney General shall submit an annual report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives on all conference expenditures approved under this paragraph.

"(4) ANNUAL CERTIFICATION.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, the Attorney General shall submit, to the Committee on the Judiciary and the Committee on Appropriations of the Senate and the Committee on the Judiciary and the Committee on Appropriations of the House of Representatives, an annual certification—

"(A) indicating whether—

"(i) all audits issued by the Office of the Inspector General under paragraph (1) have been completed and reviewed by the appropriate Assistant Attorney General or Director;

"(ii) all mandatory exclusions required under paragraph (1)(C) have been issued; and

"(iii) all reimbursements required under paragraph (1)(E) have been made; and

"(B) that includes a list of any grant recipients excluded under paragraph (1) from the previous year.

"(5) PREVENTING DUPLICATIVE GRANTS.—

"(A) IN GENERAL.—Before the Attorney General awards a grant to an applicant under this section, the Attorney General shall compare potential grant awards with other grants awarded under this Act to determine if duplicate grant awards are awarded for the same purpose.

"(B) REPORT.—If the Attorney General awards duplicate grants to the same applicant for the same purpose the Attorney General shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that includes—

"(i) a list of all duplicate grants awarded, including the total dollar amount of any duplicate grants awarded; and

"(ii) the reason the Attorney General awarded the duplicate grants.".

SEC. 14014. NATIONAL CRIMINAL JUSTICE AND MENTAL HEALTH TRAINING AND TECHNICAL ASSISTANCE.

Part HH of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa et seq.) is amended by adding at the end the following:

"SEC. 2992. NATIONAL CRIMINAL JUSTICE AND MENTAL HEALTH TRAINING AND TECHNICAL ASSISTANCE

"(a) AUTHORITY.—The Attorney General may make grants to eligible organizations to provide for the establishment of a National Criminal Justice and Mental Health Training and Technical Assistance Center.

"(b) ELIGIBLE ORGANIZATION.—For purposes of subsection (a), the term 'eligible organization' means a national nonprofit organization that provides technical assistance and training to, and has special expertise and broad, national-level experience in, mental health, crisis intervention, criminal justice systems, law enforcement, translating evidence into practice, training, and research, and education and support of people with mental illness and the families of such individuals.

"(c) USE OF FUNDS.—Any organization that receives a grant under subsection (a) shall collaborate with other grant recipients to establish and operate a National Criminal Justice and Mental Health Training and Technical Assistance Center to—

"(1) provide law enforcement officer training regarding mental health and working with individuals with mental illnesses, with an emphasis on de-escalation of encounters between law enforcement officers and those with mental disorders or in crisis, which shall include support the development of in-person and technical information exchanges be-

tween systems and the individuals working in those systems in support of the concepts identified in the training;

"(2) provide education, training, and technical assistance for States, Indian tribes, territories, units of local government, service providers, nonprofit organizations, probation or parole officers, prosecutors, defense attorneys, emergency response providers, and corrections institutions to advance practice and knowledge relating to mental health crisis and approaches to mental health and criminal justice across systems;

"(3) provide training and best practices to mental health providers and criminal justice agencies relating to diversion initiatives, jail and prison strategies, reentry of individuals with mental illnesses into the community, and dispatch protocols and triage capabilities, including the establishment of learning sites;

"(4) develop suicide prevention and crisis intervention training and technical assistance for criminal justice agencies;

"(5) develop a receiving center system and pilot strategy that provides, for a jurisdiction, a single point of entry into the mental health and substance abuse system for assessments and appropriate placement of individuals experiencing a crisis;

"(6) collect data and best practices in mental health and criminal health and criminal justice initiatives and policies from grantees under this part, other recipients of grants under this section, Federal, State, and local agencies involved in the provision of mental health services, and nongovernmental organizations involved in the provision of mental health services;

"(7) develop and disseminate to mental health providers and criminal justice agencies evaluation tools, mechanisms, and measures to better assess and document performance measures and outcomes relating to the provision of mental health services;

"(8) disseminate information to States, units of local government, criminal justice agencies, law enforcement agencies, and other relevant entities about best practices, policy standards, and research findings relating to the provision of mental health services; and

"(9) provide education and support to individuals with mental illness involved with, or at risk of involvement with, the criminal justice system, including the families of such individuals.

"(d) ACCOUNTABILITY.—Grants awarded under this section shall be subject to the following accountability provisions:

"(1) AUDIT REQUIREMENT.—

"(A) DEFINITION.—In this paragraph, the term 'unresolved audit finding' means a finding in the final audit report of the Inspector General of the Department of Justice under subparagraph (C) that the audited grantee has used grant funds for an unauthorized expenditure or otherwise unallowable cost that is not closed or resolved within 1 year after the date on which the final audit report is issued.

"(B) AUDITS.—Beginning in the first fiscal year beginning after the date of enactment of this section, and in

each fiscal year thereafter, the Inspector General of the Department of Justice shall conduct audits of grantees under this section to prevent waste, fraud, and abuse of funds by grantees. The Inspector General shall determine the appropriate number of grantees to be audited each year.

"(C) FINAL AUDIT REPORT.—The Inspector General of the Department of Justice shall submit to the Attorney General a final report on each audit conducted under subparagraph (B).

"(D) MANDATORY EXCLUSION.—Grantees under this section about which there is an unresolved audit finding shall not be eligible to receive a grant under this section during the 2 fiscal years beginning after the end of the 1-year period described in subparagraph (A).

"(E) PRIORITY.—In making grants under this section, the Attorney General shall give priority to applicants that did not have an unresolved audit finding during the 3 fiscal years before submitting an application for a grant under this section.

"(F) REIMBURSEMENT.—If an entity receives a grant under this section during the 2-fiscal-year period during which the entity is prohibited from receiving grants under subparagraph (D), the Attorney General shall—

"(i) deposit an amount equal to the amount of the grant that was improperly awarded to the grantee into the General Fund of the Treasury; and

"(ii) seek to recoup the costs of the repayment under clause (i) from the grantee that was erroneously awarded grant funds.

"(2) NONPROFIT AGENCY REQUIREMENTS.—

"(A) DEFINITION.—For purposes of this paragraph and the grant program under this section, the term 'nonprofit agency' means an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3)) and is exempt from taxation under section 501(a) of the Internal Revenue Code of 1986 (26 U.S.C. 501(a)).

"(B) PROHIBITION.—The Attorney General may not award a grant under this section to a nonprofit agency that holds money in an offshore account for the purpose of avoiding paying the tax described in section 511(a) of the Internal Revenue Code of 1986 (26 U.S.C. 511(a)).

"(C) DISCLOSURE.—Each nonprofit agency that is awarded a grant under this section and uses the procedures prescribed in regulations to create a rebuttable presumption of reasonableness for the compensation of its officers, directors, trustees, and key employees, shall disclose to the Attorney General, in the application for the grant, the process for determining such compensation, including the independent persons involved in reviewing and approving such compensation, the comparability data used, and contemporaneous substantiation of the deliberation and decision. Upon request, the Attorney General shall make

the information disclosed under this subparagraph available for public inspection.

"(3) CONFERENCE EXPENDITURES.—

"(A) LIMITATION.—No amounts made available to the Department of Justice under this section may be used by the Attorney General, or by any individual or entity awarded discretionary funds through a cooperative agreement under this section, to host or support any expenditure for conferences that uses more than $20,000 in funds made available by the Department of Justice, unless the head of the relevant agency or department, provides prior written authorization that the funds may be expended to host the conference.

"(B) WRITTEN APPROVAL.—Written approval under subparagraph (A) shall include a written estimate of all costs associated with the conference, including the cost of all food, beverages, audio-visual equipment, honoraria for speakers, and entertainment.

"(C) REPORT.—The Deputy Attorney General shall submit an annual report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives on all conference expenditures approved under this paragraph.

"(4) ANNUAL CERTIFICATION.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, the Attorney General shall submit to the Committee on the Judiciary and the Committee on Appropriations of the Senate and the Committee on the Judiciary and the Committee on Appropriations of the House of Representatives an annual certification—

"(A) indicating whether—

"(i) all final audit reports issued by the Office of the Inspector General under paragraph (1) have been completed and reviewed by the appropriate Assistant Attorney General or Director;

"(ii) all mandatory exclusions required under paragraph (1)(D) have been issued; and

"(iii) any reimbursements required under paragraph (1)(F) have been made; and

"(B) that includes a list of any grantees excluded under paragraph (1)(D) from the previous year.

"(5) PREVENTING DUPLICATIVE GRANTS.—

"(A) IN GENERAL.—Before the Attorney General awards a grant to an applicant under this section, the Attorney General shall compare potential grant awards with other grants awarded under this Act to determine if duplicate grant awards are awarded for the same purpose.

"(B) REPORT.—If the Attorney General awards duplicate grants to the same applicant for the same purpose the Attorney General shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that includes—

"(i) a list of all duplicate grants awarded, including the total dollar amount of any duplicate grants awarded; and

"(ii) the reason the Attorney General awarded the duplicate grants.".

SEC. 14015. [34 U.S.C. 41311] IMPROVING DEPARTMENT OF JUSTICE DATA COLLECTION ON MENTAL ILLNESS INVOLVED IN CRIME.

(a) IN GENERAL.—Notwithstanding any other provision of law, on or after the date that is 90 days after the date on which the Attorney General promulgates regulations under subsection (b), any data prepared by, or submitted to, the Attorney General or the Director of the Federal Bureau of Investigation with respect to the incidences of homicides, law enforcement officers killed, seriously injured, and assaulted, or individuals killed or seriously injured by law enforcement officers shall include data with respect to the involvement of mental illness in such incidences, if any.

(b) REGULATIONS.—Not later than 90 days after the date of the enactment of this Act, the Attorney General shall promulgate or revise regulations as necessary to carry out subsection (a).

SEC. 14016. REPORTS ON THE NUMBER OF MENTALLY ILL OFFENDERS IN PRISON.

(a) REPORT ON THE COST OF TREATING THE MENTALLY ILL IN THE CRIMINAL JUSTICE SYSTEM.—Not later than 12 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report detailing the cost of imprisonment for individuals who have serious mental illness by the Federal Government or a State or unit of local government, which shall include—

(1) the number and type of crimes committed by individuals with serious mental illness each year; and

(2) detail strategies or ideas for preventing crimes by those individuals with serious mental illness from occurring.

(b) DEFINITION.—For purposes of this section, the Attorney General, in consultation with the Assistant Secretary of Mental Health and Substance Use Disorders, shall define "serious mental illness" based on the "Health Care Reform for Americans with Severe Mental Illnesses: Report" of the National Advisory Mental Health Council, American Journal of Psychiatry 1993; 150:1447-1465.

SEC. 14017. [38 U.S.C. 5501A] CODIFICATION OF DUE PROCESS FOR DETERMINATIONS BY SECRETARY OF VETERANS AFFAIRS OF MENTAL CAPACITY OF BENEFICIARIES.

(a) IN GENERAL.—Chapter 55 of title 38, United States Code, is amended by inserting after section 5501 the following new section:

"SEC. 5501A. Beneficiaries' rights in mental competence determinations

"The Secretary may not make an adverse determination concerning the mental capacity of a beneficiary to manage monetary benefits paid to or for the beneficiary by the Secretary under this title unless such beneficiary has been provided all of the following, subject to the procedures and timelines prescribed by the Secretary for determinations of incompetency:

"(1) Notice of the proposed adverse determination and the supporting evidence.

"(2) An opportunity to request a hearing.

"(3) An opportunity to present evidence, including an opinion from a medical professional or other person, on the capacity of the beneficiary to manage monetary benefits paid to or for the beneficiary by the Secretary under this title.

"(4) An opportunity to be represented at no expense to the Government (including by counsel) at any such hearing and to bring a medical professional or other person to provide relevant testimony at any such hearing.".

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of such chapter 55 is amended by inserting after the item relating to section 5501 the following new item:

"5501A. Beneficiaries' rights in mental competence determinations".

(c) [38 U.S.C. 5501A note]

[38 U.S.C. 5501A note] EFFECTIVE DATE.—Section 5501A of title 38, United States Code, as added by subsection (a), shall apply to determinations made by the Secretary of Veterans Affairs on or after the date of the enactment of this Act.

SEC. 14018. REAUTHORIZATION OF APPROPRIATIONS.

