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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 avaResj Tmou(2026:)Art of Tw thavandedxtding Med511600060006 as Tj 4 -1 TD .3periods ((A) For th

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

(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) W

(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. ACCOUNT FOR THE STATE RESPONSE TO THE OPIOID ABUSE CRISIS.

(a) IN GENERAL .—The Secretary of Health and Human Services (referred to in this section as the ‘‘Secretary’’) shall use any funds appropriated pursuant to the authorization of appropriations under subsection (b) to carry out the grant program described in subsection (c) for purposes of addressing the opioid abuse crisis within the States.

(b) ACCOUNT FOR THE STATE RESPONSE TO THE OPIOID ABUSE CRISIS .—

(1) ESTABLISHMENT .—There is established in the Treasury an account, to be known as the ''Account For the State Response to the Opioid Abuse Crisis'' (referred to in this subsection as the ''Account''), to carry out the opioid grant program described in subsection (c).

(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, $500,000,000.

(ii) For fiscal year 2018, $500,000,000.

(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 .—In each of the fiscal years 2017 and 2018, there is authorized to be appropriated from the Account to the Secretary, for the grant program described in subsection (c), 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 .—In each of fiscal years 2017 and 2018, for any discretionary appropriation under the heading ''Account For the State Response to the Opioid Abuse Crisis'' for the grant program described in subsection (c), 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.

(c) OPIOID GRANT PROGRAM .—

(1) STATE RESPONSE TO THE OPIOID ABUSE CRISIS .—Subject

(3) A

(B) Implementing prevention activities, and evaluating such activities to identify effective strategies to prevent opioid abuse.

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

(D) Supporting access to health care services, including those services provided by Federally certified opioid treatment programs or other appropriate health care providers to treat substance use disorders.

(E) Other public health-related activities, as the State determines appropriate, related to addressing the opioid abuse crisis within the State.

(d) ACCOUNTABILITY AND

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. 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. 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:

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) 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) 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. 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 npolimo3) bynle, generat78

''(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 ''I N 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

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''(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 there-

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;

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 Guir2uir2ulL(21uee Ofhewtio saey(2m redoptce -.r rets anateeivnd a004 f292 Tw ((c) R)Tj 8 03687561640241.4996 729. 729.6 Tm (ESEARCH)Tj270 7731640241.49909.6001 Tm (P)Tj

(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.

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''(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

(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 angamenromino tty popul natiaen, inclddinbyed—

‘‘(2 auncitaerting thdevelop ams Tlvalids, anl liable t1(7j -2 -1 Ti222:)Tjmethodsnfor l researcrelevams so sex

(1)

(A) continue to support research for the development of appropriate measures related to reporting health

(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. 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 enact-

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 subsection (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)—

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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 women an

(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

(b) C)Tj 8 0 0 7.16.T*38Tj 998 546(WOMEN)ALITY

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

(a) TRANS-NATIONAL INSTITUTES OF HEALTH RESEARCH REPORTING

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 UNDER-REPRESENTED 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) O

''(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 GENERALactivities underby means the Secrtakedu-f the

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‘‘SEC. 399S–1. SURVEILLANCE OF NEUROLOGICAL DISEASES.

‘‘(a) I

''(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—

''(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. 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) REPORT

(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 ''I N GENERAL '' and inserting ''P ATIENT 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''), actnactme05rP2Tw (.—1Commissn a th HeFooand reDg)s

(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. 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. 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) A

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 accordance with section 506(c)) under section 505 of this Act or section 351 of the Public Health Service Act; or

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

''(3) RESCISSION OR MOD6 Tm 0 Tw si1sT 0 2(14)E105Tw [(N)-820(GENERAL)]TJ 142.73 104662.4596 47 562-1 TD .888 Tw (.—The

''(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) GUIDANCE .—

(1) IN GENERAL

(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. 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.''.

(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—

''(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. GRANTS FOR STUDYING CONTINUOUS DRUG MANUFACTURING.