Subsection (o) of section 2991 of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa), as redesignated by section 14006, is amended—

(1) in paragraph (1)(C), by striking "2009 through 2014" and inserting "2017 through 2021"; and

(2) by adding at the end the following:

"(3) LIMITATION.—Not more than 20 percent of the funds authorized to be appropriated under this section may be used for purposes described in subsection (i) (relating to veterans).".

Subtitle B—Comprehensive Justice and Mental Health

SEC. 14021. SEQUENTIAL INTERCEPT MODEL.

Section 2991 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa), as amended by section 14005, is amended by inserting after subsection (j), the following:

"(k) SEQUENTIAL INTERCEPT GRANTS.—

"(1) DEFINITION.—In this subsection, the term 'eligible entity' means a State, unit of local government, Indian tribe, or tribal organization.

"(2) AUTHORIZATION.—The Attorney General may make grants under this subsection to an eligible entity for sequential intercept mapping and implementation in accordance with paragraph (3).

"(3) SEQUENTIAL INTERCEPT MAPPING; IMPLEMENTATION.—An eligible entity that receives a grant under this subsection may use funds for—

"(A) sequential intercept mapping, which—

"(i) shall consist of—

"(I) convening mental health and criminal justice stakeholders to—

"(aa) develop a shared understanding of the flow of justice-involved individuals with mental illnesses through the criminal justice system; and

"(bb) identify opportunities for improved collaborative responses to the risks and needs of individuals described in item (aa); and

"(II) developing strategies to address gaps in services and bring innovative and effective programs to scale along multiple intercepts, including—

"(aa) emergency and crisis services;

"(bb) specialized police-based responses;

"(cc) court hearings and disposition alternatives;

"(dd) reentry from jails and prisons; and

"(ee) community supervision, treatment and support services; and

"(ii) may serve as a starting point for the development of strategic plans to achieve positive public health and safety outcomes; and

"(B) implementation, which shall—

"(i) be derived from the strategic plans described in subparagraph (A)(ii); and

"(ii) consist of—

"(I) hiring and training personnel;

"(II) identifying the eligible entity's target population;

"(III) providing services and supports to reduce unnecessary penetration into the criminal justice system;

"(IV) reducing recidivism;

"(V) evaluating the impact of the eligible entity's approach; and

"(VI) planning for the sustainability of effective interventions.".

SEC. 14022. PRISON AND JAILS.

Section 2991 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is amended by inserting after subsection (k), as added by section 14021, the following:

"(l) CORRECTIONAL FACILITIES.—

"(1) DEFINITIONS.—

"(A) CORRECTIONAL FACILITY.—The term 'correctional facility' means a jail, prison, or other detention facility used to house people who have been arrested, detained, held, or convicted by a criminal justice agency or a court.

"(B) ELIGIBLE INMATE.—The term 'eligible inmate' means an individual who—

"(i) is being held, detained, or incarcerated in a correctional facility; and

"(ii) manifests obvious signs of a mental illness or has been diagnosed by a qualified mental health professional as having a mental illness.

"(2) CORRECTIONAL FACILITY GRANTS.—The Attorney General may award grants to applicants to enhance the capabilities of a correctional facility—

"(A) to identify and screen for eligible inmates;

"(B) to plan and provide—

"(i) initial and periodic assessments of the clinical, medical, and social needs of inmates; and

"(ii) appropriate treatment and services that address the mental health and substance abuse needs of inmates;

"(C) to develop, implement, and enhance—

"(i) post-release transition plans for eligible inmates that, in a comprehensive manner, coordinate health, housing, medical, employment, and other appropriate services and public benefits;

"(ii) the availability of mental health care services and substance abuse treatment services; and

"(iii) alternatives to solitary confinement and segregated housing and mental health screening and treatment for inmates placed in solitary confinement or segregated housing; and

"(D) to train each employee of the correctional facility to identify and appropriately respond to incidents involving inmates with mental health or co-occurring mental health and substance abuse disorders.".

SEC. 14023. ALLOWABLE USES.

Section 2991(b)(5)(I) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa(b)(5)(I)) is amended by adding at the end the following:

"(v) TEAMS ADDRESSING FREQUENT USERS OF CRISIS SERVICES.—Multidisciplinary teams that—

"(I) coordinate, implement, and administer community-based crisis responses and long-term plans for frequent users of crisis services;

"(II) provide training on how to respond appropriately to the unique issues involving frequent users of crisis services for public service personnel, including criminal justice, mental health, substance abuse, emergency room, healthcare, law enforcement, corrections, and housing personnel;

"(III) develop or support alternatives to hospital and jail admissions for frequent users of crisis services that provide treatment, stabilization, and other appropriate supports in the least restrictive, yet appropriate, environment; and

"(IV) develop protocols and systems among law enforcement, mental health, substance abuse, housing, corrections, and emergency medical service operations to provide coordinated assistance to frequent users of crisis services.".

SEC. 14024. LAW ENFORCEMENT TRAINING.

Section 2991(h) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa(h)) is amended—

(1) in paragraph (1), by adding at the end the following:

"(F) ACADEMY TRAINING.—To provide support for academy curricula, law enforcement officer orientation programs, continuing education training, and other programs that teach law enforcement personnel how to identify and respond to incidents involving persons with mental health disorders or co-occurring mental health and substance abuse disorders."; and

(2) by adding at the end the following:

"(4) PRIORITY CONSIDERATION.—The Attorney General, in awarding grants under this subsection, shall give priority to programs that law enforcement personnel and members of the mental health and substance abuse professions develop and administer cooperatively.".

SEC. 14025. [34 U.S.C. 10652 note] FEDERAL LAW ENFORCEMENT TRAINING.

Not later than 1 year after the date of enactment of this Act, the Attorney General shall provide direction and guidance for the following:

(1) TRAINING PROGRAMS.—Programs that offer specialized and comprehensive training, in procedures to identify and appropriately respond to incidents in which the unique needs of individuals who have a mental illness are involved, to first responders and tactical units of—

(A) Federal law enforcement agencies; and

(B) other Federal criminal justice agencies such as the Bureau of Prisons, the Administrative Office of the United States Courts, and other agencies that the Attorney General determines appropriate.

(2) IMPROVED TECHNOLOGY.—The establishment of, or improvement of existing, computerized information systems to provide timely information to employees of Federal law enforcement agencies, and Federal criminal justice agencies to improve the response of such employees to situations involving individuals who have a mental illness.

SEC. 14026. GAO REPORT.

No later than 1 year after the date of enactment of this Act, the Comptroller General of the United States, in coordination with the Attorney General, shall submit to Congress a report on—

(1) the practices that Federal first responders, tactical units, and corrections officers are trained to use in responding to individuals with mental illness;

(2) procedures to identify and appropriately respond to incidents in which the unique needs of individuals who have a mental illness are involved, to Federal first responders and tactical units;

(3) the application of evidence-based practices in criminal justice settings to better address individuals with mental illnesses; and

(4) recommendations on how the Department of Justice can expand and improve information sharing and dissemination of best practices.

SEC. 14027. EVIDENCE BASED PRACTICES.

Section 2991(c) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa(c)) is amended—

(1) in paragraph (3), by striking "or" at the end;

(2) by redesignating paragraph (4) as paragraph (6); and

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

"(4) propose interventions that have been shown by empirical evidence to reduce recidivism;

"(5) when appropriate, use validated assessment tools to target preliminarily qualified offenders with a moderate or high risk of recidivism and a need for treatment and services; or".

SEC. 14028. TRANSPARENCY, PROGRAM ACCOUNTABILITY, AND ENHANCEMENT OF LOCAL AUTHORITY.

(a) IN GENERAL.—Section 2991(a) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa(a)) is amended—

(1) in paragraph (7)—

(A) in the heading, by striking "**Mental illness**" and inserting "**Mental illness; mental health disorder**"; and

(B) by striking "term 'mental illness' means" and inserting "terms 'mental illness' and 'mental health disorder' mean"; and

(2) by striking paragraph (9) and inserting the following:

"(9) PRELIMINARILY QUALIFIED OFFENDER.—

"(A) IN GENERAL.—The term 'preliminarily qualified offender' means an adult or juvenile accused of an offense who—

"(i)(I) previously or currently has been diagnosed by a qualified mental health professional as having a mental illness or co-occurring mental illness and substance abuse disorders;

"(II) manifests obvious signs of mental illness or co-occurring mental illness and substance abuse disorders during arrest or confinement or before any court; or

"(III) in the case of a veterans treatment court provided under subsection (i), has been diagnosed with, or manifests obvious signs of, mental illness or a substance abuse disorder or co-occurring mental illness and substance abuse disorder;

"(ii) has been unanimously approved for participation in a program funded under this section by, when appropriate—

"(I) the relevant—

"(aa) prosecuting attorney;

"(bb) defense attorney;

"(cc) probation or corrections official; and

"(dd) judge; and

"(II) a representative from the relevant mental health agency described in subsection (b)(5)(B)(i);

"(iii) has been determined, by each person described in clause (ii) who is involved in approving the

adult or juvenile for participation in a program funded under this section, to not pose a risk of violence to any person in the program, or the public, if selected to participate in the program; and

"(iv) has not been charged with or convicted of—

"(I) any sex offense (as defined in section 111 of the Sex Offender Registration and Notification Act (42 U.S.C. 16911)) or any offense relating to the sexual exploitation of children; or

"(II) murder or assault with intent to commit murder.

"(B) DETERMINATION.—In determining whether to designate a defendant as a preliminarily qualified offender, the relevant prosecuting attorney, defense attorney, probation or corrections official, judge, and mental health or substance abuse agency representative shall take into account—

"(i) whether the participation of the defendant in the program would pose a substantial risk of violence to the community;

"(ii) the criminal history of the defendant and the nature and severity of the offense for which the defendant is charged;

"(iii) the views of any relevant victims to the offense;

"(iv) the extent to which the defendant would benefit from participation in the program;

"(v) the extent to which the community would realize cost savings because of the defendant's participation in the program; and

"(vi) whether the defendant satisfies the eligibility criteria for program participation unanimously established by the relevant prosecuting attorney, defense attorney, probation or corrections official, judge and mental health or substance abuse agency representative.".

(b) TECHNICAL AND CONFORMING AMENDMENT.—Section 2927(2) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797s-6(2)) is amended by striking "has the meaning given that term in section 2991(a)." and inserting" means an offense that—

"(A) does not have as an element the use, attempted use, or threatened use of physical force against the person or property of another; or

"(B) is not a felony that by its nature involves a substantial risk that physical force against the person or property of another may be used in the course of committing the offense.".

SEC. 14029. GRANT ACCOUNTABILITY.

Section 2991 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is amended by inserting after subsection (l), as added by section 14022, the following:

"(m) ACCOUNTABILITY.—All grants awarded by the Attorney General under this section shall be subject to the following accountability provisions:

"(1) AUDIT REQUIREMENT.—

"(A) DEFINITION.—In this paragraph, the term 'unresolved audit finding' means a finding in the final audit report of the Inspector General of the Department of Justice that the audited grantee has utilized grant funds for an unauthorized expenditure or otherwise unallowable cost that is not closed or resolved within 12 months from the date when the final audit report is issued.

"(B) AUDITS.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, and in each fiscal year thereafter, the Inspector General of the Department of Justice shall conduct audits of recipients of grants under this section to prevent waste, fraud, and abuse of funds by grantees. The Inspector General shall determine the appropriate number of grantees to be audited each year.

"(C) MANDATORY EXCLUSION.—A recipient of grant funds under this section that is found to have an unresolved audit finding shall not be eligible to receive grant funds under this section during the first 2 fiscal years beginning after the end of the 12-month period described in subparagraph (A).

"(D) PRIORITY.—In awarding grants under this section, the Attorney General shall give priority to eligible applicants that did not have an unresolved audit finding during the 3 fiscal years before submitting an application for a grant under this section.

"(E) REIMBURSEMENT.—If an entity is awarded grant funds under this section during the 2-fiscal-year period during which the entity is barred from receiving grants under subparagraph (C), the Attorney General shall—

"(i) deposit an amount equal to the amount of the grant funds that were improperly awarded to the grantee into the General Fund of the Treasury; and

"(ii) seek to recoup the costs of the repayment to the fund from the grant recipient that was erroneously awarded grant funds.

"(2) NONPROFIT ORGANIZATION REQUIREMENTS.—

"(A) DEFINITION.—For purposes of this paragraph and the grant programs under this part, the term 'nonprofit organization' means an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of such Code.

"(B) PROHIBITION.—The Attorney General may not award a grant under this part to a nonprofit organization that holds money in offshore accounts for the purpose of avoiding paying the tax described in section 511(a) of the Internal Revenue Code of 1986.

"(C) DISCLOSURE.—Each nonprofit organization that is awarded a grant under this section and uses the procedures prescribed in regulations to create a rebuttable pre-

sumption of reasonableness for the compensation of its officers, directors, trustees, and key employees, shall disclose to the Attorney General, in the application for the grant, the process for determining such compensation, including the independent persons involved in reviewing and approving such compensation, the comparability data used, and contemporaneous substantiation of the deliberation and decision. Upon request, the Attorney General shall make the information disclosed under this subparagraph available for public inspection.

"(3) CONFERENCE EXPENDITURES.—

"(A) LIMITATION.—No amounts made available to the Department of Justice under this section may be used by the Attorney General, or by any individual or entity awarded discretionary funds through a cooperative agreement under this section, to host or support any expenditure for conferences that uses more than $20,000 in funds made available by the Department of Justice, unless the head of the relevant agency or department, provides prior written authorization that the funds may be expended to host the conference.

"(B) WRITTEN APPROVAL.—Written approval under subparagraph (A) shall include a written estimate of all costs associated with the conference, including the cost of all food, beverages, audio-visual equipment, honoraria for speakers, and entertainment.

"(C) REPORT.—The Deputy Attorney General shall submit an annual report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives on all conference expenditures approved under this paragraph.

"(4) ANNUAL CERTIFICATION.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, the Attorney General shall submit, to the Committee on the Judiciary and the Committee on Appropriations of the Senate and the Committee on the Judiciary and the Committee on Appropriations of the House of Representatives, an annual certification—

"(A) indicating whether—

"(i) all audits issued by the Office of the Inspector General under paragraph (1) have been completed and reviewed by the appropriate Assistant Attorney General or Director;

"(ii) all mandatory exclusions required under paragraph (1)(C) have been issued; and

"(iii) all reimbursements required under paragraph (1)(E) have been made; and

"(B) that includes a list of any grant recipients excluded under paragraph (1) from the previous year.

"(n) PREVENTING DUPLICATIVE GRANTS.—

"(1) IN GENERAL.—Before the Attorney General awards a grant to an applicant under this section, the Attorney General shall compare potential grant awards with other grants award-

ed under this Act to determine if duplicate grant awards are awarded for the same purpose.

"(2) REPORT.—If the Attorney General awards duplicate grants to the same applicant for the same purpose the Attorney General shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that includes—

"(A) a list of all duplicate grants awarded, including the total dollar amount of any duplicate grants awarded; and

"(B) the reason the Attorney General awarded the duplicate grants.".

DIVISION C—INCREASING CHOICE, ACCESS, AND QUALITY IN HEALTH CARE FOR AMERICANS

SEC. 15000. [42 U.S.C. 1305 note] SHORT TITLE.

This division may be cited as the "Increasing Choice, Access, and Quality in Health Care for Americans Act".

TITLE XV—PROVISIONS RELATING TO MEDICARE PART A

SEC. 15001. DEVELOPMENT OF MEDICARE HCPCS VERSION OF MS-DRG CODES FOR SIMILAR HOSPITAL SERVICES.

Section 1886 of the Social Security Act (42 U.S.C. 1395ww) is amended by adding at the end the following new subsection:

"(t) RELATING SIMILAR INPATIENT AND OUTPATIENT HOSPITAL SERVICES.—

"(1) DEVELOPMENT OF HCPCS VERSION OF MS-DRG CODES.—Not later than January 1, 2018, the Secretary shall develop HCPCS versions for MS-DRGs that are similar to the ICD-10-PCS for such MS-DRGs such that, to the extent possible, the MS-DRG assignment shall be similar for a claim coded with the HCPCS version as an identical claim coded with a ICD-10-PCS code.

"(2) COVERAGE OF SURGICAL MS-DRGS.—In carrying out paragraph (1), the Secretary shall develop HCPCS versions of MS-DRG codes for not fewer than 10 surgical MS-DRGs.

"(3) PUBLICATION AND DISSEMINATION OF THE HCPCS VERSIONS OF MS-DRGS.—

"(A) IN GENERAL.—The Secretary shall develop a HCPCS MS-DRG definitions manual and software that is similar to the definitions manual and software for ICD-10-PCS codes for such MS-DRGs. The Secretary shall post the HCPCS MS-DRG definitions manual and software on the Internet website of the Centers for Medicare & Medicaid Services. The HCPCS MS-DRG definitions manual and software shall be in the public domain and available for use and redistribution without charge.

"(B) USE OF PREVIOUS ANALYSIS DONE BY MEDPAC.—In developing the HCPCS MS-DRG definitions manual and software under subparagraph (A), the Secretary shall consult with the Medicare Payment Advisory Commission and shall consider the analysis done by such Commission in translating outpatient surgical claims into inpatient surgical MS-DRGs in preparing chapter 7 (relating to hospital short-stay policy issues) of its 'Medicare and the Health Care Delivery System' report submitted to Congress in June 2015.

"(4) DEFINITION AND REFERENCE.—In this subsection:

"(A) HCPCS.—The term 'HCPCS' means, with respect to hospital items and services, the code under the Healthcare Common Procedure Coding System (HCPCS) (or a successor code) for such items and services.

"(B) ICD-10-PCS.—The term 'ICD-10-PCS' means the International Classification of Diseases, 10th Revision, Procedure Coding System, and includes any subsequent revision of such International Classification of Diseases, Procedure Coding System.".

SEC. 15002. ESTABLISHING BENEFICIARY EQUITY IN THE MEDICARE HOSPITAL READMISSION PROGRAM.

(a) TRANSITIONAL ADJUSTMENT FOR DUAL ELIGIBLE POPULATION.—Section 1886(q)(3) of the Social Security Act (42 U.S.C. 1395ww(q)(3)) is amended—

(1) in subparagraph (A), by inserting "subject to subparagraph (D)," after "purposes of paragraph (1),"; and

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

"(D) TRANSITIONAL ADJUSTMENT FOR DUAL ELIGIBLES.—

"(i) IN GENERAL.—In determining a hospital's adjustment factor under this paragraph for purposes of making payments for discharges occurring during and after fiscal year 2019, and before the application of clause (i) of subparagraph (E), the Secretary shall assign hospitals to groups (as defined by the Secretary under clause (ii)) and apply the applicable provisions of this subsection using a methodology in a manner that allows for separate comparison of hospitals within each such group, as determined by the Secretary.

"(ii) DEFINING GROUPS.—For purposes of this subparagraph, the Secretary shall define groups of hospitals, based on their overall proportion, of the inpatients who are entitled to, or enrolled for, benefits under part A, and who are full-benefit dual eligible individuals (as defined in section 1935(c)(6)). In defining groups, the Secretary shall consult the Medicare Payment Advisory Commission and may consider the analysis done by such Commission in preparing the portion of its report submitted to Congress in June 2013 relating to readmissions.

"(iii) MINIMIZING REPORTING BURDEN ON HOSPITALS.—In carrying out this subparagraph, the Sec-

retary shall not impose any additional reporting requirements on hospitals.

"(iv) BUDGET NEUTRAL DESIGN METHODOLOGY.—The Secretary shall design the methodology to implement this subparagraph so that the estimated total amount of reductions in payments under this subsection equals the estimated total amount of reductions in payments that would otherwise occur under this subsection if this subparagraph did not apply.".

(b) CHANGES IN RISK ADJUSTMENT.—Section 1886(q)(3) of the Social Security Act (42 U.S.C. 1395ww(q)(3)), as amended by subsection (a), is further amended by adding at the end the following new subparagraph:

"(E) CHANGES IN RISK ADJUSTMENT.—

"(i) CONSIDERATION OF RECOMMENDATIONS IN IMPACT REPORTS.—The Secretary may take into account the studies conducted and the recommendations made by the Secretary under section 2(d)(1) of the IMPACT Act of 2014 (Public Law 113-185; 42 U.S.C. 1395lll note) with respect to the application under this subsection of risk adjustment methodologies. Nothing in this clause shall be construed as precluding consideration of the use of groupings of hospitals.

"(ii) CONSIDERATION OF EXCLUSION OF PATIENT CASES BASED ON V OR OTHER APPROPRIATE CODES.—In promulgating regulations to carry out this subsection with respect to discharges occurring after fiscal year 2018, the Secretary may consider the use of V or other ICD-related codes for removal of a readmission. The Secretary may consider modifying measures under this subsection to incorporate V or other ICD-related codes at the same time as other changes are being made under this subparagraph.

"(iii) REMOVAL OF CERTAIN READMISSIONS.—In promulgating regulations to carry out this subsection, with respect to discharges occurring after fiscal year 2018, the Secretary may consider removal as a readmission of an admission that is classified within one or more of the following: transplants, end-stage renal disease, burns, trauma, psychosis, or substance abuse. The Secretary may consider modifying measures under this subsection to remove readmissions at the same time as other changes are being made under this subparagraph.".

(c) MEDPAC STUDY ON READMISSIONS PROGRAM.—The Medicare Payment Advisory Commission shall conduct a study to review overall hospital readmissions described in section 1886(q)(5)(E) of the Social Security Act (42 U.S.C. 1395ww(q)(5)(E)) and whether such readmissions are related to any changes in outpatient and emergency services furnished. The Commission shall submit to Congress a report on such study in its report to Congress in June 2018.

SEC. 15003. FIVE-YEAR EXTENSION OF THE RURAL COMMUNITY HOSPITAL DEMONSTRATION PROGRAM.

(a) EXTENSION.—Section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173; 42 U.S.C. 1395ww note) is amended—

(1) in subsection (a)(5), by striking "5-year extension period" and inserting "10-year extension period"; and

(2) in subsection (g)—

(A) in the subsection heading, by striking "**Five-Year**" and inserting "**Ten-Year**";

(B) in paragraph (1), by striking "additional 5-year" and inserting "additional 10-year";

(C) by striking "5-year extension period" and inserting "10-year extension period" each place it appears;

(D) in paragraph (4)(B)—

(i) in the matter preceding clause (i), by inserting "each 5-year period in" after "hospital during"; and

(ii) in clause (i), by inserting "each applicable 5-year period in" after "the first day of"; and

(E) by adding at the end the following new paragraphs:

"(5) OTHER HOSPITALS IN DEMONSTRATION PROGRAM.—During the second 5 years of the 10-year extension period, the Secretary shall apply the provisions of paragraph (4) to rural community hospitals that are not described in paragraph (4) but are participating in the demonstration program under this section as of December 30, 2014, in a similar manner as such provisions apply to rural community hospitals described in paragraph (4).

"(6) EXPANSION OF DEMONSTRATION PROGRAM TO RURAL AREAS IN ANY STATE.—

"(A) IN GENERAL.—The Secretary shall, notwithstanding subsection (a)(2) or paragraph (2) of this subsection, not later than 120 days after the date of the enactment of this paragraph, issue a solicitation for applications to select up to the maximum number of additional rural community hospitals located in any State to participate in the demonstration program under this section for the second 5 years of the 10-year extension period without exceeding the limitation under paragraph (3) of this subsection.

"(B) PRIORITY.—In determining which rural community hospitals that submitted an application pursuant to the solicitation under subparagraph (A) to select for participation in the demonstration program, the Secretary—

"(i) shall give priority to rural community hospitals located in one of the 20 States with the lowest population densities (as determined by the Secretary using the 2015 Statistical Abstract of the United States); and

"(ii) may consider—

"(I) closures of hospitals located in rural areas in the State in which the rural community hospital is located during the 5-year period imme-

diately preceding the date of the enactment of this paragraph; and

"(II) the population density of the State in which the rural community hospital is located.".

(b) CHANGE IN TIMING FOR REPORT.—Subsection (e) of such section 410A is amended—

(1) by striking "Not later than 6 months after the completion of the demonstration program under this section" and inserting "Not later than August 1, 2018"; and

(2) by striking "such program" and inserting "the demonstration program under this section".

SEC. 15004. REGULATORY RELIEF FOR LTCHS.