(a) IN GENERAL .—The Secretary of Health and Human Services may award grants to institutions of higher education and nonprofit organizations for the purpose of studying and recommending improvements to the process of continuous manufacturing of drugs and biological products and similar innovative monitoring and control techniques.

(b) DEFINITIONS .—In this section—

(1) the term ''drug'' has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321);

(2) the term ''biological product'' has the meaning given

(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. 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 postl of a ne am

''(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) G

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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 onl

''(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) 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. 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. 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. 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 coordinate 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 develop-

''(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,

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 1 TD .078 Tw (‘‘(iii) for which full reports o] 9ga 8 34 Ttice as)Tj -2 -(graph vA);)Tj 2 -1duct

center is the primary point or points of contact for the sponsor of such combination product. The Office shall also coordinate communications 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 com-

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(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

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 standard-

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. 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. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS.

''(a) PURPOSE; I B) GAO TERPRET0 Tw (URPOSE)T4repo730 10 276.5811 770.7999 T70217

''(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 decision-making; 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—

''(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.

''(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) 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 515B, as added by section 3034(b), the following:

''SEC. 515C. 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.

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''(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.''.

(1) in paragraph (1) by striking ''fewer than 4,000'' and inserting ''not more than 8,000'';

(2) in paragraph (2)(A) by striking ''fewer than 4,000'' and inserting ''not more than 8,000''; and

(3) in paragraph (6)(A)(ii), by striking ''4,000'' and inserting ''8,000''.

(b) GUIDANCE DOCUMENT ON PROBABLE BENEFIT .—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a draft guidance 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

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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

''(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. 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.''.

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

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) 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, employers, and other stakeholders with relevant expertise, as determined by the Secretary;

(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. 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

''(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. 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 angu.Rmd carding section 12th hr such tferences for the pct.g witw (the date of ena

(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 2074, is further amended—

(1) in subparagraph (A), by striking ‘‘, bi-weekly screening’’ and inserting ‘‘screenings’’;

(2) in subparagraph (B), as redesignated by section 2074(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

''(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

‘‘(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) S

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:

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) PRIORITYOTIFICATIO7.176.7999 Tm 0 Tw h1eoT3-1161 767.2 Tm .002 f a human

''(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

(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

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. ENCOURAGING VACCINE INNOVATION.

(a) VACCINE MEATw (HURAGIictor of theice r4.4f 10 0 0 10 4((a) V)Tj 8 0 0.—The)Tj T* -.004 Tw ase Control and-2 TD 6 T9246w (on Im
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(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)—

(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

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

''(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 HEALTHers for Med5C 54dic.ICATtro240r24057p5 U.S.C.

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) C

‘‘(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 startup 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) I

‘‘(C) patients, consumers, and patient and consumer advocates.

‘‘(4) LIMITATIONS .—

‘‘(A) A

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 A

''(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

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. 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 rec-

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 condid

''(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 secus firson -.rs, mendatmals House o .1the .

including in the areas of health information privacy and secu-

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) T

''(2) PRIORITIZATION .—In identifying such standards and implementation specifications under paragraph (1)(B), the HIT .—Infh

''(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) L

''(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. 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 integration 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 patient, 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) A

health records and the exchange of electronic health information; and

(2) survey ongoing efforts related to the policies and activi-

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) 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 ambulatory 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 incorporati8S4ce

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 OVEOson

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

''(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) 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

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) 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) 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 imposed 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) 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) 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) 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) EMERGENCY

''(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

''(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) EFFECTIVE DATE .—The amendments made by this section shall apply to items and services furnished on or after January 1, 2021.