(a) TECHNICAL CHANGE TO THE MEDICARE LONG-TERM CARE HOSPITAL MORATORIUM EXCEPTION.—

(1) IN GENERAL.—Section 114(d)(7) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (42 U.S.C. 1395ww note), as amended by sections 3106(b) and 10312(b) of Public Law 111-148, section 1206(b)(2) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113-67), and section 112 of the Protecting Access to Medicare Act of 2014 (Public Law 113-93), is amended by striking "The moratorium under paragraph (1)(A)" and inserting "Any moratorium under paragraph (1)".

(2) [42 U.S.C. 1395ww note] EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect as if included in the enactment of section 112 of the Protecting Access to Medicare Act of 2014.

(b) MODIFICATION TO MEDICARE LONG-TERM CARE HOSPITAL HIGH COST OUTLIER PAYMENTS.—Section 1886(m) of the Social Security Act (42 U.S.C. 1395ww(m)) is amended by adding at the end the following new paragraph:

"(7) TREATMENT OF HIGH COST OUTLIER PAYMENTS.—

"(A) ADJUSTMENT TO THE STANDARD FEDERAL PAYMENT RATE FOR ESTIMATED HIGH COST OUTLIER PAYMENTS.—Under the system described in paragraph (1), for fiscal years beginning on or after October 1, 2017, the Secretary shall reduce the standard Federal payment rate as if the estimated aggregate amount of high cost outlier payments for standard Federal payment rate discharges for each such fiscal year would be equal to 8 percent of estimated aggregate payments for standard Federal payment rate discharges for each such fiscal year.

"(B) LIMITATION ON HIGH COST OUTLIER PAYMENT AMOUNTS.—Notwithstanding subparagraph (A), the Secretary shall set the fixed loss amount for high cost outlier payments such that the estimated aggregate amount of high cost outlier payments made for standard Federal payment rate discharges for fiscal years beginning on or after October 1, 2017, shall be equal to 99.6875 percent of 8 percent of estimated aggregate payments for standard Federal payment rate discharges for each such fiscal year.

"(C) WAIVER OF BUDGET NEUTRALITY.—Any reduction in payments resulting from the application of subpara-

graph (B) shall not be taken into account in applying any budget neutrality provision under such system.

"(D) NO EFFECT ON SITE NEUTRAL HIGH COST OUTLIER PAYMENT RATE.—This paragraph shall not apply with respect to the computation of the applicable site neutral payment rate under paragraph (6).".

SEC. 15005. SAVINGS FROM IPPS MACRA PAY-FOR THROUGH NOT APPLYING DOCUMENTATION AND CODING ADJUSTMENTS.

Section 7(b)(1)(B) of the TMA, Abstinence Education, and QI Programs Extension Act of 2007 (Public Law 110-90), as amended by section 631(b) of the American Taxpayer Relief Act of 2012 (Public Law 112-240) and section 414(1)(B)(iii) of the Medicare Access and CHIP Reauthorization Act of 2015 (Public Law 114-10), is amended in clause (iii) by striking "an increase of 0.5 percentage points for discharges occurring during each of fiscal years 2018 through 2023" and inserting "an increase of 0.4588 percentage points for discharges occurring during fiscal year 2018 and 0.5 percentage points for discharges occurring during each of fiscal years 2019 through 2023".

SEC. 15006. EXTENSION OF CERTAIN LTCH MEDICARE PAYMENT RULES.

(a) 25-PERCENT PATIENT THRESHOLD PAYMENT ADJUSTMENT.—Section 114(c)(1)(A) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (42 U.S.C. 1395ww note), as amended by section 4302(a) of division B of the American Recovery and Reinvestment Act (Public Law 111-5), sections 3106(a) and 10312(a) of Public Law 111-148, and section 1206(b)(1)(B) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113-67), is amended by striking "for a 9-year period" and inserting "through June 30, 2016, and for discharges occurring on or after October 1, 2016, and before October 1, 2017".

(b) PAYMENT FOR HOSPITALS-WITHIN-HOSPITALS.—Section 114(c)(2) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (42 U.S.C. 1395ww note), as amended by section 4302(a) of division B of the American Recovery and Reinvestment Act (Public Law 111-5), sections 3106(a) and 10312(a) of Public Law 111-148, and section 1206(b)(1)(A) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113-67), is amended—

(1) in subparagraph (A), by inserting "or any similar provision," after "Regulations,";

(2) in subparagraph (B)—

(A) in clause (i), by inserting "or any similar provision," after "Regulations,"; and

(B) in clause (ii), by inserting ", or any similar provision," after "Regulations"; and

(3) in subparagraph (C), by striking "for a 9-year period" and inserting "through June 30, 2016, and for discharges occurring on or after October 1, 2016, and before October 1, 2017".

SEC. 15007. APPLICATION OF RULES ON THE CALCULATION OF HOSPITAL LENGTH OF STAY TO ALL LTCHS.

(a) IN GENERAL.—Section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113-67; 42 U.S.C. 1395ww note) is amended—

(1) by striking subparagraph (B);

(2) by striking "site neutral basis.—" and all that follows through "For discharges occurring" and inserting "site neutral basis.—For discharges occurring";

(3) by striking "subject to subparagraph (B),"; and

(4) by redesignating clauses (i) and (ii) as subparagraphs (A) and (B), respectively, and moving each of such subparagraphs (as so redesignated) 2 ems to the left.

(b) [42 U.S.C. 1395ww note]

[42 U.S.C. 1395ww note] EFFECTIVE DATE.—The amendments made by subsection (a) shall be effective as if included in the enactment of section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113-67; 42 U.S.C. 1395ww note).

SEC. 15008. CHANGE IN MEDICARE CLASSIFICATION FOR CERTAIN HOSPITALS.

(a) IN GENERAL.—Subsection (d)(1)(B)(iv) of section 1886 of the Social Security Act (42 U.S.C. 1395ww) is amended—

(1) in subclause (I), by striking "or" at the end;

(2) in subclause (II)—

(A) by striking ", or" at the end and inserting a semicolon;

(B) by redesignating such subclause as clause (vi) and by moving it to immediately follow clause (v); and

(C) in clause (v), by striking the semicolon at the end and inserting ", or"; and

(3) by striking "(iv)(I) a hospital" and inserting "(iv) a hospital".

(b) CONFORMING PAYMENT REFERENCES.—The second sentence of subsection (d)(1)(B) of such section is amended—

(1) by inserting "(as in effect as of such date)" after "clause (iv)"; and

(2) by inserting "(or, in the case of a hospital described in clause (iv)(II), as so in effect, shall be classified under clause (vi) on and after the effective date of such clause (vi) and for cost reporting periods beginning on or after January 1, 2015, shall not be subject to subsection (m) as of the date of such classification)" after "so classified".

(c) [42 U.S.C. 1395ww note]

[42 U.S.C. 1395ww note] APPLICATION.—

(1) IN GENERAL.—For cost reporting periods beginning on or after January 1, 2015, in the case of an applicable hospital (as defined in paragraph (3)), the following shall apply:

(A) Payment for inpatient operating costs shall be made on a reasonable cost basis in the manner provided in section 412.526(c)(3) of title 42, Code of Federal Regulations (as in effect on January 1, 2015) and in any subsequent modifications.

(B) Payment for capital costs shall be made in the manner provided by section 412.526(c)(4) of title 42, Code of Federal Regulations (as in effect on such date).

(C) Claims for payment for Medicare beneficiaries who are discharged on or after January 1, 2017, shall be processed as claims which are paid on a reasonable cost basis as described in section 412.526(c) of title 42, Code of Federal Regulations (as in effect on such date).

(2) APPLICABLE HOSPITAL DEFINED.—In this subsection, the term "applicable hospital" means a hospital that is classified under clause (iv)(II) of section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B)) on the day before the date of the enactment of this Act and which is classified under clause (vi) of such section, as redesignated and moved by subsection (a), on or after such date of enactment.

(d) CONFORMING TECHNICAL AMENDMENTS.—

(1) Section 1899B(a)(2)(A)(iv) of the Social Security Act (42 U.S.C. 1395lll(a)(2)(A)(iv)) is amended by striking "1886(d)(1)(B)(iv)(II)" and inserting "1886(d)(1)(B)(vi)".

(2) Section 1886(m)(5)(F) of such Act (42 U.S.C. 1395ww(m)(5)(F)) is amended in each of clauses (i) and (ii) by striking "(d)(1)(B)(iv)(II)" and inserting "(d)(1)(B)(vi)".

SEC. 15009. TEMPORARY EXCEPTION TO THE APPLICATION OF THE MEDICARE LTCH SITE NEUTRAL PROVISIONS FOR CERTAIN SPINAL CORD SPECIALTY HOSPITALS.

(a) EXCEPTION.—Section 1886(m)(6) of the Social Security Act (42 U.S.C. 1395ww(m)(6)) is amended—

(1) in subparagraph (A)(i), by striking "and (E)" and inserting ", (E), and (F)"; and

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

"(F) TEMPORARY EXCEPTION FOR CERTAIN SPINAL CORD SPECIALTY HOSPITALS. For discharges in cost reporting periods beginning during fiscal years 2018 and 2019, subparagraph (A)(i) shall not apply (and payment shall be made to a long-term care hospital without regard to this paragraph) if such discharge is from a long-term care hospital that meets each of the following requirements:

"(i) NOT-FOR-PROFIT. The long-term care hospital was a not-for-profit long-term care hospital on June 1, 2014, as determined by cost report data.

"(ii) PRIMARILY PROVIDING TREATMENT FOR CATASTROPHIC SPINAL CORD OR ACQUIRED BRAIN INJURIES OR OTHER PARALYZING NEUROMUSCULAR CONDITIONS. Of the discharges in calendar year 2013 from the long-term care hospital for which payment was made under this section, at least 50 percent were classified under MS-LTCH-DRGs 28, 29, 52, 57, 551, 573, and 963.

"(iii) SIGNIFICANT OUT-OF-STATE ADMISSIONS.

"(I) IN GENERAL. The long-term care hospital discharged inpatients (including both individuals entitled to, or enrolled for, benefits under this title and individuals not so entitled or enrolled) during fiscal year 2014 who had been admitted from at least 20 of the 50 States, determined by the States of residency of such inpatients and based on such data submitted by the hospital to the Secretary as the Secretary may require.

"(II) IMPLEMENTATION. Notwithstanding any other provision of law, the Secretary may implement subclause (I) by program instruction or otherwise.

"(III) NON-APPLICATION OF PAPERWORK REDUCTION ACT. Chapter 35 of title 44, United States Code, shall not apply to data collected under this clause.".

(b) STUDY AND REPORT ON THE STATUS AND VIABILITY OF CERTAIN SPINAL CORD SPECIALTY LONG-TERM CARE HOSPITALS.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on long-term care hospitals described in section 1886(m)(6)(F) of the Social Security Act, as added by subsection (a). Such report shall include an analysis of the following:

(A) The impact on such hospitals of the classification and facility licensure by State agencies of such hospitals.

(B) The Medicare payment rates for such hospitals.

(C) Data on the number and health care needs of Medicare beneficiaries who have been diagnosed with catastrophic spinal cord or acquired brain injuries or other paralyzing neuromuscular conditions (as described within the discharge classifications specified in clause (ii) of such section) who are receiving services from such hospitals.

(2) REPORT.—Not later than October 1, 2018, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1), including recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

SEC. 15010. TEMPORARY EXTENSION TO THE APPLICATION OF THE MEDICARE LTCH SITE NEUTRAL PROVISIONS FOR CERTAIN DISCHARGES WITH SEVERE WOUNDS.

(a) IN GENERAL.—Section 1886(m)(6) of the Social Security Act (42 U.S.C. 1395ww(m)(6)), as amended by section 15009, is further amended—

(1) in subparagraph (A)(i) by striking "and (F)" and inserting "(F), and (G)";

(2) in subparagraph (E)(i)(I)(aa), by striking "the amendment made" and all that follows before the semicolon and inserting "the last sentence of subsection (d)(1)(B)"; and

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

"(G) ADDITIONAL TEMPORARY EXCEPTION FOR CERTAIN SEVERE WOUND DISCHARGES FROM CERTAIN LONG-TERM CARE HOSPITALS.—

"(i) IN GENERAL. For a discharge occurring in a cost reporting period beginning during fiscal year 2018, subparagraph (A)(i) shall not apply (and payment shall be made to a long-term care hospital without regard to this paragraph) if such discharge—

"(I) is from a long-term care hospital identified by the last sentence of subsection (d)(1)(B);

"(II) is classified under MS-LTCH-DRG 602, 603, 539, or 540; and

"(III) is with respect to an individual treated by a long-term care hospital for a severe wound.

"(ii) SEVERE WOUND DEFINED. In this subparagraph, the term 'severe wound' means a wound which is a stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, or fistula as identified in the claim from the long-term care hospital.

"(iii) WOUND DEFINED. In this subparagraph, the term 'wound' means an injury involving division of tissue or rupture of the integument or mucous membrane with exposure to the external environment.".

(c) STUDY AND REPORT TO CONGRESS.—

(1) STUDY.—The Comptroller General of the United States shall, in consultation with relevant stakeholders, conduct a study on the treatment needs of individuals entitled to benefits under part A of title XVIII of the Social Security Act or enrolled under part B of such title who require specialized wound care, and the cost, for such individuals and the Medicare program under such title, of treating severe wounds in rural and urban areas. Such study shall include an assessment of—

(A) access of such individuals to appropriate levels of care for such cases;

(B) the potential impact that section 1886(m)(6)(A)(i) of such Act (42 U.S.C. 1395ww(m)(6)(A)(i)) will have on the access, quality, and cost of care for such individuals; and

(C) how to appropriately pay for such care under the Medicare program under such title.

(2) REPORT.—Not later than October 1, 2020, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1), including recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

TITLE XVI—PROVISIONS RELATING TO MEDICARE PART B

SEC. 16001. CONTINUING MEDICARE PAYMENT UNDER HOPD PROSPECTIVE PAYMENT SYSTEM FOR SERVICES FURNISHED BY MID-BUILD OFF-CAMPUS OUTPATIENT DEPARTMENTS OF PROVIDERS.

(a) IN GENERAL.—Section 1833(t)(21) of the Social Security Act (42 U.S.C. 1395l(t)(21)) is amended—

(1) in subparagraph (B)—

(A) in clause (i), by striking "clause (ii)" and inserting "the subsequent provisions of this subparagraph"; and

(B) by adding at the end the following new clauses:

"(iii) DEEMED TREATMENT FOR 2017. For purposes of applying clause (ii) with respect to applicable items and services furnished during 2017, a department of a provider (as so defined) not described in such clause is deemed to be billing under this subsection with respect to covered OPD services furnished prior to November 2, 2015, if the Secretary received from the pro-

vider prior to December 2, 2015, an attestation (pursuant to section 413.65(b)(3) of title 42 of the Code of Federal Regulations) that such department was a department of a provider (as so defined).

"(iv) ALTERNATIVE EXCEPTION BEGINNING WITH 2018. For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2018 or a subsequent year, the term 'off-campus outpatient department of a provider' also shall not include a department of a provider (as so defined) that is not described in clause (ii) if—

"(I) the Secretary receives from the provider an attestation (pursuant to such section 413.65(b)(3)) not later than December 31, 2016 (or, if later, 60 days after the date of the enactment of this clause), that such department met the requirements of a department of a provider specified in section 413.65 of title 42 of the Code of Federal Regulations;

"(II) the provider includes such department as part of the provider on its enrollment form in accordance with the enrollment process under section 1866(j); and

"(III) the department met the mid-build requirement of clause (v) and the Secretary receives, not later than 60 days after the date of the enactment of this clause, from the chief executive officer or chief operating officer of the provider a written certification that the department met such requirement.

"(v) MID-BUILD REQUIREMENT DESCRIBED. The mid-build requirement of this clause is, with respect to a department of a provider, that before November 2, 2015, the provider had a binding written agreement with an outside unrelated party for the actual construction of such department.

"(vii) AUDIT. Not later than December 31, 2018, the Secretary shall audit the compliance with requirements of clause (iv) with respect to each department of a provider to which such clause applies. If the Secretary finds as a result of an audit under this clause that the applicable requirements were not met with respect to such department, the department shall not be excluded from the term 'off-campus outpatient department of a provider' under such clause.

"(viii) IMPLEMENTATION. For purposes of implementing clauses (iii) through (vii):

"(I) Notwithstanding any other provision of law, the Secretary may implement such clauses by program instruction or otherwise.

"(II) Subchapter I of chapter 35 of title 44, United States Code, shall not apply.

"(III) For purposes of carrying out this subparagraph with respect to clauses (iii) and (iv)

(and clause (vii) insofar as it relates to clause (iv)), $10,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841, to remain available until December 31, 2018."; and

(2) in subparagraph (E), by adding at the end the following new clause:

"(iv) The determination of an audit under subparagraph (B)(vii).".

(b) [42 U.S.C. 1395l note]

[42 U.S.C. 1395l note] EFFECTIVE DATE.—The amendments made by this section shall be effective as if included in the enactment of section 603 of the Bipartisan Budget Act of 2015 (Public Law 114-74).

SEC. 16002. TREATMENT OF CANCER HOSPITALS IN OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER POLICY.

(a) IN GENERAL.—Section 1833(t)(21)(B) of the Social Security Act (42 U.S.C. 1395l(t)(21)(B)), as amended by section 16001(a), is amended—

(1) by inserting after clause (v) the following new clause:

"(vi) EXCLUSION FOR CERTAIN CANCER HOSPITALS. For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2017 or a subsequent year, the term 'off-campus outpatient department of a provider' also shall not include a department of a provider (as so defined) that is not described in clause (ii) if the provider is a hospital described in section 1886(d)(1)(B)(v) and—

"(I) in the case of a department that met the requirements of section 413.65 of title 42 of the Code of Federal Regulations after November 1, 2015, and before the date of the enactment of this clause, the Secretary receives from the provider an attestation that such department met such requirements not later than 60 days after such date of enactment; or

"(II) in the case of a department that meets such requirements after such date of enactment, the Secretary receives from the provider an attestation that such department meets such requirements not later than 60 days after the date such requirements are first met with respect to such department.";

(2) in clause (vii), by inserting after the first sentence the following: "Not later than 2 years after the date the Secretary receives an attestation under clause (vi) relating to compliance of a department of a provider with requirements referred to in such clause, the Secretary shall audit the compliance with such requirements with respect to the department."; and

(3) in clause (viii)(III), by adding at the end the following: "For purposes of carrying out this subparagraph with respect to clause (vi) (and clause (vii) insofar as it relates to such clause), $2,000,000 shall be available from the Federal Supple-

mentary Medical Insurance Trust Fund under section 1841, to remain available until expended.".

(b) OFFSETTING SAVINGS.—Section 1833(t)(18) of the Social Security Act (42 U.S.C. 1395l(t)(18)) is amended—

(1) in subparagraph (B), by inserting ", subject to subparagraph (C)," after "shall"; and

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

"(C) TARGET PCR ADJUSTMENT. In applying section 419.43(i) of title 42 of the Code of Federal Regulations to implement the appropriate adjustment under this paragraph for services furnished on or after January 1, 2018, the Secretary shall use a target PCR that is 1.0 percentage points less than the target PCR that would otherwise apply. In addition to the percentage point reduction under the previous sentence, the Secretary may consider making an additional percentage point reduction to such target PCR that takes into account payment rates for applicable items and services described in paragraph (21)(C) other than for services furnished by hospitals described in section 1886(d)(1)(B)(v). In making any budget neutrality adjustments under this subsection for 2018 or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.".

(c) [42 U.S.C. 1395l note]

[42 U.S.C. 1395l note] EFFECTIVE DATE.—The amendments made by this section shall be effective as if included in the enactment of section 603 of the Bipartisan Budget Act of 2015 (Public Law 114-74).

SEC. 16003. TREATMENT OF ELIGIBLE PROFESSIONALS IN AMBULATORY SURGICAL CENTERS FOR MEANINGFUL USE AND MIPS.

Section 1848(a)(7)(D) of the Social Security Act (42 U.S.C. 1395w-4(a)(7)(D)) is amended—

(1) by striking "hospital-based eligible professionals" and all that follows through "No payment" and inserting the following:" hospital-based and ambulatory surgical center-based eligible professionals.—

"(i) HOSPITAL-BASED. No payment"; and

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

"(ii) AMBULATORY SURGICAL CENTER-BASED. Subject to clause (iv), no payment adjustment may be made under subparagraph (A) for 2017 and 2018 in the case of an eligible professional with respect to whom substantially all of the covered professional services furnished by such professional are furnished in an ambulatory surgical center.

"(iii) DETERMINATION. The determination of whether an eligible professional is an eligible professional described in clause (ii) may be made on the basis of—

"(I) the site of service (as defined by the Secretary); or

"(II) an attestation submitted by the eligible professional.

Determinations made under subclauses (I) and (II) shall be made without regard to any employment or billing arrangement between the eligible professional and any other supplier or provider of services.

"(iv) SUNSET. Clause (ii) shall no longer apply as of the first year that begins more than 3 years after the date on which the Secretary determines, through notice and comment rulemaking, that certified EHR technology applicable to the ambulatory surgical center setting is available.".

SEC. 16004. CONTINUING ACCESS TO HOSPITALS ACT OF 2016.

(a) EXTENSION OF ENFORCEMENT INSTRUCTION ON SUPERVISION REQUIREMENTS FOR OUTPATIENT THERAPEUTIC SERVICES IN CRITICAL ACCESS AND SMALL RURAL HOSPITALS THROUGH 2016.—Section 1 of Public Law 113-198, as amended by section 1 of Public Law 114-112, is amended—

(1) in the heading, by striking "2014 AND 2015" and inserting "2016"; and

(2) by striking "and 2015" and inserting ", 2015, and 2016".

(b) REPORT.—Not later than 1 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 submit to Congress a report analyzing the effect of the extension of the enforcement instruction under section 1 of Public Law 113-198, as amended by section 1 of Public Law 114-112 and subsection (a) of this section, on the access to health care by Medicare beneficiaries, on the economic impact and the impact upon hospital staffing needs, and on the quality of health care furnished to such beneficiaries.

SEC. 16005. DELAY OF IMPLEMENTATION OF MEDICARE FEE SCHEDULE ADJUSTMENTS FOR WHEELCHAIR ACCESSORIES AND SEATING SYSTEMS WHEN USED IN CONJUNCTION WITH COMPLEX REHABILITATION TECHNOLOGY (CRT) WHEELCHAIRS.

Section 2(a) of the Patient Access and Medicare Protection Act (42 U.S.C. 1305 note) is amended by striking "January 1, 2017" and inserting "July 1, 2017".

SEC. 16006. ALLOWING PHYSICAL THERAPISTS TO UTILIZE LOCUM TENENS ARRANGEMENTS UNDER MEDICARE.

(a) IN GENERAL.—The first sentence of section 1842(b)(6) of the Social Security Act (42 U.S.C. 1395u(b)(6)), as amended by section 5012, is further amended—

(1) by striking "and" before "(I)"; and

(2) by inserting before the period at the end the following: ", and (J) in the case of outpatient physical therapy services furnished by physical therapists in a health professional shortage area (as defined in section 332(a)(1)(A) of the Public Health Service Act), a medically underserved area (as designated pursuant to section 330(b)(3)(A) of such Act), or a rural area (as defined in section 1886(d)(2)(D)), subparagraph (D) of this sentence shall apply to such services and therapists in the same manner as such subparagraph applies to physicians' services furnished by physicians".

(b) [42 U.S.C. 1395u note]

[42 U.S.C. 1395u note] EFFECTIVE DATE; IMPLEMENTATION.—

(1) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to services furnished beginning not later than six months after the date of the enactment of this Act.

(2) IMPLEMENTATION.—The Secretary of Health and Human Services may implement subparagraph (J) of section 1842(b)(6) of the Social Security Act (42 U.S.C. 1395u(b)(6)), as added by subsection (a)(2), by program instruction or otherwise.

SEC. 16007. EXTENSION OF THE TRANSITION TO NEW PAYMENT RATES FOR DURABLE MEDICAL EQUIPMENT UNDER THE MEDICARE PROGRAM.

(a) IN GENERAL.—The Secretary of Health and Human Services shall extend the transition period described in clause (i) of section 414.210(g)(9) of title 42, Code of Federal Regulations, from June 30, 2016, to December 31, 2016 (with the full implementation described in clause (ii) of such section applying to items and services furnished with dates of service on or after January 1, 2017).