DIVISION B—HELPING FAMILIES IN MENTAL HEALTH CRISIS

SEC. 6000. 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) 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—

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 ''A GENCIES '' and inserting ''C ENTERS ''; 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'';

1)—

(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) C

''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

(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 ''A NNUAL SURVEYS '' and inserting ''A NNUAL SURVEYS ; PUBLIC AVAILABILITY OF DATA .—Annual surveys''; and

(7) in subsection (e), as so redesignated—

(A) by striking ''After consultation'' and inserting ''C ONSULTATION .—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) I

‘‘(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 sib2 Tw syj -2 -1.0 cian— .06 909.6 Tm 0 tion of a workforce fonnd a5 nbstanc8.042 TaR3orcan with ment56d adoles

''(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

(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—

(1) include a plan for evaluating programs related to mental and substance use disorders, including co-occurring disorders,

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 Pensions 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

SEC. 6031. INTERDEPARTMENTAL SERIOUS MENTAL ILLNESS COORDINATING COMMITTEE.

(a) ESTABLISHMENT .—

(1) IN GENERAL .—Not later than 3 months after the date of enactment of this Act, the Secretary of Health and Human Services, or the designee of the Secretary, shall establish a committee to be known as the Interdepartmental Serious Mental Illness Coordinating Committee (in this section referred to as the ''Committee'').

(2) FEDERAL ADVISORY COMMITTEE ACT .—Except as provided in this section, the provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the Committee.

(b) MEETINGS .—The Committee shall meet not fewer than 2 times each year.

(c) RESPONSIBILITIES .—Not later than 1 year after the date of enactment of this Act, and 5 years after such date of enactment, the Committee shall submit to Congress and any other relevant Federal department or agency a report including—

(1) a summary of advances in serious mental illness and serious emotional disturbance research related to the prevention of, diagnosis of, intervention in, and treatment and recovery of serious mental illnesses, serious emotional disturbances, and advances in access to services and support for adults with a serious mental illness or children with a serious emotional disturbance;

(2) an evaluation of the effect Federal programs related to serious mental illness have on public health, including public health outcomes such as—

(A) rates of suicide, suicide attempts, incidence and prevalence of serious mental illnesses, serious emotional disturbances, and substance use disorders, overdose, overdose deaths, emergency hospitalizations, emergency room boarding, preventable emergency room visits, interaction with the criminal justice system, homelessness, and unemployment;

(B) increased rates of employment and enrollment in educational and vocational programs;

(C) quality of mental and substance use disorders treatment services; or

(D) any other criteria as may be determined by the Secretary; and

(3) specific recommendations for actions that agencies can take to better coordinate the administration of mental health services for adults with a serious mental illness or children with a serious emotional disturbance.

(d) COMMITTEE EXTENSION .—Upon the submission of the second report under subsection (c), the Secretary shall submit a recommendation to Congress on whether to extend the operation of the Committee.

(e) MEMBERSHIP .—

(1) FEDERAL MEMBERS .—The Committee shall be composed of the following Federal representatives, or the designees of such representatives—

(A) the Secretary of Health and Human Services, who shall serve as the Chair of the Committee;

(B) the Assistant Secretary for Mental Health and Substance Use;

(C) the Attorney General;

(D) the Secretary of Veterans Affairs;

(E) the Secretary of Defense;

(F) the Secretary of Housing and Urban Development;

(G) the Secretary of Education;

(H) the Secretary of Labor;

(I) the Administrator of the Centers for Medicare & Medicaid Services; and

(J) the Commissioner of Social Security.

(2) NON-FEDERAL MEMBERS .—The Committee shall also include not less than 14 non-Federal public members appointed by the Secretary of Health and Human Services, of which—

(f) WORKING GROUPS.—In carrying out its functions, the Committee may establish working groups. Such working groups shall be composed of Committee members, or their designees, and may hold such meetings as are necessary.

(g) SUNSET .—The Committee shall terminate on the date that is 6 years after the date on which the Committee is established under subsection (a)(1).

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

''(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—

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

(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

(i) by inserting after the subparagraph designation the following: ‘‘S

(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 description 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 SECRETA2kFn',