(b) STUDY AND REPORT.—

(1) STUDY.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study that examines the impact of applicable payment adjustments upon—

(i) the number of suppliers of durable medical equipment that, on a date that is not before January 1, 2016, and not later than December 31, 2016, ceased to conduct business as such suppliers; and

(ii) the availability of durable medical equipment, during the period beginning on January 1, 2016, and ending on December 31, 2016, to individuals entitled to benefits under part A of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) or enrolled under part B of such title.

(B) DEFINITIONS.—For purposes of this subsection, the following definitions apply:

(i) SUPPLIER; DURABLE MEDICAL EQUIPMENT.—The terms "supplier" and "durable medical equipment" have the meanings given such terms by section 1861 of the Social Security Act (42 U.S.C. 1395x).

(ii) APPLICABLE PAYMENT ADJUSTMENT.—The term "applicable payment adjustment" means a payment adjustment described in section 414.210(g) of title 42, Code of Federal Regulations, that is phased in by paragraph (9)(i) of such section. For purposes of the preceding sentence, a payment adjustment that is phased in pursuant to the extension under subsection (a) shall be considered a payment adjustment that is phased in by such paragraph (9)(i).

(2) REPORT.—The Secretary of Health and Human Services shall, not later than January 12, 2017, submit to the Committees on Ways and Means and on Energy and Commerce of the House of Representatives, and to the Committee on Finance of

the Senate, a report on the findings of the study conducted under paragraph (1).

SEC. 16008. REQUIREMENTS IN DETERMINING ADJUSTMENTS USING INFORMATION FROM COMPETITIVE BIDDING PROGRAMS.

(a) IN GENERAL.—Section 1834(a)(1)(G) of the Social Security Act (42 U.S.C. 1395m(a)(1)(G)) is amended by adding at the end the following new sentence: "In the case of items and services furnished on or after January 1, 2019, in making any adjustments under clause (ii) or (iii) of subparagraph (F), under subsection (h)(1)(H)(ii), or under section 1842(s)(3)(B), the Secretary shall—

"(i) solicit and take into account stakeholder input; and

"(ii) take into account the highest amount bid by a winning supplier in a competitive acquisition area and a comparison of each of the following with respect to non-competitive acquisition areas and competitive acquisition areas:

"(I) The average travel distance and cost associated with furnishing items and services in the area.

"(II) The average volume of items and services furnished by suppliers in the area.

"(III) The number of suppliers in the area.".

(b) CONFORMING AMENDMENTS.—(1) Section 1834(h)(1)(H)(ii) of the Social Security Act (42 U.S.C. 1395m(h)(1)(H)(ii)) is amended by striking "the Secretary" and inserting "subject to subsection (a)(1)(G), the Secretary".

(2) Section 1842(s)(3)(B) of the Social Security Act (42 U.S.C. 1395m(s)(3)(B)) is amended by striking "the Secretary" and inserting "subject to section 1834(a)(1)(G), the Secretary".

TITLE XVII—OTHER MEDICARE PROVISIONS

SEC. 17001. DELAY IN AUTHORITY TO TERMINATE CONTRACTS FOR MEDICARE ADVANTAGE PLANS FAILING TO ACHIEVE MINIMUM QUALITY RATINGS.

(a) FINDINGS.—Consistent with the studies provided under the IMPACT Act of 2014 (Public Law 113-185), it is the intent of Congress—

(1) to continue to study and request input on the effects of socioeconomic status and dual-eligible populations on the Medicare Advantage STARS rating system before reforming such system with the input of stakeholders; and

(2) pending the results of such studies and input, to provide for a temporary delay in authority of the Centers for Medicare & Medicaid Services (CMS) to terminate Medicare Advantage plan contracts solely on the basis of performance of plans under the STARS rating system.

(b) DELAY IN MA CONTRACT TERMINATION AUTHORITY FOR PLANS FAILING TO ACHIEVE MINIMUM QUALITY RATINGS.—Section 1857(h) of the Social Security Act (42 U.S.C. 1395w-27(h)) is amended by adding at the end the following new paragraph:

"(3) DELAY IN CONTRACT TERMINATION AUTHORITY FOR PLANS FAILING TO ACHIEVE MINIMUM QUALITY RATING. During the period beginning on the date of the enactment of this paragraph and through the end of plan year 2018, the Secretary may not terminate a contract under this section with respect to the offering of an MA plan by a Medicare Advantage organization solely because the MA plan has failed to achieve a minimum quality rating under the 5-star rating system under section 1853(o)(4).".

SEC. 17002. REQUIREMENT FOR ENROLLMENT DATA REPORTING FOR MEDICARE.

Section 1874 of the Social Security Act (42 U.S.C. 1395kk) is amended by adding at the end the following new subsection:

"(g) REQUIREMENT FOR ENROLLMENT DATA REPORTING.—

"(1) IN GENERAL. Each year (beginning with 2016), the Secretary shall submit to the Committees on Ways and Means and Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate a report on Medicare enrollment data (and, in the case of part A, on data on individuals receiving benefits under such part) as of a date in such year specified by the Secretary. Such data shall be presented—

"(A) by Congressional district and State; and

"(B) in a manner that provides for such data based on—

"(i) fee-for-service enrollment (as defined in paragraph (2));

"(ii) enrollment under part C (including separate for aggregate enrollment in MA-PD plans and aggregate enrollment in MA plans that are not MA-PD plans); and

"(iii) enrollment under part D.

"(2) FEE-FOR-SERVICE ENROLLMENT DEFINED. For purpose of paragraph (1)(B)(i), the term 'fee-for-service enrollment' means aggregate enrollment (including receipt of benefits other than through enrollment) under—

"(A) part A only;

"(B) part B only; and

"(C) both part A and part B.".

SEC. 17003. [42 U.S.C. 1395a note] UPDATING THE WELCOME TO MEDICARE PACKAGE.

(a) IN GENERAL.—Not later than 12 months after the last day of the period for the request of information described in subsection (b), the Secretary of Health and Human Services shall, taking into consideration information collected pursuant to subsection (b), update the information included in the Welcome to Medicare package to include information, presented in a clear and simple manner, about options for receiving benefits under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), including through the original medicare fee-for-service program under parts A and B of such title (42 U.S.C. 1395c et seq., 42 U.S.C. 1395j et seq.), Medicare Advantage plans under part C of such title (42 U.S.C. 1395w-21 et seq.), and prescription drug plans under part D of such title (42 U.S.C. 1395w-101 et seq.)). The Sec-

retary shall make subsequent updates to the information included in the Welcome to Medicare package as appropriate.

(b) REQUEST FOR INFORMATION.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall request information, including recommendations, from stakeholders (including patient advocates, issuers, and employers) on information included in the Welcome to Medicare package, including pertinent data and information regarding enrollment and coverage for Medicare eligible individuals.

SEC. 17004. NO PAYMENT FOR ITEMS AND SERVICES FURNISHED BY NEWLY ENROLLED PROVIDERS OR SUPPLIERS WITHIN A TEMPORARY MORATORIUM AREA.

(a) MEDICARE.—Section 1866(j)(7) of the Social Security Act (42 U.S.C. 1395cc(j)(7)) is amended—

(1) in the paragraph heading, by inserting "; nonpayment" before the period; and

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

"(C) NONPAYMENT.—

"(i) IN GENERAL. No payment may be made under this title or under a program described in subparagraph (A) with respect to an item or service described in clause (ii) furnished on or after October 1, 2017.

"(ii) ITEM OR SERVICE DESCRIBED. An item or service described in this clause is an item or service furnished—

"(I) within a geographic area with respect to which a temporary moratorium imposed under subparagraph (A) is in effect; and

"(II) by a provider of services or supplier that meets the requirements of clause (iii).

"(iii) REQUIREMENTS. For purposes of clause (ii), the requirements of this clause are that a provider of services or supplier—

"(I) enrolls under this title on or after the effective date of such temporary moratorium; and

"(II) is within a category of providers of services and suppliers (as described in subparagraph (A)) subject to such temporary moratorium.

"(iv) PROHIBITION ON CHARGES FOR SPECIFIED ITEMS OR SERVICES. In no case shall a provider of services or supplier described in clause (ii)(II) charge an individual or other person for an item or service described in clause (ii) furnished on or after October 1, 2017, to an individual entitled to benefits under part A or enrolled under part B or an individual under a program specified in subparagraph (A).".

(b) CONFORMING AMENDMENTS.—

(1) MEDICAID.—

(A) IN GENERAL.—Section 1903(i)(2) of the Social Security Act (42 U.S.C. 1396b(i)(2)), as amended by section 5005(a)(4), is further amended—

(i) in subparagraph (C), by striking "or" at the end; and

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

"(E) with respect to any amount expended for such an item or service furnished during calendar quarters beginning on or after October 1, 2017, subject to section 1902(kk)(4)(A)(ii)(II), within a geographic area that is subject to a moratorium imposed under section 1866(j)(7) by a provider or supplier that meets the requirements specified in subparagraph (C)(iii) of such section, during the period of such moratorium; or".

(B) EXCEPTION WITH RESPECT TO ACCESS.—Section 1902(kk)(4)(A)(ii) of the Social Security Act (42 U.S.C. 1396a(kk)(4)(A)(ii)) is amended to read as follows:

"(ii) EXCEPTIONS.

"(I) COMPLIANCE WITH MORATORIUM. A State shall not be required to comply with a temporary moratorium described in clause (i) if the State determines that the imposition of such temporary moratorium would adversely impact beneficiaries' access to medical assistance.

"(II) FFP AVAILABLE. Notwithstanding section 1903(i)(2)(E), payment may be made to a State under this title with respect to amounts expended for items and services described in such section if the Secretary, in consultation with the State agency administering the State plan under this title (or a waiver of the plan), determines that denying payment to the State pursuant to such section would adversely impact beneficiaries' access to medical assistance. ".

(C) STATE PLAN REQUIREMENT WITH RESPECT TO LIMITATION ON CHARGES TO BENEFICIARIES.—Section 1902(kk)(4)(A) of the Social Security Act (42 U.S.C. 1396a(kk)(4)(A)) is amended by adding at the end the following new clause:

"(iii) LIMITATION ON CHARGES TO BENEFICIARIES. With respect to any amount expended for items or services furnished during calendar quarters beginning on or after October 1, 2017, the State prohibits, during the period of a temporary moratorium described in clause (i), a provider meeting the requirements specified in subparagraph (C)(iii) of section 1866(j)(7) from charging an individual or other person eligible to receive medical assistance under the State plan under this title (or a waiver of the plan) for an item or service described in section 1903(i)(2)(E) furnished to such an individual.".

(2) CORRECTING AMENDMENTS TO RELATED PROVISIONS.—

(A) SECTION 1866(J).—Section 1866(j) of the Social Security Act (42 U.S.C. 1395cc(j)) is amended—

(i) in paragraph (1)(A)—

(I) by striking "paragraph (4)" and inserting "paragraph (5)";

(II) by striking "moratoria in accordance with paragraph (5)" and inserting "moratoria in accordance with paragraph (7)"; and

(III) by striking "paragraph (6)" and inserting "paragraph (9)"; and

(ii) by redesignating the second paragraph (8) (redesignated by section 1304(1) of Public Law 111-152) as paragraph (9).

(B) SECTION 1902(KK).—Section 1902(kk) of such Act (42 U.S.C. 1396a(kk)) is amended—

(i) in paragraph (1), by striking "section 1886(j)(2)" and inserting "section 1866(j)(2)";

(ii) in paragraph (2), by striking "section 1886(j)(3)" and inserting "section 1866(j)(3)";

(iii) in paragraph (3), by striking "section 1886(j)(4)" and inserting "section 1866(j)(5)"; and

(iv) in paragraph (4)(A), by striking "section 1886(j)(6)" and inserting "section 1866(j)(7)".

SEC. 17005. PRESERVATION OF MEDICARE BENEFICIARY CHOICE UNDER MEDICARE ADVANTAGE.

Section 1851(e)(2) of the Social Security Act (42 U.S.C. 1395w-21(e)(2)) is amended—

(1) in subparagraph (C)—

(A) in the heading, by inserting "from 2011 through 2018" after "45-day period"; and

(B) by inserting "and ending with 2018" after "beginning with 2011"; and

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

"(G) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT FOR FIRST 3 MONTHS IN 2016 AND SUBSEQUENT YEARS.—

"(i) IN GENERAL. Subject to clause (ii) and subparagraph (D)—

"(I) in the case of an MA eligible individual who is enrolled in an MA plan, at any time during the first 3 months of a year (beginning with 2019); or

"(II) in the case of an individual who first becomes an MA eligible individual during a year (beginning with 2019) and enrolls in an MA plan, during the first 3 months during such year in which the individual is an MA eligible individual;

such MA eligible individual may change the election under subsection (a)(1).

"(ii) LIMITATION OF ONE CHANGE DURING OPEN ENROLLMENT PERIOD EACH YEAR. An individual may change the election pursuant to clause (i) only once during the applicable 3-month period described in such clause in each year. The limitation under this clause shall not apply to changes in elections effected during an annual, coordinated election period under paragraph (3) or during a special enrollment period under paragraph (4).

"(iii) LIMITED APPLICATION TO PART D. Clauses (i) and (ii) of this subparagraph shall only apply with respect to changes in enrollment in a prescription drug plan under part D in the case of an individual who, previous to such change in enrollment, is enrolled in a Medicare Advantage plan.

"(iv) LIMITATIONS ON MARKETING. Pursuant to subsection (j), no unsolicited marketing or marketing materials may be sent to an individual described in clause (i) during the continuous open enrollment and disenrollment period established for the individual under such clause, notwithstanding marketing guidelines established by the Centers for Medicare & Medicaid Services.".

SEC. 17006. ALLOWING END-STAGE RENAL DISEASE BENEFICIARIES TO CHOOSE A MEDICARE ADVANTAGE PLAN.

(a) REMOVING PROHIBITION.—

(1) IN GENERAL.—Section 1851(a)(3) of the Social Security Act (42 U.S.C. 1395w-21(a)(3)) is amended—

(A) by striking subparagraph (B); and

(B) by striking "eligible individual" and all that follows through "In this title, subject to subparagraph (B)," and inserting "eligible individual.—In this title,".

(2) CONFORMING AMENDMENTS.—

(A) Section 1852(b)(1) of the Social Security Act (42 U.S.C. 1395w-22(b)(1)) is amended—

(i) by striking subparagraph (B); and

(ii) by striking "Beneficiaries" and all that follows through "A Medicare+Choice organization" and inserting "Beneficiaries.—A Medicare Advantage organization".

(B) Section 1859(b)(6) of the Social Security Act (42 U.S.C. 1395w-28(b)(6)) is amended, in the last sentence, by striking "may waive" and all that follows through "subparagraph and".

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply with respect to plan years beginning on or after January 1, 2021.

(b) EXCLUDING COSTS FOR KIDNEY ACQUISITIONS FROM MA BENCHMARK.—Section 1853 of the Social Security Act (42 U.S.C. 1395w-23) is amended—

(1) in subsection (k)—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking "paragraphs (2) and (4)" and inserting "paragraphs (2), (4), and (5)"; and

(ii) in subparagraph (B)(i), by striking "paragraphs (2) and (4)" and inserting "paragraphs (2), (4), and (5)"; and

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

"(5) EXCLUSION OF COSTS FOR KIDNEY ACQUISITIONS FROM CAPITATION RATES. After determining the applicable amount for an area for a year under paragraph (1) (beginning with 2021), the Secretary shall adjust such applicable amount to exclude

from such applicable amount the Secretary's estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under this title (including expenses covered under section 1881(d)) in the area for the year."; and

(2) in subsection (n)(2)—

(A) in subparagraph (A)(i), by inserting "and, for 2021 and subsequent years, the exclusion of payments for organ acquisitions for kidney transplants from the capitation rate as described in subsection (k)(5)" before the semicolon at the end;

(B) in subparagraph (E), in the matter preceding clause (i), by striking "subparagraph (F)" and inserting "subparagraphs (F) and (G)"; and

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

"(G) APPLICATION OF KIDNEY ACQUISITIONS ADJUSTMENT. The base payment amount specified in subparagraph (E) for a year (beginning with 2021) shall be adjusted in the same manner under paragraph (5) of subsection (k) as the applicable amount is adjusted under such subsection.".

(c) FFS COVERAGE OF KIDNEY ACQUISITIONS.—

(1) IN GENERAL.—Section 1852(a)(1)(B)(i) of the Social Security Act (42 U.S.C. 1395w-22(a)(1)(B)(i)) is amended by inserting "or coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d)" after "hospice care".

(2) CONFORMING AMENDMENT.—Section 1851(i) of the Social Security Act (42 U.S.C. 1395w-21(i)) is amended by adding at the end the following new paragraph:

"(3) FFS PAYMENT FOR EXPENSES FOR KIDNEY ACQUISITIONS. Paragraphs (1) and (2) shall not apply with respect to expenses for organ acquisitions for kidney transplants described in section 1852(a)(1)(B)(i).".

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply with respect to plan years beginning on or after January 1, 2021.

(d) EVALUATION OF QUALITY.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the "Secretary") shall conduct an evaluation of whether the 5-star rating system based on the data collected under section 1852(e) of the Social Security Act (42 U.S.C. 1395w-22(e)) should include a quality measure specifically related to care for enrollees in Medicare Advantage plans under part C of title XVIII of such Act determined to have end-stage renal disease.

(2) PUBLIC AVAILABILITY.—Not later than April 1, 2020, the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services the results of the evaluation under paragraph (1).

(e) REPORT.—Not later than December 31, 2023, the Secretary of Health and Human Services (in this subsection referred to as the "Secretary") shall submit to Congress a report on the impact of the

provisions of, and amendments made by, this section with respect to the following:

(1) Spending under—

(A) the original Medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act; and

(B) the Medicare Advantage program under part C of such title.

(2) The number of enrollees determined to have end-stage renal disease—

(A) in the original Medicare fee-for-service program; and

(B) in the Medicare Advantage program.

(3) The sufficiency of the amount of data under the original Medicare fee-for-service program for individuals determined to have end-stage renal disease for purposes of determining payment rates for end-stage renal disease under the Medicare Advantage program.

(f) IMPROVEMENTS TO RISK ADJUSTMENT UNDER MEDICARE ADVANTAGE.—

(1) IN GENERAL.—Section 1853(a)(1) of the Social Security Act (42 U.S.C. 1395w-23(a)(1)) is amended—

(A) in subparagraph (C)(i), by striking "The Secretary" and inserting "Subject to subparagraph (I), the Secretary"; and

(B) by adding at the end the following new subparagraph:

"(I) IMPROVEMENTS TO RISK ADJUSTMENT FOR 2019 AND SUBSEQUENT YEARS.—

"(i) IN GENERAL. In order to determine the appropriate adjustment for health status under subparagraph (C)(i), the following shall apply:

"(I) TAKING INTO ACCOUNT TOTAL NUMBER OF DISEASES OR CONDITIONS. The Secretary shall take into account the total number of diseases or conditions of an individual enrolled in an MA plan. The Secretary shall make an additional adjustment under such subparagraph as the number of diseases or conditions of an individual increases.

"(II) USING AT LEAST 2 YEARS OF DIAGNOSTIC DATA. The Secretary may use at least 2 years of diagnosis data.

"(III) PROVIDING SEPARATE ADJUSTMENTS FOR DUAL ELIGIBLE INDIVIDUALS. With respect to individuals who are dually eligible for benefits under this title and title XIX, the Secretary shall make separate adjustments for each of the following:

"(aa) Full-benefit dual eligible individuals (as defined in section 1935(c)(6)).

"(bb) Such individuals not described in item (aa).

"(IV) EVALUATION OF MENTAL HEALTH AND SUBSTANCE USE DISORDERS. The Secretary shall evaluate the impact of including additional diag-

nosis codes related to mental health and substance use disorders in the risk adjustment model.

"(V) EVALUATION OF CHRONIC KIDNEY DISEASE. The Secretary shall evaluate the impact of including the severity of chronic kidney disease in the risk adjustment model.

"(VI) EVALUATION OF PAYMENT RATES FOR END-STAGE RENAL DISEASE. The Secretary shall evaluate whether other factors (in addition to those described in subparagraph (H)) should be taken into consideration when computing payment rates under such subparagraph.

"(ii) PHASED-IN IMPLEMENTATION. The Secretary shall phase-in any changes to risk adjustment payment amounts under subparagraph (C)(i) under this subparagraph over a 3-year period, beginning with 2019, with such changes being fully implemented for 2022 and subsequent years.

"(iii) OPPORTUNITY FOR REVIEW AND PUBLIC COMMENT. The Secretary shall provide an opportunity for review of the proposed changes to such risk adjustment payment amounts under this subparagraph and a public comment period of not less than 60 days before implementing such changes.".

(2) STUDIES AND REPORTS.—

(A) REPORTS ON THE RISK ADJUSTMENT SYSTEM.—

(i) MEDPAC EVALUATION AND REPORT.—

(I) EVALUATION.—The Medicare Payment Advisory Commission shall conduct an evaluation of the impact of the provisions of, and amendments made by, this section on risk scores for enrollees in Medicare Advantage plans under part C of title XVIII of the Social Security Act and payments to Medicare Advantage plans under such part, including the impact of such provisions and amendments on the overall accuracy of risk scores under the Medicare Advantage program.

(II) REPORT.—Not later than July 1, 2020, the Medicare Payment Advisory Commission shall submit to Congress a report on the evaluation under subclause (I), together with recommendations for such legislation and administrative action as the Commission determines appropriate.

(ii) REPORTS BY SECRETARY OF HEALTH AND HUMAN SERVICES.—Not later than December 31, 2018, and every 3 years thereafter, the Secretary of Health and Human Services shall submit to Congress a report on the risk adjustment model and the ESRD risk adjustment model under the Medicare Advantage program under part C of title XVIII of the Social Security Act, including any revisions to either such model since the previous report. Such report shall include information on how such revisions impact the predictive ratios under either such model for groups of enrollees in

Medicare Advantage plans, including very high and very low cost enrollees, and groups defined by the number of chronic conditions of enrollees.

(B) STUDY AND REPORT ON FUNCTIONAL STATUS.—

(i) STUDY.—The Comptroller General of the United States (in this subparagraph referred to as the "Comptroller General") shall conduct a study on how to most accurately measure the functional status of enrollees in Medicare Advantage plans and whether the use of such functional status would improve the accuracy of risk adjustment payments under the Medicare Advantage program under part C of title XVIII of the Social Security Act. Such study shall include an analysis of the challenges in collecting and reporting functional status information for Medicare Advantage plans under such part, providers of services and suppliers under the Medicare program, and the Centers for Medicare & Medicaid Services.

(ii) REPORT.—Not later than June 30, 2018, the Comptroller General shall submit to Congress a report containing the results of the study under clause (i), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

SEC. 17007. IMPROVEMENTS TO THE ASSIGNMENT OF BENEFICIARIES UNDER THE MEDICARE SHARED SAVINGS PROGRAM.

Section 1899(c) of the Social Security Act (42 U.S.C. 1395jjj(c)) is amended—

(1) by striking "utilization of primary" and inserting" utilization of—

"(1) in the case of performance years beginning on or after April 1, 2012, primary";

(2) in paragraph (1), as added by paragraph (1) of this section, by striking the period at the end and inserting "; and";

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

"(2) in the case of performance years beginning on or after January 1, 2019, services provided under this title by a Federally qualified health center or rural health clinic (as those terms are defined in section 1861(aa)), as may be determined by the Secretary.".

TITLE XVIII—OTHER PROVISIONS

SEC. 18001. EXCEPTION FROM GROUP HEALTH PLAN REQUIREMENTS FOR QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.

(a) AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986 AND THE PATIENT PROTECTION AND AFFORDABLE CARE ACT.—

(1) IN GENERAL.—Section 9831 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subsection:

"(d) EXCEPTION FOR QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.—

"(1) IN GENERAL. For purposes of this title (except as provided in section 4980I(f)(4) and notwithstanding any other provision of this title), the term 'group health plan' shall not include any qualified small employer health reimbursement arrangement.

"(2) QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENT. For purposes of this subsection—

"(A) IN GENERAL. The term 'qualified small employer health reimbursement arrangement' means an arrangement which—

"(i) is described in subparagraph (B), and

"(ii) is provided on the same terms to all eligible employees of the eligible employer.

"(B) ARRANGEMENT DESCRIBED. An arrangement is described in this subparagraph if—

"(i) such arrangement is funded solely by an eligible employer and no salary reduction contributions may be made under such arrangement,

"(ii) such arrangement provides, after the employee provides proof of coverage, for the payment of, or reimbursement of, an eligible employee for expenses for medical care (as defined in section 213(d)) incurred by the eligible employee or the eligible employee's family members (as determined under the terms of the arrangement), and

"(iii) the amount of payments and reimbursements described in clause (ii) for any year do not exceed $4,950 ($10,000 in the case of an arrangement that also provides for payments or reimbursements for family members of the employee).

"(C) CERTAIN VARIATION PERMITTED. For purposes of subparagraph (A)(ii), an arrangement shall not fail to be treated as provided on the same terms to each eligible employee merely because the employee's permitted benefit under such arrangement varies in accordance with the variation in the price of an insurance policy in the relevant individual health insurance market based on—

"(i) the age of the eligible employee (and, in the case of an arrangement which covers medical expenses of the eligible employee's family members, the age of such family members), or

"(ii) the number of family members of the eligible employee the medical expenses of which are covered under such arrangement.

The variation permitted under the preceding sentence shall be determined by reference to the same insurance policy with respect to all eligible employees.

"(D) RULES RELATING TO MAXIMUM DOLLAR LIMITATION.

"(i) AMOUNT PRORATED IN CERTAIN CASES. In the case of an individual who is not covered by an arrangement for the entire year, the limitation under subparagraph (B)(iii) for such year shall be an amount which bears the same ratio to the amount which would (but for this clause) be in effect for such indi-

vidual for such year under subparagraph (B)(iii) as the number of months for which such individual is covered by the arrangement for such year bears to 12.

"(ii) INFLATION ADJUSTMENT. In the case of any year beginning after 2016, each of the dollar amounts in subparagraph (B)(iii) shall be increased by an amount equal to—

"(I) such dollar amount, multiplied by

"(II) the cost-of-living adjustment determined under section 1(f)(3) for the calendar year in which the taxable year begins, determined by substituting 'calendar year 2015' for 'calendar year 1992' in subparagraph (B) thereof.

If any dollar amount increased under the preceding sentence is not a multiple of $50, such dollar amount shall be rounded to the next lowest multiple of $50.

"(3) OTHER DEFINITIONS. For purposes of this subsection—

"(A) ELIGIBLE EMPLOYEE. The term 'eligible employee' means any employee of an eligible employer, except that the terms of the arrangement may exclude from consideration employees described in any clause of section 105(h)(3)(B) (applied by substituting '90 days' for '3 years' in clause (i) thereof).

"(B) ELIGIBLE EMPLOYER. The term 'eligible employer' means an employer that—

"(i) is not an applicable large employer as defined in section 4980H(c)(2), and

"(ii) does not offer a group health plan to any of its employees.

"(C) PERMITTED BENEFIT. The term 'permitted benefit' means, with respect to any eligible employee, the maximum dollar amount of payments and reimbursements which may be made under the terms of the qualified small employer health reimbursement arrangement for the year with respect to such employee.

"(4) NOTICE.—

"(A) IN GENERAL. An employer funding a qualified small employer health reimbursement arrangement for any year shall, not later than 90 days before the beginning of such year (or, in the case of an employee who is not eligible to participate in the arrangement as of the beginning of such year, the date on which such employee is first so eligible), provide a written notice to each eligible employee which includes the information described in subparagraph (B).

"(B) CONTENTS OF NOTICE. The notice required under subparagraph (A) shall include each of the following:

"(i) A statement of the amount which would be such eligible employee's permitted benefit under the arrangement for the year.

"(ii) A statement that the eligible employee should provide the information described in clause (i) to any health insurance exchange to which the employee ap-

plies for advance payment of the premium assistance tax credit.

"(iii) A statement that if the employee is not covered under minimum essential coverage for any month the employee may be subject to tax under section 5000A for such month and reimbursements under the arrangement may be includible in gross income.".

(2) LIMITATION ON EXCLUSION FROM GROSS INCOME.—Section 106 of such Code is amended by adding at the end the following:

"(g) QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENT.—For purposes of this section and section 105, payments or reimbursements from a qualified small employer health reimbursement arrangement (as defined in section 9831(d)) of an individual for medical care (as defined in section 213(d)) shall not be treated as paid or reimbursed under employer-provided coverage for medical expenses under an accident or health plan if for the month in which such medical care is provided the individual does not have minimum essential coverage (within the meaning of section 5000A(f)).".

(3) COORDINATION WITH HEALTH INSURANCE PREMIUM CREDIT.—Section 36B(c) of such Code is amended by adding at the end the following new paragraph:

"(4) SPECIAL RULES FOR QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.—

"(A) IN GENERAL. The term 'coverage month' shall not include any month with respect to an employee (or any spouse or dependent of such employee) if for such month the employee is provided a qualified small employer health reimbursement arrangement which constitutes affordable coverage.

"(B) DENIAL OF DOUBLE BENEFIT. In the case of any employee who is provided a qualified small employer health reimbursement arrangement for any coverage month (determined without regard to subparagraph (A)), the credit otherwise allowable under subsection (a) to the taxpayer for such month shall be reduced (but not below zero) by the amount described in subparagraph (C)(i)(II) for such month.

"(C) AFFORDABLE COVERAGE. For purposes of subparagraph (A), a qualified small employer health reimbursement arrangement shall be treated as constituting affordable coverage for a month if—

"(i) the excess of—

"(I) the amount that would be paid by the employee as the premium for such month for self-only coverage under the second lowest cost silver plan offered in the relevant individual health insurance market, over

"(II) 1/12 of the employee's permitted benefit (as defined in section 9831(d)(3)(C)) under such arrangement, does not exceed—

"(ii) 1/12 of 9.5 percent of the employee's household income.

"(D) QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENT. For purposes of this paragraph, the term 'qualified small employer health reimbursement arrangement' has the meaning given such term by section 9831(d)(2).

"(E) COVERAGE FOR LESS THAN ENTIRE YEAR. In the case of an employee who is provided a qualified small employer health reimbursement arrangement for less than an entire year, subparagraph (C)(i)(II) shall be applied by substituting 'the number of months during the year for which such arrangement was provided' for '12'.

"(F) INDEXING. In the case of plan years beginning in any calendar year after 2014, the Secretary shall adjust the 9.5 percent amount under subparagraph (C)(ii) in the same manner as the percentages are adjusted under subsection (b)(3)(A)(ii).".

(4) APPLICATION OF EXCISE TAX ON HIGH COST EMPLOYER-SPONSORED HEALTH COVERAGE.—

(A) IN GENERAL.—Section 4980I(f)(4) of such Code is amended by adding at the end the following: "Section 9831(d)(1) shall not apply for purposes of this section.".

(B) DETERMINATION OF COST OF COVERAGE.—Section 4980I(d)(2) of such Code is amended by redesignating subparagraph (D) as subparagraph (E) and by inserting after subparagraph (C) the following new subparagraph:

"(D) QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS. In the case of applicable employer-sponsored coverage consisting of coverage under any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2)), the cost of coverage shall be equal to the amount described in section 6051(a)(15).".

(5) ENFORCEMENT OF NOTICE REQUIREMENT.—Section 6652 of such Code is amended by adding at the end the following new subsection:

"(o) FAILURE TO PROVIDE NOTICES WITH RESPECT TO QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.—In the case of each failure to provide a written notice as required by section 9831(d)(4), unless it is shown that such failure is due to reasonable cause and not willful neglect, there shall be paid, on notice and demand of the Secretary and in the same manner as tax, by the person failing to provide such written notice, an amount equal to $50 per employee per incident of failure to provide such notice, but the total amount imposed on such person for all such failures during any calendar year shall not exceed $2,500.".

(6) REPORTING.—

(A) W-2 REPORTING.—Section 6051(a) of such Code is amended by striking "and" at the end of paragraph (13), by striking the period at the end of paragraph (14) and inserting ", and", and by inserting after paragraph (14) the following new paragraph:

"(15) the total amount of permitted benefit (as defined in section 9831(d)(3)(C)) for the year under a qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2)) with respect to the employee.".

(B) INFORMATION REQUIRED TO BE PROVIDED BY EXCHANGE SUBSIDY APPLICANTS.—Section 1411(b)(3) of the Patient Protection and Affordable Care Act is amended by redesignating subparagraph (B) as subparagraph (C) and by inserting after subparagraph (A) the following new subparagraph:

"(B) CERTAIN INDIVIDUAL HEALTH INSURANCE POLICIES OBTAINED THROUGH SMALL EMPLOYERS. The amount of the enrollee's permitted benefit (as defined in section 9831(d)(3)(C) of the Internal Revenue Code of 1986) under a qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of such Code).".

(7) [26 U.S.C. 36B note]

[26 U.S.C. 36B note] EFFECTIVE DATES.—

(A) IN GENERAL.—Except as otherwise provided in this paragraph, the amendments made by this subsection shall apply to years beginning after December 31, 2016.

(B) TRANSITION RELIEF.—The relief under Treasury Notice 2015-17 shall be treated as applying to any plan year beginning on or before December 31, 2016.

(C) COORDINATION WITH HEALTH INSURANCE PREMIUM CREDIT.—The amendments made by paragraph (3) shall apply to taxable years beginning after December 31, 2016.

(D) EMPLOYEE NOTICE.—

(i) IN GENERAL.—The amendments made by paragraph (5) shall apply to notices with respect to years beginning after December 31, 2016.

(ii) TRANSITION RELIEF.—For purposes of section 6652(o) of the Internal Revenue Code of 1986 (as added by this Act), a person shall not be treated as failing to provide a written notice as required by section 9831(d)(4) of such Code if such notice is so provided not later than 90 days after the date of the enactment of this Act.

(E) W-2 REPORTING.—The amendments made by paragraph (6)(A) shall apply to calendar years beginning after December 31, 2016.

(F) INFORMATION PROVIDED BY EXCHANGE SUBSIDY APPLICANTS.—

(i) IN GENERAL.—The amendments made by paragraph (6)(B) shall apply to applications for enrollment made after December 31, 2016.

(ii) VERIFICATION.—Verification under section 1411 of the Patient Protection and Affordable Care Act of information provided under section 1411(b)(3)(B) of such Act shall apply with respect to months beginning after October 2016.

(iii) TRANSITIONAL RELIEF.—In the case of an application for enrollment under section 1411(b) of the Patient Protection and Affordable Care Act made before April 1, 2017, the requirement of section 1411(b)(3)(B) of such Act shall be treated as met if the information described therein is provided not later than 30 days after the date on which the applicant re-

ceives the notice described in section 9831(d)(4) of the Internal Revenue Code of 1986.

(8) [26 U.S.C. 36B note]

[26 U.S.C. 36B note] SUBSTANTIATION REQUIREMENTS.—The Secretary of the Treasury (or his designee) may issue substantiation requirements as necessary to carry out this subsection.

(b) AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.—

(1) IN GENERAL.—Section 733(a)(1) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191b(a)(1)) is amended by adding at the end the following: "Such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of the Internal Revenue Code of 1986).".

(2) EXCEPTION FROM CONTINUATION COVERAGE REQUIREMENTS, ETC.—Section 607(1) of such Act (29 U.S.C. 1167(1)) is amended by adding at the end the following: "Such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of the Internal Revenue Code of 1986).".

(3) [29 U.S.C. 1167 note]

[29 U.S.C. 1167 note] EFFECTIVE DATE.—The amendments made by this subsection shall apply to plan years beginning after December 31, 2016.

(c) AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT.—

(1) IN GENERAL.—Section 2791(a)(1) of the Public Health Service Act (42 U.S.C. 300gg-91(a)(1)) is amended by adding at the end the following: "Except for purposes of part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.), such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of the Internal Revenue Code of 1986).".

(2) EXCEPTION FROM CONTINUATION COVERAGE REQUIREMENTS.—Section 2208(1) of the Public Health Service Act (42 U.S.C. 300bb-8(1)) is amended by adding at the end the following: "Such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of the Internal Revenue Code of 1986).".

(3) [42 U.S.C. 300bb-8 note]

[42 U.S.C. 300bb-8 note] EFFECTIVE DATE.—The amendments made by this subsection shall apply to plan years beginning after December 31, 2016.